

# FINAL REGISTRATION REPORT

## Part B

### Section 7

#### Metabolism and Residues

Detailed summary of the risk assessment

Product code: IN005B1570

Product name: ~~INDOFIL~~ Difenoconazole 250 G/L EC greener

Chemical active substance:

Difenoconazole, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

(Article 33: Application for authorisation)

Applicant: Indofil Industries (Netherlands) B.V.

Submission date: January 2022

MS Finalisation date: 10.2022 11.2023 05.2024 08.2024 08.2025

## Version history

When	What
February 2022	V0 – Original version from applicant Indofil Industries (Netherlands) B.V. for submission to z-RMS, Poland, in the frame of the PPP Authorization according to Article 33 of Regulation (EC) No. 1107/2009
October 2022	Assessment
November 2023	Applicant supplements
November 2023	Assessment of additional data provided by the Applicant
February 2024	Applicant dRR update commenting period
March 2024	Additional applicant dRR update based on cMS cmmnts
May 2024	Assessment of the updated data
August 2024	Assessment in relation to third round of comments
August 2025	Revision of the fRR regarding the use of the product in the protection of carrots up to BBCH phase 49.

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## 7 Metabolism and residue data (KCA section 6)

### 7.1 Summary and zRMS Conclusion

#### Storage stability

##### Difenoconazole

According to EFSA Journal 2011;9(1):1967, residues of difenoconazole were found to be stable up to 24 months in potato, tomato, cotton (cottonseed oil) and wheat (straw, forage and grain) and up to 12 months in lettuce (head), soybean (beans) and banana when stored frozen at -20°C. Residues of difenoconazole were found to be stable at least 12 months in animal matrices (eggs, milk, poultry breast and beef liver) when stored frozen at -20°C. And difenoconazole and difenoconazole alcohol (CGA-205375) were found to be stable at least 10 months in animal matrices (milk, liver, kidney, fat and muscle) when stored frozen at -18°C.

##### TMDs

Storage stability data for TMDs are presented in EFSA Journal 2018;16(7):5376.

Plant products (Category)	Commodity	Stability (Months)			
		1,2,4-Triazole	TA	TAA	TLA
High water content	Apples, tomatoes, mustard leaves, wheat forage, radishes tops/roots, turnips roots, sugar beet roots, cabbages, lettuces	6	53	53	48 ((lettuce only)
High starch content	Barley, wheat	12	26	26	48
High oil content	Oilseed rape (seed), soya beans	12 (soya bean only; not stable in rape seed)	26 (soya bean only; not stable in rape seed)	53	48
High protein content	Peas, dry; Navy beans	No data	15	25	48
High acid content	Oranges	No data	No data	No data	48
Others	Cereal straw	12	53	40	No data
Animal	Animal commodity	Stability (Month/Year)			
	Muscle	No data	No data	No data	No data
	Liver	No data	No data	No data	No data
	Kidney	No data	No data	No data	No data
	Milk	No data	No data	No data	No data

	Egg	No data	No data	No data	No data
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The available storage stability data are sufficient to demonstrate the stability of residues of difenoconazole. Regarding TDMs, a new study (Longhi, D. 2021. Study plan No.: GLP-STUDY-21-124) is ongoing and will be used to assess the storage stability of triazole derivatives metabolites in high water (wheat forage, apple, tomato and carrot), in high oil (oilseed rape seeds), in high starch (wheat grain), and in dry (wheat straw) commodities.

#### November 2023

The applicant provided an acceptable storage stability study (Longhi, D. 2022). The study showed the stability of triazole derivative metabolites (TDM) at -18°C for a period of 7 months in wheat feed, wheat grain, rapeseed, wheat straw, apples, tomatoes and carrots.

The storage time of samples from field trials is acceptable in relation to storage stability data.

#### Metabolism in plants and animals

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

Oilseed rape

Proposed GAP:

Max. 2 applications (1 in autumn and 1 in spring or 2 in autumn);

BBCH: Spring applications BBCH 14-18 and BBCH 30-69;

0.125 kg a.s/ha per treatment;

PHI – not required.

New study on the magnitude of residues has been submitted by the applicant in the framework of this application (investigating difenoconazole and TDMs)

Trials GAP: 2 x 0.125 kg as/ha, outdoor

Residues (NEU, difenoconazole; E, RA): 6x<0.01, 0.01 mg/kg

The study is accepted. The trials are independent and valid with regard to storage stability data for difenoconazole. Analytical method used is accepted.

Although 7 instead of 8 northern European trials are presented, they are sufficient to support the proposed use. The residues arising from the proposed use will not exceed the MRLs for difenoconazole established

for oilseed rape (0.5 mg/kg; Reg. (EU) 2019/552).

Trials from the southern zone of Europe were not included in the evaluation.

**NL comment:**

*Considering the use on oilseed rape, 7 trials are available to support the intended use. However, according to SANTE/2019/12752, oilseed rape is a major crop and therefore 8 trials are required.*

*zRMS acknowledges that only 7 trials are available but considers this sufficient to support the intended use. However, both the applicant and zRMS do not further explain why this is considered acceptable. The Netherlands concludes that 8 trials are required, and the use can therefore not be considered sufficiently supported. An additional trial is required.*

**zRMS:** 7 trials are enough since residues in these trials practically do not vary and 6 of them are below LOQ (0.01 mg/kg) and the last one are at LOQ. The residues arising from the proposed use will not exceed the MRLs.

**Non-acceptance of this use due to the need to conduct additional study may be considered at Member State level.**

According to the applicant another residue trial in OSR is ongoing in NEU and if requested it would be submitted post registration as confirmatory data.

The information has been added.

Use is accepted in Poland.

**Applicant's statement:**

*7 trials are enough since residues in these trials practically do not vary.*

*Other 8 residue trials have been performed in SEU and the conclusion is the same (four of the SEU residue zone studies were carried out in north of Italy, bordering the NEU residue zone, thus similar climatic conditions might be extrapolated. These trials were considered valid).*

*Another residue trials in OSR is ongoing in NEU and if requested it would be submitted post registration as confirmatory data.*

TDMs: Triazole alanine

Data (NEU): 1.566, 1x<0.002, 0.205, 0.299, 0.537, 0.1198, 0.113 mg/kg

TDMs: Triazole lactic acid

Data (NEU): <0.002, 0.0044, 0.0114, 0.0207, 0.025, 0.0317, 0.0628 mg/kg

Triazole acetic acid

Data (NEU): 4x<0.002, 0.0059, 0.0123, 0.013 mg/kg

1,2,4-Triazole

Data (NEU): 6x<0.01, 0.0129 mg/kg

Data gap: storage stability data for 1,2,4 Triazole and TA in high oil content matrix (post registration requirement).

Apples, Pears

Proposed GAP:

Max. 3 applications; BBCH: 57-84; 0.05625 kg a.s/ha; PHI – 21

New study on the magnitude of residues has been submitted by the applicant in the framework of this application (investigating difenoconazole and TDMs)

Trials GAP: 3 x 0.05625 kg as/ha per treatment, PHI 21d, outdoor

Residues (NEU, apples; difenoconazole): 0.0186, 0.0264, 0.0268, 0.0322, 0.0474, 0.0585, 0.0937, 0.1058 mg/kg

TDMs: Triazole alanine: (NEU) 0.0013, 4x<0.002, 0.0044, 0.0266, 0.0299 mg/kg

TDMs: Triazole lactic acid (NEU): 0.0008, 4x<0.002, 0.003, 0.0187, 0.0222 mg/kg

Triazole acetic acid (NEU): 4x<0.002, 0.0059, 0.0123, 0.013 mg/kg

1,2,4-Triazole (NEU): 8x<0.002 mg/kg

The study is accepted. The trials are independent and valid with regard to storage stability. Analytical method used is accepted.

The residues arising from the proposed use will not exceed the MRLs for difenoconazole established for apples and pears (0.8 mg/kg; Reg. (EU) 2019/552).

According to SANTE/2019/12752 extrapolation from apples to pears is possible.

Sufficient new trials on apples are available to support the proposed uses.

#### Carrot

Proposed GAP:

Max. 3-4 applications; BBCH: 39-40; max. 0.125kg a.s/ha per treatment; PHI – 14

New studies on the magnitude of residues have been submitted by the applicant in the framework of this application (investigating difenoconazole and TDMs)

Trials GAP: 3 x 0.125 kg as/ha, PHI 14d, outdoor

Residues (carrot; difenoconazole): 0.02597, 0.02824, 0.05418, 0.05666, 0.0577, 0.06944, 0.1118, 0.1153 mg/kg

TDMs: Triazole alanine: 0.00169, <0.002, 0.0037, 0.00813, 0.00835, 0.00936, 0.01441, 0.01479 mg/kg

TDMs: Triazole lactic acid: 0.00056, 0.00114, 3x<0.002, 0.00222, 0.00321, 0.0037 mg/kg

Triazole acetic acid: 7x<0.002, 0.00356 mg/kg

1,2,4-Triazole: 8x<0.002 mg/kg

The study is accepted. The trials are independent and valid with regard to storage stability. Analytical method used is accepted.

The residues arising from the proposed use will not exceed the MRLs for difenoconazole established for carrot (0.4 mg/kg; Reg. (EU) 2019/552).

Additionally applicant refers to unprotected EU data: Sweden, 2006 N-EU GAP on which EU a.s. assessment is based: 3 x 0.125 kg as/ha, PHI 14d, outdoor

Residues: 2x 0.02, 0.03, 0.04, 0.05, 0.07, 0.11, 0.12 mg/kg

Sufficient trials on carrots are available to support the proposed use with max. number of applications of 3. There is no data to cover max. number of applications of 4.

The residue trials presented by the applicant allow for the acceptance of the use of the product in the protection of carrots up to BBCH 49 phase.

#### Cauliflower, broccoli

Applicants refers to the 6 outdoor field trials on broccoli in N-EU and 12 outdoor field trials on cauliflower in N-EU, all of which were reviewed by the JMPR (JMPR, 2007).



Data presented by the applicant are insufficient to cover proposed uses. The studies were not evaluated at EU level.

Proposed used are not accepted.

March 2024

The applicant provided new data: 4 outdoor field new trials on broccoli in N-EU and 4 outdoor field new trials on cauliflower in N-EU (Germany, Belgium, The Netherlands, Austria, Czech Republic and Poland).

Trials are acceptable.

Maximum freezer storage period between sampling and analysis: 76 days (difenoconazole) and 72 (TMDS).

Trials are independent.

Application time is later than proposed but can be accepted as worst case. Other application parameters are consistent with GAP.

Trial GAP: 3 x 125 g as/ha, BBCH 41-45, PHI 14 d, outdoor

E, RA: (difenoconazole) 5x<0.01, 0.02, 0.04, 0.13 mg/kg

The residues arising from the proposed use will not exceed the MRLs for difenoconazole established for cauliflower and broccoli (Reg. (EU) 2019/552).

Triazole alanine data: 2x <0.01, 4x 0.02, 0.03, 0.04 mg/kg

Triazole lactic acid data: 8x<0.01 mg/kg

Triazole acetic acid data: 8x<0.01 mg/kg

1,2,4-Triazole data: 8x<0.01 mg/kg

According to SANTE/2019/12752 rev.1 4 trials on cauliflower plus 4 trials on broccoli can be extrapolated to the subgroup of flowering brassica. According to the available data, the uses on cauliflower and broccoli are considered acceptable.

#### Cabbage

Applicants refers to the 15 outdoor field trials in N-EU, all of which were reviewed by the JMPR (JMPR, 2007).

Data presented by the applicant are insufficient to cover proposed uses. The studies were not evaluated at EU level.

Proposed used are not accepted.

March 2024

The applicant provided new data: 8 outdoor field new trials on cabbage in N-EU (Belgium, The Netherlands, Germany, Czech Republic and Northern France).

Trials are acceptable.

Maximum freezer storage period between sampling and analysis: 64 days.

Trials are independent.

Trial GAP: 3 x 125 g as/ha, BBCH 43-47, PHI 21 d, outdoor

E, RA: (difenoconazole): 2x <0.01, 4x 0.01, 0.04, 0.07 mg/kg

The residues arising from the proposed use will not exceed the MRLs for difenoconazole established for cabbage (Reg. (EU) 2019/552).

Triazole alanine data: 2x <0.01, 4x 0.02, 0.03, 0.04 mg/kg

Triazole lactic acid data:  $8x < 0.01$  mg/kg

Triazole acetic acid data:  $8x < 0.01$  mg/kg

1,2,4-Triazole data:  $8x < 0.01$  mg/kg

According to the available data, the use on head cabbage is considered acceptable.

### **Magnitude of residues in livestock**

Difenoconazole

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

TMDs

EFSA Journal 2018;16(7):5376:

Data Gap: Poultry and ruminant feeding studies conducted with TLA or, alternatively, metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies to determine the magnitude of TLA residues in products of animal origin.

The above requirement applies to the active substance.

### **Processing studies**

Data are available at EU level on apple, carrot, tomatoes and from acceptable new studies on oilseed rape, apple, tomatoes. The new studies investigated both difenoconazole than TDMs.

Regarding difenoconazole, it was possible to derive some PF for apple, washed and dried and for tomato, dried whereas for the other commodities, results were under LOQ (or even under LOD), so it is not possible to derive consistent conclusions.

Regarding TDMs, in the majority of the cases, data are below the LOQ in raw commodity as well as in all processed fractions, therefore calculations were not performed.

### **Magnitude of residues in representative succeeding crops**

Difenoconazole

Waiting periods before planting following succeeding crops: not required.

TMDs:

Addendum – Confirmatory Data, UK, 2018:

EFSA Journal 2018;16(7):5376: *Rotational crop field trials on cereals small grain, carrots and lettuces were submitted for the determination of all the TDMs at different plant back intervals. The maximum storage time interval of the residue samples of the trials in primary and rotational crops, however, was not provided and is required to conclude on the validity of these trials (data gap).*

The above requirement applies to the active substance.

### **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 (post registration requirement).~~

Studies were already submitted for its evaluation.

The residues of difenoconazole and the triazole-derivative metabolites (TDMs): triazole-alanine (TA), 1,2,4-triazole (1,2,4-T), triazole lactic acid (TLA), triazole acetic acid (TAA) are not above the LOD and/or LOQ, and therefore are not a risk for the consumer.

Therefore, this data gap is already covered.

### **Consumer risk assessment**

The accepted uses of Difenoconazole in the formulation IN005B1570 do not represent unacceptable acute and chronic risks for the consumer.

### 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 IN005B1570 are presented in Table 7.1-1. They have been selected from the individual GAPs in the Southern Zone for oilseed rape, pome fruits, peaches and nectarine, grapes, carrot, tomato, eggplant, pepper, potato, cucumber. A list of all intended uses within the Southern Zone is given in Part B, Section 0.

#### Overall conclusion

State whether or not the available data are sufficient for evaluation, if a risk for consumers has been detected for any European Member State and if a new MRL is required prior to authorization. Data gaps and conditions for registration should be listed (if appropriate).

The data available are considered sufficient for risk assessment. An exceedance of the current MRL mg/kg for oilseed rape, apple, pears and carrot and cauliflower, broccoli and cabbage as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of active substance residues are unlikely to present a public health concern with respect to accepted uses.

As far as consumer health protection is concerned, authority, zRMS agrees with the authorization of the following intended use(s): oilseed rape, apple, pears and carrot and cauliflower, broccoli and cabbage.

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

Or

According to available data, the following specific mitigation measures are recommended: none

#### Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

Noticed data gaps are:

- storage stability data for 1,2,4-Triazole and TA in high oil content matrix (post registration requirement);
- Residue trials on cauliflower, broccoli and cabbage
- A study to determine the residues in honey and bee products is required (oil seed rape; post registration requirement);

**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	12	13	14	15
GAP number (see part B.0)*	Member State	Crop and/or situation **	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Application				Application rate per treatment			PHI (days)	Remarks: e.g. g safener/synergist per ha <sup>(1)</sup>	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	kg as/hL min max	water L/ha min max	kg as/ha min max			
1	PL, DE, CZ, BE, NL, AT, SI, IE	BRSNW (Oilseed rape)  0401060	F	LEPTMA (Plenodomus lingam) SCLECS (Sclerotinia sclerotiorum), ALTEBI (Alternaria brassicae)	foliar spray	Autumn and Spring applications BBCH 14-18 and BBCH 30-69	2 (1 in autumn and 1 in spring or 2 in autumn)	21		100-500	a) 0.125 b) 0.250	NA PHI is defined by the application stage at last treatment.		R****  In Poland accepted
2	PL, DE, CZ, BE, NL, AT, SI, IE	MABSD, PYUCO (Apples, Pears)  0130010 0130020	F	VENTIN, VENTPI (Venturia inaequalis, Venturia pyrina) PODOLE [Powdery mildew (Podosphaera leucotricha)]	foliar spray	BBCH 57-84	3	7 (label: spray interval from 7 to 10 days)		100-1500	a) 0.05625 b) 0.16875	21		A
3	PL, DE, CZ, BE, NL, AT, SI, IE	DAUCS (Garden carrot)  0213020	F	ALTEDA (Alternaria dauci), ALTERA (Alternaria radicina) ERYSHE (Erysiphe heracleid)	foliar spray	From BBCH 39-40 49	3 <del>4</del>	14		200-1000	a) 0.125 b) 0.375	14	Max number of applications: 3	A The residue trials presented by the applicant allow for the acceptance of the use of the product in the protection of carrots up to

														BBCH 49 phase.
416	PL, DE, CZ, BE, NL, AT, SI, IE	BRSOB (cauliflow- er)  0241020	F	ALTEBI (Alternaria brassicola) MYCOBR (Mycosphaerella brassicola)	Foliar spray	From BBCH 19	3	14		200-1000	a) 0.125 b) 0.375	14		A
517	PL, DE, CZ, BE, NL, AT, SI, IE	BRSOK (broccoli)  0241010	F	ALTEBI (Alternaria brassicola) MYCOBR (Mycosphaerella brassicola)	Foliar spray	From BBCH 19-21	3	7-10		200-1000	a) 0.125 b) 0.375	14		A
618	PL, DE, CZ, BE, NL, AT, SI, IE	BRSOL (cabbage)  0242020	F	ALTEBI (Alternaria brassicola) MYCOBR (Mycosphaerella brassicola)	Foliar spray	From BBCH 19	3	7-10		200-1000	a) 0.125 b) 0.375	21		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

\*\*\*\* Non-acceptance of this use due to the need to conduct additional study may be considered at Member State level.

Explanation for Column 15 “Conclusion”

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

## 7.1.2 Summary of the evaluation

The preparation IN005B1570 is composed of Difenoconazole.

**Table 7.1-2: Toxicological reference values for the dietary risk assessment of Difenoconazole and triazole derivatives metabolites (TDMs)**

Reference value	Source	Year	Value	Study relied upon	Safety factor
<b>Difenoconazole</b>					
ADI	EFSA	2011	0.01 mg/kg bw/d	2-year rat study	100
ARfD	EFSA	2011	0.16 mg/kg bw	Rat, developmental	100
<b>1,2,4-Triazole</b>					
ADI	EFSA	2018	0.023 mg/kg bw/d	1-year rat study	300
ARfD	EFSA	2018	0.1 mg/kg bw	Rabbit, developmental	300
<b>Triazole alanine</b>					
ADI	EFSA	2018	0.3 mg/kg bw/d	Rabbit, developmental	100
ARfD	EFSA	2018	0.3 mg/kg bw	Rabbit, developmental	100
<b>Triazole acetic acid</b>					
ADI	EFSA	2018	1 mg/kg bw/d	Rat 2-generation and rabbit developmental studies	100
ARfD	EFSA	2018	1 mg/kg bw	Rat 2-generation and rabbit developmental studies	100
<b>Triazole lactic acid</b>					
ADI	EFSA	2018	0.3 mg/kg bw/d	Bridging from TA	100
ARfD	EFSA	2018	0.3 mg/kg bw	Bridging from TA	100

### 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 (7 NEU 8 SEU)	Yes	Yes	Yes	No	No
2	Apple, Pear	Yes	Yes (8 NEU 8 SEU)	Yes	Yes	Yes	No	No
3	Carrot	Yes	Yes (8 NEU 8 SEU)	Yes	Yes	Yes	No	No
46 4	Cauliflower	Yes	Yes (8 EU)	Yes	Yes	Yes	No	No
47 5	Broccoli	Yes	Yes (8 NEU)	Yes	Yes	Yes	No	No
48 6	Cabbage	Yes	Yes (8 NEU)	Yes	Yes	Yes	No	No

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

The effects of processing on the nature of difenoconazole residues have been investigated. Data on effects of processing on the amount of residue have been submitted. These data were considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

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

### 7.1.2.2 Summary for IN005B1570

**Table 7.1-4: Information on IN005B1570 (KCA 6.8)**

Crop	PHI for IN005B1570 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for IN005B1570 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Difenoconazole		
Oilseed rape	NR	NR	- PHI is defined by the applica-	-

Crop	PHI for IN005B1570 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for IN005B1570 proposed by zRMS	zRMS Comments (if different PHI pro- posed)
		Difenconazole		
			tion stage at last treatment.	
Apple, Pear	21 days	-	-	-
Carrot	14 days	-	-	-
Cauliflower	14 days	-	-	-
Broccoli	14 days	-	-	-
Cabbage	21 days	-	-	-

NR: not relevant

\* Purpose of withholding period to be specified

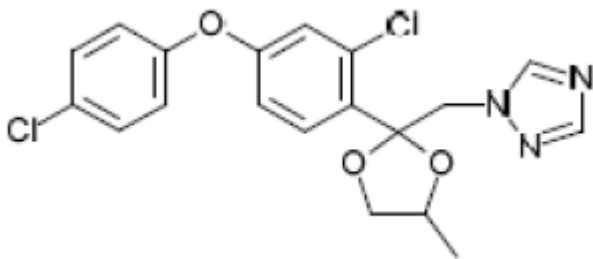


## Assessment

### 7.2 Difenoconazole

General data on Difenoconazole are summarized in the table below (last updated 2022/01/06)

**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 <sub>19</sub> H <sub>17</sub> Cl <sub>2</sub> N <sub>3</sub> O <sub>3</sub>
Molar mass	406.3 g/mol
Chemical group	Triazoles
Mode of action (if available)	Inhibition of sterol demethylation
Systemic	Yes
Company (ies)	Syngenta Crop Protection AG / Globachem NV
Rapporteur Member State (RMS)	Spain
Approval status	Approved Date of 01/01/2009 <a href="#">REGULATION (EU) No 1100/2011</a> , extensions of approval period <a href="#">REGULATION (EU) No 2020/1511</a> and <a href="#">REGULATION (EU) No 2021/1449</a> .
Restriction (e.g. is restricted to use as "...")	Restricted to use as fungicide only
Review Report	SANCO/830/08 – rev. 3 13/12/2013, 18/05/2020
Current MRL regulation	Regulation (EU) No 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
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	None

## 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  $\leq -18^{\circ}\text{C}$  (unless stated otherwise)**

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
<b>Data relied on in EU</b>			
<b>Plant products</b>			
Tomato	High water content	24 months	Sweden, 2006
Lettuce	High water content	12 months	Sweden, 2006
Banana	High water content	12 months	Sweden, 2006
Potato	High starch content	24 months	Sweden, 2006
Wheat	High starch content	24 months	Sweden, 2006
Soybean	High oil content	12 months	Sweden, 2006
Cotton, seed	High oil content	24 months	Sweden, 2006
Cotton, oil	High oil content	24 months	Sweden, 2006
Cotton, meal	No group	24 months	Sweden, 2006
Wheat, straw	No group	24 months	Sweden, 2006
Wheat, forage	No group	24 months	Sweden, 2006
<b>Animal Products</b>			
Poultry	Meat	12 months	Sweden, 2006
Ruminant	Meat	10 months	Sweden, 2006
Ruminant	Fat	10 months	Sweden, 2006
Ruminant	Liver	12 months	Sweden, 2006
Ruminant	Kidney	10 months	Sweden, 2006
Ruminant	Blood	10 months	Sweden, 2006
Ruminant	Milk	12 months	Sweden, 2006
Poultry	Egg	12 months	Sweden, 2006
<b>New studies: TDMs (triazole Derived Metabolites)</b>			
<b>Plant products</b>			
Wheat (grain)	High starch content	7 months	Longhi, D. 2022 GLP-STUDY-21-124
Wheat (straw)	Dry commodities	7 months	
Oilseed rape (seed)	High oil content	7 months	
Apple	High water content	7 months	
Carrot	High water content	7 months	
Tomato	High water content	7 months	

### Conclusion on stability of residues during storage

In the framework of the peer review (Sweden, 2006), storage stability of difenoconazole residues was demonstrated at -18 °C for 12 months in the high-water content plant matrices lettuce and banana, and for 24 months in tomato. For high oil content matrices, storage stability of 12 months was observed for soybean and 24 months for cotton seed and cotton oil. High starch content matrices (potato, wheat) as well as cotton meal and wheat straw and forage were stable for 24 months when stored frozen.

During the peer review (Sweden, 2006), difenoconazole in eggs, milk, poultry breast and beef liver was shown to be stable for at least 12 months when stored frozen, and stable for at least 10 months in blood, fat and kidney from cattle.

The available storage stability data are sufficient to demonstrate the stability of residues of difenoconazole but regarding TDMs, a new study (Longhi, D. 2021. GLP-STUDY-21-124) was performed to assess the storage stability of triazole derivatives metabolites in high water (wheat forage, apple, tomato and carrot), in high oil (oilseed rape seeds), in high start (wheat grain), and in dry (wheat straw) commodities.

After 7 months of storage, the obtained results for recovery are in compliance with the requirements of the SANTE/2020/12830 rev.1, with mean recovery in the range of 70-120% for the level of 0.1 mg/kg. For any detail about the study, reference is made to Appendix 2.

The studies demonstrated residue stability in all the matrices stored at -18°C for a period of 7 months for all TMDs, thus covering the storage periods of the supervised residue trials on various crops.

#### 7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

##### Available data

No data are available at EU level.

Study on the validation of the analytical method for oilseed rape and processed commodities (GLP-STUDY-21-31) and apple, carrot, tomato and processed commodities (GLP-STUDY-21-32) verified also the stability of sample extracts in the different matrices. The stability of the analyte in the final extracts can be considered proven for 3 days at  $5 \pm 3^\circ\text{C}$  in dark conditions for each tested matrix since the recovery of the stored spiked extracts were within the range of 70-120% measured against the freshly prepared ones, as required by the SANTE/2020/12830 rev.1 guideline.

Details of validation data are reported in part B5.

##### Conclusion on stability of residues in sample extracts

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

#### 7.2.2 Nature of residues in plants, livestock and processed commodities

##### 7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

##### Available data

No new data submitted in the framework of this application.

The plant metabolism of difenoconazole was investigated in the peer review (Sweden, 2006) in five crops, representing four crop groupings: fruits and fruiting vegetables (tomato, grape), root and tuber vegetables (potato), pulses and oilseeds (oilseed rape) and cereals (spring wheat). For each crop, two radiolabelled forms of difenoconazole were studied, [phenyl-14C] and [triazole-14C]. Foliar application (2 to 6 treatments) was used for all crops, and seed treatment in wheat was also examined.

**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 (g a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Tomato	Phenyl-14C	Foliar, G	123.5	6	Foliage: 55 (after 1st app.), 68 (before 3rd app.), 82 (before 5th app.)		Sweden, 2006
		Triazole-14C				Fruit (green): 82 (before 5th app.) Foliage, fruit (green and ripe): 106 (16 DALA)		
		Phenyl-14C	Foliar, F	247	3	Foliage: 63 (after 1st app.), 77 (before 2nd app.), 91 (before 3rd app.)		Sweden, 2006
		Triazole-14C				Fruit (green): 91 (before 3rd app.) Foliage, fruit (green and ripe): 131 (40 DALA)		
		Triazole-14C	Foliar, G	123	6	Foliage: 62 (after 1st app.), 76 (before 3rd app.), 90 (before 5th app.), 97 (before 6th app.) Fruit (green): 90 (before 5th app.), 97 (before 6th app.), 104 (7 DALA) Foliage, fruit (green, intermediate and ripe): 131 (34 DALA)		Sweden, 2006
		Phenyl-14C				Foliage: 62 (after 1st app.), 76 (before 3rd app.), 90 (before 5th app.), 97 (before 6th app.) Fruit (green): 90 (before 5th app.), 97 (before 6th app.), 104 (7 DALA) Foliage, fruit (green): 131 (34		

						DALA) Fruit (ripe): 131 (16 DALA)		
	Grape	Phenyl-14C	Foliar, F	247	5	Leaves: immature Leaves, fruit (mature): 20 DALA		Sweden, 2006
		Triazole-14C						
Root and tuber vegetables	Potato	Phenyl-14C	Foliar, G	123.5	6	Foliage: 62 (after 1st app.), 76 (before 3rd app.) Foliage, tubers: 90 (before 5th app.), 108 (11 DALA)		Sweden, 2006
		Triazole-14C						
Pulses and oilseeds	Oilseed rape	Phenyl-14C	Foliar, F	125	2	Plant: 78 (after 1st app.), 92 (before and after 2nd app.) Straw, pods, seed: 131 (39 DALA)		Sweden, 2006
		Triazole-14C						
Cereals	Spring wheat	Phenyl-14C	Foliar, G	247	4	Foliage: 43 (25% mature), 58 (50% mature) Straw, hulls, grain: 94 (29 DALA)		Sweden, 2006
		Triazole-14C						
		Phenyl-14C	Seed, F (Trial 1)	24 g a.s./ 100 kg seed	1	Foliage: 31 (25% mature), 48 (50% mature) Straw, hulls, grain: 59 (ma- ture)		Sweden, 2006
		Triazole-14C	Seed, F (Trial 1)			Foliage: 34 (25% mature), 52 (50% mature) Straw, hulls, grain: 72 (ma- ture)		
		Triazole-14C	Seed, F (Trial 2)			Foliage: 33 (25% mature), 62 (50% mature) Straw, hulls, grain: 83 (ma- ture)		
		Phenyl-14C	Seed, G	24 g a.s./ 100 kg seed	1	Foliage: 40 (25% mature), 72 (50% mature) Straw, hulls, grain: 236 (ma- ture)		Sweden, 2006
		Triazole-14C						

## Summary of plant metabolism studies reported in the EU

**Difenoconazole:** Metabolism of difenoconazole in plants was found to be similar in all four crop types. The parent difenoconazole remained the major component of the residues (mostly >10% TRR) in the majority of the plant parts, except for cereal grains, potato tubers and rape seeds, where it comprised < 10-15% TRR. In these three crops, with triazole labelling, TRRs mainly comprise the triazole derivative metabolites (TDM) triazole alanine (56% TRR in rape seeds, 79% TRR in potato tubers) and triazole acetic acid (20% TRR in cereal grain). Triazole alanine was also detected up to 42% TRR in tomato fruits and 1,2,4-triazole up to 12% TRR in grapes. TDMs were also the major components of the residues in cereal grains on seed treatment. The metabolites CGA 205374 (ketone), CGA 205375 (alcohol) and CGA 189138 (benzoic acid) were found in low proportions, < 5% TRR.

The following plant metabolic pathway is proposed: first, the dioxolane ring is hydrolysed to form the ketone metabolite, which is then reduced to the corresponding alcohol. The alcohol is oxidised, resulting in cleavage of the alkyl bridge to form the benzoic acid metabolite and the 1,2,4-triazole, which is then further metabolised to triazole alanine and triazole acetic acid.

**TDMs:** EFSA, 2018: “Primary crops metabolism data are reported for a total of 16 approved triazole compounds, 2 and 2 triazole active substances that are not approved at EU level (bitertanol, flusilazole), on fruit crops, cereals (straw and grain), pulses and oilseeds and root crops...

*Based on the metabolism data in primary and rotational crops that were compiled from the assessment of the 18 triazole active substances the triazole active substances were shown to degrade into the common metabolites 1,2,4-T, TA, TLA and TAA, known as TDMs.*

*Besides the parent compound that was identified at significant residue levels in all crop groups, TA was predominantly found in the organs of storage (79% total radioactive residue (TRR) in potato tuber, 31–88% TRR in oil seeds, 8–69% TRR in cereal grains) but also in cereal straw (1–16% TRR) and in fruit crops (up to 80% TRR). TAA was only detected at significant proportions in cereal grain and straw (5–35% and 7–41% TRR, respectively) and TLA in fruit crops (up to 67% TRR) and in cereal straw (up to 43% TRR). 1,2,4-T was detected at lower levels in all crop parts (up to 12% TRR).*

*Similar metabolic patterns were depicted both in primary and in rotational crops.”*

### Summary of new plant metabolism studies

No new studies are submitted by the applicant.

### Conclusion on metabolism in primary crops

Based on the metabolic pattern identified in metabolism studies and considering the results of hydrolysis studies, the residue definitions for plant products were proposed as difenoconazole for enforcement and risk assessment and, additionally, triazole derivative metabolites (TDMs) for the risk assessment.

No additional trials are required to cover the uses under consideration.

#### 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.

In the peer review (Sweden, 2006), metabolism in rotational crops was investigated in lettuce, sugar beet, turnips, mustard, wheat and maize. A single application was made on bare ground in open fields in each case,

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (g a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	Phenyl-14C	Bare soil, F	125	98	Head: 126, 151		Sweden, 2006
		Triazole-14C						
Root and tuber vegetables	Sugar beet	Phenyl-14C	Bare soil, F	125	369	Tops, roots: 427, 473, 488		Sweden, 2006
		Triazole-14C						
		Turnip	Phenyl-14C	Bare soil, F	32.4	30/33 (Trial 1/2)	Tops: 137/129	
Pulses and oilseeds	Mustard	Phenyl-14C	Bare soil, F	32.4	30/33 (Trial 1/2)	Mature greens: 137/129		Sweden, 2006
Cereals	Winter wheat	Phenyl-14C	Bare soil, F	125	126	Whole top: 167, 342, 369 Straw, husks, grain: 418		Sweden, 2006
	Maize	Triazole-14C	Bare soil, F	125	342	Whole top: 398, 427 Stalks, cobs, grain: 488		Sweden, 2006
	Spring wheat	Phenyl-14C	Bare soil, F	32.4	30/33 (Trial 1/2)	Whole top: 137, 179/109 Straw, grain: 218/175		Sweden, 2006

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

### Summary of plant metabolism studies reported in the EU

**Difenoconazole:** The results from the confined rotational crop studies, summarised by EFSA (2010), revealed that for [phenyl-<sup>14</sup>C]-labelled difenoconazole, TRR was at very low levels ( $\leq 0.01$  mg/kg) and was therefore not characterised. For [triazole-<sup>14</sup>C]-labelled difenoconazole, the TRR comprised triazole alanine (10.4 – 66.2 %), triazole lactic acid (9.7 – 54.3 %) and triazole acetic acid (2.7 – 39.4 %). The metabolites CGA 205375 and CGA 71019, which were identified in soil degradation/dissipation studies, were not identified in the rotational crop studies. Lettuce heads harvested at 126 and 151 DAT contained 0.021 and 0.017 mg difenoconazole equiv./kg, respectively, while mature wheat and maize grains contained 0.34 and 0.211 mg difenoconazole equiv./kg, respectively. These residues occurred from selective transport of triazole derivatives from the soil to grain.

**TDMs:** EFSA, 2018 “Based on the metabolism data in primary and rotational crops that were compiled from the assessment of the 18 triazole active substances the triazole active substances were shown to degrade into the common metabolites 1,2,4-T, TA, TLA and TAA, known as TDMs... Similar metabolic patterns were depicted both in primary and in rotational crops.”

### Summary of new plant metabolism studies

No new studies are submitted by the applicant.

### Conclusion on metabolism in rotational crops

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

#### 7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

##### Available data

No new data submitted in the framework of this application.

**Difenoconazole:** In the peer review (Sweden, 2006), the hydrolysis of difenoconazole was investigated under conditions representing the processes involved in pasteurisation, baking/boiling/brewing and sterilisation.

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

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
<b>EU data</b>		
<b>Pasteurisation</b> (20 minutes, 90°C, pH 4)	Difenoconazole (95.6%)	Sweden, 2006
<b>Baking, boiling, brewing</b> (60 minutes, 100°C, pH 5)	Difenoconazole (98.1%)	Sweden, 2006
<b>Sterilisation</b> (20 minutes, 120°C, pH 6)	Difenoconazole (98.6%)	Sweden, 2006

**TDMs:** EFSA, 2018 “*The TDMs remained stable under the standard hydrolysis conditions simulating processing of pasteurisation, baking, brewing and boiling and sterilisation.*”

### Conclusion on nature of residues in processed commodities

As at least 95.6% of the TRR following pasteurisation, baking/boiling/brewing or sterilisation consisted of parent difenoconazole, the studies on the nature of the residues in processed commodities indicate that difenoconazole is stable under standard hydrolysis conditions. Thus, the relevant residue in processed commodities is expected to be the same as for primary crops.

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

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

<b>Endpoints</b>	
Plant groups covered	Fruit crops (tomatoes, grapes) Root crops (potatoes) Cereals/grass (spring wheat) Pulses/oilseeds (rapeseeds)
Rotational crops covered	Root/tuber crops (turnip, sugar beet, radishes) Leafy crops (mustard, lettuces) Cereal (maize, wheat, sorghum)



Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	a.s. is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Difenoconazole (Regulation (EU) 2019/552)
Plant 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 (EFSA 2018)
Conversion factor from enforcement to RA	n.a.

### 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.

**Difenoconazole:** In the peer review (Sweden, 2006), the metabolism of difenoconazole was investigated in lactating ruminants and in laying poultry. The studies are summarised in the table below.

**Table 7.2-7: Summary of animal metabolism studies**

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[phenyl-14C]	1	0.23	10	Milk	Daily	Sweden, 2006
	Goat	[triazole-14C]	1	0.23	10	Urine & faeces	daily	Sweden, 2006
						Blood	Day 1, 2, 4, 6, 8, 9 & 10	
						Tissues	at sacrifice	
	Goat	[phenyl-14C]	2	3.75	3	Milk	Twice daily	Sweden, 2006
	Goat	triazole-14C]	2	3.75	3	Urine & faeces	daily	Sweden, 2006
						Tissues & blood	at sacrifice	
	Goat	[phenyl-14C]	2	3.10	4	Milk	Twice daily	Sweden, 2006
						Urine & faeces	daily	
						Tissues & blood	at sacrifice	

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
Laying poultry	Hens	[phenyl- <sup>14</sup> C]	2	0.38	14	Eggs	daily	Sweden, 2006
	Hens	[triazole- <sup>14</sup> C]	2	0.38	14	Excreta	daily	Sweden, 2006
						Tissues & blood	at sacrifice	
	Hens	[phenyl- <sup>14</sup> C]	10	5.0	3	Eggs	daily	Sweden, 2006
	Hens	[triazole- <sup>14</sup> C]	10	5.0	3	Excreta	daily	Sweden, 2006
						Tissues & blood	at sacrifice	
	Hens	[triazole- <sup>14</sup> C]	5	7.7	4	Eggs	daily	Sweden, 2006
						Excreta	daily	
						Tissues & blood	at sacrifice	

**TDMs:** EFSA, 2018 “The compilation of the poultry and ruminant metabolism studies conducted with the triazole pesticide active substances with the <sup>14</sup>C labelling on the triazole moiety showed that besides the parent compound that was detected in significant proportions in all animal matrices ranging between 27% and 81% TRR in milk, eggs and tissues, 1,2,4-T was also found to be a predominant compound of the total residues with levels ranging from 31% to 86% TRR in those matrices. TA was identified at very low levels in poultry muscle only (< 10% TRR) and at levels between 22% and 39% TRR in ruminant matrices”.

### Summary of animal metabolism studies reported in the EU

**Difenoconazole:** Conclusions drawn in the DAR, 2006 are reported below:

Metabolism studies of difenoconazole were carried out in lactating goats and laying hens. The metabolism studies were performed using two radiolabelled forms of difenoconazole, [phenyl-<sup>14</sup>C] and [triazole-<sup>14</sup>C] difenoconazole.

Capsules containing the test substance were administered orally to lactating goats and laying hens with concentrations corresponding to doses of 5 to 100 ppm in feed to the lactating goats and 5, 68 and 121 ppm in feed to the laying hens. Difenoconazole was rapidly metabolised, with the majority of the administered radioactivity excreted in the urine and faeces (up to 96.8% in hen and up to > 88% in goat).

Maximum residue levels were present in the liver and kidney, at 9.790 and 2.731 mg/kg, respectively, in lactating goats and up to 4.660 and 2.247 mg/kg, respectively, in laying hens. Higher tissue residues (up to 20.409 mg/kg in liver) were observed in the hen following an extremely high dose of difenoconazole (121 mg/kg for 4 days) and sampling immediately after the final dose.

In lactating goats and laying hens, maximum residues of parent difenoconazole were detected in the liver and fat, at concentrations up to 0.891 (9.1% TRR) and 1.912 mg/kg (18.4% TRR), respectively. In other edible tissues, residues of parents difenoconazole were ≤ 0.107 mg/kg (2.2% TRR). In milk, residues of parents difenoconazole were up to 0.028 mg/kg (8.8% TRR) and up to 0.236 mg/kg (5.3% TRR) in egg yolk.

Similar pathways of metabolism were observed in lactating goats and laying hens and consequently a study in pig is not considered required.”

**TDMs:** EFSA, 2018 “Since TA is a major component in feed items, the potential transfer of this com-

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

#### Summary of new animal metabolism studies

No new studies submitted in the framework of this application.

#### Conclusion on metabolism in livestock

The metabolism of difenoconazole and TDMs in livestock is sufficiently addressed to support the proposed uses of the product IN005B1570.

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

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

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	1) 48 hours (phenyl- <sup>14</sup> C labelled) 2) 144 hours (triazole- <sup>14</sup> C labelled) (EFSA, 2011a)
	1) 168 hours in egg yolk (phenyl- <sup>14</sup> C and triazole- <sup>14</sup> C labelled) 2) 120 hours in egg white (triazole- <sup>14</sup> C labelled) (EFSA, 2011a)
Animal residue definition for monitoring	EFSA peer review (EFSA, 2011b): Difenoconazole alcohol (CGA-205375) expressed as difenoconazole Regulation (EC) No 396/2005: Difenoconazole
Animal residue definition for risk assessment	1) Difenoconazole alcohol (CGA205375) expressed as Difenoconazole 2) TA and TLA, since these compounds share the same toxicity 3) TAA 4) 1,2,4-Triazole
Conversion factor	Not concluded (EFSA, 2011)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

## 7.2.3 **33344** Magnitude of residues in plants (KCA 6.3)

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

Studies were available at EU level and are reported in the table 7.2-9 below. New studies on the magnitude of residues have been submitted by the applicant in the framework of this application (investigating difenconazole and TDMs). The detailed assessment of these studies is presented in Appendix 2.

When data available at EU level were used together with new data to support the intended uses, they were marked in black; when data available at EU level were not used to support the intended uses (because of differences in the GAP table), they were marked in grey.

A summary of all the available data is reported in Table 7.2-9 to 7.2-13:

- table 7.2-9 resume data according to the enforcement residue definition (= difenconazole parent compound only) in order to evaluate their compliance with current MRLs, which correspond to risk assessment residue definition 1;
- table 7.2-10 resume data for triazole alanine (TA) and triazole lactic acid (TLA), which constitute residue definition 2 for risk assessment, as TA and TLA showed the same toxicity;
- table 7.2-11 resume data for triazole acetic acid (TAA), which is residue definition 3 for risk assessment;
- table 7.2-12 resume data for 1,2,4-Triazole alanine (1,2,4-T), which is residue definition 4 for risk assessment;
- table 7.2-13 shows a summary of the data for new studies expressed as sum of difenconazole and TDMs, expressed as difenconazole, in order to verify which is the impact of the TDMs on the total amount of residues in the different crops and crop matrices.

Note that the crops included in the below tables comprise all crops included in the GAPs for both the Central and Southern Zones.

**Table 7.2-9: Summary of EU reported and new data supporting the intended uses of IN005B1570 and conformity to existing MRL – difenoconazole**

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
<b>Enforcement residue definition: Difenconazole</b>								
<b>Risk assessment residue definition 1: Difenconazole (parent compound only)</b>								
Oilseed rape	New trials	N-EU	Trials GAP: 2 x 0.125 kg as/ha, outdoor E, RA: 6x<0.01, 0.0102	E: 0.010 RA: 0.010	E: 0.010 RA: 0.010	0.013	0.5	Yes
	New trials	S-EU	Trials GAP: 2 x 0.125 kg as/ha, outdoor E, RA: 5x<0.01, 0.0738, 0.0752, 0.15	E: 0.010 RA: 0.010	E: 0.15 RA: 0.15	0.251	0.5	Yes
	Overall supporting data for eGAP	N-EU + S-EU	E, RA: 11x<0.01, 0.0102, 0.074, 0.075, 0.15	E: 0.010 RA: 0.010	E: 0.15 RA: 0.15	0.190	0.5	Yes
Apple → extrapolation to Pear	Sweden, 2006	N-EU	GAP on which EU a.s. assessment is based: 4 x 0.056 kg as/ha, PHI 28d, outdoor E, RA: 0.01, 0.02, 0.03, 0.04, 2x 0.05, 0.06, 2x 0.07	N/A				
	New trials	N-EU	Trials GAP: 3 x 0.05625 kg as/ha, PHI 21d, outdoor E: 0.0186, 0.0264, 0.0268, 0.0322, 0.0474, 0.0585, 0.0937, 0.1058 0.02, 3x0.03, 0.05, 0.06, 0.09, 0.11 (rounded numbers)	E: 0.040 RA: 0.040	E: 0.106 RA: 0.106 0.11	0.182	0.8	Yes
	Sweden, 2006	S-EU	GAP on which EU a.s. assessment is based: 4 x 0.075 kg as/ha, PHI 14d, outdoor E, RA: 0.04, 0.05, 0.07, 0.08, 0.10, 0.11, 0.13, 0.14, 0.15, 0.16, 0.28	N/A				
	New trials	S-EU	Trials GAP: 3 x 0.05625 kg as/ha, PHI 21d, outdoor E, RA: 2x<0.01, 0.0212, 0.0263, 0.0324, 0.0358, 0.0581, 0.0633	E: 0.029 RA: 0.029	E: 0.063 RA: 0.063	0.112	0.8	Yes
	Overall supporting data for eGAP	N-EU + S-EU	Trials GAP: 3 x 0.05625 kg as/ha, PHI 21d, outdoor E, RA: 2x<0.01, 0.0186, 0.0212, 0.0264, 0.0268, 0.0322, 0.0324, 0.0358, 0.0474, 0.0581, 0.0585, 0.0633, 0.0937, 0.1058	E: 0.032 RA: 0.032	E: 0.106 RA: 0.106	0.154	0.8	Yes

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
Carrot	Sweden, 2006	N-EU	GAP on which EU a.s. assessment is based: 3 x 0.125 kg as/ha, PHI 14d, outdoor E, RA: 2x 0.02, 0.03, 0.04, 0.05, 0.07, 0.11, 0.12	N/A				
	New trials	N-EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 14d, outdoor E, RA: 0.02597, 0.02824, 0.05418, 0.05666, 0.0577, 0.06944, 0.1118, 0.1153					
	Overall supporting data for cGAP	N-EU (new trials + Sweden 2006)	E, RA: 2x 0.02, 0.026, 0.028, 0.03, 0.04, 0.05, 0.054, 0.057, 0.058, 0.069, 0.07, 0.11, 0.112, 0.115, 0.12 2x 0.02, 3x0.03, 0.04, 0.05, 0.05, 2x0.06, 2x0.07, 2x0.11, 2x0.12 (rounded)	E: 0.055 RA: 0.055 0.06	E: 0.120 RA: 0.120	0.203	0.4	Yes
	Sweden, 2006	S-EU	GAP on which EU a.s. assessment is based: 3 x 0.125 kg as/ha, PHI 14d, outdoor E, RA: 0.02, 0.03, 0.07, 0.11, 0.13	N/A				
	New trials	S-EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 14d, outdoor E, RA: 0.0177, 0.0674, 0.0682, 0.0704, 0.0763, 0.0967, 0.2065, 0.2197					
	Overall supporting data for cGAP	S-EU (new trials + Sweden 2006)	E, RA: 0.0177, 0.02, 0.03, 0.0674, 0.0682, 0.07, 0.0704, 0.0763, 0.0967, 0.11, 0.13, 0.2065, 0.2197	E: 0.070 RA: 0.070	E: 0.22 RA: 0.22	0.344	0.4	Yes
	Overall supporting data for cGAP	NEU + S-EU	E: 0.0177, 3x0.02, 0.026, 0.0282, 2x0.03, 0.04, 0.05, 0.0542, 0.0567, 0.0577, 0.0674, 0.0682, 2x0.07, 0.0704, 0.0763, 0.0967, 2x0.11, 0.1118, 0.1153, 0.12, 0.13, 0.2065, 0.2197	E: 0.068 RA: 0.068	E: 0.22 RA: 0.22	0.279	0.4	Yes

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
Tomato → extrapolated to Aubergine	New trials	S-EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 7d, outdoor E, RA: 0.0137, 0.0282, 0.0336, 0.0347, 0.0378, 0.0464, 0.0481, 0.0496	E: 0.036 RA: 0.036	E: 0.050 RA: 0.050	0.11	<del>2.0 (tomato)</del> 0.6 (aubergine)	Yes
	New trials	EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 3d, indoor E, RA: 0.0175, 0.0445, 0.0948, 0.1115, 0.1189, 0.1578, 0.1766, 0.1896	E: 0.115 RA: 0.115	E: 0.19 RA: 0.19	0.358	<del>2.0 (tomato)</del> 0.6 (aubergine)	Yes
	Overall supporting data for eGAP	S-EU + EU	E, RA: 0.0137, 0.0175, 0.0282, 0.0336, 0.0347, 0.0378, 0.0445, 0.0464, 0.0481, 0.0496, 0.0948, 0.1115, 0.1189, 0.1578, 0.1766, 0.1896	E: 0.047 RA: 0.047	E: 0.19 RA: 0.19	0.309	<del>2.0 (tomato)</del> 0.6 (aubergine)	Yes
211000 Potato	JMPR, 2005	S-EU	Trials GAP: 4 x 200 g as/ha, PHI 30d, outdoor E, RA: 8x<0.01	E: 0.01 RA: 0.01	E: 0.01 RA: 0.01	0.01	0.1	Yes
231020 Pepper	EFSA, 2010	S-EU	Trials GAP: 3 x 125 g as/ha, PHI 7d, outdoor E, RA: 0.07, 0.11, 0.19, 0.21	N/A				
		EU	Trials GAP: 3 x 125 g as/ha, PHI 3d, indoor E, RA: 0.06, 0.12, 0.13, 0.13, 0.15, 0.25, 0.27, 0.4					
	Overall supporting data for eGAP	EU	E, RA: 0.06, 0.07, 0.11, 0.12, 0.13, 0.13, 0.15, 0.19, 0.21, 0.25, 0.27, 0.4	E: 0.14 RA: 0.14	E: 0.40 RA: 0.40	0.60	0.9	Yes
232010 Cucumber → courgettes, gherkins	EFSA, 2012	EU	GAP on which MRL a.s. assessment is based: 3-4 x 125 g as/ha, PHI 3d E, RA: 2x<0.01, 4x0.01, 0.02, 0.03, 0.06, 0.18	E: 0.01 RA: 0.01	E: 0.18 RA: 0.18	0.30	0.3	Yes
151000 Grapes	JMPR, 2005	S-EU	Trials GAP: 4 x 50 g as/ha, PHI 21d, outdoor E, RA: 0.01, 0.02, 0.02, 0.03, 0.03, 0.04, 0.04, 0.07	E: 0.03 RA: 0.03	E: 0.07 RA: 0.07	0.11	3	Yes
140030 Peaches → nectarine	JMPR, 2005	S-EU	Trials GAP: 3 x 75 g as/ha, PHI 7d, outdoor E, RA: 0.07, 0.11, 0.14, 0.14, 0.19, 0.18, 0.16, 0.26	E: 0.15 RA: 0.15	E: 0.26 RA: 0.26	0.47	0.5	Yes

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
**241010 Broccoli, 241020 Cauliflowers	JMPR, 2005 Broccoli	N-EU	Trials GAP: 3 x 130 g as/ha, PHI 14d, outdoor E, RA: <0.02, 0.02, 0.03, 0.05, 0.08, 0.10	N/A				
	JMPR, 2005 Cauliflowers	N-EU	Trials GAP: 3 x 130 g as/ha, PHI 14d, outdoor E, RA: 0.01, 9x<0.02, 0.03, 0.10	E: 0.02 RA: 0.02	E: 0.10 RA: 0.10	0.12	0.2 cauliflowers	Yes
	Overall supporting data for eGAP	N-EU	E, RA: 0.01, 10x <0.02, 0.02, 2x 0.03, 0.05, 0.08, 2x 0.10	E: 0.02 RA: 0.02	E: 0.10 RA: 0.10	0.15	0.2 cauliflowers 1.0 broccoli	Yes
**242020 Head cabbage	JMPR, 2005	N-EU	Trials GAP: 3 x 130 g as/ha, PHI 21d, outdoor E, RA: 2x<0.01, 0.01, 11x0.02, 0.19	E: 0.02 RA: 0.02	E: 0.19 RA: 0.19	0.21	0.3	Yes
**241010 Broccoli, 241020 Cauliflowers	New trials	N-EU	Trial GAP: 3 x 125 g as/ha, PHI 14 d, outdoor E, RA: <0.002, 4x<0.01, 0.0178, 0.0415, 0.125	E: 0.01 RA: 0.01	E: 0.13 RA: 0.13	0.19	0.2 cauliflower 1.0 broccoli	Yes
**242020 Head cabbage	New trials	N-EU	Trial GAP: 3 x 125 g as/ha, PHI 21 d, outdoor E, RA: 0.00317, 0.00433, 0.0091, 0.0105, 0.0119, 0.0128, 0.0437, 0.0692	E: 0.01 RA: 0.01	E: 0.07 RA: 0.07	0.11	0.3	Yes

\* Source of EU MRL: [Regulation \(EU\) No 2019/552](#)

\*\*authorisation required in CEU only

Sweden, 2006: data assessed in DAR, reported also in [EFSA, 2011](#)

JMPR, 2005: [JMPR 2005 \(fao.org\)](#)

EFSA, 2010: [EFSA Journal 2010; 8\(6\):1651](#)

EFSA, 2012: [EFSA Journal 2012;10\(8\):2867](#)



**Table 7.2-10: Summary of EU reported and new data supporting the intended uses of IN005B1570 – Triazole alanine and triazole lactic acid**

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
<b>Risk assessment residue definition 2: Triazole alanine + Triazole lactic acid</b>								
<b>TDMs: Triazole alanine</b>								
Oilseed rape	New trials	N-EU	Trials GAP: 2 x 0.125 kg as/ha, outdoor Data: 1.566, 1x<0.002, 0.205, 0.299, 0.537, 0.1198, 0.113 <0.002, 0.11, 0.12, 0.21, 0.30, 0.54, 1.6	N/A				
	New trials	S-EU	Trials GAP: 2 x 0.125 kg as/ha, outdoor Data: 5x<0.002, 0.006, 0.165, 0.13	N/A				
	Overall supporting data for eGAP	S-EU	Data: 6x<0.002, 0.006, 0.113, 0.1198, 0.13, 0.165, 0.205, 0.299, 0.537, 1.566	0.113 0.21	1.566 1.6	1.825	n.a.	n.a.
Apple → extrapolated to Pear	New trials	N-EU	Trials GAP: 3 x 0.05625 kg as/ha, PHI 21d, outdoor Data: 0.0013, 4x<0.002, 0.0044, 0.0266, 0.0299 4x<0.002, 2x<0.01, 2x 0.03	N/A				
	New trials	S-EU	Trials GAP: 3 x 0.05625 kg as/ha, PHI 21d, outdoor Data: 2x<0.002, 0.0021, 0.0038, 0.0045, 0.0115, 0.0265, 0.0639	N/A				
	Overall supporting data for eGAP	S-EU	Data: 7x<0.002, 0.0021, 0.0038, 0.0044, 0.0115, 0.0265, 0.0266, 0.0299, 0.0045, 0.0639	0.003 0.002	0.064 0.03	0.080	n.a.	n.a.

[illegible]

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
Oilseed rape	New trials	N-EU	Trials GAP: 2 x 0.125 kg as/ha, outdoor Data: <0.002, 0.0044, 0.0114, 0.0207, 0.025, 0.0317, 0.0628 <0.002, <0.01, 0.01, 0.02, 2x0.03, 0.06	N/A				
	New trials	S-EU	Trials GAP: 2 x 0.125 kg as/ha, outdoor Data: 6x<0.002, 0.0065, 0.0067	N/A				
	Overall supporting data for eGAP	EU	Data: 7x<0.002, 0.0044, 0.0065, 0.0067, 0.0114, 0.0207, 0.025, 0.0317, 0.0628	0.004 0.02	0.063 0.06	0.080	n.a.	n.a.
Apple → extrapolation to Pear	New trials	N-EU	Trials GAP: 3 x 0.05625 kg as/ha, PHI 21d, outdoor Data: 0.0008, 4x<0.002, 0.003, 0.0187, 0.0222 5x <0.002, 2x 0.002, <0.01	N/A				
	New trials	S-EU	Trials GAP: 3 x 0.05625 kg as/ha, PHI 21d, outdoor Data: 0.0015, 3x<0.002, 0.0033, 0.01, 0.0146, 0.0208	N/A				
	Overall supporting data for eGAP	EU	Data: 9x<0.002, 0.003, 0.0033, 0.01, 0.0146, 0.0187, 0.0280, 0.0222	0.002	0.022 0.01	0.038	n.a.	n.a.
Carrot	New trials	N-EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 14d, outdoor Data: 0.00056, 0.00114, 3x<0.002, 0.00222, 0.00321, 0.0037 5x <0.002, 0.002, 3x <0.01	N/A				
	New trials	S-EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 14d, outdoor Data: 0.00024, 0.00047, 3x<0.002, 0.00224, 0.00503, 0.0092	N/A				
	Overall supporting data for eGAP	EU	Data: 10x<0.002, 0.00222, 0.00224, 0.00321, 0.0037, 0.00503, 0.0092	0.002	0.009 0.01	0.010	n.a.	n.a.
Tomato → extrapolated	New trials	S-EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 7d, outdoor Data: 0.0013, 5x<0.002, 0.003, 0.0037	N/A				

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
to Aubergine	New trials	EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 3d, indoor Data: 0.0008, 4x<0.002, 0.0033, 0.0035, 0.004	N/A				
	Overall supporting data for eGAP	EU	Data: 11x<0.002, 0.003, 0.0035, 0.0037, 0.0040	0.002	0.004	0.005	n.a.	n.a.
Broccoli, Cauliflowers	New trials	N-EU	Trial GAP: 3 x 125 g as/ha, PHI 14 d, outdoor Data: 8x<0.002	0.002	0.002	0.002	n.a.	n.a.
Head cabbage	New trials	N-EU	Trial GAP: 3 x 125 g as/ha, PHI 21 d, outdoor Data: 7x<0.002, 0.00299	0.002	0.003	0.003	n.a.	n.a.

**Table 7.2-11: Summary of EU reported and new data supporting the intended uses of IN005B1570 – triazole acetic acid**

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
<b>Risk assessment residue definition 3: Triazole acetic acid</b>								
Oilseed rape	New trials	N-EU	Trials GAP: 2 x 0.125 kg as/ha, outdoor Data: 4x<0.002, 0.0059, 0.0123, 0.013 4x<0.002, <0.01, 2x 0,01	N/A				
	New trials	S-EU	Trials GAP: 2 x 0.125 kg as/ha, outdoor Data: 6x<0.002, 0.0024, 0.004	N/A				
	Overall supporting data for eGAP	S-EU	Data: 10x<0.002, 0.0024, 0.004, 0.0059, 0.0123, 0.013	0.002	0.013 0.01	0.019	n.a.	n.a.
Apple → extrapolated to Pear	New trials	N-EU	Trials GAP: 3 x 0.05625 kg as/ha, PHI 21d, outdoor Data: 0.0012, 5x<0.002, 0.005, 0.0077 6x<0.002, 2x<0.01	N/A				
	New trials	S-EU	Trials GAP: 3 x 0.05625 kg as/ha, PHI 21d, outdoor Data: 6x<0.002, 0.0061, 0.0065	N/A				
	Overall supporting data for eGAP	S-EU	Data: 12x<0.002, 0.005, 0.0061, 0.0065, 0.0077	0.002	0.008 0.01	0.011	n.a.	n.a.
Carrot	New trials	N-EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 14d, outdoor Data: 7x<0.002, 0.00356, <0.01	N/A				
	New trials	S-EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 14d, outdoor Data: 5x<0.002, 0.00237, 0.00263, 0.00265	N/A				

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
	Overall supporting data for eGAP	S-EU	Data: 12x<0.002, 0.00237, 0.00263, 0.00265, 0.00356	0.002	0.004 0.01	0.004	n.a.	n.a.
Tomato → extrapolated to Aubergine	New trials	S-EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 7d, outdoor Data: 8x<0.002	N/A				
	New trials	EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 3d, indoor Data: 8x<0.002	N/A				
	Overall supporting data for eGAP	EU	Data: 16x<0.002	0.002	0.002	0.002	n.a.	n.a.
Broccoli, Cauliflowers	New trials	N-EU	Trial GAP: 3 x 125 g as/ha, PHI 14 d, outdoor Data: 5x<0.002, 0.00213, 0.00266, 0.004	0.002	0.004	0.004	n.a.	n.a.
Head cabbage	New trials	N-EU	Trial GAP: 3 x 125 g as/ha, PHI 21 d, outdoor Data: 7x<0.002, 0.00244	0.002	0.002	0.002	n.a.	n.a.

**Table 7.2-12: Summary of EU reported and new data supporting the intended uses of IN005B1570 – 1,2,4-Triazole**

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
<b>Risk assessment residue definition 4: TDMs: 1,2,4-Triazole</b>								
Oilseed rape	New trials	N-EU	Trials GAP: 2 x 0.125 kg as/ha, outdoor Data: 5x<0.002, 0.0129	N/A				
	New trials	S-EU	Trials GAP: 2 x 0.125 kg as/ha, outdoor Data: 7x<0.002, 0.0039	N/A				
	Overall supporting data for eGAP	EU	Data: 12x<0.002, 0.0039, 0.0129	0.002	0.013 0.01	0.015	n.a.	n.a.
Apple → extrapolation to Pear	New trials	N-EU	Trials GAP: 3 x 0.05625 kg as/ha, PHI 21d, outdoor Data: 8x<0.002	N/A				
	New trials	S-EU	Trials GAP: 3 x 0.05625 kg as/ha, PHI 21d, outdoor Data: 8x<0.002	N/A				
	Overall supporting data for eGAP	EU	Data: 16x<0.002	0.002	0.002	0.002	n.a.	n.a.

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
Carrot	New trials	N-EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 14d, outdoor Data: 8x<0.002	N/A				
	New trials	S-EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 14d, outdoor Data: 8x<0.002	N/A				
	Overall supporting data for eGAP	EU	Data: 16x<0.002	0.002	0.002	0.002	n.a.	n.a.
Tomato → extrapolation to Aubergine	New trials	S-EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 7d, outdoor Data: 8x<0.002	N/A				
	New trials	EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 3d, indoor Data: 8x<0.002	N/A				
	Overall supporting data for eGAP	EU	Data: 16x<0.002	0.002	0.002	0.002	n.a.	n.a.
Broccoli, Cauliflowers	New trials	N-EU	Trial GAP: 3 x 125 g as/ha, PHI 14 d, outdoor Data: 7x<0.002, 0.00863	0.002	0.009	0.009	n.a.	n.a.
Head cabbage	New trials	N-EU	Trial GAP: 3 x 125 g as/ha, PHI 21 d, outdoor Data: 8x<0.002	0.002	0.002	0.002	n.a.	n.a.



**Table 7.2-13: Summary of EU reported and new data supporting the intended uses of IN005B1570 – difenoconazole + TDMs**

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
<b>New trials: Difenoconazole + TDMs</b>								
Oilseed rape	New trials	N-EU	Trials GAP: 2 x 0.125 kg as/ha, outdoor E: <0.01, 0.06, 0.07, 0.08, 0.13, 0.23, 0.64 RA: <0.01, 0.06, 0.07, 0.08, 0.13, 0.23, 0.64	E: 0.08 RA: 0.08	E: 0.64 RA: 0.64	-	n.a.	n.a.
	New trials	S-EU	<del>Trials GAP: 2 x 0.125 kg as/ha, outdoor</del> E: 5x <0.01, 0.08, 0.14, 0.20 RA: 5x <0.01, 0.08, 0.14, 0.20	<del>E: 0.01</del> RA: 0.01	<del>E: 0.20</del> RA: 0.20	-	<del>n.a.</del>	<del>n.a.</del>
	Overall supporting data for eGAP	N-EU + S-EU	E: 6x <0.01, 0.06, 0.07, 2x0.08, 0.13, 0.14, 0.20, 0.23, 0.64 RA: 6x <0.01, 0.06, 0.07, 2x0.08, 0.13, 0.14, 0.20, 0.23, 0.64	E: 0.07 RA: 0.07	E: 0.64 RA: 0.64	-	<del>n.a.</del>	<del>n.a.</del>
Apple → extrapolation to Pear	New trials	N-EU	Trials GAP: 3 x 0.05625 kg as/ha, PHI 21d, outdoor E: 0.02, 2x 0.03, 2x 0.05, 0.06, 2x 0.11 RA: 0.02, 2x 0.03, 2x 0.05, 0.06, 2x 0.11	E: 0.05 RA: 0.05	E: 0.11 RA: 0.11	-	n.a.	n.a.
	New trials	S-EU	<del>Trials GAP: 3 x 0.05625 kg as/ha, PHI 21d, outdoor</del> E: <0.01, 2x 0.02, 0.03, 2x 0.04, 0.06, 0.09 RA: <0.01, 2x 0.02, 0.03, 2x 0.04, 0.06, 0.09	<del>E: 0.035</del> RA: 0.035	<del>E: 0.09</del> RA: 0.09	-	n.a.	n.a.
	Overall supporting data for eGAP	N-EU + S-EU (new trials)	E: <0.01, 3x0.02, 3x 0.03, 2x0.04, 2x 0.05, 2x0.06, 0.09, 2x 0.11 RA: <0.01, 3x0.02, 3x 0.03, 2x0.04, 2x 0.05, 2x0.06, 0.09, 2x 0.11	E: 0.04 RA: 0.04	E: 0.11 RA: 0.11	-	n.a.	n.a.

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
Carrot	New trials	N-EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 14d, outdoor E: 2x 0.03, 3x 0.06, 0.07, 2x 0.12 RA: 2x 0.03, 3x 0.06, 0.07, 2x 0.12	E: 0.06 RA: 0.06	E: 0.12 RA: 0.12	-	n.a.	n.a.
	New trials	S-EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 14d, outdoor E: 3x 0.07, 0.08, 0.11, 0.15, 0.21, 0.22 RA: 3x 0.07, 0.08, 0.11, 0.15, 0.21, 0.22	E: 0.10 RA: 0.10	E: 0.22 RA: 0.22	-	n.a.	n.a.
	Overall supporting data for eGAP	N-EU+ S-EU (new studies)	E: 2x 0.03, 3x 0.06, 4x 0.07, 0.08, 0.11, 2x 0.12, 0.15, 0.21, 0.22 RA: 2x 0.03, 3x 0.06, 4x 0.07, 0.08, 0.11, 2x 0.12, 0.15, 0.21, 0.22	E: 0.07 RA: 0.07	E: 0.22 RA: 0.22	-	n.a.	n.a.
Tomato → extrapolation to Aubergine	New trials	S-EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 7d, outdoor E: 0.02, 4x 0.04, 3x 0.05 RA: 0.02, 4x 0.04, 3x 0.05	E: 0.04 RA: 0.04	E: 0.05 RA: 0.05	-	n.a.	n.a.
	New trials	EU	Trials GAP: 3 x 0.125 kg as/ha, PHI 3d, indoor E: 0.02, 0.06, 0.10, 2x 0.12, 0.16, 0.18, 0.19 RA: 0.02, 0.06, 0.10, 2x 0.12, 0.16, 0.18, 0.19	E: 0.12 RA: 0.12	E: 0.19 RA: 0.19	-	n.a.	n.a.
	Overall supporting data for eGAP	S-EU+ EU	E: 2x 0.02, 4x 0.04, 3x 0.05, 0.06, 0.10, 2x 0.12, 0.16, 0.18, 0.19 RA: 2x 0.02, 4x 0.04, 3x 0.05, 0.06, 0.10, 2x 0.12, 0.16, 0.18, 0.19	E: 0.08 RA: 0.08	E: 0.19 RA: 0.19	-	n.a.	n.a.
Broccoli, Cauliflowers	New trials	N-EU	Trial GAP: 3 x 125 g as/ha, PHI 14 d, outdoor E: 0.0037, 0.0116, 0.0153, 0.0164, 0.0237, 0.0329, 0.0525, 0.1331 RA: 0.0037, 0.0116, 0.0153, 0.0164, 0.0237, 0.0329, 0.0525, 0.1331	E: 0.02 RA: 0.02	E: 0.13 RA: 0.13	-	n.a.	
Head cabbage	New trials	N-EU	Trial GAP: 3 x 125 g as/ha, PHI 21 d, outdoor E: 0.0115, 0.0122, 0.0132, 0.0136, 0.0145, 0.0199, 0.0454, 0.1198 RA: 0.0115, 0.0122, 0.0132, 0.0136, 0.0145, 0.0199, 0.0454, 0.1198	E: 0.01 RA: 0.01	E: 0.12 RA: 0.12	-	n.a.	

\* Source of EU MRL: Regulation (EU) No 2019/552

### 7.2.3.2 Conclusion on the magnitude of residues in plants

#### zRMS: see 7.1 Summary and zRMS Conclusion

##### **a. Compliance with EU MRLs**

**Oilseed rape:** Data supporting the intended GAP are available from 7 new field trials in N-EU and 8 new field trials in S-EU. According to the available data, the use on oilseed rape in N-EU and S-EU is considered acceptable.

**Apples:** Data supporting the intended GAP are available from 8 new field trials in N-EU and 8 in S-EU. Data are also available from DAR (Sweden, 2006), coming from 9 field trials in N-EU and 11 field trials in S-EU that were reviewed at EU level but they are derived from trials with 4 applications instead of 3 and a PHI of 28 days instead of 21, so they were not considered in the calculations. However, new studies are sufficient to support the intended uses and, according to the available data, the use on apples in both N-EU and S-EU is considered acceptable. According to Appendix D of the EU guidelines, extrapolation to pears is possible with these trials on apples.

**Carrots:** Data supporting the intended GAP are available from 8 new field trials in N-EU and 8 in S-EU and from 8 field trials in N-EU and 5 field trials in S-EU that were reviewed at EU level (Sweden, 2006); considering that trials assessed at EU level were performed with the same GAP of the intended registration, both group of data were considered together. According to the available data, the use on carrots in both N-EU and S-EU is considered acceptable.

**Cauliflower, broccoli:** Data supporting the intended GAP are available from 6 outdoor field trials on broccoli in N-EU and 12 outdoor field trials on cauliflower in N-EU, all of which were reviewed by the JMPR (JMPR, 2007). Data supporting the intended GAP are available from 4 outdoor field new trials on broccoli in N-EU and 4 outdoor field new trials on cauliflower in N-EU. According to Appendix D of the EU guidelines, 4 trials on cauliflower plus 4 trials on broccoli can be extrapolated to the subgroup of flowering brassica. According to the available data, the use on cauliflower and broccoli is considered acceptable.

**Head cabbage:** Data supporting the intended GAP are available from 15 outdoor field trials in N-EU that were reviewed by the JMPR (JMPR, 2007). Data supporting the intended GAP are available from 8 outdoor field new trials in N-EU. According to the available data, the use on head cabbage is considered acceptable.

**Conclusion:** data are available supporting the intended uses on oilseed rape, apples, pears, carrots, broccoli, cauliflower, and head cabbage in N-EU. tomatoes, aubergines, potatoes (S-EU), sweet peppers, cucumbers, courgettes, grapes, peaches, nectarines.

No exceedance of the current MRL will occur according to the current residue definition of Difenoconazole only, and all the proposed uses are considered acceptable.

##### **b. Justification for use of difenoconazole only data for risk assessment**

Table 7.2-13 shows a summary of the data from new studies expressed as sum of difenoconazole and TDMs, expressed as difenoconazole, in order to verify which is the impact of the TDMs on the total amount of residues in the different crops and crop matrices.

The table below reports a summary of the available data expressed as difenoconazole only, compared with data on sum of difenoconazole and TDMs, expressed as difenoconazole.

**Table 7.2-14: STMR and HR data coming from new studies**

Crop	Difenoconazole (mg/kg)	Difenoconazole+TDMs (mg/kg)
------	---------------------------	--------------------------------

	STMR	HR	STMR	HR
Oilseed rape	0,01	0,15	0,07	0,64
Pome fruits	0,03	0,10	0,04	0,11
Carrot	0,07	0,22	0,07	0,22
Tomato	0,05	0,19	0,08	0,19
Broccoli and Cauliflower	0.01	0.13	0.02	0.13
Head Cabbage	0.01	0.07	0.01	0.12

Considering the available data, it is evident as a modification in the residue level could be foreseen for oilseed rape only, which is a high oil content matrix whereas no significant increase is foreseen for high water matrices. It can be considered that data available at EU level for potato, grapes, peaches, pepper, cucumber, can be safely used as valid data for risk assessment purposes.

### c. TDMs data

As no MRL exists for these metabolites, no unrounded OECD has been calculated. However, to assess the potential risk following ingestion of these molecules, a consumer risk assessment has been performed for each metabolite.

Table 7.2-10 resume data for triazole alanine (TA) and triazole lactic acid (TLA), which is residue definition 2 for risk assessment, as TA and TLA showed the same toxicity whereas table 7.2-11 resume data for triazole acetic acid (TAA), which is residue definition 3 for risk assessment and table 7.2-12 resume data for 1,2,4-Triazole alanine (1,2,4-T), which is residue definition 4 for risk assessment.

Data are available coming from new studies on oilseed rape, pome fruits, carrot and tomatoes. For risk assessment purposes, it is considered to use data:

- from pome fruits to cover orchards (peaches, nectarine and grapes)
- from carrot to cover the use on potato
- from tomatoes to cover other vegetables (cucurbits).

**Triazole alanine (TA):** studies demonstrated as TA is the main component for TDMs, showing values as HR always above the LOQ (=0.01 mg/kg) for oilseed rape (1.566 mg/kg), pome fruits (=0.064 mg/kg), carrot (=0.237 mg/kg), broccoli and cauliflower (= 0.043 mg/kg), head cabbage (= 0.126 mg/kg) and tomatoes (=0.004 mg/kg). For oilseed rape, it has to be considered that the STMR is 0.205 mg/kg, so the HR is really a worst-case situation.

**Triazole lactic acid (TLA):** studies demonstrated as HR for TLA was always at values under the LOQ for carrot (=0.009 mg/kg), broccoli and cauliflower (= 0.002 mg/kg), head cabbage (= 0.003 mg/kg) and tomatoes (=0.004 mg/kg) whereas it was present above the LOQ (0.01 mg/kg) for pome fruits (=0.022 mg/kg) and oilseed rape (0.063 mg/kg).

**Triazole acetic acid (TAA):** studies demonstrated as HR for TAA was never recognized at significant levels (always below the LOD = 0.002mg/kg) for tomatoes, broccoli and cauliflower (= 0.002 mg/kg), with values under the LOQ for pome fruits (=0.008 mg/kg), head cabbage (= 0.003 mg/kg) and carrot (=0.004 mg/kg), and just above the LOQ (0.01 mg/kg) for oilseed rape (0.0013 mg/kg).

**1,2,4-Triazole alanine (1,2,4-T):** studies demonstrated as 1,2,4-T was never recognized at significant levels (always below the LOD= 0.002 mg/kg), except for broccoli and cauliflower (= 0.009 mg/kg) with values below the LOQ (0.01 mg/kg) and oilseed rape, where a HR of 0.013 mg/kg is evidenced, which is however just above the LOQ (0.01 mg/kg).

## 7.2.4 Magnitude of residues in livestock

### 7.2.4.1 Dietary burden calculation

The Dietary burden calculation was conducted taking into account as input values data coming from SRT (NEU and SEU trials).

For the majority of the commodities, it was not possible to derive any processing factor, as residues were below the LOQ. Even when it was possible to calculate a PF, it was considered to use default processing factors as they represented a worst-case scenario compared to the one derived by the studies.

**Table 7.2-15: Input values for the dietary burden calculation (considering the uses under consideration)**

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Difenoconazole</b>				
Apple pomace	0.25	STMR (0.05 mg/kg) x PF (5, default)	0.25	STMR (0.05 mg/kg) x PF (5, default)
Carrot culls	0.06	STMR	0.12	HR
Rape meal	0.16	STMR (0.08 mg/kg) x PF (2, default)	0.16	STMR (0.08 mg/kg) x PF (2, default)
Cabbage heads	0.02	STMR	0.19	HR

**Table 7.2-16: 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)
<b>Difenoconazole</b>					
Beef cattle*	0.0054	0.013	Cabbage, heads - leaves	0.53	Y
Dairy cattle*	0.0063	0.018	Cabbage, heads - leaves	0.47	Y
Ram/ewe	0.0059	0.013	Carrot culls	0.4	Y
Lamb	0.0075	0.017	Carrot culls	0.39	Y
Breeding swine	0.004	0.010	Carrot culls	0.41	Y
Finishing swine*	0.005	0.009	Carrot culls	0.29	Y
Broiler poultry	0.006	0.009	Carrot culls	0.13	Y
Layer poultry*	0.005	0.012	Carrot culls	0.18	Y
Turkey	0.006	0.010	Carrot culls	0.14	Y

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

Residues in the diets of all animal groups are above the trigger of 0.004 mg/kg bw/day and hence residues in products of animal origin must be taken into consideration.

#### zRMS:

Difenoconazole

Dietary burden calculation was updated using uses under consideration (input values from the new studies).

Results are within EU assessment.

TDMs

As the proposed uses will make a minor contribution to the overall intake of these compounds, there is no need to recalculate the intake.

Difenoconazole

Dihydrocoumatrol								
Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,005	0,011	0,19	0,34	Dairy cattle	Carrot	culls	Yes
Cattle (dairy only)	0,005	0,011	0,14	0,29	Dairy cattle	Carrot	culls	Yes
Sheep (all diets)	0,007	0,013	0,16	0,30	Lamb	Carrot	culls	Yes
Sheep (ewe only)	0,005	0,010	0,16	0,30	Ram/Ewe	Carrot	culls	Yes
Swine (all diets)	0,004	0,008	0,14	0,30	Swine (finishing)	Carrot	culls	Yes
Poultry (all diets)	0,004	0,009	0,06	0,13	Poultry layer	Carrot	culls	Yes
Poultry (layer only)	0,004	0,009	0,06	0,13	Poultry layer	Carrot	culls	Yes

#### 7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

##### Available data

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

Livestock feeding studies were reviewed in the peer review (Sweden, 2006, 2010) and considered to be acceptable. The results are summarised in the table below.

**Table 7.2-17: Overview of the values derived from livestock feeding studies**

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) <sup>(b)</sup>	Highest residue (mg/kg) <sup>(c)</sup>	Calculated MRL (mg/kg)	CF for RA <sup>(d)</sup>
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) <sup>(a)</sup>	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (Sweden, 2006, 2010)												
Difenoconazole												
Bovine meat (tenderloin)	0.007	0.017	0.036	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
			0.109	3	0.011	0.012	0.011	0.012				
			0.364	3	0.022	0.024	0.022	0.024				
Bovine meat (tenderloin)	0.007	0.017	0.036	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
			0.182	3	0.01	0.01	0.01	0.01				
			0.545	3	0.04	0.04	0.04	0.04				
Bovine fat (omental)	0.007	0.017	0.036	3	0.011	0.013	0.011	0.013	<0.01	<0.01	0.01*	1
			0.109	3	0.027	0.033	0.027	0.033				
			0.364	3	0.077	0.095	0.077	0.095				
Bovine fat (subcutaneous)	0.007	0.017	0.036	3	0.01	0.01	0.01	0.01	<0.01	<0.01	0.01*	1
			0.182	3	0.04	0.04	0.04	0.04				
			0.545	3	0.12	0.13	0.12	0.13				
Bovine liver	0.007	0.017	0.036	3	0.039	0.044	0.039	0.044	<0.01	0.02	0.02	1
			0.109	3	0.12	0.13	0.12	0.13				
			0.364	3	0.31	0.37	0.31	0.37				



Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) <sup>(b)</sup>	Highest residue (mg/kg) <sup>(c)</sup>	Calculated MRL (mg/kg)	CF for RA <sup>(d)</sup>
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) <sup>(a)</sup>	No	Result for enforce- ment		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Bovine liver	0.007	0.017	0.036	3	0.06	0.07	0.06	0.07	0.011	0.033	0.04	1
			0.182	3	0.20	0.23	0.20	0.23				
			0.545	3	0.57	0.66	0.57	0.66				
Bovine kidney	0.007	0.017	0.036	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
			0.109	3	0.017	0.018	0.017	0.018				
			0.364	3	0.044	0.052	0.044	0.052				
Bovine kidney	0.007	0.017	0.036	3	0.01	0.01	0.01	0.01	<0.01	<0.01	0.01*	1
			0.182	3	0.04	0.04	0.04	0.04				
			0.545	3	0.11	0.12	0.11	0.12				
Ovine meat (tender-loin)	0.010	0.024	0.036	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
			0.109	3	0.011	0.012	0.011	0.012				
			0.364	3	0.022	0.024	0.022	0.024				
Ovine meat (tender-loin)	0.010	0.024	0.036	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
			0.182	3	0.01	0.01	0.01	0.01				
			0.545	3	0.04	0.04	0.04	0.04				
Ovine fat (omental)	0.010	0.024	0.036	3	0.011	0.013	0.011	0.013	<0.01	<0.01	0.01*	1
			0.109	3	0.027	0.033	0.027	0.033				
			0.364	3	0.077	0.095	0.077	0.095				

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) <sup>(b)</sup>	Highest residue (mg/kg) <sup>(c)</sup>	Calculated MRL (mg/kg)	CF for RA <sup>(d)</sup>
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) <sup>(a)</sup>	No	Result for enforce-ment		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Ovine fat (subcuta- neous)	0.010	0.024	0.036	3	0.01	0.01	0.01	0.01	<0.01	<0.01	0.01*	1
			0.182	3	0.04	0.04	0.04	0.04				
			0.545	3	0.12	0.13	0.12	0.13				
Ovine liver	0.010	0.024	0.036	3	0.039	0.044	0.039	0.044	0.011	0.029	0.03	1
			0.109	3	0.12	0.13	0.12	0.13				
			0.364	3	0.31	0.37	0.31	0.37				
Ovine liver	0.010	0.024	0.036	3	0.06	0.07	0.06	0.07	0.017	0.047	0.05	1
			0.182	3	0.20	0.23	0.20	0.23				
			0.545	3	0.57	0.66	0.57	0.66				
Ovine kidney	0.010	0.024	0.036	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
			0.109	3	0.017	0.018	0.017	0.018				
			0.364	3	0.044	0.052	0.044	0.052				
Ovine kidney	0.010	0.024	0.036	3	0.01	0.01	0.01	0.01	<0.01	<0.01	0.01*	1
			0.182	3	0.04	0.04	0.04	0.04				
			0.545	3	0.11	0.12	0.11	0.12				
Swine meat (tender- loin)	0.007	0.020	0.036	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
			0.109	3	0.011	0.012	0.011	0.012				
			0.364	3	0.022	0.024	0.022	0.024				

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) <sup>(b)</sup>	Highest residue (mg/kg) <sup>(c)</sup>	Calculated MRL (mg/kg)	CF for RA <sup>(d)</sup>
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) <sup>(a)</sup>	No	Result for enforce-ment		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Swine meat (tender-loin)	0.007	0.020	0.036	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
			0.182	3	0.01	0.01	0.01	0.01				
			0.545	3	0.04	0.04	0.04	0.04				
Swine fat (omental)	0.007	0.020	0.036	3	0.011	0.013	0.011	0.013	<0.01	<0.01	0.01*	1
			0.109	3	0.027	0.033	0.027	0.033				
			0.364	3	0.077	0.095	0.077	0.095				
Swine fat (subcuta-neous)	0.007	0.020	0.036	3	0.01	0.01	0.01	0.01	<0.01	<0.01	0.01*	1
			0.182	3	0.04	0.04	0.04	0.04				
			0.545	3	0.12	0.13	0.12	0.13				
Swine liver	0.007	0.020	0.036	3	0.039	0.044	0.039	0.044	0.039	0.044	0.04	1
			0.109	3	0.12	0.13	0.12	0.13				
			0.364	3	0.31	0.37	0.31	0.37				
Swine liver	0.007	0.020	0.036	3	0.06	0.07	0.06	0.07	0.012	0.039	0.04	1
			0.182	3	0.20	0.23	0.20	0.23				
			0.545	3	0.57	0.66	0.57	0.66				
Swine kidney	0.007	0.020	0.036	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
			0.109	3	0.017	0.018	0.017	0.018				
			0.364	3	0.044	0.052	0.044	0.052				

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) <sup>(b)</sup>	Highest residue (mg/kg) <sup>(c)</sup>	Calculated MRL (mg/kg)	CF for RA <sup>(d)</sup>
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) <sup>(a)</sup>	No	Result for enforce-ment		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Swine kidney	0.007	0.020	0.036	3	0.01	0.01	0.01	0.01	<0.01	<0.01	0.01*	1
			0.182	3	0.04	0.04	0.04	0.04				
			0.545	3	0.11	0.12	0.11	0.12				
Poultry meat	0.008	0.021	0.019	15	N/A	N/A	N/A	N/A	<0.01	<0.01	0.01*	1
			0.063	15	N/A	N/A	N/A	N/A				
			0.189	15	<0.01	<0.01	<0.01	<0.01				
			0.632	15	<0.01	<0.01	<0.01	<0.01				
Poultry fat	0.008	0.021	0.019	15	N/A	N/A	N/A	N/A	<0.01	<0.01	0.01*	1
			0.063	15	N/A	N/A	N/A	N/A				
			0.189	15	<0.01	<0.01	<0.01	<0.01				
			0.632	15	<0.01	<0.01	<0.01	<0.01				
Poultry liver	0.008	0.021	0.019	15	N/A	N/A	N/A	N/A	<0.01	<0.01	0.01*	1
			0.063	15	N/A	N/A	N/A	N/A				
			0.189	15	<0.01	<0.01	<0.01	<0.01				
			0.632	15	<0.01	<0.01	<0.01	<0.01				
Bovine milk	0.007	0.017	0.036	3	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	0.005*	1
			0.109	3	<0.005	<0.005	<0.005	<0.005				
			0.364	3	0.007	0.009	0.007	0.009				

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) <sup>(b)</sup>	Highest residue (mg/kg) <sup>(c)</sup>	Calculated MRL (mg/kg)	CF for RA <sup>(d)</sup>
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) <sup>(a)</sup>	No	Result for enforce-ment		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Bovine milk	0.007	0.017	0.036	3	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	0.005*	1
			0.182	3	0.005	0.007	0.005	0.007				
			0.545	3	0.01	0.02	0.01	0.02				
Ovine milk	0.010	0.024	0.036	3	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	0.005*	1
			0.109	3	<0.005	<0.005	<0.005	<0.005				
			0.364	3	0.007	0.009	0.007	0.009				
Ovine milk	0.010	0.024	0.036	3	<0.005	<0.005	<0.005	<0.005	<0.005	<0.005	0.005*	1
			0.182	3	0.005	0.007	0.005	0.007				
			0.545	3	0.01	0.02	0.01	0.02				
Eggs	0.007	0.019	0.019	15	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
			0.063	15	<0.01 – 0.01	<0.01 – 0.01	<0.01 – 0.01	<0.01 – 0.01				
			0.189	15	<0.01 – 0.04	<0.01 – 0.04	<0.01 – 0.04	<0.01 – 0.04				
			0.632	15	0.03 – 0.14	0.03 – 0.17	0.03 – 0.14	0.03 – 0.17				

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.

n.r.: Not reported

(\*): Indicates that the MRL is set at the limit of analytical quantification.

(F): MRL is expressed as mg/kg of fat contained in the whole product.

(a): Based on a 550 kg animal consuming 20 kg feed DM/day.

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

(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

(d): The median conversion factor for enforcement to risk assessment.

(e): Mean residue level from day X until day XX (X cows, Y sampling days).

## Conclusion on feeding studies

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

## 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

Data are available and were reviewed at EU level (please refer to the table below).

New processing studies have been submitted by the applicant in the framework of this application. These studies are summarized in the table below. The detailed results are presented in Appendix 2.

**Table 7.2-18: Overview of the available processing studies**

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Difenoconazole					
Apple, washed fruit	2	0.78	1		Sweden, 2006
Apple, wet pomace	4	3.75	1	-	
Apple, dry pomace	1	16	1	-	
Apple, juice (before/after pasteurisation)	1	0.02	1		
Apple, marmalade (puree)	1	0.14	1		
Carrots, cooked	4	0.049	1		EFSA, 2010a
Carrots, canned	4	0.055	1		
Carrots, juice	4	0.063	1		
Tomatoes, washed	4	0.7	1		EFSA, 2010b
Tomatoes, wet pomace	4	2.3	1		
Tomatoes, dry pomace	4	23.4	1		
Tomatoes, juice	4	0.2	1		
Tomatoes, canned	4	0.07	1	-	
New studies					
Oilseed rape, crude oil	4	0 Residues below LOQ or LOD	1		GLP-STUDY 21-26 (Not yet evaluated)
Apple, washed	4	0.41	1		GLP-STUDY 21-28 (Not yet evaluated)
Apple, dried	4	1.4	1		GLP-STUDY 21-28 (Not yet evaluated)

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
Apple, juice (after pasteurisation)	4	Residues below LOD	1		GLP-STUDY 21-28 (Not yet evaluated)
Tomatoes, canned	6	Residues below LOQ or LOD	1		GLP-STUDY 21-29 (Not yet evaluated)
Tomatoes, juice	6	Residues below LOQ or LOD	1		GLP-STUDY 21-29 (Not yet evaluated)
Tomatoes, puree	6	Residues below LOQ or LOD (except 1 trial: 0.0137 mg/kg)	1		GLP-STUDY 21-29 (Not yet evaluated)
Tomatoes, dried	6	3.5	1		GLP-STUDY 21-29 (Not yet evaluated)
<b>Triazole derivatives metabolites (1,2,4-T, TA, TLA and TAA)</b>					
Oilseed rape, crude oil	4	In the majority of the cases, data are below the LOQ in raw commodity as well as in all processed fractions. Therefore calculations were not performed	N/A		GLP-STUDY 21-26/ (Not yet evaluated)
Oilseed rape, refined oil	4		N/A		GLP-STUDY 21-26/ (Not yet evaluated)
Apple, washed	4		N/A		GLP-STUDY 21-28 (Not yet evaluated)
Apple, dried	4		N/A		GLP-STUDY 21-28 (Not yet evaluated)
Apple, juice (after pasteurisation)	4		N/A		GLP-STUDY 21-28 (Not yet evaluated)
Tomatoes, canned	6		N/A		GLP-STUDY 21-29 (Not yet evaluated)
Tomatoes, juice	6		N/A		GLP-STUDY 21-29 (Not yet evaluated)
Tomatoes, puree	6		N/A		GLP-STUDY 21-29 (Not yet evaluated)
Tomatoes, dried	6		1		GLP-STUDY 21-29 (Not yet evaluated)

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

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

### 7.2.5.2 Conclusion on processing studies

Data are available at EU level on apple, carrot, tomatoes and from new studies on oilseed rape, apple, tomatoes. Studies investigated both difenoconazole **than and** TDMs.

Regarding difenoconazole, it was possible to derive some PF for apple, washed and dried and for tomato, dried whereas for the other commodities, results were under LOQ (or even under LOD), so it is not possible to derive consistent conclusions.

Regarding TDMs, in the majority of the cases, data are below the LOQ in raw commodity as well as in all processed fractions, therefore calculations were not performed.

## 7.2.6 Magnitude of residues in representative succeeding crops

### 7.2.6.1 Field rotational crop studies (KCA 6.6.2)

#### Available data

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

No new data submitted in the framework of this application.

**Table 7.2-19: 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					
None (bare soil)	0.750	Leafy vegetables	pinach	31	Sweden, 2006
None (bare soil)	0.750	Root and tuber vegetables	Carrot	30	Sweden, 2006

#### Conclusion on rotational crops studies

EFSA 2010a concluded that: “Two field studies on rotational crops are reported in the DAR (Sweden, 2006) and both were performed by applying Difenoconazole [and triazole alanine] on a bare soil once at an application rate of 0.750 kg a.s./ha (6N of the intended application rate). In one study carrots were sown as rotational crops 30 DAT, while in the other study spinach were sown as rotational crops 31 DAT. Samples were analysed for Difenoconazole and triazole alanine (CGA131013). Residues of parent Difenoconazole and triazole alanine in carrots and spinach were below the LOQ of 0.02 mg/kg and 0.05 mg/kg, respectively”.

*It is concluded that significant levels of parent Difenoconazole are not expected in rotational crops provided that Difenoconazole is applied according to the proposed GAP.”*

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of IN005B1570. Therefore, other special studies are not needed.

Since the intended uses are performed during flowering in a honey-relevant crop (oilseed rape), information on potential residues of difenoconazole in honey might be required in case of use on oilseed rape. Therefore, a study was carried out and submitted during this application showing that residues of difenoconazole and its metabolites in honey are not expected to be above the LOD and/or LOQ, and therefore



are not a risk for the consumer.

- ~~zRMS: A study to determine the residues in honey and bee products is required (oil seed rape; post registration requirement).~~

## 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

#### Risk assessment residue definition 1: Difenoconazole

The chronic and acute consumer risk assessment was performed using the EFSA PRIMo rev 3.1 model. For difenoconazole, the input values in the PRIMo model were STMR and HR values for the crops included in the GAP (for Southern or Central zone, in blue values); for all other commodities, the inputs were derived from EFSA, 2021 or the existing EU MRLs for difenoconazole, as set in Regulation (EU) No 2019/552.

Acute risk assessment was undertaken only with regard to the crops under consideration.

#### zRMS:

Input values were corrected by evaluator

**Table 7.2-20: Input values for the consumer risk assessment: residue definition 1**

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definition 1: difenoconazole</b>				
Citrus fruit	0.16	STMR (FAO, 2013)	-	-
Pome fruit	0.03 0.04	STMR (new studies) NEU	0.11	HR (new studies) NEU
Apricots	0.17	STMR (EFSA, 2017, 2018a)	-	-
Peaches	0.15	STMR (new studies) EFSA 2010, 2021)	0.26	HR (new studies)
Grapes	0.03 0.52	STMR (JMPR, 2005) FAO 2013, EFSA 2021	0.07	HR (JMPR, 2005)
Strawberries	0.42	STMR (FAO, 2017)	-	-
Blackberries, raspberries	0.04	STMR (EFSA 2012)	-	-
Blueberries	1.0	STMR (FAO, 2017)	-	-
Azarole/Mediterranean medlar	0.8	STMR (EFSA, 2018a)	-	-

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Olives (table and oil)	0.47	STMR (EFSA, 2010)	-	-
Kumquats	0.16	STMR (FAO, 2013)	-	-
Kaki/Japanese persimmons	0.8	STMR (EFSA, 2018a)	-	-
Prickly pears/cactus fruits	0.03	STMR (FAO, 2017)	-	-
Avocados	0.05	STMR (FAO, 2015)	-	-
Papayas	0.01	STMR-peel (EFSA, 2013)	-	-
Potatoes	0.01 0.1	STMR (JMPR, 2005) MRL Regulation (EU) 2019/552	0.01	HR (JMPR, 2005)
Beetroots	0.08	SMTR (EFSA, 2013)	-	-
Carrots	0.07 0.06	STMR (new studies) NEU	0.22 0.12	HR (new studies) NEU
Horseradish	0.08	STMR (EFSA, 2013)	-	-
Jerusalem artichoke	0.08	STMR (EFSA, 2013)	-	-
Parsnips	0.08	STMR (EFSA, 2013)	-	-
Parsley roots	0.08	STMR (EFSA, 2013)	-	-
Radishes	0.08	STMR (EFSA, 2013)	-	-
Salsifies	0.08	STMR (EFSA, 2013)	-	-
Swedes, turnips	0.08	STMR (EFSA, 2010)	-	-
Garlic	0.01	STMR (EFSA, 2013)	-	-
Onions (bulb)	0.01	STMR (EFSA, 2013)	-	-
Shallots	0.01	STMR (EFSA, 2013)	-	-
Spring onions	2.8	STMR (FAO, 2013)	-	-
Tomatoes	0.05 0.72	STMR (new studies) EFSA 2021	0.19	HR (new studies)
Peppers	0.14 0.24	STMR (EFSA, 2010b) EFSA 2021	0.40	HR (EFSA, 2010b)
Aubergines	0.05 0.18	STMR (extrapolation from tomato) EFSA 2021	0.19	HR (extrapolation from tomato)
Okra/lady's fingers	0.14 0.18	STMR (EFSA, 2010b)	0.40	HR (EFSA, 2010b)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		EFSA 2021		
Cucumbers, gherkins, courgettes	0.01	STMR (EFSA, 2012) EFSA 2021	0.18	HR (EFSA, 2012)
Melons	0.01	STMR-peel (EFSA, 2013)	-	-
Pumpkin, watermelon	0.01	STMR (EFSA, 2013)	-	-
Broccoli	0.02 0.13 0.01	STMR (JMPR, 2005) EFSA 2013 EFSA 2011 (new studies) NEU	0.10 0.41 0.19 0.13	HR (JMPR, 2005)
Other flowering brassica	0.02 0.01	STMR (JMPR, 2005) EFSA 2018	0.10 0.13	HR (JMPR, 2005)
Brussels sprouts	0.07	STMR (EFSA, 2018a)	-	-
Head cabbages	0.02 0.01	STMR (JMPR, 2005) EFSA 2017 (new studies) NEU	0.19 0.07	HR (JMPR, 2005) EFSA 2017 (new studies) NEU
Chinese cabbages/ pe-tsai	0.83	STMR (EFSA 2021)	-	-
Kales	0.83	STMR	-	-
Other leafy brassica	0.83	STMR	-	-
Lamb's lettuces	1.45	STMR (EFSA, 2014b)	-	-
Lettuces	0.52	STMR (EFSA, 2017, 2018a)	-	-
Escaroles/broadleaved endives	0.33	STMR (EFSA, 2018a,b)	-	-
Cress and other sprouts and shoots	0.52	STMR (EFSA, 2017, 2018a)	-	-
Land cress	0.52	STMR (EFSA, 2017, 2018a)	-	-
Roman rocket/rucola	0.33	STMR (EFSA, 2018a)	-	-
Red mustards	0.52	STMR (EFSA, 2017, 2018a)	-	-
Baby leaf crops (including brassica species)	0.52	STMR (EFSA, 2017, 2018a)	-	-
Other lettuce and other salad plants	0.52	STMR (EFSA, 2017, 2018a)	-	-
Spinaches	0.33	STMR (EFSA, 2018a)	-	-
Purslanes	0.33	STMR (EFSA, 2018a)	-	-

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Chards/beet leaves	0.52	STMR (EFSA, 2017, 2018a)	-	-
Other spinach and similar	0.33	STMR (EFSA, 2018a)	-	-
Witloofs/Belgian endives	1.3	STMR (EFSA, 2018a)	-	-
Chervil, celery leaves, parsley, basil and edible flowers	4.65	STMR (EFSA, 2009)	-	-
Chives, sage, rosemary, thyme, laurel/bay leaves, tarragon and other herbs	0.52	STMR (EFSA, 2017, 2018a)	-	-
Cardoons, celeries	1.22	STMR (EFSA, 2017, 2018a)	-	-
Florence fennels	1.66	STMR (EFSA, 2009)	-	-
Globe artichoke	0.51	STMR (FAO, 2017)	-	-
Leeks	0.13	STMR (EFSA, 2017, 2018a)	-	-
Rhubarbs	0.7	STMR (EFSA, 2018a)	-	-
Beans	0.02	STMR (EFSA, 2017, 2018a)	-	-
Lentils	0.02	STMR (EFSA, 2017, 2018a)	-	-
Peas	0.03	STMR (FAO, 2017)	-	-
Lupins/lupini beans and other pulses	0.02	STMR (EFSA, 2017, 2018a)	-	-
Oilseed rape	0.01	STMR (new studies) NEU	0.15 0.01	STMR (new studies)
Soya beans	0.01	STMR (FAO, 2015)	-	-
Olives for oil production	0.47	STMR European Commission, 2008) Commission Regulation (EC) No 839/2008)	-	-
Barley	0.02	STMR (EFSA, 2017, 2018a)	-	-
Rice	1.1	STMR (FAO, 2017)	-	-
Rye	0.02	STMR (EFSA, 2017, 2018a)	-	-
Wheat	0.02	STMR (EFSA, 2017, 2018a)	-	-
Liquorice, ginger, turmeric/curcuma, horseradish, root spices and other spices	0.64	STMR (carrot) x PF (8) (EFSA, 2017, 2018a)	-	-

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sugar beet roots	0.02	STMR (EFSA, 2017, 2018a)	-	-
Chicory roots	0.20	STMR (EFSA, 2013)	-	-
Other plant commodities	MRL	MRLs in Regulation (EU) 2019/552	-	-
<b>Risk assessment residue definition for animal commodities: Difenoconazole alcohol (CGA205375) expressed as difenoconazole</b>				
Swine meat	0.01	0.8 x STMR (0.01) muscle + 0.2 x STMR (0.03) fat	-	-
Swine fat	0.03	STMR	-	-
Swine liver	0.12	STMR	-	-
Swine kidney	0.02	STMR	-	-
Bovine, Sheep, Goat, Horse: meat	0.03	0.8 x STMR (0.02) muscle + 0.2 x STMR (0.06) fat	-	-
Bovine, Sheep, Goat, Horse: fat	0.06	STMR	-	-
Bovine liver	0.25	STMR	-	-
Sheep liver	0.27	STMR	-	-
Goat liver	0.27	STMR	-	-
Horse liver	0.25	STMR	-	-
Bovine, Sheep, Goat, Horse: kidney	0.04	STMR	-	-
Bovine, Sheep, Goat, Horse: milk	0.01	STMR	-	-
Poultry and eggs	MRL	MRLs in Regulation (EU) 2019/552	-	-

**Risk assessment residue definition 2: Triazole alanine and triazole lactic acid**

**Risk assessment residue definition 3: Triazole acetic acid**

**Risk assessment residue definition 4: 1,2,4-triazole**

**Combined Risk Assessment: sum of Difenoconazole + TDMs, expressed as difenoconazole**

The chronic and acute consumer risk assessment was performed using the EFSA PRIMo rev 3.1 model. The input values in the PRIMo model were STMR and HR values for the crops included in the GAP, as determined from new studies on oilseed rape, pome fruits, cauliflower, broccoli, cabbage and carrot.

**Table 7.2-21: Input values for the consumer risk assessment: residue definition 2, 3, 4**

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definition 2: Triazole alanine and triazole lactic acid</b>				
<b>Triazole alanine</b>				
Oilseed rape	0.113 0.210	STMR (trials) N-EU	1.566 1.6	HR (trials) N-EU
Pome fruits (apple, pear)	0.003 0.002	STMR (trials) N-EU	0.064 0.030	HR (trials) N-EU
Carrot	0.008 0.002	STMR (trials) N-EU	0.237 0.010	HR (trials) N-EU
Broccoli, Cauliflowers	0.018	STMR (trials) N-EU	0.043	HR (trials) N-EU
Head cabbage	0.004	STMR (trials) N-EU	0.126	HR (trials) N-EU
<b>Triazole lactic acid</b>				
Oilseed rape	0.004 0.020	STMR (trials) N-EU	0.063	HR (trials) N-EU
Pome fruits (apple, pear)	0.002	STMR (trials) N-EU	0.022 0.010	HR (trials) N-EU
Carrot	0.002	STMR (trials) N-EU	0.009 0.010	HR (trials) N-EU
Broccoli, Cauliflowers	0.002	STMR (trials) N-EU	0.002	HR (trials) N-EU
Head cabbage	0.002	STMR (trials) N-EU	0.003	HR (trials) N-EU
<b>Risk assessment residue definition 3: Triazole acetic acid</b>				
Oilseed rape	0.002	STMR (trials) N-EU	0.013	HR (trials) N-EU
Pome fruits (apple, pear)	0.002	STMR (trials) N-EU	0.008 0.010	HR (trials) N-EU
Carrot	0.002	STMR (trials) N-EU	0.004 0.010	HR (trials) N-EU
Broccoli, Cauliflowers	0.002	STMR (trials) N-EU	0.004	HR (trials) N-EU
Head cabbage	0.002	STMR (trials) N-EU	0.002	HR (trials) N-EU
<b>Risk assessment residue definition 4: 1,2,4-Triazole</b>				
Oilseed rape	0.002	STMR (trials) N-EU	0.013	HR (trials) N-EU
Pome fruits (apple, pear)	0.002	STMR (trials) N-EU	0.002	HR (trials) N-EU
Carrot	0.002	STMR (trials) N-EU	0.002	HR (trials) N-EU
Broccoli, Cauliflowers	0.002	STMR (trials) N-EU	0.009	HR (trials) N-EU
Head cabbage	0.002	STMR (trials) N-EU	0.002	HR (trials) N-EU

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Combined data: sum of difenoconazole + TDMs, expressed as difenoconazole				
Oilseed rape	0.08	STMR (calculated from trials) N-EU	0.64	HR (calculated from trials) N-EU
Pome fruits (apple, pear)	0.05	STMR (calculated from trials) N-EU	0.11	HR (calculated from trials) N-EU
Carrot	0.06	STMR (calculated from trials) N-EU	0.12	HR (calculated from trials) N-EU
Broccoli, Cauliflowers	0.02	STMR (calculated from trials) N-EU	0.13	HR (calculated from trials) N-EU
Head cabbage	0.01	STMR (calculated from trials) N-EU	0.12	HR (calculated from trials) N-EU

The plant residue definition for risk assessment is “(1) Difenoconazole; (2) Triazole derivative metabolites (TDM)”, while the animal residue definition for risk assessment is “(1) Difenoconazole alcohol (CGA-205375) expressed as difenoconazole; (2) Triazole derivative metabolites”.

### 7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

#### Risk assessment residue definition 1: Difenoconazole

**Chronic exposure:** as first screening, a TMDI was calculated. With the current EFSA model (3.1), the chronic risk assessment ranges from 23 to 351% of ADI. The diet with the highest TMDI is NL toddler population with 351% of ADI. For this diet, the highest contributors are apples with 86% of ADI. The second diet with the highest TMDI is DE child population with 280 % of ADI where apples are the major contributor with 100% of ADI. A refinement was necessary as 24 diets lead to an exceedance of ADI. After refinement calculation, the IEDI/TMDI ranges from 7% to 74% 6% to 65% of ADI. The diet with the highest TMDI is GEMS/ Food G06 NL toddler population with 74% 65% of ADI. For this diet, the highest contributors are tomatoes with 26% beans (with pods) with 8% of ADI. The second diet with the highest TMDI is NL toddler DE child population with 44% 73% of ADI where table grapes oranges are the major contributor with 6% 8% of ADI.

**Acute exposure:** for unprocessed commodities, the highest contributing crops were pears and apples peaches and peppers for children (for NL toddler and DE child diet respectively) accounting respectively for each for 10% and 7% 15% ARfD, whereas pears and broccoli (NL general) head cabbages (based on CZ females 15-17 years diet) and peppers (based on UK vegetarian) were the main contributors for adults, accounting respectively each for 15 and 5% 2% ARfD.

As far as processed commodities is concerned, Broccoli / boiled and Cauliflowers / boiled are the main contributing commodities, accounting each for 5% 6% ARfD for children (NL toddler) whereas Cauliflowers / boiled and Broccoli / boiled are the main contributing commodities, accounting each respectively for 3% and 2% ARfD for adults (NL general pop.).

**Table 7.2-22: Consumer risk assessment – risk assessment residue definition 1: difenoconazole**

TMDI (% ADI) according to EFSA PRIMo	351 % (based on NL toddler) 280% (based on DE child)
IEDI (% ADI) according to EFSA PRIMo	65% 74 % (based on GEMS/ Food G06 NL toddler)

	1 <sup>st</sup> contributor: beans (with pods) 26% table grapes 8% tomatoes 26% 2 <sup>nd</sup> contributor: rice 7% tomatoes 7% table grapes 8%
IESTI (% ARfD) according to EFSA PRIMo*	<p>Unprocessed commodities:</p> <p>Children: Peaches 15% (based on NL toddler)  Sweet peppers/bell 15% (based on DE child)</p> <p>Adults: Head cabbages 5% (based on CZ females 15-17 years)  Sweet peppers/bell 15% (based on UK vegetarian)</p> <p>Children:</p> <ul style="list-style-type: none"> <li>11% Broccoli</li> <li>10% Pears</li> <li>7% Apples</li> <li>7% Cauliflowers</li> <li>5% Head cabbages</li> <li>0,01% Rapeseeds/canola seeds</li> </ul> <p>Adults:</p> <ul style="list-style-type: none"> <li>6% Broccoli</li> <li>5% Head cabbages</li> <li>3% Cauliflowers</li> <li>2% Apples,</li> <li>2% Pears</li> <li>0,00% Rapeseeds/canola seeds</li> </ul> <p>Children:</p> <ul style="list-style-type: none"> <li>10% Pears</li> <li>7% Apples</li> <li>5% Carrots</li> <li>5% Cauliflowers</li> <li>3% Broccoli</li> <li>2% Head cabbages</li> <li>0,01% Rapeseeds/canola seeds</li> </ul> <p>Adults:</p> <ul style="list-style-type: none"> <li>2% Pears</li> <li>2% Broccoli</li> <li>2% Apples</li> <li>2% Cauliflowers</li> <li>2% Head Cabbages</li> <li>1% Carrots</li> <li>0,00% Rapeseeds/canola seeds</li> </ul> <p>Processed commodities:</p> <p>Children: Broccoli / boiled 5% (based on NL toddler)  Cauliflowers / boiled 5% (based on NL toddler)</p> <p>Adults: Cauliflowers / boiled 3% (based on NL gen. pop.)  Courgettes / boiled 3% (based on NL gen. pop.)</p> <p>Children:</p> <ul style="list-style-type: none"> <li>20% Broccoli / boiled</li> <li>9% Cauliflowers / boiled</li> <li>1% Apples / juice</li> <li>0,1% Head cabbages / canned</li> <li>0,0% Rapeseeds / oils</li> </ul> <p>Adults:</p> <ul style="list-style-type: none"> <li>6% Broccoli / boiled</li> <li>5% Cauliflowers / boiled</li> <li>0,8% Apples / juice</li> <li>0,8% Pears / juice</li> <li>0,1% Head cabbages / canned</li> </ul> <p>Children:</p>



	6% Broccoli / boiled
	6% Cauliflowers / boiled
	1% Carrots/ juice
	0.8% Pears/ juice
	0,0% Head cabbages / canned
	0,0% Rapeseeds / oils
	Adults:
	3% Cauliflowers / boiled
	2% Broccoli / boiled
	0,8% Apples / juice
	0.3 Carrots / juice
	0,06% Head cabbages / canned

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

### Risk assessment residue definition 2: Triazole alanine (TA) and triazole lactic acid (TLA)

### Risk assessment residue definition 3: Triazole acetic acid (TAA)

### Risk assessment residue definition 4: 1,2,4-triazole (1,2,4-T)

**Chronic exposure:** exposure was calculated using EFSA PRIMo model rev. 3.1 using the input data reported in Table 7.2-21.

The results ranged from 0.003% 0.004% of ADI for RA3 definition to 0.11% for RA2 0.16% R4 definition, being NL toddler the diet with the highest %ADI for all the residue definitions.

**Acute exposure:** RA2 gave the highest values for raw commodities, head cabbage carrots being for children and adults the raw commodity with the highest % of ARfD/ADI (5 and 2% respectively for TA). For processed commodities, R2 gave the highest value for children broccoli/boiled was the commodity with the highest % of ARfD/ADI 1%. And RA4 gave the highest values for adults cauliflower/ boiled was the commodity with the highest % of ARfD/ADI 0.37%. for both children and adults apples / juice was the commodity with the highest % of ARfD/ADI (1 and 0.7%, respectively).

**Table 7.2-23: Consumer risk assessment – risk assessment residue definition 2, 3, 4**

IEDI (% ADI) according to EFSA PRIMo	<b>RA2 – TA + TLA:</b> 0.1% +0.021% (based on NL toddler)
	<b>RA3 - TAA:</b> 0.003% 0.004% (NL toddler)
	<b>RA4 – 1,2,4-T:</b> 0.16% (NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	<b>RA2 – TA + TLA:</b>
	<u>Unprocessed commodities:</u>
	Children: TA: Carrots 5% (based on UK infant)
	TLA: Pears 0.1% (based on NL toddler)
	Adults: TA: Carrots 2% (based on NL general population)
	TLA: Pears 0.2% (based on NL general population)
	<u>Processed commodities:</u>
	Children: TA: Carrots / juice 0.1% (based on DE child)
	TLA: Apples / juice 0.04% (based on DE child)
	Adults: TA: Apples / juice 0.03% (based on NL general population)
	TLA: Apples / juice 0.02% (based on NL general population)
	<u>Unprocessed commodities:</u>
	Children: TA: Head cabbages 2% (based on BE toddlers)
	TLA: Pears 0.5% (based on NL toddler)
	Adults: TA: Head cabbages 2% (based on CZ females 15-17 years)
	TLA: Pears 0.1% (based on CZ females 15-17 years)
	<u>Processed commodities:</u>
	Children: TA: Broccoli/ boiled 1% (based on NL toddler)
	TLA: Broccoli/ boiled 0.1% (NL toddler)
	Adults: TA: Cauliflower/ boiled 0.6% (based on NL general population)

	<p>TLA: Cauliflower/ boiled 0.03% (based on NL general population)</p> <p><b>RA3 - TAA:</b>  <u>Unprocessed commodities:</u>  Children: Pears 0.1% (based on NL toddler)  Adults: Pears 0.02% (based on NL general population)  <u>Processed commodities:</u>  Children: Apples / juice 0.01% (based on DE child)  Adults: Apples / juice 0.01% (based on NL general population)</p> <p><u>Unprocessed commodities:</u>  Children: Pears 0.1% (based on NL toddler)  Adults: Pears 0.03% (based on NL general population)  <u>Processed commodities:</u>  Children: Broccoli/ boiled 0.03% (based on NL toddler)  Adults: Cauliflower/ boiled 0.02% (based on NL general population)</p> <p><b>RA4 – 1,2,4-T:</b>  <u>Unprocessed commodities:</u>  Children: Pears 3% (based on NL toddler)  Adults: Pears 0.6% (based on NL general population)  <u>Processed commodities:</u>  Children: Apples / juice 1% (based on DE child)  Adults: Apple / juice 0.7% (based on NL general population)</p> <p><u>Unprocessed commodities:</u>  Children: Cauliflowers 0.5% (based on UK infant)  Adults: Broccoli 0.2% (based on NL general population)  <u>Processed commodities:</u>  Children: Broccoli/ boiled 0.7% (based on NL toddler)  Adults: Cauliflower/ boiled 0.37% (based on NL general population)</p>
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**Combined Risk Assessment: sum of Difenoconazole + TDMs, expressed as difenoconazole**

**Chronic exposure:** exposure was calculated using EFSA PRIMo model rev. 3.1 using the input data reported in Table 7.2-21.

The results ranged from 0.3% of ADI to 9%, being NL toddler the diet with the highest %ADI, with apples as highest contributing commodity (5% of ADI).

**Acute exposure:** for unprocessed commodities, the highest contributing crops were pears and apples for children (NL toddler) accounting respectively for 10% and 7% ARfD, whereas head cabbages (NL general) and pears (CZ females 15-17 years diet) were the main contributors for adults, accounting respectively each for 3 and 2% ARfD.

As far as processed commodities is concerned, Broccoli / boiled and Cauliflowers / boiled are the main contributing commodities, accounting each for 6% ARfD for children (NL toddler) whereas Cauliflowers / boiled and Broccoli / boiled are the main contributing commodities for adults (NL general pop.), accounting each respectively for 3% and 2% ARfD.

**Table 7.2-24: Combined consumer risk assessment: Difenoconazole + TDMs**

IEDI (% ADI) according to EFSA PRIMo	9% (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	<u>Unprocessed commodities:</u> Children: Pears 10% (based on NL toddler) Adults: head cabbages 3% (based on NL general population) <u>Processed commodities:</u> Children: Broccoli/ boiled 6% (based on NL toddler) Adults: Cauliflower/ boiled 3% (based on NL general population)

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

Even if there is lack of information at EU level regarding TDMs, it is clear that the proposed uses will account for a minor contribution to the overall intake regarding those compounds.

#### zRMS comment on TMDs:

As the proposed uses will make a minor contribution to the overall intake of these compounds, there is no need to recalculate the intake only from the northern zone test results, nor to subtract the unacceptable trials results for this GAP.

EFSA Journal 2018;16(7):5376:

*A 'worst-case' consumer dietary intake assessment with regard to the TDMs for the complete group of triazole active substances that were assessed in the framework of these confirmatory data has been conducted and it was demonstrated that the risk for the consumers is unlikely. The overall consumer exposure assessment for the TDMs could, however, not be finalised in view of the identified data gaps for additional storage stability data for the TDMs in several crop commodities and missing data to finalise the livestock exposure assessment.*

The expected exposure to TDMs from these commodities is well below the toxicological reference values derived for the TDMs.

Deficiencies with respect to livestock exposure assessment should be filled at EU level.

#### Overall conclusion

The proposed accepted uses of Difenoconazole in the formulation IN005B1570 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.

However, additional information is here included in order to combine exposure for difenoconazole and its metabolites.

The Hazard Index (HI) was calculated for all concerned commodities for acute risk assessment in order to show that the combined risk can be considered acceptable.

Exposure values (µg/kg bw) used as input values for Hazard Index (HI) calculation were derived from EFSA PRIMo 3.1 sheets and are reported in the tables below. ARfD values reported in table 7.1-2 are used as reference values.

**Table 7.3-1: Exposure values (µg/kg bw) used as input values for Hazard Index (HI) calculation**

	Difenoconazole	TA	TLA	TAA	1,2,4-T
<b>Raw commodities - childrens</b>					
OSR	0.01	0.29	0.03	0.003	0.003
Apples	12	3.20	1.10	1.10	0.22
Pears	15	4.20	1.50	1.40	0.28
Carrot	7.6	0.63	0.63	0.63	0.13
Broccoli	5.4	1.80	0.08	0.17	0.37
Cauliflowers	7.5	2.50	0.12	0.23	0.52
Head cabbage	3.1	0.29	0.13	0.09	0.09
<b>Processed commodities - children</b>					
Broccoli / boiled	10	3.40	0.16	0.32	0.71
Cauliflowers / boiled	9	3.00	0.14	0.28	0.63
Apples / juice	2.2	0.11	0.11	0.11	0.11
Carrots / juice	2.2	0.07	0.07	0.07	0.07

	Difenoconazole	TA	TLA	TAA	1,2,4-T
Pears / juice	1.3	0.07	0.07	0.07	0.07
Head cabbages / canned	0.06	0.02	0.01	0.01	0.01
Rapeseeds / oils	0.01	0.12	0.01	0.001	0.001
<b>Raw commodities - adults</b>					
OSR	0.01	0.11	0.01	0.001	0.001
Apples	3.1	0.84	0.28	0.28	0.06
Pears	3.4	0.92	0.31	0.31	0.06
Carrot	2.4	0.2	0.2	0.20	0.04
Broccoli	3.1	1	0.05	0.10	0.21
Cauliflowers	3	1	0.05	0.09	0.21
Head cabbage	2.9	5.3	0.13	0.08	0.08
<b>Processed commodities - adults</b>					
Broccoli / boiled	3.1	1	0.05	0.10	0.22
Cauliflowers / boiled	5.4	1.8	0.08	0.17	0.37
Apples / juice	1.3	0.07	0.07	0.07	0.07
Carrots / canned	0.49	0.02	0.02	0.02	0.02
Head cabbages / canned	0.09	0.04	-	0.02	0.02

In the table below, the results of the calculations are presented.

**Table 7.3-2: Hazard Index (HI)**

	Children	Adults
<b>Raw commodities</b>		
OSR	0.001	0.0005
Apples	0.093	0.024
Pears	0.117	0.026
Carrot	0.054	0.017
Broccoli	0.044	0.025
Cauliflowers	0.061	0.024
Head cabbage	0.022	0.037
<b>Processed commodities</b>		
Broccoli / boiled	0.082	0.025
Cauliflowers / boiled	0.073	0.044
Apples / juice	0.016	0.009
Carrots / juice	0.015	-
Carrots / canned	-	0.003
Pears / juice	0.009	-
Head cabbages / canned	0.001	0.001
Rapeseeds / oils	0.001	-

According to EFSA guidelines (EFSA Journal (2008) 704, 17-84), when the HI is less than 1, the combined risk is considered acceptable. Considering the available calculations, no

risks are foreseen for the proposed uses.

## 7.4 References

EFSA (European Food Safety Authority), 2010a. Modification of the existing MRLs for difenoconazole in swedes and turnips on request from the European Commission. EFSA Journal 2010;8(2):1510. [36 pp.]. doi:10.2903/j.efsa.2010.1510. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

EFSA (European Food Safety Authority), 2010b. Modification of the existing MRLs for difenoconazole in peppers and aubergines. EFSA Journal 2010; 8(6):1651. [27 pp.]. doi:10.2903/j.efsa.2010.1651. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

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(11):1967. [71 pp.]. doi:10.2903/j.efsa.2011.1967. Available online: [www.efsa.europa.eu/efsajournal.htm](http://www.efsa.europa.eu/efsajournal.htm)

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the modification of the existing MRLs for difenoconazole in raspberries, blackberries and cucurbits (edible peel). EFSA Journal 2012;10(8):2867. [30 pp.] doi:10.2903/j.efsa.2012.2867. Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted. EFSA Journal 2018;16(7):5376, 20 pp. <https://doi.org/10.2903/j.efsa.2018.5376>

EFSA (European Food Safety Authority), 2021. Modification of the existing maximum residue levels for difenoconazole in leafy brassica. EFSA Journal 2021;19(2):6407. <https://doi.org/10.2903/j.efsa.2021.6407>

European Commission, 2008. Expert meetings report (for establishing Annexes to Regulation (EC) No 396/2005.28–31 January 2008.

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Sweden, 2006. Draft assessment report on the active substance difenoconazole prepared by the rapporteur Member State Sweden in the framework of Council Directive 91/414/EEC, May 2006.

Sweden, 2010. Final Addendum to the Draft assessment report on the active substance difenoconazole prepared by the rapporteur Member State Sweden in the framework of Council Directive 91/414/EEC, November 2010.

Scientific Opinion of the Panel on Plant Protection Products and their Residues (PPR Panel) on a request from the EFSA evaluate the suitability of existing methodologies and, if appropriate, the identification of new approaches to assess cumulative and synergistic risks from pesticides to human health with a view to set MRLs for those pesticides in the frame of Regulation (EC) 396/2005. The EFSA Journal (2008) 704, 1-85

## Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

### 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
KCA 6.1-01	Longhi, Diego	2021	Validation of an analytical method for the quantification of Difenconazole and Prothioconazole-desthio in wheat, barley, oilseed rape and processed commodities GLP-STUDY-21-31 LabAnalysis srl GLP Unpublished	N	Indofil Industries
KCA 6.1-02	Longhi, Diego	2021	Validation of an analytical method for the quantification of Difenconazole in apple, carrot, tomato and processed commodities GLP-STUDY-21-32 LabAnalysis srl GLP Unpublished	N	Indofil Industries
KCA 6.1-03	Longhi, Diego	2022	Storage stability of Triazole Derivative Metabolites (TDM) in wheat forage, wheat grain, rapeseed seeds, wheat straw, apple, tomato, carrot GLP-STUDY-21-124 LabAnalysis srl GLP Unpublished	N	Indofil Industries
KCA 6.3-01	Longhi, Diego	2022	Determination of difenconazole, prothioconazole-desthio and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of oilseed rape and processed (oilseed rape oil) following two	N	Indofil Industries

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
			applications of the formulated products IN233C1560 and IN005B1570 (Northern and Southern Europe – 16 trials + processed, year 2021 – open field) GLP-STUDY-21-26 LabAnalysis srl GLP Unpublished		
KCA 6.3-02	Longhi, Diego	2022	Determination of difenoconazole and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of apple and processed commodities (dry apple and apple juice) following three applications of the formulated product IN005B1570 (Northern and Southern Europe – 16 trials, year 2021 – open field) GLP-STUDY-21-28 LabAnalysis srl GLP Unpublished	N	Indofil Industries
KCA 6.3-03	Longhi, Diego	2022	Determination of difenoconazole and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity carrot following three applications of the formulated product IN005B1570 250 EC (Difenconazole 250 g/L) (Northern and Southern Europe – 16 trials, year 2021 – open field) GLP-STUDY-21-27 LabAnalysis srl GLP Unpublished	N	Indofil Industries
KCA 6.3-04	Longhi, Diego	2022	Determination of difenoconazole and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of tomato and processed following three applications of the formulated product IN005B1570 (Southern Europe – 8 trials, year 2021 – open field) GLP-STUDY-21-29 LabAnalysis srl GLP Unpublished	N	Indofil Industries
KCA 6.3-05	Longhi, Diego	2022	Determination of difenoconazole and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of tomato following three applications of the formulated product IN005B1570 (Southern Europe – 8 trials, year 2021 – greenhouse)	N	Indofil Industries

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-STUDY-21-30 LabAnalysis srl GLP Unpublished		
KCA 6.3-06	Longhi, D.	2024a	Determination of Difenoconazole and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of cabbage after three applications of the formulated product IN005B1570 (North Europe – 4 trials, 2023) LBN-0121-2023 LabAnalysis srl GLP Unpublished	N	Indofil Industries
KCA 6.3-07.1	Longhi, D.	2024b	Determination of Difenoconazole and Triazole Derivative Metabolites (TDMs) residues in head cabbage following foliar applications with IN005B1570 under field conditions in Northern Europe in 2023. Analytical phase report. LBN-0120-2023 LabAnalysis srl GLP Unpublished	N	Indofil Industries
KCA 6.3-07.2	Thomas-Delille, E.	2024	Determination of Difenoconazole and Triazole Derivative Metabolites (TDMs) residues in head cabbage following foliar applications with IN005B1570 under field conditions in Northern Europe in 2023. Field phase report. C3165 ANADIAG GLP Unpublished	N	Indofil Industries
KCA 6.3-08	Longhi, D.	2024c	Determination of Difenoconazole and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of broccoli and cauliflower after three applications of the formulated product IN005B1570 (North Eu-rope – 8 trials, 2023). LBN-0122-2023 LabAnalysis srl	N	Indofil Industries



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 Unpublished		
KCA 6.10-01	Rovetto, I.	2023	Magnitude of the residue of difenoconazole, prothioconazole, prothioconazole-desthio and triazole-derivative metabolites (TDMs) in honey after one application of IN233C1560 380 EC on Phacelia crop under semi field conditions in four trials in Northern Europe and Southern Europe – 2023 Study code: 1111.4F.SAG23 SAGEA Centro di Saggio s.r.l. GLP Unpublished	N	Indofil Industries

**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
n.a. Reference only	EFSA (European Food Safety Authority)	2010	Modification of the existing MRLs for difenoconazole in swedes and turnips on request from the European Commission. EFSA Journal 2010;8(2):1510. [36 pp.]. doi:10.2903/j.efsa.2010.1510. Available online: <a href="http://www.efsa.europa.eu">www.efsa.europa.eu</a> Published	N	n.a.
n.a. Reference only	EFSA (European Food Safety Authority)	2010	Modification of the existing MRLs for difenoconazole in peppers and aubergines. EFSA Journal 2010; 8(6):1651. [27 pp.]. doi:10.2903/j.efsa.2010.1651. Available online: <a href="http://www.efsa.europa.eu">www.efsa.europa.eu</a> Published	N	n.a.
n.a. Reference only	EFSA (European Food Safety Authority)	2011	Conclusion on the peer review of the pesticide risk assessment of the active substance difenoconazole.	N	n.a.

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
ence only	Food Safety Authority		EFSA Journal 2011;9(11):1967. [71 pp.]. doi:10.2903/j.efsa.2011.1967. Available online: <a href="http://www.efsa.europa.eu/efsajournal.htm">www.efsa.europa.eu/efsajournal.htm</a> Published		
n.a. Reference only	EFSA (European Food Safety Authority)	2012	Reasoned opinion on the modification of the existing MRLs for difenoconazole in raspberries, blackberries and cucurbits (edible peel). EFSA Journal 2012;10(8):2867. [30 pp.] doi:10.2903/j.efsa.2012.2867. Available online: <a href="http://www.efsa.europa.eu/efsajournal">www.efsa.europa.eu/efsajournal</a> Published	N	n.a.
n.a. Reference only	EFSA (European Food Safety Authority)	2018	Conclusion on the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted. EFSA Journal 2018;16(7):5376, 20 pp. <a href="https://doi.org/10.2903/j.efsa.2018.5376">https://doi.org/10.2903/j.efsa.2018.5376</a> Published	N	n.a.
n.a. Reference only	EFSA (European Food Safety Authority)	2018	Modification of the existing maximum residue levels for difenoconazole in leafy brassica. EFSA Journal 2021;19(2):6407. <a href="https://doi.org/10.2903/j.efsa.2021.6407">https://doi.org/10.2903/j.efsa.2021.6407</a> Published	N	n.a.
n.a. Reference only	EFSA (European Food Safety Authority)	2021	Modification of the existing maximum residue levels for difenoconazole in leafy brassica. EFSA Journal 2021;19(2):6407. <a href="https://doi.org/10.2903/j.efsa.2021.6407">https://doi.org/10.2903/j.efsa.2021.6407</a> Published	N	n.a.
n.a. Reference only	European Commission	2008	Expert meetings report (for establishing Annexes to Regulation (EC) No 396/2005.28–31 Published	N	n.a.
n.a. Reference only	FAO (Food and Agriculture Organization of the United Nations)	2007	Joint FAO/WHO Meeting on Pesticides Residues (JMPR): Evaluations 2007 Published	N	n.a.
n.a. Reference only	Spain	2019	Draft Renewal Assessment Report on the active substance Difenconazole prepared according to the Commission Regulation (EU) No 1107/2009 Published	N	n.a.

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
n.a. Reference only	Sweden	2006	Draft assessment report on the active substance difenoconazole prepared by the rapporteur Member State Sweden in the framework of Council Directive 91/414/EEC Published	N	n.a.
n.a. Reference only	Sweden	2010	Final Addendum to the Draft assessment report on the active substance difenoconazole prepared by the rapporteur Member State Sweden in the framework of Council Directive 91/414/EEC Published	N	n.a.

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
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

## Appendix 2 Detailed evaluation of the additional studies relied upon

### A 2.1 Difenconazole

#### A 2.1.1 Stability of residues

##### A 2.1.1.1 Storage stability of residues in plant products

##### A 2.1.1.1.1 Study 1 – GLP-STUDY-21-124

Comments of zRMS:	Study is accepted
Reference:	KCA 6.1-03
Report	Storage stability of Triazole Derivative Metabolites (TDM) in wheat forage, wheat grain, rapeseed seeds, wheat straw, apple, tomato, carrot Longhi D., 2022, report No GLP-STUDY-21-124
Guideline(s):	Yes
Deviations:	Yes <b>Deviation 1 of 23/05/2022</b> Reason: The timepoint t1 (2 months) of the matrix carrot was analysed after 52 days from the start. The timepoint was out of the range of 2 months $\pm$ 1 week Impact on the study: None, the difference of about 1-2 days is negligible since it was an intermediate timepoint and the analytes are stable also after 4 months <b>Deviation 2 of 01/06/2022</b> Reason: The transition of the ILIS 1,2,4-Triazole Alanine [D2] 159.0/72.0 was interfered in the matrices forage and rapeseed seeds. The transition 159.0/89.0 (already used for straw) was adopted also for these matrices Impact on the study: None. The transition 159.0/89.0 was used for the ILIS 1,2,4-Triazole Alanine [D2] for the matrix straw (its validity was successfully demonstrated in the validation study). Furthermore, the validity of the use of this transition of the ILIS 1,2,4-Triazole Alanine [D2] for the matrix forage and rapeseed seeds has been intrinsically demonstrated in the present study by the good results of recovery check samples
GLP:	Yes
Acceptability:	Yes

### Materials and methods

#### Storage stability test preparation

The matrices used to prepare the aliquots necessary for the storage stability evaluation were taken from untreated samples coming from the following residues studies:

- GLP-STUDY-21-24 (for the matrices forage [wheat], wheat grain and straw [wheat]);
- GLP-STUDY-21-26 (for the matrix rapeseed seeds);
- GLP-STUDY-21-27 (for the matrix carrot);

- GLP-STUDY-21-28 (for the matrix apple);
- GLP-STUDY-21-30 (for the matrix tomato).

Aliquots of the homogenised sample of about:

- 5 g for forage (wheat), wheat grain, rapeseed seeds
- 2.5 g for straw
- 10 g for apple, tomato, carrot

were introduced in a 50 mL PE test tube, fortified with known amounts of analytes (at 10xLOQ) and analysed according to the analytical method at the time 0 and at each specified timepoint, storing the aliquots at about -18°C in dark conditions.

At each timepoint the following samples were analysed:

- Untreated sample
- Fortified sample
- Procedural recovery sample

At the time 0 the fortified samples were spiked with the analytes at 10xLOQ level. The additions of the analytes were carried out by addition of dispersing small drops directly on the samples. The spiked samples were then manually shaken and immediately stored at -18°C. The untreated samples were not spiked. After the spiking, all the aliquots except those to be analysed at time 0, were introduced in a freezer and kept in the dark at the temperature of about -18°C for the specified period. At each timepoint, an untreated sample and 2 fortified samples were analysed according to the analytical method. At each timepoint 2 procedural recovery samples were analysed, prepared fortifying at 10 x LOQ level the following aliquots of untreated samples:

- 5 g (for the matrices forage [wheat], wheat grain and rapeseed seeds);
- 2.5 g (for the matrix straw [wheat]);
- 10 g (for the matrices apple, tomato and carrot)

Spare samples were prepared but were not analysed since it was not necessary (no problems occurred during the storage and the data obtained from the fortified samples were similar).

#### Analytical method

##### *Principle of the method:*

The applied analytical methods (AM-GLP-STUDY-21-108 and AM-GLP-STUDY-21-109) allow the determination of the following TDM:

- 1H-1,2,4-triazole (TRZ)
- 1H-1,2,4-triazole alanine (TA)
- Triazole lactic acid (TLA)
- Triazole acetic acid (TAA)

The extraction of the analytes from the matrix was carried out after addition of a proper amount of Isotope Labelled Internal Standard (ILIS) with a mixture of water and methanol. The extract was then filtered and analysed using a HPLC-MS/MS system (high-performance liquid chromatography + triple quadrupole mass spectrometry) equipped with a differential mobility separation device (DMS).

The analytical methods were validated under GLP compliance according to SANTE/2020/12830 Rev.1 in the study GLP-STUDY-21-108 and GLP-STUDY-21-109.

The LOQ of these analytical methods is of 0.01 mg/kg.

The final extracts were kept refrigerated (at  $5 \pm 3^\circ\text{C}$ ) in the instrument autosampler and were analysed just after the extraction and in any case within 24h.

##### *Sample extraction:*

An appropriate aliquot of each specimen was taken from the homogenised frozen samples and put in a 50 mL screw capped centrifuge PE test tube followed by the addition of 100 µL of the internal standard solution TDM ISTD MIX (2 mg/L of each internal standard) and deionized water (added on the basis of

QuPPE-PO-Method and considering the theoretical water content of each matrix to reach a volume of 10 mL for each sample).

Then, 10 mL of 1% formic acid in methanol were added and the obtained mixture was vigorously shaken for 3 minutes. The volume of the final extract is considered to be 20 mL: little variation due to the actual water content of each sample are corrected by the presence of the internal standard, that is added to produce a concentration in the final extract nominally of 10 µg/L of each compound.

The separation of the liquid phase from the solid one was achieved by centrifugation at 5000 rpm for 5 minutes. An aliquot of about 1 mL the supernatant was taken, filtered with a 0.45 µm PVDF filter and transferred in a 2 mL HPLC glass vial for the final analysis with a HPLC-DMS-MS/MS system.

#### *Analysis and calculations:*

The analyses were carried out using a HPLC-DMS-MS/MS system. The quantification was performed determining the area ratios between the signals of analytes and the associated internal standards and comparing them with a calibration curve prepared analysing the working standard solutions.

The quantification of each analyte was made through the building of a calibration straight line with the internal standard method. 5 analytical standard solutions for each analysed matrix (either prepared in matrix extract or in solvent) were analysed in single injections in order to obtain a calibration curve (1/x weighed) interpolated with a linear regression. The amount of each analyte was calculated from the calibration straight line applying the reverse formula. Using the calibration curve equation and the peaks areas, the concentration of each analyte in the final extract was calculated (µg/L). Recovery and precision were calculated.

#### **Results and discussions**

The method was previously validated and worked adequately to address the storage stability of TDMs in the concerned matrices.

In the tables below, a summary of the results for the different matrices is reported.

**Table A 1: Stability of TDMs residues in wheat (forage) following storage at -18°C**

Commodity/ matrix	Fortification rate/spike level of stored sam- ples (mg/kg)	Storage period (days/months)	Sample code	Concentration of stored samples		Residue Level in Freez- er Storage Stability Sample (% of spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)	Mean residue Level in Freezer Storage Stability Sample (% of spiking level) (corrected for the daily recovery)	Mean recovery of stored samples corrected for the daily recovery /mean recovery at t0 corrected for the daily recovery (%)	
				Results (mg/kg)	Mean value (mg/kg)					
Forage (wheat)										
1H-1,2,4- triazole (TRZ)	0.1	0	124 WF t0 C	< LOD	█	█	96.4, 96.1 (96.3)	█	█	
			124 WF t0 T1	0.0941	0.0934	95.4, 96.9 (96.1)		99.9	█	
			124 WF t0 T2	0.0928						
	0.1	2 months (53 days)	124 WF t1 C	< LOD	█	█	94.2, 89.8 (92.0)	█	█	
			124 WF t1 T1	0.0927	0.0925	94.6, 91.6 (93.1)		101	101	
			124 WF t1 T2	0.0924						
	0.1	4 months (116 days)	124 WF t2 C	< LOD	█	█	102.8, 98.6 (100.7)	█	█	
			124 WF t2 T1	0.0893	0.0919	88.4, 90.2 (89.3)		88.7	88.8	
			124 WF t2 T2	0.0944						
	0.1	7 months (215 days)	124 WF t3 C	< LOD	█	█	107.3, 106.7 (107.0)	█	█	
			124 WF t3 T1	0.1026	0.1030	103.6, 103.6 (103.6)		96.8	97.0	
			124 WF t3 T2	0.1034						
1H-1,2,4- triazole alanine (TA)	0.1	0	124 WF t0 C	< LOD	█	█	102.9, 103.8 (103.4)	█	█	
			124 WF t0 T1	0.0939	0.0969	95.2, 104.3 (99.8)		96.5	█	
			124 WF t0 T2	0.0999						
	0.1	2 months (53 days)	124 WF t1 C	< LOD	█	█	99.6, 102.7 (101.1)	█	█	
			124 WF t1 T1	0.1048	0.1055	106.8, 105.5 (106.2)		105	109	
			124 WF t1 T2	0.1063						
	0.1	4 months (116 days)	124 WF t2 C	< LOD	█	█	95.5, 96.6 (96.0)	█	█	
			124 WF t2 T1	0.0999	0.1006	98.9, 96.8 (97.9)		102	106	
			124 WF t2 T2	0.1013						
	0.1	7 months (215 days)	124 WF t3 C	< LOD	█	█	102.9, 103.3 (103.1)	█	█	
			124 WF t3 T1	0.0976	0.0986	98.6, 99.7 (99.1)		96.1	93.5	
			124 WF t3 T2	0.0995						



Commodity/ matrix	Fortification rate/spike level of stored sam- ples (mg/kg)	Storage period (days/months)	Sample code	Concentration of stored samples		Residue Level in Freezer Storage Stabil- ity Sample (% of spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)	Mean residue Level in Freezer Storage Stabil- ity Sample (% of spiking level) (corrected for the daily recovery)	Mean recovery of stored samples corrected for the daily recovery /mean recovery at t0 corrected for the daily recovery (%)		
				Results (mg/kg)	Mean value (mg/kg)						
Forage (wheat)											
Triazole lactic acid (TLA)	0.1	0	124 WF t0 C	< LOD	█	█	93.1, 97.7 (95.4)	█	█		
			124 WF t0 T1	0.0955	0.0926	96.8, 93.6 (95.2)		99.8	█		
			124 WF t0 T2	0.0897							
	0.1	2 months (53 days)	124 WF t1 C	< LOD	█	█	100.2, 97.9 (99.1)	█	█		
			124 WF t1 T1	0.0914	0.0925	93.2, 92.9 (93.1)		93.9	94.1		
			124 WF t1 T2	0.0937							
	0.1	4 months (116 days)	124 WF t2 C	< LOD	█	█	101.6, 101.8 (101.7)	█	92.0		
			124 WF t2 T1	0.0962	0.0960	95.2, 91.6 (93.4)		91.8			
			124 WF t2 T2	0.0958							
	0.1	7 months (215 days)	124 WF t3 C	< LOD	█	█	107.3, 106.7 (107.0)	█	█		
			124 WF t3 T1	0.1026	0.1030	103.6, 103.6 (103.6)		96.8	97.0		
			124 WF t3 T2	0.1034							
Triazole acetic acid (TAA)	0.1	0	124 WF t0 C	< LOD	█	█	98.4, 98.6 (98.5)	█	█		
			124 WF t0 T1	0.0989	0.0984	100.3, 102.3 (101.3)		103	█		
			124 WF t0 T2	0.0980							
	0.1	2 months (53 days)	124 WF t1 C	< LOD	█	█	95.2, 93.2 (94.2)	█	█		
			124 WF t1 T1	0.0989	0.1001	100.9, 100.4 (100.6)		107	104		
			124 WF t1 T2	0.1012							
	0.1	4 months (116 days)	124 WF t2 C	< LOD	█	█	97.9, 95.1 (96.5)	█	█		
			124 WF t2 T1	0.1026	0.1022	101.6, 97.3 (99.4)		103	100		
			124 WF t2 T2	0.1018							
	0.1	7 months (215 days)	124 WF t2 C	< LOD	█	█	102.9, 103.3 (103.1)	█	█		
			124 WF t2 T1	0.0976	0.0986	98.6, 99.7 (99.1)		96.1	93.5		
			124 WF t2 T2	0.0995							

**Table A 2: Stability of TDMs residues in wheat (grain) following storage at -18°C**

Commodity/ matrix	Fortification rate/spike level of stored sam- ples (mg/kg)	Storage period (days/months)	Sample code	Concentration of stored samples		Residue Level in Freezer Storage Stabil- ity Sample (% of spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)	Mean residue Level in Freezer Storage Stabil- ity Sample (% of spiking level) (corrected for the daily recovery)	Mean recovery of stored samples corrected for the daily recovery /mean recovery at t0 corrected for the daily recovery (%)	
				Results (mg/kg)	Mean value (mg/kg)					
Wheat grain										
1H-1,2,4- triazole (TRZ)	0.1	0	124 WG t0 C	< LOD	█	█	103.0, 109.6 (106.3)	█	█	
			124 WG t0 T1	0.1013	0.1043	105.5, 103.2 (104.4)		98.2	█	
			124 WG t0 T2	0.1073				█	█	
	0.1	2 months (54 days)	124 WG t1 C	< LOD	█	█	102.5, 101.3 (101.9)	█	█	
			124 WG t1 T1	0.1023	0.1028	102.3, 103.9 (103.1)		101	103	
			124 WG t1 T2	0.1033				█	█	
	0.1	4 months (116 days)	124 WG t2 C	< LOD	█	█	103.9, 108.3 (106.1)	█	█	
			124 WG t2 T1	0.1014	0.0971	99.6, 96.2 (97.9)		92.2	94.0	
			124 WG t2 T2	0.0929				█	█	
	0.1	7 months (215 days)	124 WF t2 C	< LOD	█	█	105.2, 105.0 (105.1)	█	█	
			124 WF t2 T1	0.1058	0.1033	108.4, 103.6 (106.0)		101	103	
			124 WF t2 T2	0.1008				█	█	
1H-1,2,4- triazole alanine (TA)	0.1	0	124 WG t0 C	< LOQ (0.0083)	█	█	101.6, 99.3 (100.5)	█	█	
			124 WG t0 T1	0.1060	0.1098	101.8, 101.4 (101.6)		109	█	
			124 WG t0 T2	0.1137				█	█	
	0.1	2 months (54 days)	124 WG t1 C	< LOQ (0.0058)	█	█	98.4, 102.3 (100.4)	█	█	
			124 WG t1 T1	0.1137	0.1145	107.9, 110.1 (109.0)		114	105	
			124 WG t1 T2	0.1153				█	█	
	0.1	4 months (116 days)	124 WG t2 C	< LOQ (0.0056)	█	█	104.4, 104.7 (104.5)	█	█	
			124 WG t2 T1	0.1053	0.1059	97.9, 104.5 (101.2)		102	93.5	
			124 WG t2 T2	0.1065				█	█	
	0.1	7 months (215 days)	124 WF t2 C	< LOQ (0.0052)	█	█	97.8, 106.1 (102.0)	█	█	
			124 WF t2 T1	0.1037	0.1026	100.9, 99.0 (99.9)		98.0	96.9	
			124 WF t2 T2	0.1015				█	█	

Commodity/ matrix	Fortification rate/spike level of stored sam- ples (mg/kg)	Storage period (days/months)	Sample code	Concentration of stored samples		Residue Level in Freezer Storage Stabil- ity Sample (% of spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)	Mean residue Level in Freezer Storage Stabil- ity Sample (% of spiking level) (corrected for the daily recovery)	Mean recovery of stored samples corrected for the daily recovery /mean recovery at t0 corrected for the daily recovery (%)	
				Results (mg/kg)	Mean value (mg/kg)					
Wheat grain										
Triazole lactic acid (TLA)	0.1	0	124 WG t0 C	< LOD	█	█	107.8, 104.8 (106.3)	█	█	
			124 WG t0 T1	0.1015	0.1060	105.7, 106.4 (106.1)		99.8	█	
			124 WG t0 T2	0.1106						
	0.1	2 months (54 days)	124 WG t1 C	< LOD	█	█	105.7, 103.7 (104.7)	█	█	
			124 WG t1 T1	0.1066	0.1053	106.6, 104.6 (105.6)		101	101	
			124 WG t1 T2	0.1040						
	0.1	4 months (116 days)	124 WG t2 C	< LOD	█	█	111.1, 111.1 (111.1)	█	█	
			124 WG t2 T1	0.1002	0.1005	98.4, 104.4 (101.4)		91.3	91.5	
			124 WG t2 T2	0.1008						
	0.1	7 months (215 days)	124 WG t2 C	< LOD	█	█	101.7, 105.1 (103.4)	█	█	
			124 WG t2 T1	0.1047	0.1034	107.2, 105.0 (106.1)		103	103	
			124 WG t2 T2	0.1022						
Triazole acetic acid (TAA)	0.1	0	124 WG t0 C	< LOQ (0.0044)	█	█	102.4, 96.6 (99.5)	█	█	
			124 WG t0 T1	0.1039	0.1060	103.7, 99.8 (101.7)		107	█	
			124 WG t0 T2	0.1081						
	0.1	2 months (54 days)	124 WG t1 C	< LOQ (0.0034)	█	█	102.6, 100.8 (101.7)	█	█	
			124 WG t1 T1	0.1057	0.1052	102.3, 102.0 (102.2)		104	97.3	
			124 WG t1 T2	0.1047						
	0.1	4 months (116 days)	124 WG t2 C	< LOQ (0.0034)	█	█	103.9, 104.2 (104.0)	█	█	
			124 WG t2 T1	0.1047	0.1008	99.5, 97.0 (98.2)		97.7	91.6	
			124 WG t2 T2	0.0970						
	0.1	7 months (215 days)	124 WG t2 C	< LOQ (0.0026)	█	█	98.3, 102.5 (100.4)	█	█	
			124 WG t2 T1	0.1055	0.1031	105.4, 100.7 (103.1)		103	100	
			124 WG t2 T2	0.1006						

**Table A 3: Stability of TDMs residues in rapeseed seeds following storage at -18°C**

Commodity/ matrix	Fortification rate/spike level of stored sam- ples (mg/kg)	Storage period (days/months)	Sample code	Concentration of stored samples		Residue Level in Freezer Storage Stability Sample (% of spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)	Mean residue Level in Freezer Storage Stability Sample (% of spiking level) (corrected for the daily recovery)	Mean recovery of stored samples corrected for the daily recovery /mean recovery at t0 corrected for the daily recovery (%)	
				Results (mg/kg)	Mean value (mg/kg)					
Rapeseed seeds										
1H-1,2,4- triazole (TRZ)	0.1	0	124 RS t0 C	< LOQ (0.0031)	█	█	100.9, 105.9 (103.4)	█	█	
			124 RS t0 T1	0.1023	0.1054	100.6, 102.1 (101.3)		98.0	█	
			124 RS t0 T2	0.1084						
	0.1	2 months (54 days)	124 RS t1 C	< LOD	█	█	104.1, 99.7 (101.9)	█	█	
			124 RS t1 T1	0.1062	0.1037	104.5, 102.7 (103.6)		102	104	
			124 RS t1 T2	0.1013						
	0.1	4 months (116 days)	124 RS t2 C	< LOD	█	█	104.1, 109.7 (106.9)	█	█	
			124 RS t2 T1	0.0894	0.0890	86.8, 87.4 (87.1)		81.4	83.1	
			124 RS t2 T2	0.0886						
	0.1	7 months (215 days)	124 RS t3 C	< LOD	█	█	96.6, 99.4 (98.0)	█	█	
			124 RS t3 T1	0.1042	0.1076	103.8, 109.0 (106.4)		109	111	
			124 RS t3 T2	0.1110						
1H-1,2,4- triazole alanine (TA)	0.1	0	124 RS t0 C	0.0358	█	█	107.8, 105.5 (106.6)	█	█	
			124 RS t0 T1	0.1400	0.1416	105.6, 104.2 (104.9)		98.4	█	
			124 RS t0 T2	0.1433						
	0.1	2 months (54 days)	124 RS t1 C	0.0166	█	█	97.0, 102.2 (99.6)	█	█	
			124 RS t1 T1	0.1076	0.1076	89.6, 92.2 (90.9)		91.3	92.8	
			124 RS t1 T2	0.1075						
	0.1	4 months (116 days)	124 RS t2 C	0.0231	█	█	105.0, 104.1 (104.6)	█	█	
			124 RS t2 T1	0.1244	0.1250	98.3, 101.1 (99.7)		95.4	96.9	
			124 RS t2 T2	0.1256						
	0.1	7 months (215 days)	124 RS t3 C	< LOQ (0.0084)	█	█	96.5, 94.8 (95.6)	█	█	
			124 RS t3 T1	0.1070	0.1085	98.2, 99.8 (99.0)		103	105	
	124 RS t3 T2	0.1100								

Commodity/ matrix	Fortification rate/spike level of stored sam- ples (mg/kg)	Storage period (days/months)	Sample code	Concentration of stored samples		Residue Level in Freezer Storage Stability Sample (% of spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)	Mean residue Level in Freezer Storage Stability Sample (% of spiking level) (corrected for the daily recovery)	Mean recovery of stored samples corrected for the daily recovery /mean recovery at t0 corrected for the daily recovery (%)	
				Results (mg/kg)	Mean value (mg/kg)					
Rapeseed seeds										
Triazole lactic acid (TLA)	0.1	0	124 RS t0 C	< LOQ (0.0026)	█	█	105.7, 99.6 (102.6)	█	█	
			124 RS t0 T1	0.1082	0.1085	107.1, 103.1 (105.1)		102	█	
			124 RS t0 T2	0.1089						
	0.1	2 months (54 days)	124 RS t1 C	< LOD	█	█	104.3, 101.7 (103.0)	█	█	
			124 RS t1 T1	0.1042	0.1024	102.6, 102.0 (102.3)		99.3	97.0	
			124 RS t1 T2	0.1006						
	0.1	4 months (116 days)	124 RS t2 C	< LOD	█	█	101.4, 102.8 (102.1)	█	█	
			124 RS t2 T1	0.0974	0.0972	94.5, 95.6 (95.1)		93.1	90.9	
			124 RS t2 T2	0.0970						
	0.1	7 months (215 days)	124 RS t3 C	< LOD	█	█	102.1, 96.6 (99.4)	█	█	
			124 RS t3 T1	0.1063	0.1086	105.8, 108.9 (107.4)		108	106	
			124 RS t3 T2	0.1109						
Triazole acetic acid (TAA)	0.1	0	124 RS t0 C	< LOD	█	█	106.9, 104.6 (105.7)	█	█	
			124 RS t0 T1	0.1044	0.1063	105.9, 104.9 (105.4)		99.7	█	
			124 RS t0 T2	0.1082						
	0.1	2 months (54 days)	124 RS t1 C	< LOD	█	█	101.8, 102.4 (102.1)	█	█	
			124 RS t1 T1	0.0987	0.0980	97.2, 98.6 (97.9)		95.8	96.1	
			124 RS t1 T2	0.0972						
	0.1	4 months (116 days)	124 RS t2 C	< LOD	█	█	97.0, 99.0 (98.0)	█	█	
			124 RS t2 T1	0.1020	0.1012	98.9, 99.1 (99.0)		101	101	
			124 RS t2 T2	0.1005						
	0.1	7 months (215 days)	124 RS t3 C	< LOD	█	█	102.2, 100.5 (101.3)	█	█	
			124 RS t3 T1	0.1044	0.1078	104.0, 109.2 (106.6)		105	106	
			124 RS t3 T2	0.1112						

**Table A 4: Stability of TDMs residues in wheat (Straw) following storage at -18°C**

Commodity/ matrix	Fortification rate/spike level of stored sam- ples (mg/kg)	Storage period (days/months)	Sample code	Concentration of stored samples		Residue Level in Freezer Storage	Procedural Recovery for Freshly Spiked Control Sample (%)	Mean residue Level in Freezer Storage Stability	Mean recovery of stored
				Results (mg/kg)	Mean value (mg/kg)	Stability Sample (%) of spiking level) (range plus mean)		Sample (% of spiking level) (corrected for the daily recovery)	samples corrected for the daily recovery /mean recovery at t0 corrected for the daily recovery (%)
Straw (wheat)									
1H-1,2,4- triazole (TRZ)	0.1	0	124 SW t0 C	< LOD	█	█	102.9, 94.8 (98.9)	█	█
			124 SW t0 T1	0.0897	0.0934	90.8, 97.8 (94.3)		95.4	█
			124 SW t0 T2	0.0970					
	0.1	2 months (53 days)	124 SW t1 C	< LOD	█	█	102.3, 96.7 (99.5)	█	█
			124 SW t1 T1	0.0979	0.0963	99.5, 92.5 (96.0)		96.5	101
			124 SW t1 T2	0.0948					
	0.1	4 months (116 days)	124 SW t2 C	< LOD	█	█	90.9, 95.0 (92.9)	█	█
			124 SW t2 T1	0.0866	0.0843	89.0, 82.7 (85.8)		92.4	96.9
			124 SW t2 T2	0.0820					
	0.1	7 months (215 days)	124 SW t3 C	< LOD	█	█	98.5, 99.6 (99.1)	█	█
			124 SW t3 T1	0.0863	0.0858	89.1, 86.7 (87.9)		88.7	93.0
			124 SW t3 T2	0.0853					
1H-1,2,4- triazole alanine (TA)	0.1	0	124 SW t0 C	< LOD	█	█	102.3, 97.8 (100.0)	█	█
			124 SW t0 T1	0.1030	0.1013	104.3, 100.4 (102.4)		102	█
			124 SW t0 T2	0.0997					
	0.1	2 months (53 days)	124 SW t1 C	< LOD	█	█	102.1, 107.9 (105.0)	█	█
			124 SW t1 T1	0.0913	0.0939	92.7, 94.2 (93.5)		89.0	87.0
			124 SW t1 T2	0.0966					
	0.1	4 months (116 days)	124 SW t2 C	< LOD	█	█	94.3, 99.0 (96.7)	█	█
			124 SW t2 T1	0.0916	0.0856	94.2, 80.2 (87.2)		90.2	88.1
			124 SW t2 T2	0.0795					
	0.1	7 months (215 days)	124 SW t3 C	< LOD	█	█	97.8, 97.0 (97.4)	█	█
			124 SW t3 T1	0.0790	0.0797	81.6, 81.6 (81.6)		83.7	81.9
			124 SW t3 T2	0.0803					

Commodity/ matrix	Fortification rate/spike level of stored sam- ples (mg/kg)	Storage period (days/months)	Sample code	Concentration of stored samples		Residue Level in Freezer Storage Stabili- ty Sample (% of spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)	Mean residue Level in Freezer Storage Stability Sample (% of spiking level) (corrected for the daily recovery)	Mean recovery of stored samples corrected for the daily recovery /mean recovery at t0 corrected for the daily recovery (%)
				Results (mg/kg)	Mean value (mg/kg)				
Straw (wheat)									
Triazole lactic acid (TLA)	0.1	0	124 SW t0 C	< LOD	█	█	99.5, 102.8 (101.2)	█	█
			124 SW t0 T1	0.0899	0.0929	91.0, 96.7 (93.9)		92.8	█
			124 SW t0 T2	0.0959					
	0.1	2 months (53 days)	124 SW t1 C	< LOQ (0.0032)	█	█	101.9, 99.5 (100.7)	█	█
			124 SW t1 T1	0.0970	0.0975	95.3, 92.5 (93.9)		93.3	101
			124 SW t1 T2	0.0980					
	0.1	4 months (116 days)	124 SW t2 C	< LOD	█	█	99.1, 107.1 (103.1)	█	█
			124 SW t2 T1	0.1017	0.0946	104.6, 88.1 (96.3)		93.4	101
			124 SW t2 T2	0.0874					
	0.1	7 months (215 days)	124 SW t3 C	< LOQ (0.0039)	█	█	98.1, 92.5 (95.3)	█	█
			124 SW t3 T1	0.1061	0.1070	105.5, 105.6 (105.6)		111	119
			124 SW t3 T2	0.1079					
Triazole acetic acid (TAA)	0.1	0	124 SW t0 C	< LOD	█	█	98.8, 100.1 (99.4)	█	█
			124 SW t0 T1	0.0951	0.0970	96.2, 99.7 (98.0)		98.5	█
			124 SW t0 T2	0.0989					
	0.1	2 months (53 days)	124 SW t1 C	< LOD	█	█	101.1, 100.5 (100.8)	█	█
			124 SW t1 T1	0.1073	0.1065	109.0, 103.2 (106.1)		105	107
			124 SW t1 T2	0.1058					
	0.1	4 months (116 days)	124 SW t2 C	< LOD	█	█	98.3, 103.8 (101.0)	█	█
			124 SW t2 T1	0.1082	0.0992	111.2, 91.0 (101.1)		100	102
			124 SW t2 T2	0.0903					
	0.1	7 months (215 days)	124 SW t3 C	< LOD	█	█	99.1, 94.3 (96.7)	█	█
			124 SW t3 T1	0.0942	0.0959	97.2, 99.1 (98.2)		101	103
				124 SW t3 T2	0.0976				

**Table A 5: Stability of TDMs residues in apple following storage at -18°C**

Commodity/ matrix	Fortification rate/spike level of stored sam- ples (mg/kg)	Storage period (days/months)	Sample code	Concentration of stored samples		Residue Level in Freezer Storage Stability Sample (% of spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)	Mean residue Level in Freezer Storage Stability Sample (% of spiking level) (corrected for the daily recovery)	Mean recovery of stored samples corrected for the daily recovery /mean recovery at t0 corrected for the daily recovery (%)	
				Results (mg/kg)	Mean value (mg/kg)					
Apple										
1H-1,2,4- triazole (TRZ)	0.1	0	124 AP t0 C	< LOQ (0.0026)	█	█	105.0, 101.9 (103.5)	█	█	
			124 AP t0 T1	0.1041	0.1020	102.4, 98.0 (100.2)		96.9	█	
			124 AP t0 T2	0.0999						
	0.1	2 months (56 days)	124 AP t1 C	< LOD	█	█	103.5, 100.1 (101.8)	█	█	
			124 AP t1 T1	0.1099	0.1161	108.0, 120.0 (114.0)		112	116	
			124 AP t1 T2	0.1224						
	0.1	4 months (114 days)	124 AP t2 C	< LOD	█	█	103.1, 106.2 (104.6)	█	█	
			124 AP t2 T1	0.0972	0.1025	96.5, 104.3 (100.4)		96.0	99.1	
			124 AP t2 T2	0.1079						
	0.1	7 months (213 days)	124 AP t3 C	< LOD	█	█	101.8, 93.1 (97.5)	█	█	
			124 AP t3 T1	0.0983	0.0989	97.7, 101.0 (99.3)		102	105	
			124 AP t3 T2	0.0995						
1H-1,2,4- triazole alanine (TA)	0.1	0	124 AP t0 C	< LOD	█	█	101.2, 102.4 (101.8)	█	█	
			124 AP t0 T1	0.1003	0.0967	101.2, 93.8 (97.5)		95.8	█	
			124 AP t0 T2	0.0931						
	0.1	2 months (56 days)	124 AP t1 C	< LOD	█	█	107.8, 111.6 (109.7)	█	█	
			124 AP t1 T1	0.1206	0.1204	118.5, 117.8 (118.2)		108	113	
			124 AP t1 T2	0.1202						
	0.1	4 months (114 days)	124 AP t2 C	< LOD	█	█	103.3, 100.4 (101.9)	█	█	
			124 AP t2 T1	0.1010	0.1036	100.3, 102.7 (101.5)		99.7	104	
			124 AP t2 T2	0.1062						
	0.1	7 months (213 days)	124 AP t3 C	< LOD	█	█	106.3, 107.1 (106.7)	█	█	
			124 AP t3 T1	0.1084	0.1069	107.6, 107.1 (107.3)		101	105	
			124 AP t3 T2	0.1055						



Commodity/ matrix	Fortification rate/spike level of stored sam- ples (mg/kg)	Storage period (days/months)	Sample code	Concentration of stored samples		Residue Level in Freezer Storage Stability Sample (% of spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)	Mean residue Level in Freezer Storage Sta- bility Sample (% of spiking level) (correct- ed for the daily recov- ery)	Mean recovery of stored samples cor- rected for the daily recovery /mean recov- ery at t0 corrected for the daily recovery (%)	
				Results (mg/kg)	Results (mg/kg)					
Apple										
Triazole lactic acid (TLA)	0.1	0	124 AP t0 C	< LOD	█	█	103.7, 102.9 (103.3)	█	█	
			124 AP t0 T1	0.1010	0.1017	101.9, 103.1 (102.5)		99.2	█	
			124 AP t0 T2	0.1023						
	0.1	2 months (56 days)	124 AP t1 C	< LOD	█	█	97.0, 97.1 (97.0)	█	█	
			124 AP t1 T1	0.0977	0.0989	96.0, 98.0 (97.0)		100	101	
			124 AP t1 T2	0.1000						
	0.1	4 months (114 days)	124 AP t2 C	< LOD	█	█	102.6, 106.2 (104.4)	█	█	
			124 AP t2 T1	0.0980	0.0996	97.3, 97.8 (97.6)		93.4	94.1	
			124 AP t2 T2	0.1012						
	0.1	7 months (213 days)	124 AP t3 C	< LOD	█	█	109.2, 108.8 (109.0)	█	█	
			124 AP t3 T1	0.1106	0.1105	109.8, 112.1 (111.0)		102	103	
			124 AP t3 T2	0.1105						
Triazole acetic acid (TAA)	0.1	0	124 AP t0 C	< LOD	█	█	98.6, 99.1 (98.9)	█	█	
			124 AP t0 T1	0.0992	0.0994	100.1, 100.4 (100.3)		101	█	
			124 AP t0 T2	0.0996						
	0.1	2 months (56 days)	124 AP t1 C	< LOD	█	█	100.3, 99.8 (100.0)	█	█	
			124 AP t1 T1	0.1074	0.1085	105.5, 107.5 (106.5)		106	105	
			124 AP t1 T2	0.1097						
	0.1	4 months (114 days)	124 AP t2 C	< LOD	█	█	102.7, 102.1 (102.4)	█	█	
			124 AP t2 T1	0.1072	0.1089	106.4, 107.0 (106.7)		104	103	
			124 AP t2 T2	0.1107						
	0.1	7 months (213 days)	124 AP t3 C	< LOD	█	█	99.5, 100.4 (99.9)	█	█	
			124 AP t3 T1	0.1052	0.1034	104.4, 103.1 (103.7)		104	102	
			124 AP t3 T2	0.1015						

**Table A 6: Stability of TDMs residues in tomato following storage at -18°C**

Commodity/ matrix	Fortification rate/spike level of stored sam- ples (mg/kg)	Storage period (days/months)	Sample code	Concentration of stored samples		Residue Level in Freezer Storage Stability Sample (% of spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)	Mean residue Level in Freezer Storage Stability Sample (% of spiking level) (corrected for the daily recovery)	Mean recovery of stored samples corrected for the daily recovery /mean recovery at t0 corrected for the daily recovery (%)	
				Results (mg/kg)	Results (mg/kg)					
Tomato										
1H-1,2,4- triazole (TRZ)	0.1	0	124 TO t0 C	< LOD	█	█	100.4, 99.6 (100.0)	█	█	
			124 TO t0 T1	0.1033	0.1031	101.3, 100.8 (101.0)		101		
			124 TO t0 T2	0.1028						
	0.1	2 months (56 days)	124 TO t1 C	< LOQ (0.0031)	█	█	96.6, 96.6 (96.6)	█	█	
			124 TO t1 T1	0.1031	0.1037	100.8, 102.1 (101.4)		105	104	
			124 TO t1 T2	0.1042						
	0.1	4 months (114 days)	124 TO t2 C	< LOD	█	█	97.3, 101.4 (99.4)	█	█	
			124 TO t2 T1	0.1002	0.0998	99.5, 101.2 (100.4)		101	99.9	
			124 TO t2 T2	0.0994						
	0.1	7 months (213 days)	124 TO t3 C	< LOD	█	█	100.6, 99.3 (99.9)	█	█	
			124 TO t3 T1	0.1023	0.1022	101.4, 102.2 (101.8)		102	101	
			124 TO t3 T2	0.1022						
1H-1,2,4- triazole alanine (TA)	0.1	0	124 TO t0 C	< LOD	█	█	99.2, 108.8 (104.0)	█	█	
			124 TO t0 T1	0.1074	0.1064	105.3, 103.3 (104.3)		100	█	
			124 TO t0 T2	0.1053						
	0.1	2 months (56 days)	124 TO t1 C	< LOD	█	█	111.3, 112.5 (111.9)	█	█	
			124 TO t1 T1	0.1160	0.1163	116.9, 117.6 (117.2)		105	105	
			124 TO t1 T2	0.1166						
	0.1	4 months (114 days)	124 TO t2 C	< LOD	█	█	97.3, 97.3 (97.3)	█	█	
			124 TO t2 T1	0.1040	0.1030	103.3, 104.0 (103.7)		107	106	
			124 TO t2 T2	0.1021						
	0.1	7 months (213 days)	124 TO t3 C	< LOD	█	█	104.7, 106.3 (105.5)	█	█	
			124 TO t3 T1	0.1049	0.1046	104.0, 104.3 (104.2)		98.7	98.5	
			124 TO t3 T2	0.1043						

Commodity/ matrix	Fortification rate/spike level of stored samples (mg/kg)	Storage period (days/months)	Sample code	Concentration of stored samples		Residue Level in Freezer Storage Stability Sample (% of spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)	Mean residue Level in Freezer Storage Stabil- ity Sample (% of spik- ing level) (corrected for the daily recovery)	Mean recovery of stored samples corrected for the daily recovery /mean recovery at t0 corrected for the daily recovery (%)	
				Results (mg/kg)	Mean value (mg/kg)					
Tomato										
Triazole lactic acid (TLA)	0.1	0	124 TO t0 C	< LOD	█	█	104.1, 106.6 (105.3)	█	█	
			124 TO t0 T1	0.1068	0.1072	104.6, 105.6 (105.1)		99.8	█	
			124 TO t0 T2	0.1076						
	0.1	2 months (56 days)	124 TO t1 C	< LOD	█	█	98.0, 98.7 (98.4)	█	█	
			124 TO t1 T1	0.0958	0.0955	96.5, 96.2 (96.3)		97.9	98.1	
			124 TO t1 T2	0.0953						
	0.1	4 months (114 days)	124 TO t2 C	< LOD	█	█	99.8, 100.6 (100.2)	█	█	
			124 TO t2 T1	0.0994	0.0984	98.7, 99.2 (99.0)		98.8	99.0	
			124 TO t2 T2	0.0974						
	0.1	7 months (213 days)	124 TO t3 C	< LOD	█	█	100.8, 103.1 (102.0)	█	█	
			124 TO t3 T1	0.1080	0.1079	107.1, 107.7 (107.4)		105	106	
			124 TO t3 T2	0.1077						
Triazole acetic acid (TAA)	0.1	0	124 TO t0 C	< LOD	█	█	98.1, 97.0 (97.6)	█	█	
			124 TO t0 T1	0.1048	0.1032	102.7, 99.6 (101.2)		104	█	
			124 TO t0 T2	0.1016						
	0.1	2 months (56 days)	124 TO t1 C	< LOD	█	█	103.6, 105.5 (104.6)	█	█	
			124 TO t1 T1	0.1104	0.1098	111.3, 110.2 (110.7)		106	102	
			124 TO t1 T2	0.1092						
	0.1	4 months (114 days)	124 TO t2 C	< LOD	█	█	97.2, 98.8 (98.0)	█	█	
			124 TO t2 T1	0.1027	0.1014	102.0, 101.9 (102.0)		104	100	
			124 TO t2 T2	0.1000						
	0.1	7 months (213 days)	124 TO t3 C	< LOD	█	█	106.4, 103.9 (105.1)	█	█	
			124 TO t3 T1	0.1091	0.1087	108.2, 108.4 (108.3)		103	99.3	
			124 TO t3 T2	0.1084						

**Table A 7: Stability of TDMs residues in carrot following storage at -18°C**

Commodity/ matrix	Fortification rate/spike level of stored sam- ples (mg/kg)	Storage period (days/months)	Sample code	Concentration of stored samples		Residue Level in Freezer Storage Stability Sample (% of spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)	Mean residue Level in Freezer Storage Stability Sample (%) (corrected for the daily recovery)	Mean recovery of stored samples corrected for the daily recovery /mean recovery at t0 corrected for the daily recovery (%)	
				Results (mg/kg)	Mean value (mg/kg)					
Carrot										
1H-1,2,4- triazole (TRZ)	0.1	0	124 CA t0 C	< LOD	█	█	100.1, 99.6 (99.8)	█	█	
			124 CA t0 T1	0.0943	0.0954	96.3, 97.1 (96.7)		96.8	█	
			124 CA t0 T2	0.0965				█	█	
	0.1	2 months (52 days)	124 CA t1 C	< LOD	█	█	98.3, 97.3 (97.8)	█	█	
			124 CA t1 T1	0.1070	0.1056	107.7, 104.4 (106.0)		108	112	
			124 CA t1 T2	0.1043				█	█	
	0.1	4 months (114 days)	124 CA t2 C	< LOD	█	█	97.5, 98.0 (97.8)	█	█	
			124 CA t2 T1	0.0933	0.0919	97.8, 91.3 (94.5)		96.7	99.9	
			124 CA t2 T2	0.0904				█	█	
	0.1	7 months (213 days)	124 CA t3 C	< LOD	█	█	107.2, 101.7 (104.4)	█	█	
			124 CA t3 T1	0.0936	0.0994	96.3, 106.5 (101.4)		97.1	100	
			124 CA t3 T2	0.1052				█	█	
1H-1,2,4- triazole alanine (TA)	0.1	0	124 CA t0 C	< LOD	█	█	96.1, 99.3 (97.7)	█	█	
			124 CA t0 T1	0.0939	0.0939	95.9, 94.5 (95.2)		97.4	█	
			124 CA t0 T2	0.0939				█	█	
	0.1	2 months (52 days)	124 CA t1 C	< LOD	█	█	110.2, 102.8 (106.5)	█	█	
			124 CA t1 T1	0.1168	0.1149	117.6, 113.1 (115.4)		108	111	
			124 CA t1 T2	0.1130				█	█	
	0.1	4 months (114 days)	124 CA t2 C	< LOD	█	█	97.3, 104.1 (100.7)	█	█	
			124 CA t2 T1	0.0983	0.0983	103.0, 99.4 (101.2)		100	103	
			124 CA t2 T2	0.0984				█	█	
	0.1	7 months (213 days)	124 CA t3 C	< LOD	█	█	107.5, 98.8 (103.1)	█	█	
			124 CA t3 T1	0.1062	0.1070	109.3, 109.1 (109.2)		106	109	
			124 CA t3 T2	0.1078				█	█	

Commodity/ matrix	Fortification rate/spike level of stored sam- ples (mg/kg)	Storage period (days/months)	Sample code	Concentration of stored samples		Residue Level in Freezer Storage Stability Sample (% of spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)	Mean residue Level in Freezer Storage Sta- bility Sample (% of spiking level) (correct- ed for the daily recov- ery)	Mean recovery of stored samples corrected for the daily recovery /mean recovery at t0 corrected for the daily recovery (%)	
				Results (mg/kg)	Mean value (mg/kg)					
Carrot										
Triazole lactic acid (TLA)	0.1	0	124 CA t0 C	< LOD	█	█	98.0, 98.9 (98.4)	█	█	
			124 CA t0 T1	0.0950	0.0961	97.0, 97.7 (97.3)		98.9	█	
			124 CA t0 T2	0.0971				█	█	
	0.1	2 months (52 days)	124 CA t1 C	< LOD	█	█	102.4, 100.5 (101.5)	█	█	
			124 CA t1 T1	0.0985	0.0993	99.2, 100.1 (99.7)		98.2	99.3	
			124 CA t1 T2	0.1000						
	0.1	4 months (114 days)	124 CA t2 C	< LOD	█	█	99.8, 100.1 (100.0)	█	█	
			124 CA t2 T1	0.0929	0.0959	97.3, 99.9 (98.6)		98.6	99.8	
			124 CA t2 T2	0.0989						
	0.1	7 months (213 days)	124 CA t3 C	< LOD	█	█	109.6, 109.8 (109.7)	█	█	
			124 CA t3 T1	0.1130	0.1133	116.3, 114.9 (115.6)		105	107	
			124 CA t3 T2	0.1136						
Triazole acetic acid (TAA)	0.1	0	124 CA t0 C	< LOD	█	█	97.0, 96.5 (96.7)	█	█	
			124 CA t0 T1	0.0963	0.0966	98.3, 97.5 (97.9)		101	█	
			124 CA t0 T2	0.0969						
	0.1	2 months (52 days)	124 CA t1 C	< LOD	█	█	97.4, 99.1 (98.2)	█	█	
			124 CA t1 T1	0.1039	0.1043	104.7, 104.8 (104.7)		107	105	
			124 CA t1 T2	0.1047						
	0.1	4 months (114 days)	124 CA t2 C	< LOD	█	█	101.5, 103.2 (102.4)	█	█	
			124 CA t2 T1	0.0978	0.0999	102.5, 103.0 (102.7)		100	99.2	
			124 CA t2 T2	0.1020						
	0.1	7 months (213 days)	124 CA t3 C	< LOD	█	█	107.9, 106.1 (107.0)	█	█	
			124 CA t3 T1	0.1010	0.1045	103.9, 109.2 (106.6)		99.6	98.5	
			124 CA t3 T2	0.1079						

**Table A 8: Procedural recovery results summary – 1,2,4-triazole**

Analyte	Matrix	Fortification level (mg/kg) (nominal)	timepoint	Recoveries (%)		Mean recovery (%) (each timepoint)	SD (each timepoint)	RSD (%) (each timepoint)	Overall mean recovery (%)	Overall SD	Overall RSD (%)
1,2,4-triazole (TRZ)	Apple	0.1	t0	105.0	101.9	103.5	2.2	2.1	101.8	4.0	3.9
			t1	103.5	100.1	101.8	2.4	2.4			
			t2	103.1	106.2	104.7	2.2	2.1			
			t3	101.8	93.1	97.5	6.2	6.3			
	Carrot		t0	100.1	99.6	99.9	0.4	0.4	100.0	3.3	3.3
			t1	98.3	97.3	97.8	0.7	0.7			
			t2	97.5	98.0	97.8	0.4	0.4			
			t3	107.2	101.7	104.5	3.9	3.7			
	Tomato		t0	100.4	99.6	100.0	0.6	0.6	99.0	1.9	1.9
			t1	96.6	96.6	96.6	0.0	0.0			
			t2	97.3	101.4	99.4	2.9	2.9			
			t3	100.6	99.3	100.0	0.9	0.9			
	Rape-seed seeds		t0	100.9	105.9	103.4	3.5	3.4	102.6	4.2	4.1
			t1	104.1	99.7	101.9	3.1	3.1			
			t2	104.1	109.7	106.9	4.0	3.7			
			t3	96.6	99.4	98.0	2.0	2.0			
	Grain (wheat)		t0	103.0	109.6	106.3	4.7	4.4	104.9	2.9	2.7
			t1	102.5	101.3	101.9	0.8	0.8			
			t2	103.9	108.3	106.1	3.1	2.9			
			t3	105.2	105.0	105.1	0.1	0.1			
	Forage (wheat)		t0	96.4	96.1	96.3	0.2	0.2	99.0	6.2	6.2
			t1	94.2	89.8	92.0	3.1	3.4			
			t2	102.8	98.6	100.7	3.0	2.9			
			t3	105.4	108.3	106.9	2.1	1.9			
	Straw (wheat)		t0	102.9	94.8	98.9	5.7	5.8	97.6	4.1	4.2
			t1	102.3	96.7	99.5	4.0	4.0			
			t2	90.9	95.0	93.0	2.9	3.1			
			t3	98.5	99.6	99.1	0.8	0.8			

**Table A 9: Procedural recovery results summary – Triazole-alanine**

Analyte	Matrix	Fortification level (mg/kg) (nominal)	timepoint	Recoveries (%)		Mean recovery (%) (each timepoint)	SD (each timepoint)	RSD (%) (each timepoint)	Overall mean recovery (%)	Overall SD	Overall RSD (%)
Triazole Alanine (TA)	Apple	0.1	t0	101.2	102.4	101.8	0.8	0.8	105.0	3.8	3.6
			t1	107.8	111.6	109.7	2.7	2.4			
			t2	103.3	100.4	101.9	2.1	2.0			
			t3	106.3	107.1	106.7	0.6	0.5			
	Carrot		t0	96.1	99.3	97.7	2.3	2.3	102.0	5.0	4.9
			t1	110.2	102.8	106.5	5.2	4.9			
			t2	97.3	104.1	100.7	4.8	4.8			
			t3	107.5	98.8	103.2	6.2	6.0			
	Tomato		t0	99.2	108.8	104.0	6.8	6.5	104.7	6.1	5.9
			t1	111.3	112.5	111.9	0.8	0.8			
			t2	97.3	97.3	97.3	0.0	0.0			
			t3	104.7	106.3	105.5	1.1	1.1			
	Rape-seed seeds		t0	107.8	105.5	106.7	1.6	1.5	101.6	4.9	4.8
			t1	97.0	102.2	99.6	3.7	3.7			
			t2	105.0	104.1	104.6	0.6	0.6			
			t3	96.5	94.8	95.7	1.2	1.3			
	Grain (wheat)		t0	101.6	99.3	100.5	1.6	1.6	101.8	3.1	3.1
			t1	98.4	102.3	100.4	2.8	2.7			
			t2	104.4	104.7	104.6	0.2	0.2			
			t3	97.8	106.1	102.0	5.9	5.8			
	Forage (wheat)		t0	102.9	103.8	103.4	0.6	0.6	101.5	4.1	4.0
			t1	99.6	102.7	101.2	2.2	2.2			
			t2	95.5	96.6	96.1	0.8	0.8			
			t3	108.0	102.5	105.3	3.9	3.7			
	Straw (wheat)		t0	102.3	97.8	100.1	3.2	3.2	99.8	4.2	4.2
			t1	102.1	107.9	105.0	4.1	3.9			
			t2	94.3	99.0	96.7	3.3	3.4			
			t3	97.8	97.0	97.4	0.6	0.6			

**Table A 10: Procedural recovery results summary – Triazole-lactic acid**

Ana-lyte	Matrix	Fortifica-tion level (mg/kg) (nominal)	timepoint	Recoveries (%)		Mean recovery (%) (each timepoint)	SD (each timepoint)	RSD (%) (each timepoint)	Overall mean recov-ery (%)	Over-all SD	Over-all RSD (%)
Tria-zole lactic acid (TLA)	Apple	0.1	t0	103.7	102.9	103.3	0.6	0.5	103.4	4.7	4.5
			t1	97.0	97.1	97.1	0.1	0.1			
			t2	102.6	106.2	104.4	2.5	2.4			
			t3	109.2	108.8	109.0	0.3	0.3			
	Carrot		t0	98.0	98.9	98.5	0.6	0.6	102.4	4.7	4.6
			t1	102.4	100.5	101.5	1.3	1.3			
			t2	99.8	100.1	100.0	0.2	0.2			
			t3	109.6	109.8	109.7	0.1	0.1			
	Tomato		t0	104.1	106.6	105.4	1.8	1.7	101.5	2.9	2.9
			t1	98.0	98.7	98.4	0.5	0.5			
			t2	99.8	100.6	100.2	0.6	0.6			
			t3	100.8	103.1	102.0	1.6	1.6			
	Rape-seed seeds		t0	105.7	99.6	102.7	4.3	4.2	101.8	2.8	2.7
			t1	104.3	101.7	103.0	1.8	1.8			
			t2	101.4	102.8	102.1	1.0	1.0			
			t3	102.1	96.6	99.4	3.9	3.9			
	Grain (wheat)		t0	107.8	104.8	106.3	2.1	2.0	106.4	3.4	3.2
			t1	105.7	103.7	104.7	1.4	1.4			
			t2	111.1	111.1	111.1	0.0	0.0			
			t3	101.7	105.1	103.4	2.4	2.3			
	Forage (wheat)		t0	93.1	97.7	95.4	3.3	3.4	100.8	4.7	4.7
			t1	100.2	97.9	99.1	1.6	1.6			
			t2	101.6	101.8	101.7	0.1	0.1			
			t3	107.3	106.7	107.0	0.4	0.4			
	Straw (wheat)		t0	99.5	102.8	101.2	2.3	2.3	100.1	4.2	4.2
			t1	101.9	99.5	100.7	1.7	1.7			
			t2	99.1	107.1	103.1	5.7	5.5			
			t3	98.1	92.5	95.3	4.0	4.2			



**Table A 11: Procedural recovery results summary – Triazole-acetic acid**

Ana-lyte	Matrix	Fortifica-tion level (mg/kg) (nominal)	timepoint	Recoveries (%)		Mean recovery (%) (each timepoint)	SD (each timepoint)	RSD (%) (each timepoint)	Overall mean recovery (%)	Over-all SD	Over-all RSD (%)
Tria-zole acetic acid (TAA)	Apple	0.1	t0	98.6	99.1	98.9	0.4	0.4	100.3	1.4	1.4
			t1	100.3	99.8	100.1	0.4	0.4			
			t2	102.7	102.1	102.4	0.4	0.4			
			t3	99.5	100.4	100.0	0.6	0.6			
	Carrot		t0	97.0	96.5	96.8	0.4	0.4	101.1	4.3	4.3
			t1	97.4	99.1	98.3	1.2	1.2			
			t2	101.5	103.2	102.4	1.2	1.2			
			t3	107.9	106.1	107.0	1.3	1.2			
	Tomato		t0	98.1	97.0	97.6	0.8	0.8	101.3	3.9	3.9
			t1	103.6	105.5	104.6	1.3	1.3			
			t2	97.2	98.8	98.0	1.1	1.2			
			t3	106.4	103.9	105.2	1.8	1.7			
	Rape-seed seeds		t0	106.9	104.6	105.8	1.6	1.5	101.8	3.1	3.0
			t1	101.8	102.4	102.1	0.4	0.4			
			t2	97.0	99.0	98.0	1.4	1.4			
			t3	102.2	100.5	101.4	1.2	1.2			
	Grain (wheat)		t0	102.4	96.6	99.5	4.1	4.1	101.4	2.7	2.7
			t1	102.6	100.8	101.7	1.3	1.3			
			t2	103.9	104.2	104.1	0.2	0.2			
			t3	98.3	102.5	100.4	3.0	3.0			
	Forage (wheat)		t0	98.4	98.6	98.5	0.1	0.1	98.1	3.6	3.7
			t1	95.2	93.2	94.2	1.4	1.5			
			t2	97.9	95.1	96.5	2.0	2.1			
			t3	102.9	103.3	103.1	0.3	0.3			
	Straw (wheat)		t0	98.8	100.1	99.5	0.9	0.9	99.5	2.7	2.7
			t1	101.1	100.5	100.8	0.4	0.4			
			t2	98.3	103.8	101.1	3.9	3.8			
			t3	99.1	94.3	96.7	3.4	3.5			

## **Conclusion**

The studies demonstrated residue stability in the different matrices samples stored at -18°C for a period of 7 months for all TMDs, thus covering the storage periods of the supervised residue trials on different commodities.

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

#### **A 2.1.2.1 Nature of residue in plants**

No new studies submitted in the framework of this application.

#### **A 2.1.2.2 Nature of residues in livestock**

No new studies submitted in the framework of this application.

## A 2.1.3 Magnitude of residues in plants

### A 2.1.3.1 Oilseed rape

**Table A 12: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (RAR, Spain, 2019)	2 (1 in autumn and 1 in spring, or 2 in autumn)	125	21 days	BBCH 14-18 and BBCH 30-69	n/a
Intended cGAP (number 1*)	2 (1 in autumn and 1 in spring, or 2 in autumn)	125	21 days	BBCH 14-18 and BBCH 30-69	n/a

\* 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:	<p>The study is accepted. The trials are independent and valid with regard to storage stability data for difenoconazole and for TMDs. Acceptable following analytical methods were used.</p> <p><del>Data gap:</del></p> <p><del>Storage stability data for 1,2,4 Triazole and TA in high oil content matrix (post registration requirement).</del></p> <p>Difenoconazole:</p> <p>The analytical determinations were carried out performing extractions of the analytes from the matrices using the QuEChERS method and in instrumental analyses using a high-performance liquid chromatography with a triple quadrupole mass spectrometry detection (HPLC-MS/MS). The method was validated in compliance with SANTE/2020/12830, Rev.1 guideline.</p> <p>TMDs:</p> <p>The analytical determination was carried out using a HPLC-DMS-MS/MS method that was validated in compliance with SANTE/2020/12830, Rev.1 guideline</p> <p>Maximum specimens storage time (days, difenoconazole):</p> <table> <tr><td>Seeds</td><td>107</td></tr> <tr><td>Whole plant</td><td>138</td></tr> <tr><td>Whole plant without pods</td><td>111</td></tr> <tr><td>Pods</td><td>110</td></tr> <tr><td>Seeds before processing</td><td>85</td></tr> <tr><td>Crude oil</td><td>72</td></tr> <tr><td>Refined oil</td><td>69</td></tr> </table> <p>Maximum specimens storage time (days, TMDs):</p> <table> <tr><td>Seeds</td><td>113</td></tr> <tr><td>Whole plant</td><td>149</td></tr> <tr><td>Whole plant without pods</td><td>114</td></tr> <tr><td>Pods</td><td>113</td></tr> <tr><td>Seeds before processing</td><td>91</td></tr> </table>	Seeds	107	Whole plant	138	Whole plant without pods	111	Pods	110	Seeds before processing	85	Crude oil	72	Refined oil	69	Seeds	113	Whole plant	149	Whole plant without pods	114	Pods	113	Seeds before processing	91
Seeds	107																								
Whole plant	138																								
Whole plant without pods	111																								
Pods	110																								
Seeds before processing	85																								
Crude oil	72																								
Refined oil	69																								
Seeds	113																								
Whole plant	149																								
Whole plant without pods	114																								
Pods	113																								
Seeds before processing	91																								

	Crude oil	72
	Refined oil	69
	Trials from the southern zone of Europe were included in the evaluation only with regard to residues in processed products.	

Reference:	KCA 6.3-01
Report	Determination of difenoconazole, prothioconazole-desthio and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of oilseed rape and processed (oilseed rape oil) following two applications of the formulated products IN233C1560 and IN005B1570 (Northern and Southern Europe – 16 trials + processed, year 2021 – open field) Longhi, Diego (2022) Report No: GLP-STUDY-21-26
Guideline(s):	Yes OECD 507: Nature of the Pesticide Residues in Processed Commodities - High Temperature Hydrolysis OECD 508: Magnitude of the Pesticide Residues in Processed Commodities OECD 509: Guideline for the Testing of Chemicals (Crop Field Trial) SANTE/2019/12752: Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin SANTE/2020/12830 Rev.1: Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes
Deviations:	Yes A number of deviations occurred that were deemed to have no impact on the study. Trial PL12: Distance between plot T1 (Prothioconazole + Difenoconazole) and T2 (Difenoconazole) was 5 m instead of minimum 10 m. Specimens from T2 were found to contain Prothioconazole residues, showing that contamination occurred. PL10: For U41, T41 and T42, quantities of specimens received were about 1 kg per plot. Sub specimens of seeds before processing were not taken.
GLP:	Yes
Acceptability:	Yes

The study was conducted to determine the residue levels of difenoconazole, prothioconazole and the triazole derivative metabolites (TDMs) 1H-1,2,4-triazole (1,2,4-T), 1H-1,2,4-triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA) in oilseed rape after spray applications of two products. The first product, IN233C1560 380 EC, is an emulsifiable concentrate (EC) formulation containing 130 g/L difenoconazole and 250 g/L prothioconazole; the second product, IN005B1570 250 EC, is an emulsifiable concentrate formulation containing 250 g/L difenoconazole. The study was conducted in open field conditions in Northern and Southern Europe (7 residues at harvest trials (8 planned; 1 failed due to bad weather) and 8 residue in decline curve trials). The residues on the rapeseed oil were monitored from the processing of the seeds coming from the trials.

The validated analytical method for the determination of Difenoconazole (AM-GLP-STUDY-21-31) was based on the QuEChERS method. All extracts for analysis were kept in refrigerated conditions and analysed within the verified stability period (3 days at  $5 \pm 3^\circ\text{C}$  in dark conditions). TDMs were analysed using the validated analytical method AM-GLP-STUDY-21-108.

The results presented below are only for the difenconazole product, IN005B1570 250 EC, as the difenconazole application rate for the other product does not correspond with the intended GAP.

A corrected figure for each of the TDMs is presented in the table summarising the trials. This correction accounts for the occurrence of detectable TDMs in untreated controls. The individual TDMs for each of the treated samples is determined to be the difference between the TDM in the treated vs untreated sample, where the TDM in the untreated sample is >LOD; where the difference is negative (i.e. untreated sample has higher TDM than treated sample), the corrected value is set to zero.

The total difenconazole according to the proposed residue definition was determined as the sum of difenconazole + TDMs expressed as difenconazole:  $\text{Difenconazole} + (1,24\text{-T} \times 69.07/406.26) + (\text{TA} \times 156.14/406.26) + (\text{TAA} \times 157.13/406.26) + (\text{TLA} \times 127.1/406.26)$ .

**Table A 13:** Summary of the study 1 trials. TDM residues are corrected taking into account TDM residues in control samples.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)						PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Difeno- conazole	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
CMN-21- 49724 FR01 37110 - Dame Marie les Bois Centre Val de Loire, France NEU 2021	Tempo (Winter rape – BRSNW)		131.3 128.2	304 297		20/04/2021 12/05/2021	65-67 69	Rapeseed seeds	< LOQ (0.0078)	0	1.566	0.0628	0.0123	0.6378	70	
								Seeds before processing	< LOQ (0.0044)	0.002	0.63	0.0389	0.009	0.2647	70	
								Crude oil	< LOQ (0.0038)	0.002	0.002	0.002	0.002	0.0063	70	
								Refined oil	< LOQ (0.0039)	0.002	0.002	0.002	0.002	0.0064	70	
CMN-21- 49724 PL02 14-100 – Samborowo Warمیński- Mazurskie, Poland NEU 2021	LG Arabella (Winter rape – BRSNW)		127.7 130.0	296 301		20/05/2021 09/06/2021	63- 65 69	Rapeseed seeds	< LOQ (0.0072)	0.002	0	0	0	0.0075	41	
								Seeds before processing	< LOD (0.002)	0.002	0	0.0316	0.0160	0.0023	41	
								Crude oil	< LOQ (0.0051)	0.002	0.002	0.002	0.002	0.0076	41	
								Refined oil	< LOD (0.002)	0.002	0.002	0.002	0.002	0.0081	41	
CMN-21- 49724 HU03 2141 – Csömör Pest county, Hun- gary NEU 2021	KWS Hy- brirock (Winter rape – BRSNW)		130.0 130.5	302 302		21/04/2021 11/05/2021	59- 61 69	Rapeseed seeds	< LOD (0.002)	0.002	0.205	0.0044	0.002	0.0835	56	
								Seeds before processing	< LOD (0.002)	0.002	0	0	0	0.0023	56	
								Crude oil	< LOD (0.002)	0.002	0.002	0.002	0.002	0.0045	56	
								Refined oil	< LOQ (0.0021)	0.002	0.002	0.002	0.002	0.0046	56	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)						PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Difeno- conazole	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
CMN-21- 49724 HU04 NEU 2021	FAILED															
CMN-21- 49724 GR05 61300- Filiria- Goumenissa Kilkis, Greece SEU 2021	Sy-Cassidy (Oilseed rape- BRSNN)		126.7 130.0	391 502		27/04/2021 17/05/2021		Rapeseed-seeds	≤LOQ (0.0059)	0.002	0	0	0.0024	0.0070	37	
CMN-21- 49724 ES06 24791- Villaestrigo Del Paramo Leon, Spain SEU 2021	Veritas-CL (Winter-rape -BRSNW)		133.1 132.6	309 307		05/05/2021 25/05/2021		Rapeseed-seeds	0.0752	0	0	0	0	0.0752	41	
CMN-21- 49724 ES07 24723- Lucillo-Leon, Spain SEU 2021	Cesareo (Winter Rape- BRSNW)		136.2 132.1	316 307		11/05/2021 01/06/2021		Rapeseed-seeds	≤LOQ (0.0039)	0.002	0.006	0	0.0002	0.0066	60	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)						PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Difeno- conazole	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
CMN-21- 49724 IT08 25025 – Manerbio Lombardy, Italy SEU 2021	Pioneer D06 (Oilseed rape – BRSNN)		12.82 —124.6	297 289		22/04/2021 14/05/2021		Rapeseed-seeds	0.0738	0.002	0.165	0.0065	0.002	0.1407	40	
CMN-21- 49724 FR09 68320 – Bischwihr Grand Est, France NEU 2021	LG Acropole (Oilseed rape – BRSNN)		131.1 131.1	303 303		29/04/2021 20/05/2021	65 69	Whole plant	0.961 0.372 0.0874	0.002 0.002 0.002	0.0157 0.0182 0.0784	0.002 0.002 0.002	0.002 0.002 0.0036	0.9688 0.3807 0.1198	0 7 22	
								Pods	0.0225	0.002	0.15	0.0144	0.0094	0.0890	35	
								Whole plant without pods	0.0556	0.002	0.0115	0.002	0.0026	0.0619	35	
								Seeds	< LOD (0.002)	0	0.299	0.0207	0.0059	0.1268	61	
CMN-21- 49724 PL10 62-100 – Werkowo Wielkopolska, Poland NEU 2021	Chrobry (Winter rape – BRSNW)		124.6 131.3	289 304		05/05/2021 26/05/2021	57-63 69	Whole plant	1.68 0.946 0.370	0.002 0.002 0.002	0.0026 0.047 0.041	0.0017 0.0046 0.0031	0.0026 0.005 0.0065	1.6918 0.9677 0.3893	0 7 21	
								Pods	0.0779	0.002	0.136	0.0153	0.009	0.1392	35	
								Whole plant without pods	0.191	0.002	0	0	0.0002	0.1914	35	
								Seeds	< LOQ (0.0035)	0.002	0.537	0.0317	0.013	0.2266	57	
								Crude oil	< LOQ (0.0037)	0.002	0.002	0.002	0.002	0.0062	57	
								Refined oil	< LOQ (0.0034)	0.002	0.002	0.002	0.002	0.0059	57	



Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)						PHI (days) (d)	Detail on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Difeno- conazole	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
CMN-21- 49724 AT11 2471 – Ger- haus Burgen- land, Austria NEU 2021	Architect (Winter oilseed rape – BRSNW)		130.3	302		26/04/2021 18/05/2021	61-65 69	Whole plant	2.54	0.002	0.0047	0.002	0.002	2.5435	0	
			131.8	306					0.710	0.002	0.0082	0.002	0.7149	7		
									0.353	0.002	0.0137	0.002	0.3600	20		
			Pods	0.0584				0.002	0.0455	0.0061	0.0034	0.0797	34			
							Whole plant without pods	0.115	0.002	0.002	0.002	0.002	0.1175	34		
							Seeds	<u>≤ LOQ</u> <u>(0.0068)</u>	<u>0.002</u>	<u>0.1198</u>	<u>0.0114</u>	<u>0.002</u>	<u>0.0582</u>	<u>65</u>		
CMN-21- 49724 PL12 63-130 – Brzóstownia Wielkopolskie, Poland NEU 2021	Architect (Winter rape – BRSNW)		131.1	303		06/05/2021 27/05/2021	63-65 69	Whole plant	2.73	0.002	0.0114	0.002	0.002	2.7361	0	
			131.6	305					1.63	0.002	0.0319	0.002	0.0022	1.6441	7	
									1.03	0.002	0.0713	0.005	0.0061	1.0616	21	
			Pods	0.176				0.002	0.055	0.014	0.0021	0.2036	33			
							Whole plant without pods	0.350	0.002	0.0075	0.002	0.0034	0.3551	33		
							Seeds	<u>0.0102</u>	<u>0.0129</u>	<u>0.113</u>	<u>0.0254</u>	<u>0.002</u>	<u>0.0663</u>	<u>54</u>		

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)						PHI (days) (d)	Details on trial (e)
			g a.s/ ha	Water (l/ha)	g a.s./hl				Difeno- conazole	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
CMN-21- 49724 IT13 15042 – Bassignana Piedmont, Italy SEU 2021	Miranda (Winter oilseed rape – BRSNW)		Difeno- conazole	383 383		20/04/2021 10/05/2021		Whole plant	1.53 0.318 0.159	0.002 0.002 0.002	0.0463 0.0455 0.0739	0.002 0.002 0.0032	0.002 0.002 0.0024	1.5495 0.3372 0.1897	0 7 23	The study was includ- ed in the as- sess- ment with regard to resi- dues in pro- cessed prod- ucts
			124.3 124.3	Pods				0.0245	0.002	0.1114	0.0061	0.0046	0.0715	35		
				Whole plant without pods				0.100	0.002	0.011	0.002	0.002	0.1060	35		
				Seeds				<u>&lt; LOQ</u> <u>(0.0089)</u>	<u>0.002</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0.0092</u>	<u>44</u>		
CMN-21- 49724 ES14 24713 - Sueros De Cepeda Leon, Spain SEU 2021	Invigor (Rape – BRSNN)		133.1 128.7	308 298		05/05/2021 26/05/2021		Whole plant	2.13 0.686 0.362	0.002 0.002 0.002	0 0.174 0.151	0 0.004 0.0162	0 0.0042 0.0071	2.1303 0.7561 0.4289	0 7 23	The study was includ- ed in the as- sess- ment with regard to resi- dues in pro- cessed prod- ucts
				Pods				0.0289	0.002	0.013	0.0085	0	0.0375	35		
				Whole plant without pods				0.186	0.002	0	0.002	0.0014	0.1876	35		
				Seeds				<u>0.0037</u>	<u>0.002</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0.0040</u>	<u>62</u>		

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)						PHI (days) (d)	Detail on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Difeno- conazole	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
CMN-21- 49724 IT15 37069- Villafranca di Verona Veneto, Italy SEU 2021	Pioneer D06 (Oilseed rape— BRSNN)		126.1	292		22/04/2021		Whole plant	2.37	0.002	0.0074	0.002	0.002	2.3746	0	
			128.7	298		13/05/2021		0.934	0.002	0.0368	0.0025	0.0021	0.9501	7		
								0.257	0.002	0.0436	0.0068	0.0038	0.2779	21		
			Pods	0.0927		0.002		0.1064	0.0118	0.0107	0.1418	34				
							Whole plant without pods	0.144	0.002	0.0065	0.002	0.0031	0.1486	34		
							Seeds	0.15	0.002	0.13	0.0067	0.004	0.2041	47		
CMN-21- 49724 IT16 14043- Castello di Annone Piedmont, Italy SEU 2021	Pioneer PR44D06 (Winter oilseed rape —BRSNW)		127.9	395		20/04/2021		Whole plant	2.01	0.002	0	0	0	2.0103	0	
			131.3	405		10/05/2021		0.57	0.002	0	0	0	0.5703	7		
								0.447	0.002	0	0	0	0.4473	19		
			Pods	0.4409		0.002		0	0	0	0.0412	35				
							Whole plant without pods	0.184	0.002	0.0069	0	0	0.1870	35		
							Seeds	≤LOQ (0.0035)	0.0039	0	0	0	0.0042	45		

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

LOD = 0.002 mg/kg for Difenoconazole, 1,2,4-T, TA, TLA, TAA

LOQ = 0.010 mg/kg for Difenoconazole, 1,2,4-T, TA, TLA, TAA

(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 Apple

**Table A 14: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (RAR, Spain, 2019)	3	58	7 days	BBCH 57-84	21
Intended cGAP (number 2*)	3	56.25	7 days	BBCH 57-84	21

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

### A 2.1.3.2.1 Study 2

Comments of zRMS:	<p>The study is accepted. The trials are independent and valid with regard to storage stability data. Acceptable following analytical methods were used:</p> <p>Difenconazole:</p> <p>The analytical determinations were carried out performing extractions of the analytes from the matrices using the QuEChERS method and in instrumental analyses using a high-performance liquid chromatography with a triple quadrupole mass spectrometry detection (HPLC-MS/MS). The method was validated in compliance with SANTE/2020/12830, Rev.1 guideline.</p> <p>TMDs:</p> <p>HPLC-MS/MS technique. The analytical method was validated under GLP compliance according to SANTE/2020/12830 rev.1.</p> <p>Maximum freezer storage period between sampling and analysis (days):</p> <p>difenconazole</p> <p>Apple - 62</p> <p>Apple before processing - 43</p> <p>Dried apple - 33</p> <p>Apple juice – 35</p> <p>TMDS</p> <p>Apple - 63</p> <p>Apple before processing - 43</p> <p>Dried apple - 33</p> <p>Apple juice – 35</p> <p>The trials from the southern zone of Europe were included in the evaluation only with regard to residues in processed products.</p>
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Reference: KCA 6.3-02

Report

Determination of difenconazole and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of apple and processed commodities (dry apple and apple juice) following three applications of the formulated product IN005B1570 (Northern and Southern Europe – 16 trials, year 2021 – open field)

Longhi, Diego. (2022)

Report No: GLP-STUDY-21-28

Guideline(s): Yes  
OECD 507: Nature of the Pesticide Residues in Processed Commodities - High Temperature Hydrolysis  
OECD 508: Magnitude of the Pesticide Residues in Processed Commodities  
OECD 509: Guideline for the Testing of Chemicals (Crop Field Trial)  
SANTE/2019/12752: Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin  
SANTE/2020/12830 Rev.1: Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes

Deviations: Yes  
The following deviations were considered to have had some impact on the study:  
Trial ES14: The ship samples arrived defrosted and were not analysed.  
Trial FR10: The trial site had received 3 applications of penconazole the previous year, potentially affecting the amount of TDMs in samples collected. The impact is not considered zero but is negligible.  
Trial DE03: The previous year, a product containing difenconazole had been applied. This may explain values of TA and TLA >LOQ in the untreated sample.  
Trial IT16: A tebuconazole based product was used twice in 2020 on the trial site. However, no TDMs were found in amounts >LOQ.

GLP: Yes

Acceptability: Yes

The study was conducted to determine the residue levels of difenconazole and the triazole derivative metabolites (TDMs) 1H-1,2,4-triazole (1,2,4-T), 1H-1,2,4-triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA) in apples after 3 foliar applications of the product IN005B1570 250 EC, an emulsifiable concentrate formulation containing 250 g/L difenconazole. The study was conducted in open field conditions in Northern and Southern Europe (8 residues at harvest trials and 8 residue in decline curve trials) and on the processed apple products (dried apple, apple juice) obtained processing the apple collected in 4 trials.

The validated analytical method for the determination of Difenconazole (AM-GLP-STUDY-21-32) was based on the QuEChERS method. All extracts for analysis were kept in refrigerated conditions and analysed within the verified stability period (3 days at  $5 \pm 3^\circ\text{C}$  in dark conditions). TDMs were analysed using the validated analytical method AM-GLP-STUDY-21-109.

A corrected figure for each of the TDMs is presented in the table summarising the trials. This correction accounts for the occurrence of detectable TDMs in untreated controls. The individual TDMs for each of the treated samples is determined to be the difference between the TDM in the treated vs untreated sample, where the TDM in the untreated sample is >LOD; where the difference is negative (i.e. untreated sample has higher TDM than treated sample), the corrected value is set to zero.

The total difenconazole according to the proposed residue definition was determined as the sum of difenconazole + TDMs expressed as difenconazole: Difenconazole + (1,2,4-T x 69.07/406.26) + (TA x 156.14/406.26) + (TAA x 157.13/406.26) + (TLA x 127.1/406.26).

**Table A 15:** Summary of the study 1 trials. TDM residues are corrected taking into account TDM residues in control samples.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			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	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
EKI – 21 – 50296 – PL01 11-010 Bark, Poland NEU 2021	Apple/ Anto- nowka		60.61 57.24 59.05	1041 983 1014		12/08/2021 19/08/2021 25/08/2021	74 76 78	Apple	<u>0.0186</u>	<u>0.002</u>	<u>0.002</u>	<u>0.002</u>	<u>0.002</u>	<u>0.0211</u>	<u>21</u>	
EKI – 21 – 50296 – PL02 96 – 515 Lubie- jew, Poland NEU 2021	Apple/Szampion		59.31 58.53 61.38	915 905 947		24/08/2021 01/09/2021 08/09/2021	81 81 85	Apple	<u>0.1058</u>	<u>0.002</u>	<u>0</u>	<u>0</u>	<u>0.002</u>	<u>0.1068</u>	<u>19</u>	
								Apple before processing	0.0503	0.002	0.0064	0.0105	0.002	0.0578	19	
								Dried Apple	0.1073	0.002	0	0	0.0029	0.1085	19	
								Apple Juice	0.002	0.002	0.0036	0.0015	0.002	0.0049	19	
EKI – 21 – 50296 –DE03 97334 Neuses am Berg, Ger- many NEU 2021	Apple/Boskoop		59.57 55.94 58.28	1021 960 1000		24/08/2021 31/08/2021 07/09/2021	81-83 83 85	Apple	<u>0.0585</u>	<u>0.002</u>	<u>0</u>	<u>0</u>	<u>0.002</u>	<u>0.0595</u>	<u>20</u>	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			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	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
EKI – 21 – 50296 – HU04 2694 Magya- rnándor – Hungary NEU 2021	Apple/Red Spur Delicious		56.98	782.7		30/08/2021 06/09/2021 13/09/2021	77 81 85	Apple	<u>0.0937</u>	<u>0.002</u>	<u>0.0266</u>	<u>0.0187</u>	<u>0.0077</u>	<u>0.1139</u>	<u>21</u>	
			58.02	796.7				Apple before processing	0.0534	0.002	0.0112	0.0136	0.0034	0.0644	21	
			59.05	810.3				Dried apple	0.3072	0.002	0.0083	0.039	0.0149	0.3305	21	
								Apple juice	0.0025	0.002	0.014	0.0093	0.0042	0.0131	21	
EKI – 21 – 50296 – IT05 95010 Milo, Italy SEU 2021	Apple/Red Delicious		58.02	994		17/08/2021 24/08/2021 31/08/2021		Apple	<u>0.0633</u>	<u>0.002</u>	<u>0</u>	<u>0</u>	<u>0.002</u>	<u>0.0643</u>	<u>20</u>	The study was included in the as- sessment with regard to residues in processed products
			57.76	991				Apple before processing	0.0223	0.002	0	0	0.002	0.0233	20	
			59.05	1013				Dried apple	0.0882	0.002	0	0.0001	0.0024	0.0893	20	
								Apple juice	0.0025	0.002	0	0	0	0.0028	20	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			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	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
EKI – 21 – 50296 – ES06 21292 Fuente- heridos-, Spain SEU 2021	Apple/Golden		58.79 56.98 57.76	1006 977 987		16/09/2021 22/09/2021 29/09/2021		Apple	≤ LOQ (0.0084)	0.002	0.0115	0.0146	0.0022	0.0195	20	
EKI – 21 – 50296 – ES07 46160 Ademuz, Spain SEU 2021	Apple/Esperiega de Ademuz		59.83 57.50 56.98	1028 987 977		08/09/2021 15/09/2021 23/09/2021		Apple	0.0212	0.002	0.0045	0	0	0.0233	21	
EKI – 21 – 50296 – IT08 37060 Castagnaro- Mena, Italy SEU 2021	Apple/Red Delicious		60.35 61.64 63.46	1032 1054 1088		13/08/2021 20/08/2021 27/08/2021		Apple	0.0324	0.002	0	0	0.002	0.0334	19	The trial was included in the assessment with regard to residues in processed products
								Apple before processing	< LOQ (0.0094)	0.002	0.0031	0.0008	0.002	0.0119	19	
								Dried apple	0.0441	0.002	0.002	0	0.0029	0.0461	19	
								Apple juice	< LOD (0.002)	0.002	0.0269	0.021	0.0047	0.0223	19	



Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			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	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
EKI – 21 – 50296 – PL09 89-240 Miastowice, Poland NEU 2021	Apple/Cortland		56.20 58.79 55.69	963 1011 957		24/08/2021 01/09/2021 08/09/2021	79 81 85	Apple	0.0569 0.0479 0.0343 0.0346 0.0322	0.002 0.002 0.002 0.002 0.002	0 0.0223 0.0242 0.0263 0	0 0.0133 0.0151 0.0157 0	0.002 0.002 0.002 0.002 0.002	0.0579 0.0626 0.0504 0.0517 0.0332	0 3 7 14 21	
EKI – 21 – 50296 – FR10 37110 Dame Marie les Bois, France NEU 2021	Apple/Antarés		54.65 59.31 60.35	563 612 622		19/08/2021 26/08/2021 02/09/2021	79-81 81 81	Apple	0.0852 0.0817 0.0612 0.0417 0.0264	0.002 0.002 0.002 0.002 0.002	0.002 0.005 0.0047 0.0063 0.0013	0.0029 0.0029 0.0028 0.0035 0.0003	0.002 0.002 0.002 0.002 0.002	0.0881 0.0857 0.0651 0.0464 0.0280	0 3 7 14 21	
EKI – 21 – 50296 – HU11 6795 Bordány, Hungary NEU 2021	Apple/Jonagored		58.28 57.76 55.94	1003 991 963		06/08/2021 13/08/2021 20/08/2021	81 83 83	Apple	0.0814 0.0706 0.0448 0.0417 0.0268	0.002 0.002 0.002 0.002 0.002	0.0258 0.0447 0.0461 0.0529 0.0299	0.0204 0.0431 0.0417 0.046 0.0222	0.0011 0.0034 0.0041 0.0043 0.005	0.0999 0.1059 0.0803 0.0815 0.0488	0 3 6 14 20	
EKI – 21 – 50296 – HU12 2119 Pécel, Hungary NEU 2021	Apple/Gloster		56.98 56.72 59.83	784 777 822		30/08/2021 06/09/2021 13/09/2021	77 81 85	Apple	0.1589 0.0993 0.0465 0.0501 0.0474	0.002 0.002 0.002 0.002 0.002	0.0015 0.0161 0.017 0.0088 0.0044	0.0044 0.0168 0.0142 0.0069 0.0008	0.0007 0.0084 0.0079 0.003 0.0012	0.1617 0.1150 0.0613 0.0574 0.0501	0 3 7 14 21	
EKI – 21 – 50296 – IT13 95019 Zafferana Etnea, Italy SEU 2021	Apple/Golden		57.50 57.50 58.79	984 988 1009		31/08/2021 07/09/2021 14/09/2021		Apple	0.0801 0.0717 0.0919 0.0266 0.0263	0.002 0.002 0.002 0.002 0.002	0.021 0.0404 0.0598 0.0588 0.0265	0.0078 0.0159 0.0182 0.0216 0.01	0.0031 0.0037 0.0047 0.0056 0.0061	0.0925 0.0949 0.1237 0.0596 0.0426	0 3 7 14 21	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			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	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
EKI—21— 50296— ES14 24240 Santa Maria-del Páramo, Spain SEU 2021	Apple/Golden		58.28 57.24 57.76	1000 983 990		25/08/2021 31/08/2021 08/09/2021			0.1729 0.1549 0.1046 0.0631 0.0581	0.002 0.002 0.002 0.002 0.002	0.0619 0.0598 0.0647 0.0719 0.0639	0.0154 0.0153 0.0164 0.0207 0.0208	0.0045 0.0047 0.0058 0.006 0.0065	0.2044 0.1856 0.1380 0.1010 0.0931	0 3 7 14 21	
EKI—21— 50296— IT15 14050 San Marzano Oliveto, Italy SEU 2021	Apple/Jonagold		58.28 57.50 57.24	996 986 981		10/08/2021 17/08/2021 24/08/2021			0.0793 0.0399 0.0127 0.0108 <LOQ (0.0051)	0.034 0.0043 0.0025 0.0046 0.002	0.0094 0.0185 0.0253 0.0205 0.0038	0.0051 0.008 0.0103 0.0095 0.0015	0.0024 0.0023 0.0023 0.0025 0.002	0.0862 0.0516 0.0276 0.0239 0.0081	0 3 7 14 23	
EKI—21— 50296— IT16 37051 Bovolone, Italy SEU 2021	Apple/Golden Delicious		58.53 58.02 59.83	806 797 822		10/08/2021 17/08/2021 24/08/2021			0.1029 0.0901 0.0676 0.0501 0.0358	0.002 0.002 0.002 0.002 0.002	0.005 0.0116 0.0107 0.0105 0.0021	0.0049 0.0113 0.0117 0.0097 0.0033	0.002 0.002 0.002 0.002 0.002	0.1077 0.0999 0.0772 0.0589 0.0388	0 3 7 14 21	

(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

LOD = 0.002 mg/kg for Difenoconazole, TRZ, TA, TLA, TAA

LOQ = 0.010 mg/kg for Difenoconazole, TRZ, TA, TLA, TAA

### A 2.1.3.3 Carrot

**Table A 16: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, Sweden, 2006)	1-3	125	14 days min.	BBCH 40-49	14
Intended cGAP (number 4*)	1-3	125	14 days min.	From BBCH 39-40	14

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

### A 2.1.3.3.1 Study 3

Comments of zRMS:	<p>The study is accepted. The trials are independent and valid with regard to storage stability data. Acceptable following analytical methods were used:</p> <p>Difenoconazole:</p> <p>The analytical determinations were carried out performing extractions of the analytes from the matrices using the QuEChERS method and in instrumental analyses using a high-performance liquid chromatography with a triple quadrupole mass spectrometry detection (HPLC-MS/MS). The method was validated in compliance with SANTE/2020/12830, Rev.1 guideline.</p> <p>TMDs:</p> <p>HPLC-MS/MS technique. The analytical method was validated under GLP compliance according to SANTE/2020/12830 rev.1.</p> <p>Maximum freezer storage period between sampling and analysis (days):</p> <p>difenoconazole</p> <p>The trials from the southern zone of Europe were not included in the evaluation.</p>
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Reference: KCA 6.3-03

Report: Determination of difenoconazole and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity carrot following three applications of the formulated product IN005B1570 250 EC (Difenoconazole 250 g/L) (Northern and Southern Europe – 16 trials, year 2021 – open field)  
Sala, Alberto (2022)  
Report No: GLP-STUDY-21-27

Guideline(s): Yes  
OECD 508: Magnitude of the Pesticide Residues in Processed Commodities  
OECD 509: Guideline for the Testing of Chemicals (Crop Field Trial)  
SANTE/2019/12752: Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin  
SANTE/2020/12830 Rev.1: Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes

Deviations: Yes  
The following deviations were considered to potentially have an impact on

the study:

Trial FR13: Application 2 not performed – trial cancelled and relocated.

Trial FR03: Sampling S1 for plot C carried out before last application.

Trial GR15: Interval between applications 2 and 3 was 17 days rather than 14 days.

Trial FR05: Farmer applied difenconazole, thus contaminating all trial samples.

Trial FR05: First rainfall 1.75 h after application 2.

Trials PL02 and PL09: Specimens were not sent within 14 days after last sampling.

Trial ES06: Samples were shipped after more than 14 days.

GLP: Yes

Acceptability: Yes

The study was conducted to determine the residue levels of difenconazole and the triazole derivative metabolites (TDMs) 1H-1,2,4-triazole (1,2,4-T), 1H-1,2,4-triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA) in carrots after 3 foliar applications of the product IN005B1570 250 EC, an emulsifiable concentrate formulation containing 250 g/L difenconazole. The study was conducted in open field conditions in Southern Europe (4 residues at harvest trials and 4 residue in decline curve trials) and Northern Europe (4 residues at harvest trials and 4 residue in decline curve trials).

The validated analytical method for the determination of Difenconazole (AM-GLP-STUDY-21-32) was based on the QuEChERS method. All extracts for analysis were kept in refrigerated conditions and analysed within the verified stability period (3 days at  $5 \pm 3^\circ\text{C}$  in dark conditions). TDMs were analysed using the validated analytical method AM-GLP-STUDY-21-109.

A corrected figure for each of the TDMs is presented in the table summarising the trials. This correction accounts for the occurrence of detectable TDMs in untreated controls. The individual TDMs for each of the treated samples is determined to be the difference between the TDM in the treated vs untreated sample, where the TDM in the untreated sample is  $>\text{LOD}$ ; where the difference is negative (i.e. untreated sample has higher TDM than treated sample), the corrected value is set to zero.

The total difenconazole according to the proposed residue definition was determined as the sum of difenconazole + TDMs expressed as difenconazole:  $\text{Difenconazole} + (1,2,4\text{-T} \times 69.07/406.26) + (\text{TA} \times 156.14/406.26) + (\text{TAA} \times 157.13/406.26) + (\text{TLA} \times 127.1/406.26)$ .

**Table A 17:** Summary of the study 1 trials. TDM residues are corrected taking into account TDM residues in control samples.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treat- ment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)					SUM of Difeno + TDMs	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Difeno- conazole	1,2,4-T	TA	TLA	TAA			
(a)	(b)					(c)									(d)	(e)
MLI-21-50281- PL01 96-116- Józefatów, Poland NEU 2021	Carrot/ Laguna F1		141.9	329		25/08/2021	BBCH 46		0.0755	0.002	0	0	0.002	0.0765	0	
			131.3	304		08/09/2021	BBCH 49		0.1023	0.002	0.06432	0.02779	0.002	0.1387	3	
			133.4	309		22/09/2021	BBCH 49		0.0843	0.002	0.0545	0.02964	0.002	0.1177	5	
									0.1112	0.002	0.07916	0.02226	0.002	0.1512	7	
									<u>0.05418</u>	<u>0.002</u>	<u>0</u>	<u>0</u>	<u>0.002</u>	<u>0.0551</u>	<u>14</u>	
MLI-21-50281- PL02 63-304- Pieruszyce, Poland NEU 2021	Carrot/ Joba		133.9	310		10/08/2021	BBCH 47		0.05797	0.002	0	0	0.002	0.0589	0	
			132.3	307		24/08/2021	BBCH 49		0.03962	0.002	0.0275	0.01179	0.002	0.0557	3	
			125.1	290		07/09/2021	BBCH 49		0.03752	0.002	0.03909	0.01484	0.002	0.0592	5	
									0.04434	0.002	0.03068	0.01247	0.002	0.0619	7	
									<u>0.0577</u>	<u>0.002</u>	<u>0.00835</u>	<u>0.00222</u>	<u>0.002</u>	<u>0.0627</u>	<u>14</u>	
MLI-21-50281- FR03 62860-Inchy en Artois, France NEU 2021	Carrot/ Norway F1		125.4	387		03/09/2021	BBCH 42		0.06131	0.002	0.00252	0	0.002	0.0632	0	
			129.8	400		17/09/2021	BBCH 43		0.05702	0.002	0.01255	0.00475	0.002	0.0646	3	
			131.8	407		01/10/2021	BBCH 45		0.07208	0.002	0.01077	0.00583	0.002	0.0794	5	
									0.04204	0.002	0.01222	0.00442	0.002	0.0494	7	
									<u>0.06944</u>	<u>0.002</u>	<u>0.00169</u>	<u>0.00056</u>	<u>0.002</u>	<u>0.0713</u>	<u>14</u>	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety  (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest  (b)	Application rate per treat- ment			Dates of treatment or no. of treat- ments and last date  (c)	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)					SUM of Difeno + TDMs	PHI (days)  (d)	Details on trial  (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Difeno- conazole	1,2,4-T	TA	TLA	TAA			
MLI-21-50281- HU04 6795-Bordány, Hungary NEU 2021	Carrot/ Soprano		127.4 130.0 134.4	393 402 415		26/08/2021 09/09/2021 23/09/2021	BBCH 45 BBCH 46 BBCH 47		0.03527 0.05701 0.02664 0.04806 0.02824	0.002 0.002 0.002 0.002 0.002	0 0.03585 0.03589 0.0299 0	0 0.01793 0.01603 0.017 0.0037	0.002 0.00242 0.002 0.002 0.002	0.0362 0.0788 0.0476 0.0671 0.0306	0 3 5 7 14	
MLI-21-50281- FR05 34590- Marsillargues, France SEU 2021	Carrot/ Maestro		138.1 129.5 132.9	427 400 410		15/10/2021 28/10/2021 12/11/2021	BBCH 46 BBCH 47 BBCH 48		0.2207 0.1448 0.1769 0.3389 0.2065	0.002 0.002 0.00513 0.002 0.002	0.01353 0.04379 0.04429 0.05355 0.00817	0.00713 0.01514 0.01618 0.01524 0.00503	0.002 0.002 0.002 0.002 0.002	0.2296 0.1685 0.2017 0.3663 0.2126	0 3 5 7 14	
MLI-21-50281- ES06 24723-Fließ, Spain SEU 2021	Carrot/ Bangor F1		132.6 129.5 126.9	513 500 490		26/08/2021 09/09/2021 23/09/2021	BBCH 45 BBCH 47 BBCH 48		0.1448 0.1307 0.09363 0.07736 0.07626	0.002 0.002 0.002 0.002 0.002	0.00359 0.00343 0.00481 0.00481 0.00149	0 0.002 0.002 0.002 0	0.002 0.002 0.002 0.002 0.002	0.1471 0.1338 0.0972 0.0809 0.0778	0 3 5 7 14	
MLI-21-50281- ES07 02639-Barrax, Spain SEU 2021	Carrot/ Soprano		130.0 141.7 143.5	502 547 554		20/07/2021 03/08/2021 16/08/2021	BBCH 44 BBCH 46 BBCH 48		0.02038 0.01817 0.02193 0.01503 0.01774	0.002 0.002 0.002 0.002 0.002	0.1505 0.4379 0.4224 0.3679 0.2366	0.026 0.1977 0.2245 0.1948 0.0092	0.00105 0.00358 0.00432 0.00376 0.00263	0.0889 0.2644 0.2728 0.2333 0.1482	0 3 5 7 14	
MLI-21-50281- FR17 31330-Grenade sur Garonne, France SEU 2021	Carrot/ Bolero		130.8 133.9 130.8	403 413 403		13/09/2021 27/09/2021 11/10/2021	BBCH 43 BBCH 45 BBCH 47		0.1338 0.2033 0.1702 0.1405 0.2197	0.002 0.002 0.002 0.002 0.002	0.00323 0.0082 0.00936 0.00865 0.00368	0 0.00301 0.0031 0.00254 0.00024	0.002 0.002 0.002 0.002 0.002	0.1360 0.2086 0.1760 0.1458 0.2222	0 3 5 7 14	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety  (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest  (b)	Application rate per treat- ment			Dates of treatment or no. of treat- ments and last date  (c)	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)					SUM of Difeno + TDMs	PHI (days)  (d)	Details on trial  (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Difeno- conazole	1,2,4-T	TA	TLA	TAA			
MLI-21-50281- PL09 21-311-Wiski, Poland NEU 2021	Carrot/ Flakkee		129.5 127.9 129.5	300 297 300		03/09/2021 16/09/2021 29/09/2021	BBCH 48 BBCH 49 BBCH 49		<u>0.1118</u>	<u>0.002</u>	<u>0.01441</u>	<u>0.00321</u>	<u>0.002</u>	<u>0.1195</u>	<u>14</u>	
MLI-21-50281- FR10 41350-St Claude de Diray, France NEU 2021	Carrot/ Maestro		121.0 140.9 129.5	280 327 300		13/09/2021 27/09/2021 11/10/2021	BBCH 41-42 BBCH 42-43 BBCH 45-46		<u>0.1153</u>	<u>0.002</u>	<u>0.00936</u>	<u>0</u>	<u>0.002</u>	<u>0.1199</u>	<u>14</u>	
MLI-21-50281- HU11 6060- Tiszakécske, Hungary NEU 2021	Carrot/ Sirocco		133.6 140.6 138.0	517 543 533		30/08/2021 13/09/2021 27/09/2021	BBCH 42 BBCH 44-45 BBCH 47-48		<u>0.05666</u>	<u>0.002</u>	<u>0.01479</u>	<u>0</u>	<u>0.00356</u>	<u>0.0638</u>	<u>14</u>	
MLI-21-50281- HU12 6060- Tiszakécske, Hungary NEU 2021	Carrot/ Melodio		130.8 136.0 137.0	707 735 740		18/08/2021 01/09/2021 15/09/2021	BBCH 42 BBCH 43 BBCH 47-48		<u>0.02597</u>	<u>0.002</u>	<u>0.00813</u>	<u>0.00114</u>	<u>0.002</u>	<u>0.0305</u>	<u>14</u>	
MLI-21-50281- IT08 00057-Fiumicino, Italy SEU 2021	Carrot/ Soprano		132.1 132.6 131.3	610 613 607		09/09/2021 23/09/2021 08/10/2021	BBCH 41 BBCH 43 BBCH 46		<u>0.09666</u>	<u>0.002</u>	<u>0.0197</u>	<u>0.00224</u>	<u>0.002</u>	<u>0.1061</u>	<u>14</u>	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treat- ment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)					SUM of Difeno + TDMs	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Difeno- conazole	1,2,4-T	TA	TLA	TAA			
(a)	(a)	(b)				(c)									(d)	(e)
MLI-21-50281- ES14 40241-Chatun, Spain SEU 2021	Carrot/ Brilliance		133.1 133.1 127.9	513 513 493		03/09/2021 17/09/2021 01/10/2021	BBCH 47 BBCH 48 BBCH 48		<u>0.06738</u>	<u>0.002</u>	<u>0.00103</u>	<u>0</u>	<u>0.002</u>	<u>0.0687</u>	<u>14</u>	
MLI-21-50281- GR15 Gr-57008-Nea Magnisia, Greece SEU 2021	Carrot/ Bolero		128.0 130.8 130.5	494 505 503		17/09/2021 01/10/2021 18/10/2021	BBCH 41 BBCH 43 BBCH 47		<u>0.07044</u>	<u>0.002</u>	<u>0.00519</u>	<u>0</u>	<u>0.00237</u>	<u>0.0735</u>	<u>14</u>	
MLI-21-50281- IT16 67058-San Benedetto dei Marsi, Italy SEU 2021	Carrot/ Maestro		130.5 131.3 129.0	603 607 597		01/09/2021 16/09/2021 01/10/2021	BBCH 41-42 BBCH 43-44 BBCH 45-46		<u>0.06818</u>	<u>0.002</u>	<u>0.01259</u>	<u>0.00047</u>	<u>0.00265</u>	<u>0.0744</u>	<u>14</u>	

(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

LOD = 0.002 mg/kg for Difenoconazole, TRZ, TA, TLA, TAA

LOQ = 0.010 mg/kg for Difenoconazole, TRZ, TA, TLA, TAA



#### A 2.1.3.4 Tomato

**Table A 18: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (RAR, Spain, 2019) [field]	2-3	125	7 days	BBCH 20-87	7
Intended cGAP (5*) [field]	3	125	7 days	From BBCH 19-20	7
Intended cGAP (11*) [greenhouse]	3	125	7 days	From BBCH 19-20	3

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

#### A 2.1.3.4.1 Study 4

Comments of zRMS:	The study is accepted. The study was included in the assessment with regard to residues in processed products.
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Reference: KCA 6.3-04

Report Determination of difenoconazole and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of tomato and processed following three applications of the formulated product IN005B1570 (Southern Europe – 8 trials, year 2021 – open field)  
Longhi, Diego (2022)  
Report No: GLP-STUDY-21-29

Guideline(s): Yes  
OECD 508: Magnitude of the Pesticide Residues in Processed Commodities  
OECD 509: Guideline for the Testing of Chemicals (Crop Field Trial)  
SANTE/2019/12752: Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin  
SANTE/2020/12830 Rev.1: Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes

Deviations: Yes  
Field Phase; Trial 21 – 00557 – 04 DEC: Sampling 4 was done at 4 DALA instead 5 DALA.

GLP: Yes

Acceptability: Yes

The study was conducted to determine the residue levels of difenoconazole and the triazole derivative metabolites (TDMs) 1H-1,2,4-triazole (1,2,4-T), 1H-1,2,4-triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA) in tomatoes and processed commodities (tomato juice, canned to-

mato, tomato puree) after 3 foliar applications of the product IN005B1570 250 EC, an emulsifiable concentrate formulation containing 250 g/L difenconazole. The study was conducted in open field conditions in Southern Europe (4 residues at harvest trials and 4 residue in decline curve trials) and on the processed tomato products (canned, juice, puree, dried) obtained from the tomatoes collected in 6 trials.

The validated analytical method for the determination of Difenconazole (AM-GLP-STUDY-21-32) was based on the QuEChERS method. All extracts for analysis were kept in refrigerated conditions and analysed within the verified stability period (3 days at  $5 \pm 3^{\circ}\text{C}$  in dark conditions). TDMs were analysed using the validated analytical method AM-GLP-STUDY-21-109.

A corrected figure for each of the TDMs is presented in the table summarising the trials. This correction accounts for the occurrence of detectable TDMs in untreated controls. The individual TDMs for each of the treated samples is determined to be the difference between the TDM in the treated vs untreated sample, where the TDM in the untreated sample is  $>\text{LOD}$ ; where the difference is negative (i.e. untreated sample has higher TDM than treated sample), the corrected value is set to zero.

The total difenconazole according to the proposed residue definition was determined as the sum of difenconazole + TDMs expressed as difenconazole:  $\text{Difenconazole} + (1,24\text{-T} \times 69.07/406.26) + (\text{TA} \times 156.14/406.26) + (\text{TAA} \times 157.13/406.26) + (\text{TLA} \times 127.1/406.26)$ .

**Table A 19:** Summary of the study 1 trials. TDM residues are corrected taking into account TDM residues in control samples.

Trial No./ Location/ EU zone/ Year	Commodity/ Vari- ety (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	TRZ	TA	TLA	TAA	SUM of Difeno + TDMs		
RA 21 081 BPL IT 01 64026 Roseto degli Abruzzi (TE), Abruzzo, Italy SEU 2021	Tomato/ Romanella		130.0	1004.167		14/07/2021 21/07/2021 28/07/2021		Tomato	<u>0.0496</u>	<u>0.002</u>	<u>0.0042</u>	<u>0.002</u>	<u>0.002</u>	<u>0.0530</u>	<u>7</u>	
			132.4	1022.917				Canned	< LOQ (0.0025)	0.002	0.0042	0.002	0.002	0.0059	7	
			123.8	956.250				Juice	< LOD (0.002)	0.002	0.0032	0.002	0.002	0.0050	7	
								Puree	< LOQ (0.0021)	0.002	0.0056	0.0028	0.002	0.0063	7	
								Dried	0.1739	0.035	0.0224	0.0063	0.0042	0.1869	7	
RA 21 081 BPL IT 02 63828 Campofi- lone (FM), Marche, Italy SEU 2021	Tomato/ Templar		127.7	986.667		05/07/2021 12/07/2021 19/07/2021		Tomato	<u>0.0282</u>	<u>0.002</u>	<u>0.0187</u>	<u>0.0037</u>	<u>0.002</u>	<u>0.0378</u>	<u>7</u>	
			128.3	991.111				Canned	< LOQ (0.0026)	0.002	0.0063	0.0052	0.002	0.0080	7	
			126.6	977.778				Juice	< LOD (0.002)	0.002	0.0199	0.0131	0.002	0.0157	7	
								Puree	0.0137	0.002	0.0111	0.0075	0.002	0.0218	7	
								Dried	0.3579	0.002	0.0286	0.0391	0.0085	0.3870	7	

Trial No./ Location/ EU zone/ Year	Commodity/ Vari- ety (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	TRZ	TA	TLA	TAA	SUM of Difeno + TDMs		
21-00557-03 H 41740 Lebrija, Sevilla, Andalucia, Spain SEU 2021	Tomato/ H1015		134.2	828.88		27/07/2021 03/08/2021 10/08/2021		Tomato	<u>0.0137</u>	<u>0.002</u>	<u>0.0104</u>	<u>0.002</u>	<u>0.002</u>	<u>0.0194</u>	<u>7</u>	
			135.6	837.77				Canned	< LOD (0.002)	0.002	0.0021	0.002	0.002	0.0045	7	
			131.3	811.11				Juice	< LOD (0.002)	0.002	0.0055	0.0023	0.002	0.0060	7	
								Puree	< LOQ (0.0054)	0.002	0.003	0.002	0.002	0.0083	7	
								Dried	0.0402	0.002	0.0176	0.0023	0.002	0.0488	7	
21-00557-01 H 57300 Chalas- tra, Thessaloni- ki, Greece SEU 2021	Tomato/ Heinz 3402 F1		133.0 122.9 129.5	1026.7 950.0 1000.0		13/08/2021 20/08/2021 26/08/2021		Tomato	<u>0.0464</u>	<u>0.002</u>	<u>0.0148</u>	<u>0.002</u>	<u>0.002</u>	<u>0.0538</u>	<u>8</u>	
RA 21 081 BPL IT 03 64014 Martinsicuro (TE), Abruzzo, Italy SEU 2021	Tomato/ Kero		125.0	965.333		11/08/2021 18/08/2021 25/08/2021		Toamto	0.0579 0.0634 0.1129 0.1393 <u>0.0481</u>	0.002 0.002 0.002 0.002 <u>0.002</u>	0.0102 0.0071 0.0075 0.0097 <u>0.0113</u>	0.002 0.002 0.002 0.002 <u>0.002</u>	0.002 0.002 0.002 0.002 <u>0.002</u>	0.0636 0.0679 0.1175 0.1448 <u>0.0542</u>	0 1 3 5 <u>7</u>	
			123.3	952.800				Canned	< LOD (0.002)	0.002	0.0057	0.0007	0.002	0.0054	7	
			128.1	989.333				Juice	< LOD (0.002)	0.002	0.0122	0.0073	0.002	0.0105	7	
								Puree	< LOQ (0.0024)	0.002	0.0077	0.0027	0.002	0.0074	7	
								Dried	0.1778	0.002	0.0193	0.0166	0.0051	0.1936	7	

Trial No./ Location/ EU zone/ Year	Commodity/ Vari- ety (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	TRZ	TA	TLA	TAA	SUM of Difeno + TDMs		
RA 21 081 BPL IT 04 64020 Sant'Omero (TE), Abruzzo, Italy SEU 2021	Tomato/ Romanella		126.3	975.446		19/07/2021 26/07/2021 02/08/2021		Tomato	0.0993	0.002	0.0092	0.002	0.002	0.1046	0	
			132.2	1021.205					0.0409	0.002	0.0089	0.002	0.002	0.0461	1	
			131.5	1015.625					0.0797	0.0028	0.0118	0.002	0.002	0.0861	3	
									0.0427	0.002	0.0108	0.002	0.002	0.0486	5	
									0.0336	0.002	0.0107	0.002	0.002	0.0387	7	
21-00557-04 DEC 18128 Zafarraya, Granada, Andalucia, Spain SEU 2021	Tomato/Calabradina		127.8	789.47		09/08/2021 16/08/2021 23/08/2021		Tomato	0.0106	0.002	0.008	0.0033	0.002	0.0159	0	
			133.8	826.51					0.0123	0.002	0.0088	0.003	0.002	0.0178	1	
			133.8	826.51					0.0128	0.002	0.0075	0.0027	0.002	0.0177	3	
									0.0156	0.002	0.0104	0.0029	0.002	0.0217	4	
									0.0347	0.002	0.0098	0.003	0.002	0.0406	7	
								Canned	< LOQ (0.0032)	0.002	0.0095	0.002	0.002	0.0049	7	
									< LOD (0.002)	0.002	0.0099	0.0027	0.002	0.0040	7	
									< LOD (0.002)	0.002	0.0074	0.002	0.002	0.0037	7	
									0.1218	0.002	0.0398	0.006	0.0052	0.1414	7	

Trial No./ Location/ EU zone/ Year	Commodity/ Vari- ety (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	TRZ	TA	TLA	TAA	SUM of Difeno + TDMs		
21-00557-02 DEC 57006 Lakkia, Thessaloniki, Greece SEU 2021	Tomato/ Scooter F1		125.1	773.3		16/08/2021		Tomato	0.0696	0.002	0	0	0.002	0.0706	0	
			133.7	826.7		23/08/2021			0.0429	0.002	0.0246	0.0082	0.002	0.0565	1	
			131.5	813.3		30/08/2021			0.0351	0.002	0.0322	0.0118	0.002	0.0530	3	
									0.0300	0.002	0.0142	0.0038	0.002	0.0379	5	
									<u>0.0378</u>	<u>0.002</u>	<u>0.0102</u>	<u>0.0013</u>	<u>0.002</u>	<u>0.0432</u>	<u>7</u>	

(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

LOD = 0.002 mg/kg for Difenoconazole, TRZ, TA, TLA, TAA

LOQ = 0.010 mg/kg for Difenoconazole, TRZ, TA, TLA, TAA

#### A 2.1.3.4.2 Study 5

Comments of zRMS:	The study was not included in the evaluation as tomatoes are not among the proposed uses
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Reference:	KCA 6.3-05
Report	Determination of difenoconazole and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of tomato and processed following three applications of the formulated product IN005B1570 (Southern Europe – 8 trials, year 2021 – greenhouse) Longhi, Diego (2022) Report No: GLP-STUDY-21-30
Guideline(s):	Yes OECD 508: Magnitude of the Pesticide Residues in Processed Commodities OECD 509: Guideline for the Testing of Chemicals (Crop Field Trial) SANTE/2019/12752: Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin SANTE/2020/12830 Rev.1: Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes
Deviations:	Yes Field phase; Trial 21-00558-01 H: the deviation of application Nr 2 on 09/08/2021 was calculated based on actual content and the density of the Test Item CoA was 11.3%, which is not within $\pm 10\%$ that was requested by the Study Plan.
GLP:	Yes
Acceptability:	Yes

The study was conducted to determine the residue levels of difenoconazole and the triazole derivative metabolites (TDMs) 1H-1,2,4-triazole (1,2,4-T), 1H-1,2,4-triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA) in tomatoes in greenhouse after 3 foliar applications of the product IN005B1570 250 EC, an emulsifiable concentrate formulation containing 250 g/L difenoconazole. The study was conducted in greenhouse in Southern Europe (4 residues at harvest trials and 4 residue in decline curve trials).

The validated analytical method for the determination of Difenoconazole (AM-GLP-STUDY-21-32) was based on the QuEChERS method. All extracts for analysis were kept in refrigerated conditions and analysed within the verified stability period (3 days at  $5 \pm 3^\circ\text{C}$  in dark conditions). TDMs were analysed using the validated analytical method AM-GLP-STUDY-21-109.

A corrected figure for each of the TDMs is presented in the table summarising the trials. This correction accounts for the occurrence of detectable TDMs in untreated controls. The individual TDMs for each of the treated samples is determined to be the difference between the TDM in the treated vs untreated sample, where the TDM in the untreated sample is  $>\text{LOD}$ ; where the difference is negative (i.e. untreated sample has higher TDM than treated sample), the corrected value is set to zero.

The total difenconazole according to the proposed residue definition was determined as the sum of difenconazole + TDMs expressed as difenconazole:  $\text{Difenconazole} + (1,24\text{-T} \times 69.07/406.26) + (\text{TA} \times 156.14/406.26) + (\text{TAA} \times 157.13/406.26) + (\text{TLA} \times 127.1/406.26)$ .



**Table A 20:** Summary of the study 2 trials. TDM residues are corrected taking into account TDM residues in control samples.

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	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
RA 21 082 BPL IT 01 63066 Grottammare (AP) – Marche Region, Italy SEU 2021	Tomato cano- py/ Montecarlo		141.9 131.3 133.4	991.304 996.522 987.826		07/06/2021 14/06/2021 21/06/2021		Tomato	<u>0.1896</u> 0.056	<u>0.002</u> 0.002	<u>0.0034</u> 0.0044	<u>0.002</u> 0.002	<u>0.002</u> 0.002	<u>0.1926</u> 0.0594	<u>3</u> 7	
RA 21 082 BPL IT 02 63068 Montalto Marche (AP) – Marche Region, Italy SEU 2021	Tomato (not canopy)/ Rossano		129.9 126.2 129.6	1003.46 974.66 1001.33		20/08/2021 27/08/2021 03/09/2021		Tomato	<u>0.1578</u> 0.2081	<u>0.002</u> 0.002	<u>0.0107</u> 0.0107	<u>0.0035</u> 0.0028	<u>0.002</u> 0.002	<u>0.1642</u> 0.2143	<u>3</u> 7	
21-00558-03 H 29770 Torrox – Malaga (Andalucia), Spain SEU 2021	Tomato cano- py/Macizo		126.0 126.1 131.2	973.33 973.33 1013.33		11/08/2021 17/08/2021 24/08/2021		Tomato	<u>0.0948</u> 0.0393	<u>0.002</u> 0.002	<u>0.012</u> 0.0188	<u>0.004</u> 0.0071	<u>0.002</u> 0.002	<u>0.1019</u> 0.0502	<u>3</u> 7	
21-00558-01 H 57007 Eleousa, Thessaloniki, Greece SEU 2021	Tomato cano- py/Optima F1		137.49 139.11 137.49	1062.5 1075.0 1062.5		02/08/2021 09/08/2021 16/08/2021		Tomato	<u>0.0175</u> 0.0155	<u>0.002</u> 0.002	<u>0.0053</u> 0.0038	<u>0.002</u> 0.002	<u>0.002</u> 0.002	<u>0.0213</u> 0.0187	<u>3</u> 7	

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	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
RA 21 082 BPL IT 03 64024 Notaresco (TE) – Abruzzo Region , Italy SEU 2021	Tomato cano- py/San Marza- no		129.80	1002.381		07/06/2021 14/06/2021 21/06/2021		Tomato	0.1920	0.002	0.0032	0.002	0.002	0.1950	0	
			125.80	971.429					0.2563	0.002	0.0051	0.002	0.002	0.2600	1	
			128.26	990.476					0.1766	0.002	0.0053	0.002	0.002	0.1804	3	
									0.1788	0.002	0.0061	0.002	0.002	0.1829	5	
									0.1452	0.002	0.0084	0.002	0.002	0.1502	7	
RA 21 082 BPL IT 04 64014 Martinsicuro (TE) – Abruzzo Region, Italy SEU 2021	Tomato cano- py/ Gigawak		127.66	985.814		28/06/2021 05/07/2021 12/07/2021		Tomato	0.0839	0.002	0	0.0015	0.002	0.0854	0	
			126.59	977.59					0.0596	0.002	0	0	0.002	0.0606	1	
			129.31	998.56					0.1189	0.002	0	0.0008	0.002	0.1202	3	
									0.0734	0.002	0	0.0026	0.002	0.0754	5	
									0.0792	0.002	0.0046	0.0041	0.002	0.0835	7	
21-00558-04 DEC 29700 Velez- Malaga - Malaga (Andalucia), Spain SEU 2021	Tomato cano- py/Cabrera		128.6	993.57		10/08/2021 17/08/2021 24/08/2021		Tomato	0.0478	0.002	0.0031	0.002	0.002	0.0507	0	
			129.9	1003.22					0.0404	0.002	0.0026	0.002	0.002	0.0431	1	
			128.3	990.35					0.1115	0.002	0.0057	0.002	0.002	0.1154	3	
									0.0310	0.002	0.005	0.002	0.002	0.0347	5	
									0.0789	0.002	0.0049	0.002	0.002	0.0820	7	
21-00558-02 DEC 57006 Vasilika, Thessaloniki, Greece SEU 2021	Tomato cano- py/Finalist		135	730.0		24/08/2021 01/09/2021 08/09/2021		Tomato	0.0798	0.002	0.028	0.0037	0.002	0.0930	0	
			124.0	957.5					0.0487	0.002	0.0269	0.0031	0.002	0.0612	1	
			134.4	1040					0.0445	0.002	0.029	0.0033	0.002	0.0579	3	
									0.0483	0.002	0.397	0.0048	0.002	0.0664	5	
									0.0485	0.002	0.0226	0.0027	0.002	0.0592	7	

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

LOD = 0.002 mg/kg for Difenconazole, TRZ, TA, TLA, TAA

LOQ = 0.010 mg/kg for Difenconazole, TRZ, TA, TLA, TAA

(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 2.1.3.4.3 Study 6

**Table A 21: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 6*)	1-3	125	7- 10 days min.	From BBCH 19	21

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

Comments of zRMS: Study is accepted

Reference: KCA 6.3-06

Report Determination of Difenoconazole and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of cabbage after three applications of the formulated product IN005B1570 (North Europe – 4 trials, 2023). Longhi, D. 2024. Report No: LBN-0121-2023

Guideline(s): Yes  
Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 11, The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP) OECD ENV/MC/CHEM(98)16.  
Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals - Crop Field Trial (14 June 2021).  
Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999).  
Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990.  
Commission of the European Communities Working Document 7029/VI/95 rev.5 Appendix B: “General Recommendations for the Design, Preparation and Realization of Residue Trials, 22 July 1997.”  
European Commission, Directorate General Health and Consumer Protection: SANTE/2019/12752 Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin  
SANTE/2020/12830 Rev.2, dated 14 February 2023: Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes

Deviations: No.

GLP: Yes

Acceptability: Yes

The objective of this study was to determine the residues level of difenoconazole and of the following Triazole Derivative Metabolites (TDMs): 1H-1,2,4-triazole (TRZ), 1H-1,2,4-triazole alanine (TA), Triazole lactic acid (TLA), Triazole acetic acid (TAA) in cabbage after 3 foliar spray applications of IN005B1570 250 EC, an emulsifiable concentrate formulation containing 250 g/L difenoconazole. This residue study was carried out on cabbage performing 2 HS (residues at harvest) and 2 DCS trials (decline study) set in open field under Northern European growing conditions (Belgium, The Netherlands, Germany).

The analytical method for the determination of Difenoconazole (AM-GLP-STUDY-21-32) was based on the QuEChERS method (EN 15662-2018). The instrumental determination was carried out using a HPLC-MS/MS system (high-performance liquid chromatography + triple quadrupole mass spectrometry). The analytical method was validated under GLP compliance according to SANTE/2020/12830 rev.1 guideline in GLP study GLP-STUDY-21-32.

The analytical method for the determination of TDMs (AM-GLP-STUDY-21-109) was based on the method “Quick Method for the Analysis of Highly Polar Pesticides in Food Involving Extraction with Acidified Methanol and LC- or IC-MS/MS Measurement - Food of Plant Origin (QuPPE-PO-Method) - Method 8 (M8)”. The instrumental determination was carried out using a HPLC-MS/MS system (high-performance liquid chromatography + triple quadrupole mass spectrometry) equipped with a differential mobility separation device (DMS). The analytical method was validated under GLP compliance according to SANTE/2020/12830 rev.1 guideline in GLP study GLP-STUDY-21-109. The applied analytical method allowed the determination of the following TDM (triazole-derivative metabolites): 1,2,4-triazole (TRZ), Triazole-alanine (TA), Triazole-lactic acid (TLA), Triazole-acetic acid (TAA).

The final extracts were kept refrigerated (at  $5 \pm 3^{\circ}\text{C}$ ) in the dark and were analysed just after the extraction and in any case within 24h.

Limit of detection (LOD) and quantification (LOQ) for these analytical methods are:

- LOD (Limit of Detection) corresponds to:
  - o 0.002 mg/kg for: Difenoconazole, TRZ, TA, TLA, TAA
- LOQ (Limit of Quantification) corresponds to:
  - o 0.010 mg/kg for: Difenoconazole, TRZ, TA, TLA, TAA
  - o

A corrected figure for each of the TDMs is presented in the table summarising the trials. This correction accounts for the occurrence of detectable TDMs in untreated controls. The individual TDMs for each of the treated samples is determined to be the difference between the TDM in the treated vs untreated sample, where the TDM in the untreated sample is >LOD; where the difference is negative (i.e. untreated sample has higher TDM than treated sample), the corrected value is set to zero.

The total difenoconazole according to the proposed residue definition was determined as the sum of difenoconazole + TDMs expressed as difenoconazole:  $\text{Difenoconazole} + (1,24\text{-T} \times 69.07/406.26) + (\text{TA} \times 156.14/406.26) + (\text{TAA} \times 157.13/406.26) + (\text{TLA} \times 127.1/406.26)$ .

**Table A 22: Summary of the study 4 trials. TDM residues are corrected taking into account TDM residues in control samples.**

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	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
Trial No: 23 1069 573 / 59320, Enniger- loh - North Rhine- Westphalia / Warendorf – Germany/ NEU/ 2023	BRSOL/ Brassicas/ Head cab- bage/ KORSUMA F1	1) 18/08/2023 2) NA 3) 11/12/2023	133.3 129.2 126.0	426.7 413.3 403.3	31.2 31.2 31.2	07/11/2023 15/11/2023 21/11/2023	BBCH 41-43 BBCH 45 BBCH 46-47	Cabbage head	0.00910	0.002	0.0061	0.002	0.002	0.0132	20	Untreated samples with residues > LOD: Cabbage head: - TA: 0.0135
Trial No: 23 1069 575 / 3470, Korte- naken - Flemish Brabant / Leuven – Belgium/ NEU/ 2023	BRSOL/ Brassicas/ Head cab- bage/ Lennox F1	1) 16/08/2023 2) NA 3) 18/12/2023	132.3 126.0 129.2	423.3 403.3 413.3	31.2 31.2 31.2	15/11/2023 21/11/2023 28/11/2023	BBCH 43 BBCH 43-45 BBCH 45	Cabbage head	0.0128	0.002	0	0.002	0.002	0.0145	20	Untreated samples with residues > LOD: Cabbage head: - TA: 0.0141
Trial No: 23 1069 572 / 46342, Velen- Ramsdorf - North Rhine- Westphalia / Borken – Germany/ NEU/ 2023	BRSOL/ Brassicas/ Head cab- bage/ Krautman F1	1) 11/08/2023 2) NA 3) 15/11/2023 18/11/2023 22/11/2023 29/11/2023 06/12/2023	128.7 121.2 123.7	412.0 388.0 396.0	31.2 31.2 31.2	30/10/2023 07/11/2023 15/11/2023	BBCH 43 BBCH 45 BBCH 46	Cabbage plant	1.38 0.236 0.241 0.194	0.002 0.002 0.002 0.002	0 0 0.0051 0	0.002 0.002 0.002 0.002	0.002 0.002 0.002 0.002	1.3817 0.2377 0.2447 0.1957	0 3 7 14	Untreated samples with residues > LOD: Cabbage plant (PHI 0):- TA: 0.0277 Cabbage head (PHI 21):- TA: 0.0415
								Cabbage head	0.0105	0.002	0	0.002	0.002	0.0122	21	

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	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
Trial No: 23 1069 574 / 6599 AV, Ven- Zelderheide - Limburg / Gennep - The Netherlands/ NEU/ 2023	BRSOL/ Brassicas/ Head cab- bage/ Perfecta FI	1) 11/08/2023	128.3	410.7	31.2	18/10/2023	BBCH 43	Cabbage	1.33	0.002	0	0.002	0.002	1.3317	0	Untreated
		2) NA	124.6	398.7	31.2	24/10/2023	BBCH 43-45	plant	0.403	0.002	0	0.002	0.002	0.4047	3	samples
		3) 31/10/2023	126.2	404.0	31.2	31/10/2023	BBCH 43-45		0.190	0.002	0	0.002	0.002	0.1917	7	with
		03/11/2023							0.224	0.002	0	0.002	0.002	0.2257	14	residues >
		07/11/2023						Cabbage	0.0119	0.002	0	0.002	0.002	0.0136	20	LOD:
		14/11/2023						head								Cabbage
		20/11/2023														plant (PHI
																0):- TA:
																0.0151
																Cabbage
																head (PHI
																20):- TA:
																0.0220

- (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

LOD = 0.002 mg/kg for Difenoconazole, TRZ, TA, TLA, TAA  
LOQ = 0.010 mg/kg for Difenoconazole, TRZ, TA, TLA, TAA

#### A 2.1.3.4.4 Study 7

Comments of zRMS: Study is accepted

Reference: KCA 6.3-07.1 / KCA 6.3-07.2

Report Determination of Difenconazole and Triazole Derivative Metabolites (TDMs) residues in head cabbage following foliar applications with IN005B1570 under field conditions in Northern Europe in 2023. Analytical phase report. Longhi, D. 2024. Report No: LBN-0120-2023  
 Field phase report. Thomas-Delille, E. 2024. Report No. C3165

Guideline(s): Yes  
 Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 11, The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP) OECD ENV/MC/CHEM(98)16.  
 Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals - Crop Field Trial (14 June 2021).  
 Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999).  
 Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990.  
 Commission of the European Communities Working Document 7029/VI/95 rev.5 Appendix B: "General Recommendations for the Design, Preparation and Realization of Residue Trials, 22 July 1997."  
 European Commission, Directorate General Health and Consumer Protection: SANTE/2019/12752 Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin  
 SANTE/2020/12830 Rev.2, dated 14 February 2023: Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes

Deviations: No.

GLP: Yes

Acceptability: Yes

The objective of this study was to determine the residues level of difenconazole and of the following Triazole Derivative Metabolites (TDMs): 1H-1,2,4-triazole (TRZ), 1H-1,2,4-triazole alanine (TA), Triazole lactic acid (TLA), Triazole acetic acid (TAA) in cabbage after 3 foliar spray applications of IN005B1570 250 EC, an emulsifiable concentrate formulation containing 250 g/L difenconazole. This residue study was carried out on cabbage performing 2 HS (residues at harvest) and 2 DCS trials (decline study) set in open field under Northern European growing conditions (Czech Republic, Northern France and Germany).

The analytical method for the determination of Difenconazole (AM-GLP-STUDY-21-32) was based on the QuEChERS method (EN 15662-2018). The instrumental determination was carried out using a HPLC-MS/MS system (high-performance liquid chromatography + triple quadrupole mass spectrometry). The analytical method was validated under GLP compliance according to SANTE/2020/12830 rev.1 guideline in GLP study GLP-STUDY-21-32.

The analytical method for the determination of TDMs (AM-GLP-STUDY-21-109) was based on the

method “Quick Method for the Analysis of Highly Polar Pesticides in Food Involving Extraction with Acidified Methanol and LC- or IC-MS/MS Measurement - Food of Plant Origin (QuPPE-PO-Method) - Method 8 (M8)”. The instrumental determination was carried out using a HPLC-MS/MS system (high-performance liquid chromatography + triple quadrupole mass spectrometry) equipped with a differential mobility separation device (DMS). The analytical method was validated under GLP compliance according to SANTE/2020/12830 rev.1 guideline in GLP study GLP-STUDY-21-109. The applied analytical method allowed the determination of the following TDM (triazole-derivative metabolites): 1,2,4-triazole (TRZ), Triazole-alanine (TA), Triazole-lactic acid (TLA), Triazole-acetic acid (TAA).

The final extracts were kept refrigerated (at  $5 \pm 3^{\circ}\text{C}$ ) in the dark and were analysed just after the extraction and in any case within 24h.

Limit of detection (LOD) and quantification (LOQ) for these analytical methods are:

- LOD (Limit of Detection) corresponds to:
  - o 0.002 mg/kg for: Difenconazole, TRZ, TA, TLA, TAA
- LOQ (Limit of Quantification) corresponds to:
  - o 0.010 mg/kg for: Difenconazole, TRZ, TA, TLA, TAA
  - o

A corrected figure for each of the TDMs is presented in the table summarising the trials. This correction accounts for the occurrence of detectable TDMs in untreated controls. The individual TDMs for each of the treated samples is determined to be the difference between the TDM in the treated vs untreated sample, where the TDM in the untreated sample is >LOD; where the difference is negative (i.e. untreated sample has higher TDM than treated sample), the corrected value is set to zero.

The total difenconazole according to the proposed residue definition was determined as the sum of difenconazole + TDMs expressed as difenconazole:  $\text{Difenconazole} + (1,24\text{-T} \times 69.07/406.26) + (\text{TA} \times 156.14/406.26) + (\text{TAA} \times 157.13/406.26) + (\text{TLA} \times 127.1/406.26)$ .



**Table A 23: Summary of the study 4 trials.** TDM residues are corrected taking into account TDM residues in control samples.

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	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
Trial No. C3165 AN1 / 67240 Bischwiller, Northern France/ NEU/ 2023	BRSOL/ Brassicas/ Head cab- bage/ Alaska	1) 15/06/2023 2) NA 3) 13/10/2023 to 27/11/2023	134.0 125.7 129.9	322 302 312	41.7 41.7 41.7	06/09/2023 12/09/2023 19/09/2023	BBCH 41 BBCH 41-43 BBCH 43	Cabbage Head	1.50 0.308 0.221 0.158 0.0692	0.0077 0.00296 0.00514 0.00471 0.002	0 0.034 0.109 0.033 0.126	0 0.00093 0.00252 0.00327 0.00299	0 0 0.0015 0.00673 0.00244	1.5013 0.3219 0.2651 0.1751 0.1198	0 3 7 14 21	
Trial No. C3165 ND1/ 59189 Steenbec- que, Northern France/ NEU/ 2023	BRSOL/ Brassicas/ Head cab- bage/ Congama	1) 20/06/2023 2) NA 3) 30/10/2023	125.0 127.8 122.2	300 307 293	41.7 41.7 41.7	19/09/2023 26/09/2023 04/10/2023	BBCH 45 BBCH 46 BBCH 47	Cabbage Head	0.0437	0.002	0	0.002	0.002	0.0454	21	
Trial No. C3165 BW1/ 79227 Schallstadt, Germany/ NEU/ 2023	BRSOL/ Brassicas/ Head cab- bage/ Congama	1) 09/06/2023 2) NA 3) 30/10/2023 to 17/11/2023	122.9 116.7 114.6	393 373 367	31.3 31.3 31.3	20/09/2023 27/09/2023 04/10/2023	BBCH 43 BBCH 45 BBCH 45-47	Cabbage Head	0.00317	0.002	0.0172	0.002	0.002	0.0115	21	
Trial No. C3165 CZ1/ 56601 Vysoké Myto, Czech Republic/ NEU/ 2023	BRSOL/ Brassicas/ Head cab- bage/ Typhoon	1) 24/05/2023 2) NA 3) 09/10/2023 to 20/10/2023	122.2 126.4 133.3	293 303 320	41.7 41.7 41.7	11/09/2023 17/09/2023 24/09/2023	BBCH 47 BBCH 47 BBCH 47	Cabbage Head	0.13 0.0495 0.0527 0.0295 0.00433	0.002 0.002 0.002 0.002 0.002	0.0151 0.0021 0.0409 0.0357 0.0360	0.002 0.002 0.002 0.002 0.002	0.002 0.002 0.002 0.002 0.002	0.1375 0.0520 0.0702 0.0450 0.0199	0 3 7 14 21	

(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

LOD = 0.002 mg/kg for Difenoconazole, TRZ, TA, TLA, TAA

LOQ = 0.010 mg/kg for Difenoconazole, TRZ, TA, TLA, TAA

#### A 2.1.3.4.5 Study 8

**Table A 24: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
Intended cGAP (number 4*)	1-3	125	14 days min.	From BBCH 19-21	14
Intended cGAP (number 5*)	1-3	125	7- 10 days min.	From BBCH 19-21	14

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

Comments of zRMS: Study is accepted

Reference: KCA 6.3-08

Report Determination of Difenoconazole and Triazole Derivative Metabolites (TDMs) residues in raw agricultural commodity of broccoli and cauliflower after three applications of the formulated product IN005B1570 (North Europe – 8 trials, 2023). Longhi, D. 2024.Report No: LBN-0122-2023

Guideline(s): Yes  
Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 11, The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP) OECD ENV/MC/CHEM(98)16.  
Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals - Crop Field Trial (14 June 2021).  
Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999).  
Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990.  
Commission of the European Communities Working Document 7029/VI/95 rev.5 Appendix B: "General Recommendations for the Design, Preparation and Realization of Residue Trials, 22 July 1997."  
European Commission, Directorate General Health and Consumer Protection: SANTE/2019/12752 Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin  
SANTE/2020/12830 Rev.2, dated 14 February 2023: Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes

Deviations: Yes.  
Deviation LBN-0122-2023-DEV-01 (Trial 23 1069 571):  
Due to a human error followed by a technical malfunction of the alarm system starting late 24.10.2023 until the early morning of 25.10.2023, the temperatures in freezer storage AGR-GL-04-0215, used for the storage of retain samples, raised.  
For the core temperature, which is measured inside a representative sample amount (dummy) the following temperatures were registered:  
Above -18.0°C for a duration of ca. 19:30 (hh:mm) and above -12.0°C for a

duration of ca. 13:00 (hh:mm) with a maximum of -4.7°C.  
For the air temperature the following temperatures were registered:  
Above -18.0°C a duration of ca. 13:00 (hh:mm), above -12.0°C a duration of ca. 12:15 (hh:mm); above 0°C a duration of ca. 10:00 (hh:mm) with a maximum of +4.7°C.  
The following specimens were stored inside this freezer storage and were affected: 23-571-C-001R, 23-571-C-003R, 23-571-T-002R, 23-571-T-004R, 23-571-T-005R, 23-571-T-006R, 23-571-T-007R, 23-571-T-008R.  
Since no unexpected events occurred during the analysis of ship samples, retain samples were not necessary, therefore the deviation has no impact.  
Deviation LBN-0122-2023-DEV-02 (Trial 23 47 GRU 0053):  
Because of the climatic conditions, inflorescences developed until BBCH 41-43 and the specimen weights for inflorescences were 0.084 kg for specimen 23-053-C-001 and 0.104 kg for specimen 23-053-T-002 (instead of 2 kg each, as indicated in the study plan). Furthermore, retain specimens could not be taken.  
The collected amount of ship samples was enough for the analysis. Furthermore, since no unexpected events occurred during the analysis of ship samples, retain samples were not necessary, therefore the deviation has no impact.

GLP: Yes

Acceptability: Yes

The objective of this study was to determine the residues level of difenoconazole and of the following Triazole Derivative Metabolites (TDMs): 1H-1,2,4-triazole (TRZ), 1H-1,2,4-triazole alanine (TA), Triazole lactic acid (TLA), Triazole acetic acid (TAA) in cabbage after 3 foliar spray applications of IN005B1570 250 EC, an emulsifiable concentrate formulation containing 250 g/L difenoconazole. This residue study was carried out on broccoli and cauliflower performing 4 HS (residues at harvest) and 4 DCS trials (decline study) set in open field under Northern European growing conditions (Germany, Belgium, The Netherlands, Austria, Czech Republic and Poland).

The analytical method for the determination of Difenoconazole (AM-GLP-STUDY-21-32) was based on the QuEChERS method (EN 15662-2018). The instrumental determination was carried out using a HPLC-MS/MS system (high-performance liquid chromatography + triple quadrupole mass spectrometry). The analytical method was validated under GLP compliance according to SANTE/2020/12830 rev.1 guideline in GLP study GLP-STUDY-21-32.

The analytical method for the determination of TDMs (AM-GLP-STUDY-21-109) was based on the method “Quick Method for the Analysis of Highly Polar Pesticides in Food Involving Extraction with Acidified Methanol and LC- or IC-MS/MS Measurement - Food of Plant Origin (QuPPE-PO-Method) - Method 8 (M8)”. The instrumental determination was carried out using a HPLC-MS/MS system (high-performance liquid chromatography + triple quadrupole mass spectrometry) equipped with a differential mobility separation device (DMS). The analytical method was validated under GLP compliance according to SANTE/2020/12830 rev.1 guideline in GLP study GLP-STUDY-21-109. The applied analytical method allowed the determination of the following TDM (triazole-derivative metabolites): 1,2,4-triazole (TRZ), Triazole-alanine (TA), Triazole-lactic acid (TLA), Triazole-acetic acid (TAA).

The final extracts were kept refrigerated (at  $5 \pm 3^\circ\text{C}$ ) in the dark and were analysed just after the extraction and in any case within 24h.

Limit of detection (LOD) and quantification (LOQ) for these analytical methods are:

- LOD (Limit of Detection) corresponds to:
  - o 0.002 mg/kg for: Difenoconazole, TRZ, TA, TLA, TAA
- LOQ (Limit of Quantification) corresponds to:

- 0.010 mg/kg for: Difenconazole, TRZ, TA, TLA, TAA
- 

A corrected figure for each of the TDMs is presented in the table summarising the trials. This correction accounts for the occurrence of detectable TDMs in untreated controls. The individual TDMs for each of the treated samples is determined to be the difference between the TDM in the treated vs untreated sample, where the TDM in the untreated sample is >LOD; where the difference is negative (i.e. untreated sample has higher TDM than treated sample), the corrected value is set to zero.

The total difenconazole according to the proposed residue definition was determined as the sum of difenconazole + TDMs expressed as difenconazole:  $\text{Difenconazole} + (1,24\text{-T} \times 69.07/406.26) + (\text{TA} \times 156.14/406.26) + (\text{TAA} \times 157.13/406.26) + (\text{TLA} \times 127.1/406.26)$ .

**Table A 25: Summary of the study 8 trials. TDM residues are corrected taking into account TDM residues in control samples.**

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			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	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
Trial No: 23 1069 570 / 59320, Enniger- loh - North Rhine- Westphalia / Warendorf – Germany/ NEU/ 2023	BRSOK/ Brassicas/ Broccoli/ Covina F1	1) 18/08/2023 2) NA 3) 28/11/2023	124.0 128.1 130.2	396.7 410.0 416.7	31.2 31.2 31.2	30/10/2023 07/11/2023 15/11/2023	BBCH 41- 43 BBCH 43 BBCH 45	Broccoli (inflorescence)	0.00581	0.00863	0.0152	0.002	0.004	0.0153	13	Untreated samples with residues > LOD: Broccoli inflorescence: - TA: 0.0782
Trial No: 23 47 GRU 0053 / 3133 Gemeinlebarn – Austria/ NEU/ 2023	BRSOK/ Brassicas/ Broccoli/ Parthenon F1	1) 24/08/2023 2) NA 3) 29/11/2023	127 130 134	607 622 645	20.84 20.83 20.83	30/10/2023 07/11/2023 15/11/2023	BBCH 38 BBCH 39 BBCH 41	Broccoli (inflorescence)	0.0415	0.002	0.024	0.002	0.002	0.0525	14	Untreated samples with residues > LOD: Broccoli inflorescence: - TA: 0.0103
Trial No: 23 1069 569 / 3470, Kortenaken - Flemish Brabant / Leuven – Belgium/ NEU/ 2023	BRSOB/ Brassica/ Cauliflower/ Castellum	1) 16/08/2023 2) NA 3) 05/12/2023	131.2 125.0 124.0	420.0 400.0 396.7	31.2 31.2 31.2	07/11/2023 15/11/2023 21/11/2023	BBCH 41- 43 BBCH 43 BBCH 45	Cauliflower (inflorescence)	0.0178	0.002	0.0347	0.002	0.002	0.0329	14	Untreated samples with residues > LOD: Cauli- flower inflo- rescence: - TA: 0.0203
Trial No: 23 47 GRU 0051 / 68724 Uherský Ostroh - Czech Republic/ NEU/ 2023	BRSOB/ Brassica/ Cauliflower/ Guideline F1	1) 22/08/2023 2) NA 3) 14/11/2023	128 126 127	617 607 611	20.83 20.84 20.83	16/10/2023 23/10/2023 30/10/2023	BBCH 39 BBCH 41 BBCH 43	Cauliflower (inflorescence)	0.002	0.002	0	0.002	0.002	0.0037	15	Untreated samples with residues > LOD: Cauli- flower inflo- rescence: - TA: 0.0163

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			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	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
Trial No: 23 1069 571 / 6599 AV, Ven- Zelderheide - Limburg / Gennep - The Netherlands/ NEU/ 2023	BRSOK/ Brassicas/ Broccoli/ Marathon FI	1) 11/08/2023	121.7	389.3	31.2	05/10/2023	BBCH 41	Plant	2.54	0.002	0	0.002	0.002	2.5417	0	Untreated
		2) NA	122.5	392.0	31.2	11/10/2023	BBCH 41- 43	Inflorescence	0.599	0.002	0	0.002	0.00358	0.6014	0	samples with
		3) 18/10/2023	129.2	413.3	31.2	18/10/2023		Plant	0.922	0.002	0	0.002	0.002	0.9237	4	residues >
		22/10/2023					BBCH 43	Inflorescence	0.0698	0.002	0.0353	0.002	0.002	0.0851	4	LOD: Broccoli
		24/10/2023						Plant	0.629	0.002	0.004	0.002	0.002	0.6323	6	plant (0 PHI): -
		27/10/2023						Inflorescence	0.0567	0.002	0.0786	0.002	0.00256	0.0889	6	TA: 0.0140
		02/11/2023						Plant	0.430	0.002	0	0.002	0.002	0.4317	9	Broccoli
								Inflorescence	0.0361	0.002	0	0.002	0.00258	0.0381	9	inflorescence
								Inflorescence	0.00959	0.002	0	0.002	0.00266	0.0116	15	(0 PHI): - TA:
																0.149Broccoli
																plant (9 PHI): -
																TA: 0.0148
																Broccoli
																inflorescence
																(9 PHI): - TA:
																0.148 Broccoli
																inflorescence
																(15 PHI): -
																TA: 0.102

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			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	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
Trial No: 23 47 GRU 0052 / 64-600 Berdychowo – Poland/ NEU/ 2023	BRSOK/ Brassicas/ Broccoli/ Ironman	1) 22/08/2023	127	608	20.83	17/10/2023	BBCH41	Plant	2.68	0.002	0	0.002	0.002	2.6817	0	Untreated
		2) NA	123	592	20.83	24/10/2023	BBCH 43	Inflorescence	0.748	0.002	0	0.002	0.00231	0.7499	0	samples with
		3) 31/10/2023	121	581	20.83	31/10/2023	BBCH 45	Plant	0.769	0.002	0	0.002	0.002	0.7707	3	residues >
		03/11/2023						Inflorescence	0.170	0.002	0.0017	0.002	0.0029	0.1727	3	LOD: Broccoli
		07/11/2023						Plant	0.533	0.002	0.0002	0.002	0.002	0.5348	7	plant (0 PHI): -
		10/11/2023						Inflorescence	0.0627	0.002	0	0.002	0.00222	0.0645	7	TA:
		14/11/2023						Plant	0.559	0.002	0.0015	0.002	0.002	0.5613	10	0.0142Broccoli
								Inflorescence	0.0370	0.002	0	0.002	0.00226	0.0388	10	inflorescence
								Inflorescence	0.00681	0.002	0.0204	0.002	0.00213	0.0164	14	(0 PHI): - TA:
																0.0965
																Broccoli plant
																(10 PHI): -
																TA: 0.0110
																Broccoli
																inflorescence
																(10 PHI): -
																TA: 0.0833
																Broccoli
																inflorescence
																(14 PHI): -
																TA: 0.0586

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			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	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
Trial No: 23 1069 568 / 46342, Velen- Ramsdorf - North Rhine- Westphalia / Borken – Germany/ NEU/ 2023	BRSOB/ Brassica/ Cauliflower/ Aviso F1	1) 11/08/2023	120.0	384.0	31.2	07/11/2023	BBCH 41-	Plant	2.71	0.002	0.0038	0.002	0.002	2.7132	0	Untreated
		2) NA	126.7	405.3	31.2	15/11/2023	43	Inflorescence	0.180	0.002	0.0108	0.002	0.002	0.1859	0	samples with
		3) 21/11/2023	125.4	401.3	31.2	21/11/2023	BBCH 43-	Plant	0.723	0.002	0.0046	0.002	0.002	0.7265	4	residues >
		25/11/2023					45	Inflorescence	0.168	0.002	0	0.002	0.002	0.1697	4	LOD: Cauli-
		29/11/2023					BBCH 45	Plant	1.49	0.002	0.0045	0.002	0.002	1.4935	8	flower plant (0
		02/12/2023						Inflorescence	0.250	0.002	0	0.002	0.002	0.2517	8	PHI): - TA:
		06/12/2023						Plant	1.21	0.002	0.00873	0.002	0.002	1.2151	11	0.0110 Cauli-
								Inflorescence	0.0473	0.002	0.0224	0.002	0.002	0.0576	11	flower inflo-
								Inflorescence	0.125	0.002	0.0165	0.002	0.002	0.1331	15	rescence (0
																PHI): - TA:
																0.0434 Cauli-
																flower plant



Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment			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	1,2,4-T	TA	TLA	TAA	SUM of Difeno + TDMs		
Trial No: 23 47 GRU 0050 / 04827 Machern OT Gerichshain – Germany/ NEU/ 2023	BRSOB/ Brassica/ Cauliflower/ Lecanu F1	1) 11/08/2023	137	660	20.83	11/10/2023	BBCH 41	Plant	2.72	0.002	0	0.002	0.002	2.7217	0	Untreated
		2) NA	127	611	20.84	18/10/2023	BBCH 43	Inflorescence	0.178	0.002	0.0277	0.002	0.002	0.1904	0	samples with
		3) 25/10/2023	134	644	20.82	25/10/2023	BBCH 43- 45	Plant	0.470	0.002	0	0.002	0.002	0.4717	3	residues >
		28/10/2023						Inflorescence	0.175	0.002	0.0134	0.002	0.002	0.1819	3	LOD: Cauli-
		01/11/2023						Plant	0.384	0.002	0	0.002	0.002	0.3857	7	flower plant (0
		03/11/2023						Inflorescence	0.0705	0.002	0.0052	0.002	0.002	0.0742	7	PHI): - TA:
		08/11/2023						Plant	0.320	0.002	0	0.002	0.002	0.3217	9	0.0375 Cauli-
								Inflorescence	0.0396	0.002	0.0275	0.002	0.002	0.0519	9	flower inflo-
								Inflorescence	0.00540	0.002	0.0432	0.002	0.002	0.0237	14	rescence (0
																PHI): - TA:
																0.0585 Cauli-
																flower plant (9
																PHI): - TA:
																0.0234 Cauli-

(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

LOD = 0.002 mg/kg for Difenoconazole, TRZ, TA, TLA, TAA

LOQ = 0.010 mg/kg for Difenoconazole, TRZ, TA, TLA, TAA

#### **A 2.1.4 Magnitude of residues in livestock**

No studies performed in the framework of this application.

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

No studies performed in the framework of this application.  
 Data on processed commodities can be found in the supervised residue trials in section A 2.1.3.

#### **A 2.1.6 Magnitude of residues in representative succeeding crops**

No studies performed in the framework of this application.

#### **A 2.1.7 Other/Special Studies**

##### **A 2.1.7.1 Study 1**

Comments of zRMS:	Study is accepted
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**Reference:** KCP 6.10.1

**Report** Magnitude of the residue of difenoconazole, prothioconazole, prothioconazole-desthio and triazole-derivative metabolites (TDMs) in honey after one application of IN233C1560 380 EC on Phacelia crop under semi field conditions in four trials in Northern Europe and Southern Europe – 2023. Rovetto, I., 20203, Study code: 1111.4F.SAG23

**Guideline(s):** Yes  
 European Community Guidelines 7029/VI/95 – Rev. 5, 22/07/97: General recommendations for the design, preparation and realization of residue trials.  
 European Community Guidelines SANTE/2019/12752 on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin (Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3).  
 Regulation (EC) no. 1107/2009 of the European Parliament and of the Council of 21st October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EC and 91/414/EEC, 21/10/2019.  
 Regulation (EU) No. 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, 01/03/2013.  
 OECD Test Guideline 509: Crop field trials, 14/06/2021.  
 SANTE/11956/2016 rev. 9, Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in

honey, 14 September 2018.

**Deviations:**

Yes

Field phase, deviation 7981.F.SAG23 (23SAG01359-1) (22/09/2023):

14 days after the A1 treatment, on 06 Sep 23, an attempt was made to obtain material for analysis, unfortunately the amount of honey produced by the bees was marginal, not allowing for the collection of a representative sample. A new trial, replacing failed trial, was set up in Italy. Instruction about reporting and archiving was provided in Amendment 2.

**GLP:**

Yes

**Acceptability:**

Yes

**Materials and methods**

The objective of this study was to determine the magnitude of residues of difenoconazole, prothioconazole, its metabolite prothioconazole-desthio and the triazole-derivative metabolites (TDMs): triazole-alanine (TA), 1,2,4-triazole (1,2,4-T), triazole lactic acid (TLA), triazole acetic acid (TAA) in honey after one application of IN233C1560 380 EC on flowering Phacelia crop.

For this purpose, four trials were initially conducted in Germany, Poland and Italy in 2023. As it was not possible to obtain representative honey samples in the trial performed in Poland, according to Amendment 2 to the Study Plan a new trial was set up in Italy to replace the failed trial and to obtain honey samples for the analysis.

In the treated plot T, one application of the formulated product IN233C1560 380 EC was carried out at crop full flowering (BBCH 65) at a rate of 1.0 L f.p./ha (250 g prothioconazole + 130 g difenoconazole/ha). The application was performed one day after introduction of the beehives in the tunnels. Mature honey specimens were collected when honey was ripe, 11-14 days after the application and anyway before the end of the flowering.

Specimens were stored deep frozen (temperature  $\leq -18^{\circ}\text{C}$ ) within 12 hours from sampling. Treated and untreated specimens were maintained in deep-frozen condition and adequately separated during storage and shipment. The final destination of the specimens was the analytical test site. The analysis of the specimens was completed within 30 days from the sampling date.

The analytical method to quantify Difenoconazole, Prothioconazole and Prothioconazole-desthio in honey was based on the QuEChERS method (EN 15662\_2018). The instrumental determination was carried out using a HPLC-MS/MS system (high-performance liquid chromatography + triple quadrupole mass spectrometry).

Samples were analysed according to the analytical method AM1-LBN-0092-2023. All the extracts and diluted extracts were analyzed within 24 hours from their preparation, keeping them at a temperature of  $5 \pm 3^{\circ}\text{C}$  until the analysis.

The applied analytical method (AM-LBN-0093-2023) allows the determination of the following TDM (triazole-derivative metabolites) in honey:

- 1,2,4-triazole (TRZ)
- Triazole-alanine (TA)
- Triazole-lactic acid (TLA)
- Triazole-acetic acid (TAA)

The analytical method was based on the method "Quick Method for the Analysis of Highly Polar Pesticides in Food Involving Extraction with Acidified Methanol and LC- or IC-MS/MS Measurement - Food of Plant Origin (QuPPe-PO-Method) - Method 8 (M8)". The instrumental determination was carried out using a HPLCMS/ MS system (high-performance liquid chromatography + triple quadrupole mass spec-

trometry) equipped with a differential mobility separation device (DMS).

## Results and discussions

During the analytical session for the determination of Difenconazole, Prothioconazole and Prothioconazoledesthio, two recovery check tests were carried out fortifying aliquots of an untreated honey sample (CDS- 23-1469 and CDS-23-1565) at the following fortification levels:

- LOQ (0.01 mg/kg), adding 50 µL of Solution B (containing 1.00 mg/L of each analyte) to aliquots of about 5 g of untreated sample.
- 10xLOQ (0.1 mg/kg), adding 50 µL of Solution A (containing 10.0 mg/L of each analyte) to aliquots of about 5 g of untreated sample.

During the analytical session for the determination of TDM (1,2,4-triazole, triazole-alanine, triazole-lactic acid and triazole-acetic acid), two recovery check tests were carried out fortifying aliquots of an untreated honey sample (CDS-23-1469 and CDS-23-1565) at the following fortification levels:

- LOQ (0.01 mg/kg), adding 50 µL of TDM Mix solution B (containing 1.00 mg/L of each TDM) to aliquots of about 5 g of untreated sample.
- 10xLOQ (0.1 mg/kg), adding 50 µL of TDM Mix solution A (containing 10.0 mg/L of each TDM) to aliquots of about 5 g of untreated sample.

The mean recoveries for each spiking level were in compliance with the SANTE 2020/12830 rev.2.

Results related to the determination of residues of Difenconazole, Prothioconazole, and its metabolite Prothioconazole-desthio and triazole-derivative metabolites (TDMs): triazole-alanine (TA), 1,2,4-triazole (1,2,4-T), triazole lactic acid (TLA), triazole acetic acid (TAA) in honey specimens are reported below:

Trial code	Specimen Id	Plot	Specimen type	Results (mg/kg)						
				Difenoconazole	Prothioconazole	Prothioconazole desthio	1,2,4-triazole	Triazole Alanine	Triazole Lactic acid	Triazole Acetic acid
1111.F.SAG23/r	1-U-1111.F.SAG23S	U	Mature honey	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD
	3-T-1111.F.SAG23S	T	Mature honey	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD
1112.F.SAG23/r	5-U-1112.F.SAG23S	U	Mature honey	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD
	7-T-1112.F.SAG23S	T	Mature honey	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD
1147.F.SAG23/r	9-U-1147.F.SAG23S	U	Mature honey	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD
	11-T-1147.F.SAG23S	T	Mature honey	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD
7982.F.SAG23	13-U-7982.F.SAG23S	U	Mature honey	< LOD	< LOD	< LOD	< LOD	< LOQ (0.00214)	< LOQ (0.00517)	< LOD
	15-T-7982.F.SAG23S	T	Mature honey	< LOD	< LOD	< LOD	< LOD	< LOD	< LOQ (0.00308)	< LOD

U: untreated plot  
T: treated plot  
LOQ: limit of quantification (0.010 mg/kg)  
LOD: limit of detection (0.002 mg/kg)

## Conclusion

The test item was applied, and specimens were generated and analysed according to the recommendations of the sponsor and the study objectives. Results of residue analysis may therefore be used in order to predict the residue behaviour of Difenconazole, Prothioconazole and Prothioconazole-desthio after one foliar application of the test item IN233C1560 380 EC when applied as per study indications.

As shown in the results, the residues of difenconazole, prothioconazole, its metabolite prothioconazole-desthio and the triazole-derivative metabolites (TDMs): triazole-alanine (TA), 1,2,4-triazole (1,2,4-T), triazole lactic acid (TLA), triazole acetic acid (TAA) are not expected to be above the LOD and/or LOQ, and therefore are not a risk for the consumer.

## Appendix 3 Pesticide Residue Intake Model (PRIMo)

### A 3.1 TMDI calculations

#### a. Difenoconazole


Chronic risk assessment: JMPR methodology (IEDI/TMDI)										
			No of diets exceeding the ADI :							
	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)
										commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	351%	NL toddler	35,13	86%	Apples	46%	Table grapes	35%	Pears	8%
	280%	DE child	28,04	100%	Apples	41%	Table grapes	24%	Oranges	2%
	241%	GEMS/Food G06	24,08	72%	Tomatoes	47%	Rice	32%	Table grapes	2%
	195%	NL child	19,50	46%	Apples	31%	Table grapes	17%	Sugar beet roots	3%
	188%	GEMS/Food G11	18,82	31%	Wine grapes	20%	Celeries	18%	Tomatoes	2%
	183%	GEMS/Food G10	18,29	38%	Rice	27%	Tomatoes	13%	Lettuces	2%
	183%	GEMS/Food G07	18,26	44%	Wine grapes	22%	Tomatoes	10%	Rice	2%
	180%	PT general	17,98	75%	Wine grapes	24%	Rice	18%	Tomatoes	0,4%
	177%	GEMS/Food G08	17,72	31%	Wine grapes	23%	Tomatoes	16%	Olives for oil production	2%
	176%	IE adult	17,58	38%	Wine grapes	12%	Rhubarbs	9%	Celeries	1%
	155%	GEMS/Food G15	15,52	30%	Wine grapes	24%	Tomatoes	10%	Table grapes	2%
	155%	RO general	15,51	50%	Wine grapes	39%	Tomatoes	11%	Apples	2%
	150%	FR child 3 15 yr	14,96	20%	Oranges	17%	Tomatoes	13%	Apples	3%
	135%	FR adult	13,51	70%	Wine grapes	9%	Tomatoes	6%	Apples	1%
	130%	DE women 14-50 yr	13,04	25%	Wine grapes	21%	Apples	15%	Tomatoes	1%
	129%	FR toddler 2 3 yr	12,89	25%	Apples	18%	Rice	10%	Tomatoes	2%
	125%	ES child	12,47	20%	Tomatoes	17%	Lettuces	15%	Olives for oil production	2%
	121%	DE general	12,08	25%	Wine grapes	19%	Apples	13%	Tomatoes	1%
	115%	SE general	11,50	16%	Lettuces	15%	Tomatoes	12%	Rice	1%
	111%	ES adult	11,11	21%	Lettuces	16%	Tomatoes	12%	Wine grapes	0,7%
	108%	NL general	10,77	18%	Wine grapes	12%	Apples	8%	Tomatoes	2%
	105%	UK toddler	10,53	17%	Rice	14%	Apples	12%	Oranges	2%
	103%	IT toddler	10,34	29%	Tomatoes	12%	Lettuces	7%	Apples	0,9%
	100%	IT adult	10,04	23%	Tomatoes	15%	Lettuces	6%	Apples	0,4%
	96%	DK child	9,55	19%	Apples	11%	Tomatoes	9%	Rice	1%
	89%	UK vegetarian	8,92	24%	Wine grapes	12%	Tomatoes	11%	Rice	0,5%
	89%	UK infant	8,90	19%	Rice	13%	Apples	8%	Oranges	3%
	86%	FI 3 yr	8,63	17%	Rice	11%	Tomatoes	8%	Apples	0,5%
	82%	UK adult	8,18	32%	Wine grapes	11%	Rice	9%	Tomatoes	0,4%
	78%	DK adult	7,83	29%	Wine grapes	10%	Tomatoes	8%	Apples	0,5%
	68%	FI 6 yr	6,83	13%	Rice	9%	Tomatoes	6%	Strawberries	0,4%
	67%	FR infant	6,68	13%	Apples	8%	Spinaches	5%	Beans (with pods)	1%
	63%	PL general	6,29	18%	Tomatoes	16%	Apples	10%	Table grapes	0,1%
	57%	FI adult	5,70	11%	Tomatoes	9%	Wine grapes	6%	Lettuces	3%
	51%	LT adult	5,14	15%	Apples	12%	Tomatoes	6%	Rice	0,6%
	23%	IE child	2,34	9%	Rice	3%	Apples	2%	Table grapes	0,3%
<b>Conclusion:</b> The estimated TMDI/NEDI/IEDI was in the range of 0 % to 351,3 % of the ADI. For 24 diet(s) the ADI is exceeded.										


## A 3.2 IEDI calculations

### a. Difenoconazole

Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
			No of diets exceeding the ADI : ---						Exposure resulting from		
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
average food consumption)	65%	NL toddler	6,48	8%	Beans (with pods)	7%	Rice	6%	Milk: Cattle	5%	8%
	44%	DE child	4,43	6%	Oranges	4%	Apples	3%	Rice	1%	7%
	42%	GEMS/Food G06	4,18	17%	Rice	2%	Olives for oil production	2%	Tomatoes	2%	4%
	41%	GEMS/Food G10	4,09	14%	Rice	2%	Parsley	2%	Oranges	2%	2%
	40%	IE adult	4,01	4%	Sweet potatoes	3%	Rice	3%	Celeriacs/turnip rooted celeries	1%	2%
	37%	GEMS/Food G11	3,70	6%	Celeriacs/turnip rooted celeries	3%	Celeries	3%	Rice	2%	3%
	35%	FR child 3 15 yr	3,49	5%	Oranges	5%	Rice	5%	Beans (with pods)	2%	2%
	34%	FR toddler 2 3 yr	3,43	8%	Beans (with pods)	7%	Rice	3%	Milk: Cattle	0,9%	2%
	32%	GEMS/Food G07	3,18	4%	Rice	2%	Oranges	2%	Peas (with pods)	2%	3%
	31%	NL child	3,15	3%	Beans (with pods)	2%	Milk: Cattle	2%	Oranges	2%	4%
	30%	GEMS/Food G08	3,01	4%	Olives for oil production	3%	Rice	2%	Parsley	2%	3%
	29%	UK infant	2,89	7%	Rice	6%	Peas (without pods)	4%	Milk: Cattle	1%	2%
	29%	ES child	2,85	5%	Rice	3%	Oranges	3%	Olives for oil production	0,9%	2%
	28%	SE general	2,77	4%	Rice	2%	Lettuces	2%	Bananas	0,6%	3%
	27%	GEMS/Food G15	2,74	3%	Rice	3%	Celeriacs/turnip rooted celeries	1%	Parsley	2%	3%
	24%	PT general	2,42	9%	Rice	3%	Beans (without pods)	2%	Peas (without pods)	0,4%	3%
	24%	UK toddler	2,41	6%	Rice	3%	Oranges	3%	Peas (without pods)	0,6%	2%
TMDI/NEDI/IEDI calculation (based on average food consumption)	21%	DE women 14-50 yr	2,08	3%	Oranges	2%	Hybiscus/roselle	1%	Milk: Cattle	0,8%	2%
	20%	ES adult	2,01	3%	Lettuces	3%	Rice	2%	Beans (with pods)	0,5%	2%
	19%	DE general	1,88	3%	Oranges	2%	Hybiscus/roselle	1%	Milk: Cattle	0,7%	2%
	19%	NL general	1,87	2%	Beans (with pods)	2%	Witloofs/Belgian endives	2%	Oranges	1%	2%
	17%	IT toddler	1,69	2%	Rice	2%	Lettuces	1%	Florence fennels	0,9%	2%
	17%	FR infant	1,67	5%	Beans (with pods)	2%	Milk: Cattle	0,9%	Spinaches	0,2%	2%
	17%	IT adult	1,66	2%	Rice	2%	Lettuces	2%	Florence fennels	0,4%	2%
	16%	DK child	1,65	3%	Rice	1%	Milk: Cattle	1%	Bananas	0,7%	3%
	16%	FI 3 yr	1,63	6%	Rice	2%	Strawberries	1%	Bananas	0,5%	2%
	16%	FR adult	1,61	2%	Beans (with pods)	2%	Rice	1,0%	Witloofs/Belgian endives	0,8%	2%
	16%	RO general	1,59	3%	Rice	1%	Beans (with pods)	1%	Milk: Cattle	1%	4%
	13%	UK vegetarian	1,31	4%	Rice	1%	Oranges	1%	Peas (without pods)	0,4%	1%
	13%	FI 6 yr	1,26	5%	Rice	1%	Strawberries	0,8%	Bananas	0,4%	2%
	12%	UK adult	1,15	4%	Rice	1%	Peas (without pods)	0,9%	Oranges	0,3%	1%
	9%	FI adult	0,93	3%	Coffee beans	1%	Rice	0,7%	Lettuces	3%	1%
	8%	DK adult	0,84	1%	Peas (without pods)	0,9%	Rice	0,5%	Milk: Cattle	0,2%	2%
	7%	LT adult	0,73	2%	Rice	0,6%	Apples	0,4%	Milk: Cattle	0,4%	2%
	7%	IE child	0,67	3%	Rice	0,9%	Beans (without pods)	0,4%	Milk: Cattle	0,1%	0,4%
	6%	PL general	0,64	0,9%	Plums	0,7%	Celeriacs/turnip rooted celeries	0,7%	Apples	0,1%	2%
<b>Conclusion:</b> The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Difenoconazole (F) 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.											

## IEDI – difenoconazole (input values corrected by zRMS table 7.2-20)


 <p>European Food Safety Authority</p> <p>EFSA PRIMo revision 3.1; 2021/01/06</p>		<b>Difenoconazole</b>				<b>Input values</b>							
		LOQs (mg/kg) range from: <b>0,01</b> to: <b>0,05</b>				Details - chronic risk assessment							
		<b>Toxicological reference values</b>				Supplementary results - chronic risk assessment							
		ADI (mg/kg bw/day): <b>0,01</b> ARID (mg/kg bw): <b>0,16</b>				Details - acute risk assessment/children							
Source of ADI: Year of evaluation:				Source of ARID: Year of evaluation:				Details - acute risk assessment/adults					
Comments:													
<b>Normal mode</b>													
<b>Chronic risk assessment: JMPR methodology (IEDI/TMDI)</b>													
				No of diets exceeding the ADI : ---								Exposure resulting from	
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)		
TMDI/NEDI/IEDI calculation (based on average food consumption)	74%	NL toddler	7,44	8%	Table grapes	7%	Tomatoes	7%	Rice	5%			
	73%	GEMS/Food G06	7,32	26%	Tomatoes	17%	Rice	5%	Table grapes	2%			
	59%	DE child	5,90	7%	Tomatoes	7%	Table grapes	6%	Oranges	1%			
	51%	GEMS/Food G10	5,09	14%	Rice	10%	Tomatoes	3%	Potatoes	2%			
	45%	GEMS/Food G11	4,46	7%	Tomatoes	6%	Celeriacs/turnip rooted celeries	4%	Potatoes	2%			
	43%	IE adult	4,33	4%	Sweet potatoes	3%	Tomatoes	3%	Rice	1%			
	41%	GEMS/Food G08	4,14	8%	Tomatoes	4%	Potatoes	4%	Olives for oil production	2%			
	41%	GEMS/Food G07	4,07	8%	Tomatoes	4%	Rice	4%	Potatoes	2%			
	40%	NL child	3,98	5%	Table grapes	4%	Tomatoes	3%	Potatoes	2%			
	39%	GEMS/Food G15	3,87	9%	Tomatoes	4%	Potatoes	3%	Rice	2%			
	37%	FR child 3 15 yr	3,73	6%	Tomatoes	5%	Oranges	5%	Rice	1%			
	35%	SE general	3,46	6%	Tomatoes	4%	Rice	4%	Potatoes	0,6%			
	34%	ES child	3,39	7%	Tomatoes	5%	Rice	3%	Oranges	0,7%			
	33%	RO general	3,28	14%	Tomatoes	4%	Potatoes	3%	Rice	1%			
	31%	PT general	3,13	9%	Rice	6%	Tomatoes	5%	Potatoes	0,4%			
	31%	FR toddler 2 3 yr	3,11	7%	Rice	3%	Tomatoes	3%	Milk: Cattle	0,8%			
	30%	UK toddler	2,98	6%	Rice	4%	Tomatoes	3%	Potatoes	0,6%			
	29%	UK infant	2,89	7%	Rice	4%	Milk: Cattle	3%	Potatoes	1%			
	27%	DE women 14-50 yr	2,73	5%	Tomatoes	3%	Oranges	2%	Hybiscus/roselle	0,7%			
	27%	IT toddler	2,66	10%	Tomatoes	2%	Rice	2%	Lettuces	0,1%			
	25%	FI 3 yr	2,49	6%	Rice	5%	Potatoes	4%	Tomatoes	0,5%			
	25%	IT adult	2,45	8%	Tomatoes	2%	Rice	2%	Lettuces	0,1%			
	24%	DE general	2,44	5%	Tomatoes	3%	Oranges	2%	Hybiscus/roselle	0,7%			
	24%	ES adult	2,37	6%	Tomatoes	3%	Lettuces	3%	Rice	0,4%			
	24%	DK child	2,36	4%	Tomatoes	3%	Rice	2%	Potatoes	0,7%			
	22%	NL general	2,19	3%	Tomatoes	2%	Potatoes	2%	Witloofs/Belgian endives	1%			
	19%	FI 6 yr	1,94	5%	Rice	4%	Potatoes	3%	Tomatoes	0,3%			
	18%	UK vegetarian	1,82	4%	Tomatoes	4%	Rice	1%	Oranges	0,4%			
	17%	FR adult	1,73	3%	Tomatoes	2%	Rice	1,0%	Witloofs/Belgian endives	0,8%			
	17%	PL general	1,69	6%	Tomatoes	3%	Potatoes	2%	Table grapes	0,1%			
	16%	FR infant	1,57	2%	Potatoes	2%	Milk: Cattle	1%	Courgettes	0,2%			
	15%	UK adult	1,47	4%	Rice	3%	Tomatoes	1%	Potatoes	0,3%			
	14%	FI adult	1,44	4%	Tomatoes	3%	Coffee beans	1%	Rice	3%			
14%	LT adult	1,42	4%	Tomatoes	3%	Potatoes	2%	Rice	0,4%				
13%	DK adult	1,27	4%	Tomatoes	1%	Potatoes	0,9%	Rice	0,2%				
7%	IE child	0,70	3%	Rice	0,6%	Potatoes	0,4%	Tomatoes	0,1%				
<b>Conclusion:</b> 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.													

 European Food Safety Authority EFSA PRIMo revision 3.1; 2021/01/06		<b>Difenoconazole Reg. (EU) 2019/552</b>				Input values																																																																																																																																																																																																																																																																																																																																																																																																																																										
		LOQs (mg/kg) range from: <b>0.005</b> to: <b>0.05</b>				Details - chronic risk assessment		Supplementary results - chronic risk assessment																																																																																																																																																																																																																																																																																																																																																																																																																																								
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		ADI (mg/kg bw/day): <b>0.01</b>		ARID (mg/kg bw): <b>0.16</b>																																																																																																																																																																																																																																																																																																																																																																																																																																												
		Source of ADI: <b>Dir 08/69</b>		Source of ARID: <b>Dir 08/69</b>		Details - acute risk assessment/children		Details - acute risk assessment/adults																																																																																																																																																																																																																																																																																																																																																																																																																																								
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<table border="1"> <thead> <tr> <th colspan="4"></th> <th colspan="2">No of diets exceeding the ADI :</th> <th colspan="2">---</th> <th colspan="2"></th> <th colspan="2">Exposure resulting from</th> </tr> <tr> <th></th> <th>Calculated exposure (% of ADI)</th> <th>MS Diet</th> <th>Exposure (µg/kg bw per day)</th> <th>Highest contributor to MS diet (in % of ADI)</th> <th>Commodity / group of commodities</th> <th>2nd contributor to MS diet (in % of ADI)</th> <th>Commodity / group of commodities</th> <th>3rd contributor to MS diet (in % of ADI)</th> <th>Commodity / group of commodities</th> <th>MRLs set at the LOQ (in % of ADI)</th> <th>commodities not under assessment (in % of ADI)</th> </tr> </thead> <tbody> <tr><td rowspan="35">TMDI/NEDI/IEDI calculation (based on average food consumption)</td><td>74%</td><td>GEMS/Food G06</td><td>7.42</td><td>26%</td><td>Tomatoes</td><td>17%</td><td>Rice</td><td>5%</td><td>Table grapes</td><td>2%</td><td>0.5%</td></tr> <tr><td>73%</td><td>NL toddler</td><td>7.27</td><td>8%</td><td>Table grapes</td><td>7%</td><td>Tomatoes</td><td>7%</td><td>Rice</td><td>8%</td><td>7%</td></tr> <tr><td>60%</td><td>DE child</td><td>5.99</td><td>7%</td><td>Tomatoes</td><td>7%</td><td>Table grapes</td><td>6%</td><td>Oranges</td><td>2%</td><td>6%</td></tr> <tr><td>54%</td><td>GEMS/Food G10</td><td>5.38</td><td>14%</td><td>Rice</td><td>10%</td><td>Tomatoes</td><td>3%</td><td>Potatoes</td><td>2%</td><td>0.6%</td></tr> <tr><td>51%</td><td>GEMS/Food G11</td><td>5.14</td><td>7%</td><td>Tomatoes</td><td>6%</td><td>Celeriacs/turnip rooted celeries</td><td>5%</td><td>Wine grapes</td><td>2%</td><td>1%</td></tr> <tr><td>51%</td><td>IE adult</td><td>5.07</td><td>7%</td><td>Wine grapes</td><td>4%</td><td>Sweet potatoes</td><td>3%</td><td>Tomatoes</td><td>1%</td><td>0.7%</td></tr> <tr><td>50%</td><td>GEMS/Food G07</td><td>5.00</td><td>8%</td><td>Tomatoes</td><td>8%</td><td>Wine grapes</td><td>4%</td><td>Rice</td><td>2%</td><td>0.8%</td></tr> <tr><td>47%</td><td>GEMS/Food G08</td><td>4.66</td><td>8%</td><td>Tomatoes</td><td>5%</td><td>Wine grapes</td><td>4%</td><td>Potatoes</td><td>2%</td><td>0.9%</td></tr> <tr><td>46%</td><td>PT general</td><td>4.62</td><td>13%</td><td>Wine grapes</td><td>9%</td><td>Rice</td><td>6%</td><td>Tomatoes</td><td>0.4%</td><td>1.0%</td></tr> <tr><td>45%</td><td>GEMS/Food G15</td><td>4.52</td><td>9%</td><td>Tomatoes</td><td>5%</td><td>Wine grapes</td><td>4%</td><td>Potatoes</td><td>2%</td><td>0.9%</td></tr> <tr><td>41%</td><td>RO general</td><td>4.10</td><td>14%</td><td>Tomatoes</td><td>9%</td><td>Wine grapes</td><td>4%</td><td>Potatoes</td><td>2%</td><td>1%</td></tr> <tr><td>40%</td><td>FR child 3 15 yr</td><td>3.96</td><td>6%</td><td>Tomatoes</td><td>5%</td><td>Oranges</td><td>5%</td><td>Rice</td><td>3%</td><td>1%</td></tr> <tr><td>39%</td><td>NL child</td><td>3.94</td><td>5%</td><td>Table grapes</td><td>4%</td><td>Tomatoes</td><td>3%</td><td>Potatoes</td><td>3%</td><td>3%</td></tr> <tr><td>34%</td><td>SE general</td><td>3.45</td><td>6%</td><td>Tomatoes</td><td>4%</td><td>Rice</td><td>4%</td><td>Potatoes</td><td>1%</td><td>1%</td></tr> <tr><td>34%</td><td>ES child</td><td>3.42</td><td>7%</td><td>Tomatoes</td><td>5%</td><td>Rice</td><td>3%</td><td>Oranges</td><td>2%</td><td>0.8%</td></tr> <tr><td>32%</td><td>UK infant</td><td>3.22</td><td>7%</td><td>Rice</td><td>6%</td><td>Peas (without pods)</td><td>3%</td><td>Potatoes</td><td>3%</td><td>2%</td></tr> <tr><td>32%</td><td>DE women 14-50 yr</td><td>3.16</td><td>5%</td><td>Tomatoes</td><td>4%</td><td>Wine grapes</td><td>3%</td><td>Oranges</td><td>1%</td><td>1%</td></tr> <tr><td>31%</td><td>UK toddler</td><td>3.14</td><td>6%</td><td>Rice</td><td>4%</td><td>Tomatoes</td><td>3%</td><td>Potatoes</td><td>2%</td><td>1%</td></tr> <tr><td>31%</td><td>FR toddler 2 3 yr</td><td>3.11</td><td>7%</td><td>Rice</td><td>3%</td><td>Tomatoes</td><td>2%</td><td>Oranges</td><td>2%</td><td>2%</td></tr> <tr><td>29%</td><td>FR adult</td><td>2.92</td><td>12%</td><td>Wine grapes</td><td>3%</td><td>Tomatoes</td><td>2%</td><td>Rice</td><td>1%</td><td>0.5%</td></tr> <tr><td>29%</td><td>DE general</td><td>2.88</td><td>5%</td><td>Tomatoes</td><td>4%</td><td>Wine grapes</td><td>3%</td><td>Oranges</td><td>1%</td><td>1%</td></tr> <tr><td>27%</td><td>DK child</td><td>2.74</td><td>6%</td><td>Rye</td><td>4%</td><td>Tomatoes</td><td>3%</td><td>Rice</td><td>1%</td><td>2%</td></tr> <tr><td>27%</td><td>IT toddler</td><td>2.74</td><td>10%</td><td>Tomatoes</td><td>2%</td><td>Rice</td><td>2%</td><td>Lettuces</td><td>0.9%</td><td>0.6%</td></tr> <tr><td>27%</td><td>FI 3 yr</td><td>2.68</td><td>6%</td><td>Rice</td><td>5%</td><td>Potatoes</td><td>4%</td><td>Tomatoes</td><td>0.5%</td><td>1.0%</td></tr> <tr><td>26%</td><td>ES adult</td><td>2.61</td><td>6%</td><td>Tomatoes</td><td>3%</td><td>Lettuces</td><td>3%</td><td>Rice</td><td>0.7%</td><td>0.5%</td></tr> <tr><td>25%</td><td>NL general</td><td>2.51</td><td>3%</td><td>Wine grapes</td><td>3%</td><td>Tomatoes</td><td>2%</td><td>Potatoes</td><td>2%</td><td>0.9%</td></tr> <tr><td>25%</td><td>IT adult</td><td>2.47</td><td>8%</td><td>Tomatoes</td><td>2%</td><td>Rice</td><td>2%</td><td>Lettuces</td><td>0.4%</td><td>0.5%</td></tr> <tr><td>23%</td><td>UK vegetarian</td><td>2.31</td><td>4%</td><td>Tomatoes</td><td>4%</td><td>Wine grapes</td><td>4%</td><td>Rice</td><td>0.5%</td><td>0.4%</td></tr> <tr><td>21%</td><td>UK adult</td><td>2.12</td><td>6%</td><td>Wine grapes</td><td>4%</td><td>Rice</td><td>3%</td><td>Tomatoes</td><td>0.4%</td><td>0.3%</td></tr> <tr><td>21%</td><td>FI 6 yr</td><td>2.12</td><td>5%</td><td>Rice</td><td>4%</td><td>Potatoes</td><td>3%</td><td>Tomatoes</td><td>0.4%</td><td>0.7%</td></tr> <tr><td>19%</td><td>DK adult</td><td>1.88</td><td>4%</td><td>Wine grapes</td><td>4%</td><td>Tomatoes</td><td>1%</td><td>Potatoes</td><td>0.5%</td><td>0.8%</td></tr> <tr><td>17%</td><td>PL general</td><td>1.73</td><td>6%</td><td>Tomatoes</td><td>3%</td><td>Potatoes</td><td>2%</td><td>Table grapes</td><td>0.1%</td><td>1%</td></tr> <tr><td>17%</td><td>FI adult</td><td>1.68</td><td>4%</td><td>Tomatoes</td><td>3%</td><td>Coffee beans</td><td>2%</td><td>Wine grapes</td><td>3%</td><td>0.5%</td></tr> <tr><td>15%</td><td>LT adult</td><td>1.54</td><td>4%</td><td>Tomatoes</td><td>3%</td><td>Potatoes</td><td>2%</td><td>Rice</td><td>0.6%</td><td>1.0%</td></tr> <tr><td>13%</td><td>FR infant</td><td>1.30</td><td>2%</td><td>Potatoes</td><td>0.9%</td><td>Spinaches</td><td>0.6%</td><td>Milk: Cattle</td><td>1%</td><td>1%</td></tr> <tr><td>7%</td><td>IE child</td><td>0.67</td><td>3%</td><td>Rice</td><td>0.6%</td><td>Potatoes</td><td>0.4%</td><td>Tomatoes</td><td>0.3%</td><td>0.3%</td></tr> </tbody> </table>																No of diets exceeding the ADI :		---				Exposure resulting from			Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % 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grapes	4%	Potatoes	2%	0.9%	41%	RO general	4.10	14%	Tomatoes	9%	Wine grapes	4%	Potatoes	2%	1%	40%	FR child 3 15 yr	3.96	6%	Tomatoes	5%	Oranges	5%	Rice	3%	1%	39%	NL child	3.94	5%	Table grapes	4%	Tomatoes	3%	Potatoes	3%	3%	34%	SE general	3.45	6%	Tomatoes	4%	Rice	4%	Potatoes	1%	1%	34%	ES child	3.42	7%	Tomatoes	5%	Rice	3%	Oranges	2%	0.8%	32%	UK infant	3.22	7%	Rice	6%	Peas (without pods)	3%	Potatoes	3%	2%	32%	DE women 14-50 yr	3.16	5%	Tomatoes	4%	Wine grapes	3%	Oranges	1%	1%	31%	UK toddler	3.14	6%	Rice	4%	Tomatoes	3%	Potatoes	2%	1%	31%	FR toddler 2 3 yr	3.11	7%	Rice	3%	Tomatoes	2%	Oranges	2%	2%	29%	FR adult	2.92	12%	Wine grapes	3%	Tomatoes	2%	Rice	1%	0.5%	29%	DE general	2.88	5%	Tomatoes	4%	Wine grapes	3%	Oranges	1%	1%	27%	DK child	2.74	6%	Rye	4%	Tomatoes	3%	Rice	1%	2%	27%	IT toddler	2.74	10%	Tomatoes	2%	Rice	2%	Lettuces	0.9%	0.6%	27%	FI 3 yr	2.68	6%	Rice	5%	Potatoes	4%	Tomatoes	0.5%	1.0%	26%	ES adult	2.61	6%	Tomatoes	3%	Lettuces	3%	Rice	0.7%	0.5%	25%	NL general	2.51	3%	Wine grapes	3%	Tomatoes	2%	Potatoes	2%	0.9%	25%	IT adult	2.47	8%	Tomatoes	2%	Rice	2%	Lettuces	0.4%	0.5%	23%	UK vegetarian	2.31	4%	Tomatoes	4%	Wine grapes	4%	Rice	0.5%	0.4%	21%	UK adult	2.12	6%	Wine grapes	4%	Rice	3%	Tomatoes	0.4%	0.3%	21%	FI 6 yr	2.12	5%	Rice	4%	Potatoes	3%	Tomatoes	0.4%	0.7%	19%	DK adult	1.88	4%	Wine grapes	4%	Tomatoes	1%	Potatoes	0.5%	0.8%	17%	PL general	1.73	6%	Tomatoes	3%	Potatoes	2%	Table grapes	0.1%	1%	17%	FI adult	1.68	4%	Tomatoes	3%	Coffee beans	2%	Wine grapes	3%	0.5%	15%	LT adult	1.54	4%	Tomatoes	3%	Potatoes	2%	Rice	0.6%	1.0%	13%	FR infant	1.30	2%	Potatoes	0.9%	Spinaches	0.6%	Milk: Cattle	1%	1%	7%	IE child	0.67	3%	Rice	0.6%	Potatoes	0.4%	Tomatoes	0.3%	0.3%
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	27%	IT toddler	2.74	10%	Tomatoes	2%	Rice	2%	Lettuces	0.9%	0.6%																																																																																																																																																																																																																																																																																																																																																																																																																																					
	27%	FI 3 yr	2.68	6%	Rice	5%	Potatoes	4%	Tomatoes	0.5%	1.0%																																																																																																																																																																																																																																																																																																																																																																																																																																					
	26%	ES adult	2.61	6%	Tomatoes	3%	Lettuces	3%	Rice	0.7%	0.5%																																																																																																																																																																																																																																																																																																																																																																																																																																					
	25%	NL general	2.51	3%	Wine grapes	3%	Tomatoes	2%	Potatoes	2%	0.9%																																																																																																																																																																																																																																																																																																																																																																																																																																					
	25%	IT adult	2.47	8%	Tomatoes	2%	Rice	2%	Lettuces	0.4%	0.5%																																																																																																																																																																																																																																																																																																																																																																																																																																					
	23%	UK vegetarian	2.31	4%	Tomatoes	4%	Wine grapes	4%	Rice	0.5%	0.4%																																																																																																																																																																																																																																																																																																																																																																																																																																					
	21%	UK adult	2.12	6%	Wine grapes	4%	Rice	3%	Tomatoes	0.4%	0.3%																																																																																																																																																																																																																																																																																																																																																																																																																																					
	21%	FI 6 yr	2.12	5%	Rice	4%	Potatoes	3%	Tomatoes	0.4%	0.7%																																																																																																																																																																																																																																																																																																																																																																																																																																					
	19%	DK adult	1.88	4%	Wine grapes	4%	Tomatoes	1%	Potatoes	0.5%	0.8%																																																																																																																																																																																																																																																																																																																																																																																																																																					
	17%	PL general	1.73	6%	Tomatoes	3%	Potatoes	2%	Table grapes	0.1%	1%																																																																																																																																																																																																																																																																																																																																																																																																																																					
	17%	FI adult	1.68	4%	Tomatoes	3%	Coffee beans	2%	Wine grapes	3%	0.5%																																																																																																																																																																																																																																																																																																																																																																																																																																					
	15%	LT adult	1.54	4%	Tomatoes	3%	Potatoes	2%	Rice	0.6%	1.0%																																																																																																																																																																																																																																																																																																																																																																																																																																					
	13%	FR infant	1.30	2%	Potatoes	0.9%	Spinaches	0.6%	Milk: Cattle	1%	1%																																																																																																																																																																																																																																																																																																																																																																																																																																					
7%	IE child	0.67	3%	Rice	0.6%	Potatoes	0.4%	Tomatoes	0.3%	0.3%																																																																																																																																																																																																																																																																																																																																																																																																																																						
<b>Conclusion:</b> The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Difenoconazole Reg. (EU) 2019/552 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.																																																																																																																																																																																																																																																																																																																																																																																																																																																




**b. Triazole alanine**

Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
			No of diets exceeding the ADI : --						Exposure resulting from		
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
average food consumption)	0.1%	NL toddler	0.16	0.0%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Pears		0.1%
	0.0%	NL child	0.08	0.0%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	GEMS/Food G07	0.07	0.0%	Rapeseeds/canola seeds	0.0%	Carrots	0.0%	Apples		0.0%
	0.0%	DE child	0.05	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G08	0.05	0.0%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Carrots		0.0%
	0.0%	NL general	0.04	0.0%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Carrots		0.0%
	0.0%	GEMS/Food G10	0.03	0.0%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Carrots		0.0%
	0.0%	GEMS/Food G15	0.03	0.0%	Rapeseeds/canola seeds	0.0%	Carrots	0.0%	Apples		0.0%
	0.0%	DK child	0.02	0.0%	Carrots	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	FI 3 yr	0.02	0.0%	Rapeseeds/canola seeds	0.0%	Carrots	0.0%	Apples		0.0%
	0.0%	FR toddler 2 3 yr	0.02	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK infant	0.02	0.0%	Carrots	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	FR infant	0.01	0.0%	Carrots	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	FI 6 yr	0.01	0.0%	Rapeseeds/canola seeds	0.0%	Carrots	0.0%	Apples		0.0%
	0.0%	DE women 14-50 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Rapeseeds/canola seeds		0.0%
	0.0%	DE general	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Rapeseeds/canola seeds		0.0%
	0.0%	GEMS/Food G11	0.01	0.0%	Carrots	0.0%	Apples	0.0%	Pears		0.0%
TMDI/NED/MEDI calculation (based on	0.0%	SE general	0.01	0.0%	Carrots	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	FR child 3 15 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Rapeseeds/canola seeds		0.0%
	0.0%	UK toddler	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	PT general	0.01	0.0%	Carrots	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	PL general	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	RO general	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	DK adult	0.01	0.0%	Carrots	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	GEMS/Food G06	0.01	0.0%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Carrots		0.0%
	0.0%	LT adult	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	ES child	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	IE adult	0.01	0.0%	Carrots	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	IT toddler	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	FI adult	0.00	0.0%	Carrots	0.0%	Apples	0.0%	Rapeseeds/canola seeds		0.0%
	0.0%	FR adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Rapeseeds/canola seeds		0.0%
	0.0%	ES adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	IT adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK vegetarian	0.00	0.0%	Carrots	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	UK adult	0.00	0.0%	Carrots	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	IE child	0.00	0.0%	Carrots	0.0%	Apples	0.0%	Pears		0.0%
<b>Conclusion:</b> The estimated long-term dietary intake (TMDI/NED/MEDI) was below the ADI. The long-term intake of residues of Triazole alanine 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.											

 European Food Safety Authority EFSA PRIMo revision 3.1; 2021/01/06		<b>Triazole alanine</b>				Input values					
		LOQs (mg/kg) range from: to:									
		<b>Toxicological reference values</b>									
		ADI (mg/kg bw/day): 0.3				ARfD (mg/kg bw): 0.3					
		Source of ADI:				Source of ARfD:					
Year of evaluation:				Year of evaluation:							
Comments:											
<b>Refined calculation mode</b>											
<b>Chronic risk assessment: JMPR methodology (IEDI/TMDI)</b>											
		No of diets exceeding the ADI :		---						Exposure resulting from	
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/IEDI calculation (based on average food consumption)	0.1%	NL toddler	0.25	0.1%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Cauliflowers		0.1%
	0.0%	GEMS/Food G07	0.12	0.0%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Cauliflowers		0.0%
	0.0%	NL child	0.12	0.0%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Cauliflowers		0.0%
	0.0%	GEMS/Food G08	0.08	0.0%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Head cabbages		0.0%
	0.0%	NL general	0.06	0.0%	Rapeseeds/canola seeds	0.0%	Cauliflowers	0.0%	Apples		0.0%
	0.0%	GEMS/Food G10	0.06	0.0%	Rapeseeds/canola seeds	0.0%	Head cabbages	0.0%	Apples		0.0%
	0.0%	GEMS/Food G15	0.05	0.0%	Rapeseeds/canola seeds	0.0%	Head cabbages	0.0%	Apples		0.0%
	0.0%	DE child	0.04	0.0%	Apples	0.0%	Broccoli	0.0%	Broccoli		0.0%
	0.0%	FI 3 yr	0.02	0.0%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Carrots		0.0%
	0.0%	FR toddler 2-3 yr	0.02	0.0%	Apples	0.0%	Cauliflowers	0.0%	Broccoli		0.0%
	0.0%	FI 6 yr	0.02	0.0%	Rapeseeds/canola seeds	0.0%	Carrots	0.0%	Apples		0.0%
	0.0%	FR infant	0.01	0.0%	Cauliflowers	0.0%	Apples	0.0%	Broccoli		0.0%
	0.0%	DE general	0.01	0.0%	Apples	0.0%	Rapeseeds/canola seeds	0.0%	Cauliflowers		0.0%
	0.0%	DE women 14-50 yr	0.01	0.0%	Apples	0.0%	Cauliflowers	0.0%	Rapeseeds/canola seeds		0.0%
	0.0%	FR child 3-15 yr	0.01	0.0%	Cauliflowers	0.0%	Apples	0.0%	Rapeseeds/canola seeds		0.0%
	0.0%	UK infant	0.01	0.0%	Cauliflowers	0.0%	Apples	0.0%	Carrots		0.0%
	0.0%	GEMS/Food G06	0.01	0.0%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Head cabbages		0.0%
	0.0%	DK child	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	RO general	0.01	0.0%	Head cabbages	0.0%	Apples	0.0%	Carrots		0.0%
	0.0%	IE adult	0.01	0.0%	Broccoli	0.0%	Cauliflowers	0.0%	Apples		0.0%
	0.0%	SE general	0.01	0.0%	Head cabbages	0.0%	Apples	0.0%	Carrots		0.0%
	0.0%	PL general	0.01	0.0%	Apples	0.0%	Cauliflowers	0.0%	Head cabbages		0.0%
	0.0%	UK toddler	0.01	0.0%	Apples	0.0%	Cauliflowers	0.0%	Broccoli		0.0%
	0.0%	GEMS/Food G11	0.01	0.0%	Apples	0.0%	Cauliflowers	0.0%	Carrots		0.0%
	0.0%	FR adult	0.01	0.0%	Cauliflowers	0.0%	Apples	0.0%	Rapeseeds/canola seeds		0.0%
	0.0%	LT adult	0.01	0.0%	Apples	0.0%	Head cabbages	0.0%	Carrots		0.0%
	0.0%	UK vegetarian	0.01	0.0%	Cauliflowers	0.0%	Broccoli	0.0%	Apples		0.0%
	0.0%	DK adult	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Cauliflowers		0.0%
	0.0%	ES child	0.00	0.0%	Apples	0.0%	Cauliflowers	0.0%	Pears		0.0%
	0.0%	PT general	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
0.0%	FI adult	0.00	0.0%	Apples	0.0%	Rapeseeds/canola seeds	0.0%	Cauliflowers		0.0%	
0.0%	UK adult	0.00	0.0%	Broccoli	0.0%	Cauliflowers	0.0%	Apples		0.0%	
0.0%	IT toddler	0.00	0.0%	Apples	0.0%	Cauliflowers	0.0%	Pears		0.0%	
0.0%	IT adult	0.00	0.0%	Apples	0.0%	Cauliflowers	0.0%	Pears		0.0%	
0.0%	ES adult	0.00	0.0%	Apples	0.0%	Cauliflowers	0.0%	Pears		0.0%	
0.0%	IE child	0.00	0.0%	Broccoli	0.0%	Apples	0.0%	Cauliflowers		0.0%	
<b>Conclusion:</b> The estimated long-term dietary intake (TMDI/IEDI/IEDI) was below the ADI. The long-term intake of residues of Triazole alanine 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.											


c. Triazole lactic acid

Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
			No of diets exceeding the ADI : ---						Exposure resulting from		
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
average food consumption)	0.01%	NL toddler	0.04	0.0%	Apples	0.0%	Pears	0.0%	Rapeseeds/canola seeds		0.0%
	0.0%	DE child	0.03	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	NL child	0.02	0.0%	Apples	0.0%	Pears	0.0%	Rapeseeds/canola seeds		0.0%
	0.0%	DK child	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	FR toddler 2 3 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK infant	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	DE women 14-50 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	FR infant	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	DE general	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G07	0.01	0.0%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Carrots		0.0%
	0.0%	PL general	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G11	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G08	0.00	0.0%	Apples	0.0%	Rapeseeds/canola seeds	0.0%	Carrots		0.0%
	0.0%	FR child 3 15 yr	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK toddler	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	NL general	0.00	0.0%	Apples	0.0%	Rapeseeds/canola seeds	0.0%	Carrots		0.0%
	0.0%	SE general	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
TMDI/NEDIEDI calculation (based on	0.0%	LT adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	FI 3 yr	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G15	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Rapeseeds/canola seeds		0.0%
	0.0%	PT general	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	RO general	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	DK adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	ES child	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	GEMS/Food G10	0.00	0.0%	Apples	0.0%	Rapeseeds/canola seeds	0.0%	Carrots		0.0%
	0.0%	FI 6 yr	0.00	0.0%	Carrots	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	IE adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	IT toddler	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	ES adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	GEMS/Food G06	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	IT adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	FR adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	FI adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK vegetarian	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	IE child	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
<b>Conclusion:</b> The estimated long-term dietary intake (TMDI/NEDIEDI) was below the ADI. The long-term intake of residues of Triazole lactic acid 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.											

 European Food Safety Authority EFSA PRIMo revision 3.1; 2021/01/06		<b>Triazole lactic acid (TLA)</b>				Input values					
		LOQs (mg/kg) range from: to:				Details - chronic risk assessment		Supplementary results - chronic risk assessment			
		<b>Toxicological reference values</b>				Details - acute risk assessment/children		Details - acute risk assessment/adults			
		ADI (mg/kg bw/day): <b>0.3</b>		ARID (mg/kg bw): <b>0.3</b>							
		Source of ADI:		Source of ARID:							
		Year of evaluation:		Year of evaluation:							
Comments:											
<b>Refined calculation mode</b>											
<b>Chronic risk assessment: JMPR methodology (IEDI/TMDI)</b>											
		No of diets exceeding the ADI :		---							
	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)	commodities not under assessment (in % of ADI)
TMDI/IEDI calculation (based on average food consumption)	0.02%	NL toddler	0.05	0.0%	Apples	0.0%	Rapeseeds/canola seeds	0.0%	Pears		0.0%
	0.0%	DE child	0.03	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	NL child	0.02	0.0%	Apples	0.0%	Rapeseeds/canola seeds	0.0%	Pears		0.0%
	0.0%	GEMS/Food G07	0.01	0.0%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Carrots		0.0%
	0.0%	GEMS/Food G08	0.01	0.0%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Carrots		0.0%
	0.0%	NL general	0.01	0.0%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Carrots		0.0%
	0.0%	FR toddler 2-3 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G15	0.01	0.0%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Head cabbages		0.0%
	0.0%	DK child	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G10	0.01	0.0%	Rapeseeds/canola seeds	0.0%	Apples	0.0%	Head cabbages		0.0%
	0.0%	UK infant	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	DE women 14-50 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Cauliflowers		0.0%
	0.0%	RO general	0.01	0.0%	Head cabbages	0.0%	Apples	0.0%	Carrots		0.0%
	0.0%	FR infant	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Cauliflowers		0.0%
	0.0%	DE general	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Head cabbages		0.0%
	0.0%	PL general	0.01	0.0%	Apples	0.0%	Head cabbages	0.0%	Carrots		0.0%
	0.0%	SE general	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Head cabbages		0.0%
	0.0%	FI 3 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Rapeseeds/canola seeds		0.0%
	0.0%	FR child 3-15 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G11	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK toddler	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	LT adult	0.01	0.0%	Apples	0.0%	Head cabbages	0.0%	Carrots		0.0%
	0.0%	PT general	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	FI 6 yr	0.00	0.0%	Carrots	0.0%	Apples	0.0%	Rapeseeds/canola seeds		0.0%
	0.0%	IE adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	DK adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	ES child	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	GEMS/Food G06	0.00	0.0%	Apples	0.0%	Rapeseeds/canola seeds	0.0%	Head cabbages		0.0%
	0.0%	IT toddler	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	FR adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
0.0%	ES adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%	
0.0%	IT adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%	
0.0%	UK vegetarian	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Cauliflowers		0.0%	
0.0%	FI adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Head cabbages		0.0%	
0.0%	UK adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Broccoli		0.0%	
0.0%	IE child	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Broccoli		0.0%	
<b>Conclusion:</b> The estimated long-term dietary intake (TMDI/IEDI/IEDI) was below the ADI. The long-term intake of residues of 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.											

**d. Triazole acetic acid**


Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
			No of diets exceeding the ADI : ---						Exposure resulting from		
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
average food consumption)	0.003%	NL toddler	0.03	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	DE child	0.03	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	NL child	0.01	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	DK child	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	FR toddler 2 3 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK infant	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	DE women 14-50 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	FR infant	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	DE general	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	PL general	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G11	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	FR child 3 15 yr	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK toddler	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	SE general	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	LT adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	PT general	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	RQ general	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.0%	FI 3 yr	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	NL general	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G08	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	DK adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	ES child	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	GEMS/Food G15	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G07	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	IE adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	IT toddler	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	FI 6 yr	0.00	0.0%	Carrots	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	ES adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	GEMS/Food G10	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	IT adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	GEMS/Food G06	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	FR adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	FI adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK vegetarian	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	IE child	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
<b>Conclusion:</b> The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Triazole acetic acid 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.											

 European Food Safety Authority EFSA PRIMo revision 3.1; 2021/01/06		<b>Triazole acetic acid (TAA)</b>				Input values					
		LOQs (mg/kg) range from:		to:		Toxicological reference values		Details - chronic risk assessment Supplementary results - chronic risk assessment			
		ADI (mg/kg bw/day): 1		ARID (mg/kg bw): 1		Details - acute risk assessment/children Details - acute risk assessment/adults					
Source of ADI:		Source of ARID:									
Year of evaluation:		Year of evaluation:									
Comments:											
<b>Refined calculation mode</b>											
<b>Chronic risk assessment: JMPR methodology (IEDI/TMDI)</b>											
				No of diets exceeding the ADI :		---				Exposure resulting from	
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI calculation (based on average food consumption)	0.004%	NL toddler	0.04	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	DE child	0.03	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	NL child	0.02	0.0%	Apples	0.0%	Pears	0.0%	Rapeseeds/canola seeds		0.0%
	0.0%	FR toddler 2-3 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	DK child	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK infant	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	RO general	0.01	0.0%	Head cabbages	0.0%	Apples	0.0%	Carrots		0.0%
	0.0%	FR infant	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Cauliflowers		0.0%
	0.0%	DE women 14-50 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Cauliflowers		0.0%
	0.0%	DE general	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Head cabbages		0.0%
	0.0%	PL general	0.01	0.0%	Apples	0.0%	Head cabbages	0.0%	Carrots		0.0%
	0.0%	SE general	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Head cabbages		0.0%
	0.0%	GEMS/Food G15	0.01	0.0%	Apples	0.0%	Head cabbages	0.0%	Carrots		0.0%
	0.0%	FR child 3-15 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G08	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Head cabbages		0.0%
	0.0%	GEMS/Food G11	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK toddler	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	LT adult	0.01	0.0%	Apples	0.0%	Head cabbages	0.0%	Carrots		0.0%
	0.0%	NL general	0.01	0.0%	Apples	0.0%	Rapeseeds/canola seeds	0.0%	Carrots		0.0%
	0.0%	GEMS/Food G07	0.00	0.0%	Apples	0.0%	Rapeseeds/canola seeds	0.0%	Carrots		0.0%
	0.0%	FI 3 yr	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	PT general	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	IE adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	DK adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G10	0.00	0.0%	Apples	0.0%	Head cabbages	0.0%	Carrots		0.0%
	0.0%	ES child	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	FI 6 yr	0.00	0.0%	Carrots	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	IT toddler	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	GEMS/Food G06	0.00	0.0%	Apples	0.0%	Head cabbages	0.0%	Carrots		0.0%
	0.0%	ES adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
0.0%	FR adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%	
0.0%	IT adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%	
0.0%	UK vegetarian	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Cauliflowers		0.0%	
0.0%	FI adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Head cabbages		0.0%	
0.0%	UK adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Broccoli		0.0%	
0.0%	IE child	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Broccoli		0.0%	
<b>Conclusion:</b> 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.											

e. 1,2,4-Triazole

Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
			No of diets exceeding the ADI : ---						Exposure resulting from		
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDIEDI calculation (based on average food consumption)	0.1%	NL toddler	0.03	0.1%	Apples	0.0%	Pears	0.0%	Carrots		0.1%
	0.1%	DE child	0.03	0.1%	Apples	0.0%	Carrots	0.0%	Pears		0.1%
	0.1%	NL child	0.02	0.1%	Apples	0.0%	Pears	0.0%	Rapeseeds/canola seeds		0.1%
	0.0%	DK child	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	FR toddler 2 3 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK infant	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	DE women 14-50 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	FR infant	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	DE general	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	PL general	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G11	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	FR child 3 15 yr	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK toddler	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	SE general	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	LT adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G07	0.00	0.0%	Apples	0.0%	Rapeseeds/canola seeds	0.0%	Carrots		0.0%
	0.0%	GEMS/Food G08	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Rapeseeds/canola seeds		0.0%
TMDI/NEDIEDI calculation (based on average food consumption)	0.0%	NL general	0.00	0.0%	Apples	0.0%	Rapeseeds/canola seeds	0.0%	Carrots		0.0%
	0.0%	PT general	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	FI 3 yr	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	RO general	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G15	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Rapeseeds/canola seeds		0.0%
	0.0%	DK adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	ES child	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	IE adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	GEMS/Food G10	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Rapeseeds/canola seeds		0.0%
	0.0%	FI 6 yr	0.00	0.0%	Carrots	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	IT toddler	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	ES adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	IT adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	GEMS/Food G06	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	FR adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	FI adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK vegetarian	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	IE child	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
<b>Conclusion:</b> The estimated long-term dietary intake (TMDI/NEDIEDI) was below the ADI. The long-term intake of residues of 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.											



 European Food Safety Authority EFSA PRIMo revision 3.1; 2021/01/06		<b>1,2,4-triazole (1,2,4-T)</b>				Input values					
		LOQs (mg/kg) range from: to:				Details - chronic risk assessment		Supplementary results - chronic risk assessment			
		Toxicological reference values									
		ADI (mg/kg bw/day): 0.023		ARID (mg/kg bw): 0.1		Details - acute risk assessment/children		Details - acute risk assessment/adults			
Source of ADI:		Source of ARID:									
Year of evaluation:		Year of evaluation:									
Comments:											
Refined calculation mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
				No of diets exceeding the ADI :		---				Exposure resulting from	
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/IEDI calculation (based on average food consumption)	0.16%	NL toddler	0.04	0.1%	Apples	0.0%	Pears	0.0%	Carrots		0.2%
	0.1%	DE child	0.03	0.1%	Apples	0.0%	Carrots	0.0%	Pears		0.1%
	0.1%	NL child	0.02	0.1%	Apples	0.0%	Pears	0.0%	Rapeseeds/canola seeds		0.1%
	0.0%	FR toddler 2-3 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	DK child	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK infant	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	RO general	0.01	0.0%	Head cabbages	0.0%	Apples	0.0%	Carrots		0.0%
	0.0%	FR infant	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Cauliflowers		0.0%
	0.0%	DE women 14-50 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Cauliflowers		0.0%
	0.0%	DE general	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Head cabbages		0.0%
	0.0%	PL general	0.01	0.0%	Apples	0.0%	Head cabbages	0.0%	Carrots		0.0%
	0.0%	SE general	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Head cabbages		0.0%
	0.0%	GEMS/Food G15	0.01	0.0%	Apples	0.0%	Head cabbages	0.0%	Carrots		0.0%
	0.0%	FR child 3-15 yr	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G08	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Head cabbages		0.0%
	0.0%	GEMS/Food G11	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	UK toddler	0.01	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	LT adult	0.01	0.0%	Apples	0.0%	Head cabbages	0.0%	Carrots		0.0%
	0.0%	NL general	0.01	0.0%	Apples	0.0%	Rapeseeds/canola seeds	0.0%	Carrots		0.0%
	0.0%	GEMS/Food G07	0.00	0.0%	Apples	0.0%	Rapeseeds/canola seeds	0.0%	Carrots		0.0%
	0.0%	FI 3 yr	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	PT general	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	IE adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	DK adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%
	0.0%	GEMS/Food G10	0.00	0.0%	Apples	0.0%	Head cabbages	0.0%	Carrots		0.0%
	0.0%	ES child	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	FI 6 yr	0.00	0.0%	Carrots	0.0%	Apples	0.0%	Pears		0.0%
	0.0%	IT toddler	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
	0.0%	GEMS/Food G06	0.00	0.0%	Apples	0.0%	Head cabbages	0.0%	Carrots		0.0%
	0.0%	ES adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%
0.0%	FR adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Pears		0.0%	
0.0%	IT adult	0.00	0.0%	Apples	0.0%	Pears	0.0%	Carrots		0.0%	
0.0%	UK vegetarian	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Cauliflowers		0.0%	
0.0%	FI adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Head cabbages		0.0%	
0.0%	UK adult	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Broccoli		0.0%	
0.0%	IE child	0.00	0.0%	Apples	0.0%	Carrots	0.0%	Broccoli		0.0%	
<b>Conclusion:</b> The estimated long-term dietary intake (TMDI/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.											



### A 3.3 IESTI calculations - Raw commodities

#### a. Difenoconazole

Unprocessed commodities	Results for children				Results for adults				IESTI new Results for children				IESTI new Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI new):				No. of commodities for which ARfD/ADI is exceeded (IESTI new):			
	---				---				---				---			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	15%	Peaches	0,5 / 0,26	25	5%	Head cabbages	0,3 / 0,19	8,0	82%	Table grapes	3 / 3	131	44%	Wine grapes	3 / 3	71
	15%	Sweet peppers/bell	0,9 / 0,4	24	4%	Sweet peppers/bell	0,9 / 0,4	6,5	38%	Tomatoes	2 / 2	61	38%	Table grapes	3 / 3	61
	9%	Pears	0,8 / 0,11	15	3%	Aubergines/egg plants	0,6 / 0,19	5,1	31%	Apples	0,8 / 0,8	49	24%	Tomatoes	2 / 2	39
	9%	Carrots	0,4 / 0,22	14	3%	Cucumbers	0,3 / 0,18	5,0	30%	Pears	0,8 / 0,8	47	18%	Pears	0,8 / 0,8	29
	7%	Cucumbers	0,3 / 0,18	12	3%	Peaches	0,5 / 0,26	4,9	17%	Wine grapes	3 / 3	28	15%	Apples	0,8 / 0,8	24
	7%	Apples	0,8 / 0,11	11	3%	Carrots	0,4 / 0,22	4,3	17%	Peaches	0,5 / 0,5	27	12%	Broccoli	1 / 1	19
	7%	Tomatoes	2 / 0,19	11	3%	Courgettes	0,3 / 0,18	4,2	16%	Broccoli	1 / 1	25	7%	Aubergines/egg plants	0,6 / 0,6	12
	5%	Head cabbages	0,3 / 0,19	8,4	2%	Pears	0,8 / 0,11	3,2	14%	Sweet peppers/bell	0,9 / 0,9	23	6%	Peaches	0,5 / 0,5	10
	5%	Courgettes	0,3 / 0,18	8,4	2%	Tomatoes	2 / 0,19	3,0	7%	Cucumbers	0,3 / 0,3	12	5%	Head cabbages	0,3 / 0,3	7,6
	4%	Cauliflowers	0,2 / 0,1	5,8	2%	Apples	0,8 / 0,11	3,0	7%	Carrots	0,4 / 0,4	11	4%	Sweet peppers/bell peppers	0,9 / 0,9	6,3
	3%	Table grapes	3 / 0,07	5,1	1%	Broccoli	1 / 0,1	2,4	6%	Aubergines/egg plants	0,6 / 0,6	9,0	3%	Cucumbers	0,3 / 0,3	5,0
	3%	Aubergines/egg plants	0,6 / 0,19	4,8	1%	Table grapes	3 / 0,07	2,4	5%	Head cabbages	0,3 / 0,3	8,0	3%	Carrots	0,4 / 0,4	4,7
	3%	Broccoli	1 / 0,1	4,2	1%	Cauliflowers	0,2 / 0,1	2,3	4%	Cauliflowers	0,2 / 0,2	7,0	2%	Courgettes	0,3 / 0,3	3,6
	1,0%	Potatoes	0,1 / 0,01	1,5	1%	Wine grapes	3 / 0,07	1,7	4%	Potatoes	0,1 / 0,1	6,6	2%	Potatoes	0,1 / 0,1	3,1
	0,4%	Wine grapes	3 / 0,07	0,65	0,7%	Gherkins	0,3 / 0,18	1,1	4%	Courgettes	0,3 / 0,3	6,0	2%	Cauliflowers	0,2 / 0,2	2,8
	Expand/collapse list															
	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)							

<b>Results for children</b> No. of commodities for which ARfD/ADI is exceeded (IESTI):				---	<b>Results for adults</b> No. of commodities for which ARfD/ADI is exceeded (IESTI):				---
<b>IESTI</b>					<b>IESTI</b>				
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)		Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	
10%	Pears	0.8 / 0.11	15		2%	Pears	0.8 / 0.11	3.4	
7%	Apples	0.8 / 0.11	12		2%	Broccoli	1 / 0.13	3.1	
5%	Carrots	0.4 / 0.12	7.6		2%	Apples	0.8 / 0.11	3.1	
5%	Cauliflowers	0.2 / 0.13	7.5		2%	Cauliflowers	0.2 / 0.13	3.0	
3%	Broccoli	1 / 0.13	5.4		2%	Head cabbages	0.3 / 0.07	2.9	
2%	Head cabbages	0.3 / 0.07	3.1		1%	Carrots	0.4 / 0.12	2.4	
0.01%	Rapeseeds/canola seeds	0.5 / 0.01	0.01		0.00%	Rapeseeds/canola seeds	0.5 / 0.01	0.01	
Expand/collapse list									
<b>Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)</b>									

**b. Triazole alanine**

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				IESTI				IESTI new				IESTI new			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	5%	Carrots	0 / 0.24	15	2%	Carrots	0 / 0.24	4.7								
	3%	Pears	0 / 0.06	8.9	0.7%	Pears	0 / 0.06	2.0								
	2%	Apples	0 / 0.06	6.9	0.6%	Apples	0 / 0.06	1.8								
	0.05%	Rapeseeds/canola	0 / 0.11	0.16	0.02%	Rapeseeds/canola seeds	0 / 0.11	0.06								
Expand/collapse list																
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)							

Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	2%	Head cabbages	0 / 0.13	5.6	2%	Head cabbages	0 / 0.13	5.3
	1%	Pears	0 / 0.03	4.2	0.3%	Broccoli	0 / 0.04	1.0
	1%	Apples	0 / 0.03	3.2	0.3%	Cauliflowers	0 / 0.04	1.00
	0.8%	Cauliflowers	0 / 0.04	2.5	0.3%	Pears	0 / 0.03	0.92
	0.6%	Broccoli	0 / 0.04	1.8	0.3%	Apples	0 / 0.03	0.84
	0.2%	Carrots	0 / 0.01	0.63	0.07%	Carrots	0 / 0.01	0.20
	0.10%	Rapeseeds/canola seeds	0 / 0.21	0.29	0.04%	Rapeseeds/canola seeds	0 / 0.21	0.11
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								

c. Triazole lactic acid

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				IESTI				IESTI new				IESTI new			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	1%	Pears	0.8 / 0.02	3.0	0.2%	Pears	0.8 / 0.02	0.67	16%	Apples	0.8 / 0.8	49	10%	Pears	0.8 / 0.8	29
	0.8%	Apples	0.8 / 0.02	2.4	0.2%	Apples	0.8 / 0.02	0.62	16%	Pears	0.8 / 0.8	47	8%	Apples	0.8 / 0.8	24
	0.2%	Carrots	0.4 / 0.01	0.57	0.06%	Carrots	0.4 / 0.01	0.18	4%	Carrots	0.4 / 0.4	11	2%	Carrots	0.4 / 0.4	4.7
	0.00%	Rapeseeds/canola	0.5 / 0	0.01	0.00%	Rapeseeds/canola seeds	0.5 / 0	0.00	0.2%	Rapeseeds/canola	0.5 / 0.5	0.69	0.09%	Rapeseeds/canola seeds	0.5 / 0.5	0.26
Expand/collapse list																
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)							

Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	0.5%	Pears	0 / 0.01	1.4	0.1%	Pears	0 / 0.01	0.31
	0.4%	Apples	0 / 0.01	1.1	0.09%	Apples	0 / 0.01	0.28
	0.2%	Carrots	0 / 0.01	0.63	0.07%	Carrots	0 / 0.01	0.20
	0.04%	Head cabbages	0 / 0	0.13	0.04%	Head cabbages	0 / 0	0.13
	0.04%	Cauliflowers	0 / 0	0.12	0.02%	Broccoli	0 / 0	0.05
	0.03%	Broccoli	0 / 0	0.08	0.02%	Cauliflowers	0 / 0	0.05
	0.01%	Rapeseeds/canola seeds	0 / 0.02	0.03	0.00%	Rapeseeds/canola seeds	0 / 0.02	0.01
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								

**d. Triazole acetic acid**

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				IESTI				IESTI new				IESTI new			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	0.1%	Pears	0.8 / 0.01	1.1	0.02%	Pears	0.8 / 0.01	0.24	5%	Apples	0.8 / 0.8	49	3%	Pears	0.8 / 0.8	29
	0.09%	Apples	0.8 / 0.01	0.86	0.02%	Apples	0.8 / 0.01	0.22	5%	Pears	0.8 / 0.8	47	2%	Apples	0.8 / 0.8	24
	0.03%	Carrots	0.4 / 0	0.25	0.01%	Carrots	0.4 / 0	0.08	1%	Carrots	0.4 / 0.4	11	0.5%	Carrots	0.4 / 0.4	4.7
Expand/collapse list																
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)							

Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	0.1%	Pears	0 / 0.01	1.4	0.03%	Pears	0 / 0.01	0.31
	0.1%	Apples	0 / 0.01	1.1	0.03%	Apples	0 / 0.01	0.28
	0.06%	Carrots	0 / 0.01	0.63	0.02%	Carrots	0 / 0.01	0.20
	0.02%	Cauliflowers	0 / 0	0.23	0.01%	Broccoli	0 / 0	0.10
	0.02%	Broccoli	0 / 0	0.17	0.01%	Cauliflowers	0 / 0	0.09
	0.01%	Head cabbages	0 / 0	0.09	0.01%	Head cabbages	0 / 0	0.08
	0.00%	Rapeseeds/canola seeds	0 / 0	0.00	0.00%	Rapeseeds/canola seeds	0 / 0	0.00
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								

e. 1,2,4-Triazole

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				IESTI				IESTI new				IESTI new			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	3%	Pears	0 / 0	0.28	0.6%	Pears	0 / 0	0.06								
	2%	Apples	0 / 0	0.22	0.6%	Apples	0 / 0	0.06								
	1%	Carrots	0 / 0	0.13	0.4%	Carrots	0 / 0	0.04								
	0.03%	Rapeseeds/canola	0 / 0	0.00	0.01%	Rapeseeds/canola seeds	0 / 0	0.00								
Expand/collapse list																
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)							

Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	0.5%	Cauliflowers	0 / 0.01	0.52	0.2%	Broccoli	0 / 0.01	0.21
	0.4%	Broccoli	0 / 0.01	0.37	0.2%	Cauliflowers	0 / 0.01	0.21
	0.3%	Pears	0 / 0	0.28	0.08%	Head cabbages	0 / 0	0.08
	0.2%	Apples	0 / 0	0.22	0.06%	Pears	0 / 0	0.06
	0.1%	Carrots	0 / 0	0.13	0.06%	Apples	0 / 0	0.06
	0.09%	Head cabbages	0 / 0	0.09	0.04%	Carrots	0 / 0	0.04
	0.00%	Rapeseeds/canola seeds	0 / 0	0.00	0.00%	Rapeseeds/canola seeds	0 / 0	0.00
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								

### A 3.4 IESTI calculations - Processed commodities

#### a. Difenconazole

Processed commodities	Results for children				Results for adults				Results for children				Results for adults			
	No of processed commodities for which ARID/ADI is exceeded (IESTI):				No of processed commodities for which ARID/ADI is exceeded (IESTI):				No of processed commodities for which ARID/ADI is exceeded (IESTI new):				No of processed commodities for which ARID/ADI is exceeded (IESTI new):			
	---				---				---				---			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL /input for RA (mg/kg)	Exposure (µg/kg bw)
	5%	Broccoli / boiled	1 / 0,1	7,9	3%	Cauliflowers / boiled	0,2 / 0,1	4,2	82%	Wine grapes / juice	3 / 3	131	39%	Wine grapes / juice	3 / 3	62
	4%	Cauliflowers / boiled	0,2 / 0,1	7,0	3%	Courgettes / boiled	0,3 / 0,18	4,1	30%	Broccoli / boiled	1 / 1	47	18%	Wine grapes / wine	3 / 3	28
	4%	Peaches / canned	0,5 / 0,26	6,8	2%	Broccoli / boiled	1 / 0,1	2,4	27%	Apples / juice	0,8 / 0,8	43	17%	Apples / juice	0,8 / 0,8	27
	4%	Courgettes / boiled	0,3 / 0,18	6,4	1%	Peaches / canned	0,5 / 0,26	2,1	24%	Tomatoes / juice	2 / 2	38	13%	Broccoli / boiled	1 / 1	20
	3%	Gherkins / pickled	0,3 / 0,18	4,1	0,7%	Apples / juice	0,8 / 0,03	1,1	16%	Pears / juice	0,8 / 0,8	26	11%	Table grapes / raisins	3 / 14,1	17
	2%	Peaches / juice	0,5 / 0,15	2,5	0,4%	Wine grapes / wine	3 / 0,07	0,66	12%	Tomatoes / sauce/puree	2 / 2	19	10%	Tomatoes / sauce/puree	2 / 2	16
	2%	Carrots / juice	0,4 / 0,07	2,4	0,4%	Okra, lady's fingers /	0,6 / 0,4	0,65	9%	Carrots / juice	0,4 / 0,4	14	3%	Cauliflowers / boiled	0,2 / 0,2	5,0
	1%	Apples / juice	0,8 / 0,03	1,7	0,4%	Wine grapes / juice	3 / 0,03	0,62	6%	Peaches / canned	0,5 / 0,5	9,7	3%	Courgettes / boiled	0,3 / 0,3	4,8
	0,8%	Wine grapes / juice	3 / 0,03	1,3	0,3%	Carrots / canned	0,4 / 0,07	0,55	5%	Cauliflowers / boiled	0,2 / 0,2	8,4	3%	Peaches / canned	0,5 / 0,5	4,1
	0,7%	Pears / juice	0,8 / 0,03	1,0	0,3%	Table grapes / raisins	3 / 0,33	0,40	5%	Peaches / juice	0,5 / 0,5	8,3	2%	Carrots / canned	0,4 / 0,4	3,3
	0,6%	Potatoes / fried	0,1 / 0,01	0,93	0,2%	Tomatoes / sauce/puree	2 / 0,05	0,39	4%	Courgettes / boiled	0,3 / 0,3	6,4	2%	Head cabbages / canned	0,3 / 0,3	2,8
	0,6%	Tomatoes / juice	2 / 0,05	0,89	0,1%	Head cabbages / canned	0,3 / 0,02	0,19	4%	Potatoes / dried (flakes)	0,1 / 0,46	5,9	0,6%	Okra, lady's fingers / boiled	0,6 / 0,6	0,97
	0,4%	Potatoes / dried (flakes)	0,1 / 0,05	0,59	0,05%	Potatoes / chips	0,1 / 0,01	0,08	3%	Potatoes / fried	0,1 / 0,1	4,4	0,5%	Potatoes / chips	0,1 / 0,1	0,85
	0,3%	Tomatoes / sauce/puree	2 / 0,05	0,45	0,04%	Potatoes / dried (flakes)	0,1 / 0,05	0,06	2%	Gherkins / pickled	0,3 / 0,3	3,0	0,4%	Potatoes / dried (flakes)	0,1 / 0,46	0,58
	0,1%	Head cabbages / canned	0,3 / 0,02	0,12	#NUM!	#NUM!	#NUM!	#NUM!	1%	Head cabbages / canned	0,3 / 0,3	1,7	#NUM!	#NUM!	#NUM!	#NUM!
Expand/collapse list																
<b>Conclusion:</b> No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Difenconazole (F) is unlikely to present a public health risk. For processed commodities, no exceedance of the ARID/ADI was identified.																

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	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)
	6%	Broccoli / boiled	1 / 0.13	10	3%	Cauliflowers / boiled	0.2 / 0.13	5.4
	6%	Cauliflowers / boiled	0.2 / 0.13	9.0	2%	Broccoli / boiled	1 / 0.13	3.1
	1%	Apples / juice	0.8 / 0.04	2.2	0.8%	Apples / juice	0.8 / 0.04	1.3
	1%	Carrots / juice	0.4 / 0.06	2.2	0.3%	Carrots / canned	0.4 / 0.06	0.49
	0.8%	Pears / juice	0.8 / 0.04	1.3	0.06%	Head cabbages / canned	0.3 / 0.01	0.09
	0.0%	Head cabbages / canned	0.3 / 0.01	0.06	#NUM!	#NUM!	#NUM!	#NUM!
	0.0%	Rapeseeds / oils	0.5 / 0.02	0.01	#NUM!	#NUM!	#NUM!	#NUM!

## b) Triazole alanine

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	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)
	1%	Broccoli / boiled	0 / 0.04	3.4	0.6%	Cauliflowers / boiled	0 / 0.04	1.8
	1.0%	Cauliflowers / boiled	0 / 0.04	3.0	0.3%	Broccoli / boiled	0 / 0.04	1.0
	0.0%	Rapeseeds / oils	0 / 0.42	0.12	0.02%	Apples / juice	0 / 0	0.07
	0.0%	Apples / juice	0 / 0	0.11	0.01%	Head cabbages / canned	0 / 0	0.04
	0.0%	Carrots / juice	0 / 0	0.07	0.01%	Carrots / canned	0 / 0	0.02
	0.0%	Pears / juice	0 / 0	0.07	#NUM!	#NUM!	#NUM!	#NUM!
	0.0%	Head cabbages / canned	0 / 0	0.02	#NUM!	#NUM!	#NUM!	#NUM!
	Expand/collapse list							



**c) Triazole lactic acid**

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	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%	Broccoli / boiled	0 / 0	0.16	0.03%	Cauliflowers / boiled	0 / 0	0.08
	0.0%	Cauliflowers / boiled	0 / 0	0.14	0.02%	Apples / juice	0 / 0	0.07
	0.0%	Apples / juice	0 / 0	0.11	0.02%	Broccoli / boiled	0 / 0	0.05
	0.0%	Carrots / juice	0 / 0	0.07	0.01%	Head cabbages / canned	0 / 0	0.02
	0.0%	Pears / juice	0 / 0	0.07	0.01%	Carrots / canned	0 / 0	0.02
	0.0%	Rapeseeds / oils	0 / 0.04	0.01	#NUM!	#NUM!	#NUM!	#NUM!
	0.0%	Head cabbages / canned	0 / 0	0.01	#NUM!	#NUM!	#NUM!	#NUM!

**d) Triazole acetic acid**

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	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)
	0.03%	Broccoli / boiled	0 / 0	0.32	0.02%	Cauliflowers / boiled	0 / 0	0.17
	0.0%	Cauliflowers / boiled	0 / 0	0.28	0.01%	Broccoli / boiled	0 / 0	0.10
	0.0%	Apples / juice	0 / 0	0.11	0.01%	Apples / juice	0 / 0	0.07
	0.0%	Carrots / juice	0 / 0	0.07	0.00%	Head cabbages / canned	0 / 0	0.02
	0.0%	Pears / juice	0 / 0	0.07	0.00%	Carrots / canned	0 / 0	0.02
	0.0%	Head cabbages / canned	0 / 0	0.01	#NUM!	#NUM!	#NUM!	#NUM!
	0.0%	Rapeseeds / oils	0 / 0	0.00	#NUM!	#NUM!	#NUM!	#NUM!

e) 1,2,4-Triazole

Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
---				---			
IESTI				IESTI			
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%	Broccoli / boiled	0 / 0.01	0.71	0.37%	Cauliflowers / boiled	0 / 0.01	0.37
0.6%	Cauliflowers / boiled	0 / 0.01	0.63	0.2%	Broccoli / boiled	0 / 0.01	0.22
0.1%	Apples / juice	0 / 0	0.11	0.07%	Apples / juice	0 / 0	0.07
0.1%	Carrots / juice	0 / 0	0.07	0.02%	Head cabbages / canned	0 / 0	0.02
0.1%	Pears / juice	0 / 0	0.07	0.02%	Carrots / canned	0 / 0	0.02
0.0%	Head cabbages / canned	0 / 0	0.01	#NUM!	#NUM!	#NUM!	#NUM!
0.0%	Rapeseeds / oils	0 / 0	0.00	#NUM!	#NUM!	#NUM!	#NUM!

## IESTI– difenoconazole (input values corrected by zRMS table 7.2-20)

Acute risk assessment /children					Acute risk assessment / adults / general population				
Details - acute risk assessment /children					Details - acute risk assessment/adults				
<p>The acute risk assessment is based on the ARID. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the EU.</p> <p>The calculation is based on the large portion of the most critical consumer group.</p>									
Show results for all crops									
Unprocessed commodities	Results for children No. of commodities for which ARID/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARID/ADI is exceeded (IESTI):				
	---				---				
	IESTI				IESTI				
	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	
	11%	Broccoli	0 / 0,41	17	6%	Broccoli	0 / 0,41	9,8	
10%	Pears	0 / 0,11	15	5%	Head cabbages	0 / 0,19	8,0		
7%	Apples	0 / 0,11	12	3%	Cauliflowers	0,2 / 0,2	4,6		
7%	Cauliflowers	0,2 / 0,2	12	2%	Pears	0 / 0,11	3,4		
5%	Head cabbages	0 / 0,19	8,4	2%	Apples	0 / 0,11	3,1		
0,01%	Rapeseeds/canola	0 / 0,01	0,01	0,00%	Rapeseeds/canola seeds	0 / 0,01	0,01		
Expand/collapse list									
Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)									
Processed commodities	Results for children No. of processed commodities for which ARID/ADI is exceeded (IESTI):				Results for adults No. of processed commodities for which ARID/ADI is exceeded (IESTI):				
	---				---				
	IESTI				IESTI				
	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	
	20%	Broccoli / boiled	0 / 0,41	32	6%	Broccoli / boiled	0 / 0,41	9,9	
9%	Cauliflowers / boiled	0,2 / 0,2	14	5%	Cauliflowers / boiled	0,2 / 0,2	8,3		
1%	Apples / juice	0 / 0,04	2,2	0,8%	Apples / juice	0 / 0,04	1,3		
0,8%	Pears / juice	0 / 0,04	1,3	0,1%	Head cabbages / canned	0 / 0,02	0,19		
0,1%	Head cabbages / canned	0 / 0,02	0,12						
Expand/collapse list									
<p><b>Conclusion:</b></p> <p>No exceedance of the toxicological reference value was identified for any unprocessed commodity.</p> <p>A short term intake of residues of Difenoconazole is unlikely to present a public health risk.</p> <p>For processed commodities, no exceedance of the ARID/ADI was identified.</p>									

b.

## Triazole alanine

[illegible]

### c. Triazole lactic acid

[illegible]

#### d. Triazole acetic acid

[illegible]

e. **1,2,4-Triazole**

[illegible]

## **Appendix 4    Additional information provided by the applicant**

No additional information submitted.