FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SHA 7216 A

Product name: CIAZ

Chemical active substances:

Boscalid, 233 g/L

Difenoconazole, 66 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

Submission date: August 2021

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MS Finalisation date: 03/2022; 12/2022

Version history

When	What
December 2021	Applicant update
February 2022	Applicant update
February 2022	Applicant update
March 2022	Assessment
December 2022	Updated assessment after commenting period

Table of Contents

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Storage stability

Boscalid

Storage stability of Boscalid was demonstrated for a period of 16 months at -18 °C in commodities with high acid content (grape) and 24 months at -18 °C in commodities with high water content (cabbage, peach, pea), high oil content (rape seed), dry commodities (wheat grain) and cereal straw. Degradation of residues during storage of the trial samples is therefore not expected.

Storage stability of Boscalid and M510F01 in milk, muscle, fat, liver and kidney ~~and egg~~ for up to 5 months was demonstrated, when stored deep frozen. Boscalid and M510F01 residue storage stability in poultry eggs was found to be 9 months. No additional studies are required.

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 TDMs are presented in EFSA Journal 2018;16(7):5376. Residues are stable in wheat and barley grain for 12 month - 1,2,4-Triazole, for 26 month – TA, for 26 month – TAA and for 48 month – TLA.

Residues are stable in cereal straw for 12 month - 1,2,4-Triazole, for 53 month – TA, for 40 month – TAA and there is no data for TLA.

Metabolism in plants and animals

Boscalid

Metabolism of boscalid was investigated for foliar treatment on fruits and fruiting vegetables (grapes), on pulses and oilseeds (beans) and on leafy vegetables (lettuce), using U-^{14}C-diphenyl and 3-^{14}C-pyridine labelled boscalid.

Plant residue definition for monitoring and risk assessment: boscalid

Animal residue definition for monitoring: Boscalid in muscle, fat milk and eggs; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney

Animal residue definition for risk assessment:

Boscalid in muscle, fat milk and eggs;

Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney;

Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates and the bound residues (measured as M510F52 or M510F53) expressed as Boscalid in Liver (ruminant and pig);

(EFSA 2014)

Difenoconazole

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

Boscalid

Proposed GAP:

Winter wheat, BBCH 30-59, 2 applications, 0.35 kg a.s/ha, PHI – not required.

Sufficient new trials according to the proposed GAP on wheat are available to support the proposed uses. The residue data are valid with regard to storage stability data. The residues arising from the proposed uses will not exceed the MRLs established for wheat (0.8 mg/kg, Reg. (EU) 2021/590).

50 days is proposed as PHI (according to the new trials).

Difenoconazole

Proposed GAP:

Winter wheat, BBCH 30-59, 2 applications, 0.10 kg a.s/ha, PHI – not required.

Sufficient new trials on wheat are available to support the proposed uses. The residue data are valid with regard to storage stability data. Trials GAP: BBCH 61-75; 2 applications, 0.100 kg a.s/ha.

The residues arising from the proposed uses will not exceed the MRLs for Difenoconazole established for cereals (0.1 mg/kg; Reg. (EU) 2019/552).

50 days is proposed as PHI (see boscalid).

TMDs

Trials GAP (new studies): 2x 0.1 kg Difenoconazole/ha, Interval= 14 days, last application: BBCH 69-75; PHI= 42, 43, outdoor.

GAP (EU unprotected data): GAP: 1 x 0.125 kg Difenoconazole/ha, BBCH 69, PHI 39-64 d

~~EU data is not in line with proposed GAP. Unprotected EU residue trials are considered for informational purposes only.~~

The sufficient data submitted for residues TMDs in wheat are available and presented in EFSA Journal 2018;16(7):5376. Proposed GAP is within acceptable range with respect to trials GAP (±25%).

NEW trials:

Residues:

TA

Grain (new studies): 5 x n.d. (<0.003), 0.089, 0.14 mg/kg

Straw (new studies): 7 x n.d. (<0.003) mg/kg

TLA

Grain (new studies): 7 x n.d. (<0.003) mg/kg

Straw (new studies): 7 x n.d. (<0.003) mg/kg

TAA

Grain (new studies): 5 x n.d. (<0.003), <0.01 (<LOQ), 0.013 mg/kg

Straw (new studies): 7 x n.d. (<0.003) mg/kg

1,2,4-T

Grain (new studies): 0.24, 0.13, 0.11, 0.11, 0.09, 0.57, 0.098 mg/kg

Straw (new studies): 8 x n.d. (<0.003) mg/kg

Study Paszek G., 2019

The samples were analyses in November 2019. Therefore, two trials conducted in Germany (2016) could not be accepted due to lack of stability data over time from sampling to analysis. The available storage stability data does not cover that time.

Time from sampling to analysis of 1,2,4-T is more than 12 months in all other trials. The applicant should provide data to document 1,2,4-T stability in the test samples.

Study Romero S., Niewelt S., 2019

Time from sampling to analysis of 1,2,4-T is more than 12 months. The applicant should provide data to document the stability of the 1,2,4-T in the test samples.

Magnitude of residues in livestock

Boscalid

The Applicant refers to data of active ingredient since, the data protection was expired.

There is no risk for animal MRL to be exceeded (Reg. (EU) 2021/590). Additional studies are no required.

ZRMS remark:
The dietary burden was calculated in the framework of the Article 12 procedure. The intended uses are covered by the uses assessed in EFSA Journal 2014;12(7):3799.
STMR/HR values from the supervised residue trials presented in this submission are lower than were used as input values stated in EFSA Journal 2014;12(7):3799 (presented below).
Wheat grain STMR: 0.12 (EFSA, 2014)
Wheat straw STMR: 33.7 and HR: 52.7 (EFSA, 2014)
No further calculation is needed.
Nevertheless, the evaluator has been performed the calculations using the currently valid calculator (animal model 2017) for the proposed uses only.

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Boscalid				
Wheat grain	0.01	Median residue	0.01	Median residue
Wheat Straw	1.5	Median residue	5.08	Highest residue

Results:

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,014	0,045	0,37	1,18	Dairy cattle	Wheat	straw	Yes
Cattle (dairy only)	0,014	0,045	0,37	1,18	Dairy cattle	Wheat	straw	Yes
Sheep (all diets)	0,031	0,100	0,72	2,35	Lamb	Wheat	straw	Yes
Sheep (ewe only)	0,024	0,078	0,72	2,34	Ram/Ewe	Wheat	straw	Yes
Swine (all diets)	0,001	0,001	0,05	0,05	Swine (finishing)	Wheat	milled bypdts	No
Poultry (all diets)	0,013	0,041	0,19	0,60	Poultry layer	Wheat	straw	Yes
Poultry (layer only)	0,013	0,041	0,19	0,60	Poultry layer	Wheat	straw	Yes

There is no risk for animal MRL to be exceeded.

Difenoconazole

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

Calculation using the input data from the EFSA Journal 2021 19 (2): 64 as input; except for wheat were done (see rev. B7, point 7.3.4.1).

Input data for wheat (residue trials):

Grain

STMR – 0.02

Straw

STMR – 0.75

HR – 2.14

TMDs

Applicant refers to unprotected EU data.

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

Boscalid, Difenoconazole

No new studies for determination of residues in processed commodities have been performed. The Applicant refers to data of active ingredients since, the data protection was expired. Further processing studies are not required as they are not expected to affect the outcome of the risk assessment.

TDMs

Applicant refers to Addendum – Confirmatory Data, UK, 2018.

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

Magnitude of residues in representative succeeding crops

Boscalid

Taking relatively low application rate of boscalid into account it can be concluded that specific plant-back restrictions related to the use of Boscalid 23.3% + Difenoconazole 6.6% SC are not required, provided that the product is used according to GAP. Exceedance of the MRLs set based on rotational crops residue studies is unlikely. Waiting periods before planting following succeeding crops: not required.

Difenoconazole

Waiting periods before planting following succeeding crops: not required.

TMDs:

Applicant refers to 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.

Consumer risk assessment

The proposed uses of CIAZ do not represent unacceptable chronic risks for the consumer.

TMDs:

Results from Sharda field trials were not used in the risk assessment calculations and can be considered as additional.

Applicant's statement: *Time between sampling and extraction varies from 28 to 39 months. Such long period has been a result of hard-to-reach situation with TDMs standards on the market at the time of performing study. Therefore applicant wants to refer to Confirmatory Data on Triazole Derivative Metabolites and its addendum (February 2018) already evaluated and accepted at EU level.*

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 Boscalid 23.3% + Difenoconazole 6.6% SC are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central zone of for winter wheat. A list of all intended uses within the Central zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.1 mg/kg for Difenoconazole and 0,8 mg/kg for Boscalid as laid down in Reg. (EU) 2019/552 and Reg. (EU) 2016/156 respectively, is not expected.
The chronic and the short-term intakes of Difenoconazole and Boscalid residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, Poland agrees with the authorization of the intended use(s).

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).
TMDs (post registration requirement): The applicant should provide data to document the stability of the TMDs in the test samples obtained from the new trials conducted in Germany and in Poland.

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0) *	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as a) Boscalid b) difenocona-zole**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha a) per app b) per crop/season**		
1	**Winter wheat**	CEU	Boscalid 23.3% + Dif-enoconazole 6.6% SC	F	*Septoria spp.*	SC	a) 233 g/L b) 66 g/L	Foliar spray	BBCH 30-59	2	14	-	200-400	a) 0.35 boscalid + ~~0.01~~ 0.10 difenoconazole b) 0.7 boscalid + ~~0.02~~ 0.20 difenoconazole	50	A
2	**Winter wheat**	CEU	Boscalid 23.3% + Dif-enoconazole 6.6% SC	F	*Puccinia spp.*	SC	a) 233 g/L b) 66 g/L	Foliar spray	BBCH 30-59	2	14	-	200-400	a) 0.35 boscalid + ~~0.01~~ 0.10 difenoconazole b) 0.7 boscalid + ~~0.02~~ 0.20 difenoconazole	50	A
3	**Winter wheat**	CEU	Boscalid 23.3% + Dif-enoconazole 6.6% SC	F	*Fusarium spp.*	SC	a) 233 g/L b) 66 g/L	Foliar spray	BBCH 39-59	2	14	-	200-400	a) 0.35 boscalid + ~~0.01~~ 0.10 difenoconazole b) 0.7 boscalid + ~~0.02~~ 0.20 difenoconazole	50	A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005
*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 "Conclusion"

A	Exposure acceptable without risk mitigation measures, safe use

R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation CIAZ is composed of Boscalid and Difenoconazole.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Boscalid					
ADI	EC	2008	0.04 mg/kg bw/d	Rat 2-year oral feed study	100
ARfD	EC	2008	Not allocated.		
Difenoconazole					
ADI	EFSA	2011	0.01 mg/kg bw/d	2-year rat study	100
ARfD	EFSA	2011	0.16 mg/kg bw	Developmental study in rat	1000
1,2,4-triazole					
ADI	EFSA	2018	0.023 mg/kg bw/d	Rat 12-month study	300
ARfD	EFSA	2018	0.1 mg/kg bw	Rabbit developmental study	300
Triazole alanine					
ADI	EFSA	2018	0.3 mg/kg bw/d	Rabbit developmental study	100
ARfD	EFSA	2018	0.3 mg/kg bw	Rabbit developmental study	100
Triazole acetic acid					
ADI	EFSA	2018	1 mg/kg bw/d	Rat 2-generation and rabbit developmental study	100
ARfD	EFSA	2018	1 mg/kg bw/d	Rat 2-generation and rabbit developmental study	100
Triazole lactic acid					
ADI	EFSA	2018	0.3 mg/kg bw/d	Bridging from TA	-
ARfD	EFSA	2018	0.3 mg/kg bw	Bridging from TA	-

7.1.2.1 Summary for Boscalid

Table 7.1-3: Summary for Boscalid

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, 2, 3	**Winter wheat**	~~No~~ Yes	Yes	~~NR~~ 50 days	Yes	~~No~~ Yes	No	NR

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

7.1.2.2 Summary for Difenoconazole

Table 7.1-4: 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, 2, 3	**Winter wheat**	Yes	Yes	~~NR~~ 50 days	Yes	~~No~~ 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

7.1.2.3 Summary for SHA 7216 A

Table 7.1-5: Information on SHA 7216 A (KCA 6.8)

Crop	PHI for SHA 7216 A proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for SHA 7216 A proposed by zRMS	zRMS Comments (if different PHI proposed)
		Boscalid	Difenoconazole		
Winter wheat	NR	NR	NR	50 days	According to the new trials

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

Table 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for SHA 7216 A
Crop group	Led by Boscalid	Led by Difenoconazole	
Cereals	NR	NR	

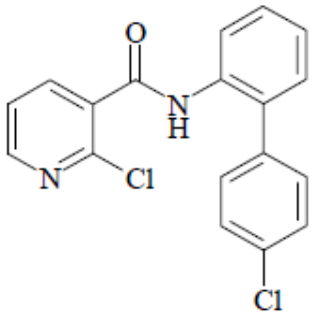
NR: not relevant

Assessment

7.2 Boscalid

General data on Boscalid are summarized in the table below (last updated 2018/11/16)

Table 7.2-1: General information on Boscalid

Active substance (ISO Common Name)	Boscalid
IUPAC	2-Chloro-N-(4'-chlorobiphenyl-2-yl) nicotinamide
Chemical structure	
Molecular formula	$C_{18}H_{12}Cl_2N_2O$
Molar mass	343.21 g/mol
Chemical group	Carboxamide compounds
Mode of action (if available)	It inhibits succinate dehydrogenase enzyme and affects the mitochondrial respiration chain.
Systemic	Yes
Company	BASF AG
Rapporteur Member State (RMS)	Original RMS: Germany RMS: Slovakia Co-RMS: France
Approval status	Approved Date of (01/08/2008) and reference to decision (COMMISSION DIRECTIVE 08/44/EC - REGULATION (EU) No 2018/917) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008L0044&from=EN https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0917&from=EN
Restriction	Only uses as fungicide may be authorised
Review Report	SANCO/3919/2007-rev.5 21/01/2008
Current MRL regulation	~~Reg. (EU) 2016/156~~ Reg. (EU) 2021/590
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal: Conclusion on the peer review	Pending
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	EFSA-Q-2008-500

	All commodities Reasoned opinion available (EFSA Journal 2014;12(7):3799)

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

No new stability studies have been performed. The Applicant refers to data of active ingredient since, the data protection was expired.

Available data

No new data submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Cabbage, peach and pea	High water content	24 months	DAR, 2002 EFSA Journal 2014;12(7):3799
Grape	High acid content	16 months	DAR, 2002 EFSA Journal 2014;12(7):3799
Rape seed	High lipid content	24 months	DAR, 2002 EFSA Journal 2014;12(7):3799
Wheat grain and straw	Dry commodities / high starch content	24 months	DAR, 2002 EFSA Journal 2014;12(7):3799
Animal Products			
Ruminant	Liver	5 months	DAR, 2002 EFSA Journal 2014;12(7):3799
Ruminant	Milk	5 months	DAR, 2002 EFSA Journal 2014;12(7):3799
Ruminant	Muscle	5 months	DAR, 2002 EFSA Journal 2014;12(7):3799
Ruminant	Fat	5 months	DAR, 2002 EFSA Journal 2014;12(7):3799
Ruminant	Kidney	5 months	DAR, 2002 EFSA Journal 2014;12(7):3799

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Poultry	Egg	~~5 months~~ 9 months	DAR, 2002 EFSA Journal 2014;12(7):3799

Conclusion on stability of residues during storage

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:
Storage stability of Boscalid was demonstrated for a period of 16 months at -18 °C in commodities with high acid content (grape) and 24 months at -18 °C in commodities with high water content (cabbage, peach, pea), high oil content (rape seed), dry commodities (wheat grain) and cereal straw. Degradation of residues during storage of the trial samples is therefore not expected. Storage stability of Boscalid and M510F01 in milk, muscle, fat, liver,and kidney ~~and egg~~ for up to 5 months was demonstrated, when stored deep frozen. Boscalid and M510F01 residue storage stability in poultry eggs was found to be 9 months.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No data was submitted and required at EU level during the EU Review of Boscalid

7.2.2 Nature of residues in plants, livestock and processed commodities

No new metabolism studies were performed. The Applicant refers to data of active ingredient since, the data protection was expired.

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Grape	U-^{14}C-diphenyl and 3-^{14}C-pyridine	foliar treatment, F	0.8	3	45	-	DAR, 2002 EFSA Journal 2014;12(7):3799
Leafy vegetables	Lettuce		foliar treatment, G	0.7	3	18	-	DAR, 2002 EFSA Journal 2014;12(7):3799
Pulses and oilseeds	Bean		foliar treatment,	0.5	3	0[(a)], 14[(b)], 53[(c)]	-	DAR, 2002 EFSA Journal

			G					2014;12(7):3799

(a) whole plant
(b) forage, green beans, pods and seeds
(c) bean straw, bean dry pods and dry seeds

Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:
Metabolism of Boscalid was investigated for foliar treatment on fruits and fruiting vegetables (grapes), on pulses and oilseeds (beans) and on leafy vegetables (lettuce), using U-14C-diphenyl and 3-14C-pyridine labelled Boscalid (DAR, 2002).
In grapes, the highest TRR was identified in leaves and stalks (63.4 and 19.6 mg eq/kg respectively), whereas only 2 mg eq/kg was found in grapes (fruits). Unchanged parent Boscalid was the main component of the TRR in all plant parts, ranging from 92.7 % in grape fruits to 96.4 % in stalks. In lettuce, Boscalid was almost not metabolised. The residues in beans (edible part) were much lower compared to the rest of the plant. When separating greens beans into pods and seeds, the major part of radioactivity was found in pods (0.9 mg eq/kg) rather than in seeds (0.2 mg eq/kg). Residue levels were also higher in dry pods (6.1 mg eq/kg) than in dry seeds (0.2 mg eq/kg). Parent Boscalid was identified as the major compound of the TRR in bean leaves and forage (>98 %), in green beans and green pods (97 %), in bean straw (≥94 %), in dry pods (80-95 %) and in dry seeds (72 %). The cleavage products chlorophenylaminobenzene and 2-chloronicotinic acid were also identified in green beans and seeds but only in low concentrations (< 0.01 mg eq/kg). The metabolism studies showed that the metabolic pathway is similar in all crops.

Conclusion on metabolism in primary crops

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:
Consequently, the residue for enforcement and risk assessment in all plant commodities is defined as Boscalid only. Validated analytical methods for enforcement of the proposed residue definition are available, except for hops, spices and herbal infusions. The conclusions reached by EFSA reflect the views of the RMS and are also in line with those of the JMPR (FAO, 2006).

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

No new metabolism studies in rotational crops were performed. The Applicant refers to data of active ingredient since, the data protection was expired.

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	U-^{14}C-diphenyl and	Bare soil, G	2.1	30, 120, 270, 365	Mature crops	-	DAR, 2002 EFSA Journal 2014;12(7):3799
Root and tuber	Radish						-	

vegetables		3-^{14}C-pyridine						
Cereals	Wheat						-	

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

Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:
The metabolism of Boscalid in rotational crops – lettuce, radish, wheat – has been evaluated (DAR, 2002). One confined rotational crop study investigating the nature of residues following different plant-back intervals is available.
The highest TRR values were observed in radish leaves (0.34 mg eq/kg; 30 DAT, pyridine study) and in wheat straw (9.83 mg eq/kg, 30 DAT, diphenyl study and 4.01 mg eq/kg, 120 DAT, pyridine study). The highest TRR in lettuce amounted to 0.16 mg eq/kg (120 DAT, pyridine study), in radish root to 0.098 mg eq/kg (270 DAT, diphenyl study) and 0.066 mg eq/kg (365 DAT, pyridine study) and in wheat grain to 0.285 mg eq/kg (120 DAT, pyridine study) and 0.243 mg eq/kg (120 DAT, diphenyl study).
Except in wheat grain, parent Boscalid was the major component of the TRR in all crops. Levels of the parent compound ranged from 50 % TRR in wheat straw (270 DAT, pyridine label) to 93 % TRR in wheat forage (270 DAT, pyridine label), and in lettuce leaves from 55.6 % TRR (270 DAT, diphenyl label) to 94.1 % TRR (365 DAT, diphenyl label). In wheat grain, the concentration of parent was low (between 1.9 % TRR at 270 DAT with the pyridine label and 16.8 % TRR at 30 DAT with the diphenyl label). Most of the radioactive residues in grain were not extractable (65 to 96 % TRR) and were detected in the starch fraction (36.2 to 48.4 % TRR, 0.06-0.12 mg eq/kg, pyridine label). The metabolite M510F61 (sugar conjugate of hydroxylated Boscalid) was the only metabolite identified at levels exceeding 10 % TRR, in wheat forage (18.1 % TRR, diphenyl label, 270 DAT) and in radish leaves (21.2 % TRR for diphenyl label, 270 DAT and 11.2-15.5 % TRR, 365 DAT).

Conclusion on metabolism in rotational crops

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:
The proposed metabolic pathway in succeeding crops involves hydroxylation and conjugation reactions. A part of the residue was also incorporated into and/or associated with natural products, such as starch, cellulose and lignin. The parent compound is therefore the main substance of concern in rotational crops and no metabolites of concern were identified in soil. Consequently, metabolic patterns in primary and rotational crops are 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)

No new studies in processed commodities were performed. The Applicant refers to data of active ingredient since, the data protection was expired.

Available data

No new data submitted in the framework of this application.

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

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Parent (99.3%)	DAR, 2002 EFSA Journal 2014;12(7):3799
Baking, boiling, brewing	Parent (100.2%)	DAR, 2002

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
(60 minutes, 100°C, pH 5)		EFSA Journal 2014;12(7):3799
Sterilisation (20 minutes, 120°C, pH 6)	Parnt (91.1%)	DAR, 2002 EFSA Journal 2014;12(7):3799

Conclusion on nature of residues in processed commodities

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:
The effect of processing on the nature of Boscalid was investigated in the framework of the peer review. Studies were conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). From these studies, it was concluded that these processing conditions are not expected to have a significant impact on the composition of residues in matrices of plant origin (DAR, 2002). The relevant residue for enforcement and risk assessment in processed commodities is therefore 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

Endpoints	
Plant groups covered	Fruits and fruiting vegetables (grapes) Leafy vegetables (lettuce) Pulses and oilseeds (bean)
Rotational crops covered	Root and tuber vegetables (Radish) Leafy vegetables (Lettuce) Cereals (Wheat)
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	Boscalid (~~Regulation (EU) No. 2016/156~~ Reg. (EU) 2021/590)
Plant residue definition for risk assessment	Boscalid (EFSA Journal 2014;12(7):3799)
Conversion factor from enforcement to RA	None (DAR, 2002; EFSA Journal 2014;12(7):3799)

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

No new metabolism studies in livestock were performed. The Applicant refers to data of active ingredient since, the data protection was expired.

Available data

No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	U-^{14}C-diphenyl	2	1.46 - 1.73	5	Milk	Twice daily	DAR, 2002 EFSA Journal 2014;12(7):3799
						Urine and faeces	Daily	
						Tissues	After sacrifice	
Laying poultry	Hens	U-^{14}C-diphenyl	10	0.80 - 1.14	10	Eggs	Daily	DAR, 2002 EFSA Journal 2014;12(7):3799
						Excreta	Daily	
						Tissues	After sacrifice	

Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

The nature of Boscalid residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (DAR, 2002). Reported metabolism studies include one study in lactating goats and one study in laying hens, both using [U-^{14}C-diphenyl] labelled Boscalid.

Lactating goats were dosed with 1.46 - 1.73 mg/kg bw per day of Boscalid. These dose levels represent at least 0.7 (including uptake of residues from previously treated soil) and 1 (resulting from the primary crop use only) time the maximum dietary burden of meat ruminant.

Boscalid is extensively excreted (89-93 % AR), with a relatively low transfer or residues to tissues (0.4-0.6 % AR in liver, 0.01-0.02 % AR for muscle, fat and kidney) and milk (0.06-0.15 % AR). The highest TRR was found in liver (2.59 mg eq/kg). Other TRR values were 0.27 mg eq/kg in kidney, 0.04 mg eq/kg in milk, 0.036 mg eq/kg in fat and 0.012 mg eq/kg in muscle.

Boscalid was the most abundant compound in fat (0.012 mg eq/kg; 34.6 % TRR) and represented a major part of the residue in muscle (0.002 mg eq/kg; 20.4 % TRR). It was also detected in liver (0.129 mg eq/kg; 5 % TRR), milk (0.001 mg eq/kg; 3.2 % TRR) and kidney (0.007 mg eq/kg; 2.5 % TRR). The metabolite M510F01 was the most abundant compound in muscle (0.003 mg eq/kg; 20.6 % TRR) and represented a major part of the residue in fat (0.009 mg eq/kg; 26.3 % TRR). It was also detected in liver (0.074 mg eq/kg; 2.9 % TRR), milk (0.006 mg eq/kg; 14.9 % TRR) and kidney (0.023 mg eq/kg; 8.6 % TRR). M510F02, the glucuronide conjugate of M510F01, is the most abundant compound in kidney (0.136 mg eq/kg; 50.3 % TRR) and was also detected in muscle (0.001 mg eq/kg; 11.9 % TRR) and milk (0.002 mg eq/kg, 6.4 % TRR).

Non-extractable residues accounted for 85 % TRR (2.2 mg eq/kg) in liver. Further extraction was conducted with either a mixture of acetic acid and acetone or with formic acid. Extraction released either M510F53 (43.6 % TRR; 1.13 mg eq/kg) or M510F52 (35.4 % TRR; 0.92 mg eq/kg), respectively for each solvent. Other compounds were detected but these compounds were demonstrated to be formed from extractable residues only (DAR, 2002).

Laying hens were dosed with 0.80 – 1.14 mg/kg bw per day of Boscalid. These dose levels represent at least 3.5 (including uptake of residues from previously treated soil) and 4.4 (resulting from the primary crop use only) times the maximum dietary burden of poultry.

Boscalid is extensively excreted (97.7 % AR), with a relatively low transfer of residues to tissues (0.04 % AR in liver, 0.003-0.004 % AR for muscle and fat) and eggs (0.12 % AR). The highest TRR was found in liver (0.17 mg eq/kg). Other TRR values were 0.058 mg eq/kg in eggs (with a maximum of 0.08 mg eq/kg),

0.025 mg eq/kg in fat and 0.003 mg eq/kg in muscle. A plateau is reached in eggs at day 6 (0.07 mg eq/kg).

Boscalid is the main compound in fat (0.023 mg eq/kg; 93.3 % TRR) and eggs (0.02 mg eq/kg; 35.5 % TRR). M510F01 was detected in eggs (0.015 mg eq/kg; 26.9 % TRR) and liver (0.009 mg eq/kg; 5.6 % TRR) and its conjugate M510F02 was detected in muscle (0.001 mg eq/kg; 11.9 % TRR) and eggs (0.01 mg eq/kg, 17.3 % TRR). Liver was only analysed using the microwave extraction used in the metabolism study on goats (only with formic acid). The results are similar to those observed in goats, M510F52 being the main compound (0.071 mg eq/kg; 42 % TRR).

The metabolism studies on both ruminant and poultry show that parent compound, its hydroxy metabolite M510F01 and its conjugate are the main components of the residue in animal tissues and products, except in liver where the bound residues (measured as M510F53 and M510F52) were found to be the main components of the residue but the actual identity of those bound residues was not elucidated. The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs.

Conclusion on metabolism in livestock

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:
During the Member States' consultation, it was agreed that conjugates of M510F01 are difficult to analyse routinely and that, based on the findings from metabolism study, Boscalid and M510F01 (free form) are deemed to be sufficient markers in liver and kidney. Nevertheless, as the available livestock feeding studies do not provide separate results for M510F01 and its conjugates, it is not possible to exclude conjugates of M510F01 from the enforcement residue definition in liver and kidney without additional data. Therefore, the relevant residue for enforcement is defined as Boscalid in muscle, fat, milk and eggs and as the sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney.
For risk assessment in liver, bound residues (measured as M510F53 and M510F52, but expressed as Boscalid) should also be included, but data is sufficient to derive a conversion factor for ruminant and pig livers only and supplementary data on the nature and magnitude of the bound residues in poultry liver are required. Since log Po/w of Boscalid is close to 3 (DAR, 2002) and residues in fat were found to be higher than in muscle, EFSA concludes that the residue in commodities of animal origin is fat soluble.
Validated analytical methods are available in all animal commodities.
The definition for enforcement derived by the JMPR is the same in muscle, fat, milk and eggs, but differs for liver and kidney, for which the residue definition is limited to Boscalid only (FAO, 2006).

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	2-3 days in milk
	6 days in eggs
Animal residue definition for monitoring	Boscalid in muscle, fat milk and eggs; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney; (~~EU) No. 2018/832)~~ Reg. (EU) 2021/590

Animal residue definition for risk assessment	Boscalid in muscle, fat milk and eggs; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates and the bound residues (measured as M510F52 or M510F53) expressed as Boscalid in Liver (ruminant and pig); (EFSA Journal 2014;12(7):3799)
Conversion factor	None (DAR, 2002; EFSA Journal 2014;12(7):3799)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

Comparison of critical GAPs for Wheat

Crop	Type of GAP	Number of applications	Application rate per treatment (kg/ha)	Interval between application	Growth stage at last application	PHI (days)
Wheat	EFSA (2014) NEU	2	350 g a.s./ha	-	BBCH 69	35
	EFSA (2014) SEU	2	350 g a.s./ha	-	BBCH 69	35
	Intended NEU SHA7216A	2	350 g a.s./ha	14	BBCH 30-59	n.a.

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of SHA 7216 A and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Wheat grain	New trials	N-EU	GAP: 2x0,35 kg Boscalid/ha, Interval= 14 days, last application: BBCH 69-75, PHI= N/A, outdoor. 5x<0.01, ~~0.013~~ 0.01, ~~0.015~~ 0.02, ~~0.017~~ 0.02	N/A				
	Overall supporting data for cGAP	EU	5x<0.01, ~~0.013~~ 0.01, ~~0.015~~ 0.02, ~~0.017~~ 0.02	0.02	~~0.27~~ 0.02	~~0,023~~ 0.02	0.8	Yes
Wheat straw	New trials	N-EU	1.19, 1.38, 1.44, 1.48, 1.52, 3.27, 4.97, 5.08	N/A				
	Overall	EU	1.19, 1.38, 1.44, 1.48, 1.52, 3.27, 4.97, 5.08	~~0.02~~	~~0.27~~	9.21	NR	NR

	supporting data for cGAP			1.5	5.08			

* Source of EU MRL~~: Regulation (EU) 2016/156 and SANTE/11426/2020~~ Reg. (EU) 2021/590

7.2.3.2 Conclusion on the magnitude of residues in plants

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

The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

Additionally Sharda Cropchem España S.L refers to the JMPR data, which show that no exceedance of the MRL will occur.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

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

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Boscalid				
Cabbage	1.10	Median residue	2.82	Highest residue
Kale	1.10	Median residue	4.10	Highest residue
Apple pomace	2.52	Median residue x PF (6) EFSA Journal 2014;12(7):3799	2.52	Median residue x PF (6)
Wheat, rye grain	0.12	Median residue	0.12	Median residue
Wheat straw	6.85	Median residue JMPR	15	Highest residue JMPR
Distiller's grain - dried	0.40	Median residue x PF (3.3)	0.56	Median residue x PF (3.3)
Wheat gluten, meal	0.22	Median residue x PF (1.8)	0.31	Median residue x PF (1.8)
Wheat, milled by-ptds	0.84	Median residue x PF (7)	1.19	Median residue x PF (7)
Barley, oat grain	1.07	Median residue	1.07	Median residue
Brewer's grain dried	3.53	Median residue x PF (3.3)	3.53	Median residue x PF (3.3)
Barley, oat straw	15.0	Median residue	26.9	Highest residue
Rye straw	19.6	Median residue	39.5	Highest residue
Peas (dry)	0.13	Median residue	0.13	Median residue
Beans (dry)	0.13	Median residue	0.13	Median residue
Potatoes	0.05	Median residue	0.05	Highest residue
Potato, process waste	1.00	Median residue x PF (20)	2.00	Median residue x PF (20)
Potato, dried pulp	1.90	Median residue x PF (38)	3.80	Median residue x PF (38)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Turnips	0.09	Median residue	0.28	Highest residue
Rape seed meal	0.10	Median residue x PF (2)	0.10	Median residue x PF (2)
Canola, meal	0.10	Median residue x PF (2)	0.10	Median residue x PF (2)
Linseed, meal	0.10	Median residue x PF (2)	0.10	Median residue x PF (2)
Suflower seed, meal	0.32	Median residue x PF (2)	0.32	Median residue x PF (2)
Soybean, seed	0.05	Median residue	0.05	Median residue
Soybean, meal	0.07	Median residue x PF (1.3)	0.07	Median residue x PF (1.3)
Soybean, hulls	0.65	Median residue x PF (13)	0.65	Median residue x PF (13)
Peanuts meal	0.10	Median residue x PF (2)	0.10	Median residue x PF (2)

Table 7.2-11: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: Boscalid					
Cattle (all diets)	0.309	0.469	Barley, straw	12.90	Yes
Cattle (dairy only)	0.309	0.469	Barley, straw	12.18	Yes
Sheep (all diets)	0.511	0.857	Barley, straw	21.47	Yes
Sheep (ewe only)	0.448	0.716	Barley, straw	21.47	Yes
Swine (all diets)	0.075	0.127	Kale leaves	5.51	Yes
Poultry (all diets)	0.155	0.214	Barley, straw	3.13	Yes
Poultry (layer only)	0.155	0.214	Barley, straw	3.13	Yes

ZRMS remark:
The dietary burden was calculated in the framework of the Article 12 procedure. The intended uses are covered by the uses assessed in EFSA Journal 2014;12(7):3799.
STMR/HR values from the supervised residue trials presented in this submission are lower than were used as input values stated in EFSA Journal 2014;12(7):3799 (presented below).
Wheat grain STMR: 0.12
Wheat straw STMR: 33.7 and HR: 52.7
No further calculation is needed.
Nevertheless, the evaluator performed the calculations using the currently valid calculator (animal model 2017) for the proposed uses only.

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Boscalid				
Wheat grain	0.01	Median residue	0.01	Median residue
Wheat Straw	1.5	Median residue	5.08	Highest residue

Results:

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,014	0,045	0,37	1,18	Dairy cattle	Wheat	straw	Yes
Cattle (dairy only)	0,014	0,045	0,37	1,18	Dairy cattle	Wheat	straw	Yes
Sheep (all diets)	0,031	0,100	0,72	2,35	Lamb	Wheat	straw	Yes
Sheep (ewe only)	0,024	0,078	0,72	2,34	Ram/Ewe	Wheat	straw	Yes
Swine (all diets)	0,001	0,001	0,05	0,05	Swine (finishing)	Wheat	milled bypdts	No
Poultry (all diets)	0,013	0,041	0,19	0,60	Poultry layer	Wheat	straw	Yes
Poultry (layer only)	0,013	0,041	0,19	0,60	Poultry layer	Wheat	straw	Yes

There is no risk for animal MRL to be exceeded.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

No new livestock feeding studies have been performed. The Applicant refers to data of active ingredient since, the data protection was expired.

Available data

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

Table 7.2-12: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	Calculated MRL (mg/kg)	CF for RA[d]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[a]	No	Result for enforce-ment		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (DAR, 2002; EFSA, 2014)												
Enforcement residue definition: Muscle, fat: Boscalid Kidney, liver: Sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as Boscalid												
Pig meat	0.09	0.26	1.22	3	<0.025	<0.025	<0.025	<0.025	0.025	0.025	0.025*	1.00
			3.36	3	<0.025	<0.025	<0.025	<0.025				
Pig fat			1.22	9	0.15	0.22	0.15	0.22	0.025	0.05	0.05	1.00
			3.36	9	0.17	0.25	0.17	0.25				
Pig liver			1.22	3	0.09	0.11	-	-	0.005	0.05	0.05* (tentative)	1.50[h]
			3.36	3	0.20	0.24	-	-				
Pig kidney			1.22	3	0.11	0.11	0.11	0.11	0.05	0.05	0.05*	1.00
			3.36	3	0.18	0.24	0.18	0.24				
Ruminant meat	0.990	1.77	1.22	3	<0.025	<0.025	<0.025	<0.025	0.025	0.025	0.025*	1.00
			3.36	3	<0.025	<0.025	<0.025	<0.025				
Ruminant fat			1.22	9	0.15	0.22	0.15	0.22	0.12	0.23	0.3	1.00
			3.36	9	0.17	0.25	0.17	0.25				
Ruminant liver			1.22	3	0.09	0.11	-	-	0.08	0.14	0.15 (tentative)	1.50[h]
			3.36	3	0.20	0.24	-	-				
Ruminant kidney			1.22	3	0.11	0.11	0.11	0.11	0.09	0.14	0.15	1.00

			3.36	3	0.18	0.24	0.18	0.24				
Poultry meat	0.09	0.18	0.06	3	<0.025	<0.025	<0.025	<0.025	0.025	0.025	0.025*	1.00
			0.32	3	<0.025	<0.025	<0.025	<0.025				
			1.26	3	<0.025	<0.025	<0.025	<0.025				
Poultry fat			0.06	3	<0.025	<0.025	<0.025	<0.025	0.03	0.06	0.06	1.00
			0.32	3	0.06	0.10	0.06	0.10				
			1.26	3	0.14	0.17	0.14	0.17				
Poultry liver			0.06	3	<0.05	0.05	0.08	0.05	0.06	0.11	0.15 (tentative)	1.00
			0.32	3	0.14	0.18	0.14	0.18				
			1.26	3	0.41	0.47	0.41	0.47				
Milk	0.41	0.86	1.22	30	0.01[(d)]	N/A	0.01[(d)]	N/A	0.01	0.01	0.01*	1.00
			3.36	60	0.05[(e)]	N/A	0.05[(e)]	N/A				
Eggs	0.09	0.18	0.06	30	<0.01[(f)]	N/A	<0.01[(f)]	N/A	0.01	0.01	0.01*	1.00
			0.32	30	<0.01[(f)]	N/A	<0.01[(f)]	N/A				
			1.26	30	0.02[(g)]	N/A	0.02[(g)]	N/A				

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): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(b): Highest residue value (tissues, 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).
(c): The median conversion factor for enforcement to risk assessment.
(d): Mean residue level from day 1 until day 28 (3 cows, 10 sampling days).
(e): Mean residue level from day 1 until day 28 (6 cows, 10 sampling days).
(f): Mean residue level from day 1 until day 28 (3 hens, 10 sampling days).
(g): Mean residue level from day 1 until day 28 (5 hens, 10 sampling days).
(h): Tentative conversion factor derived from a separate ruminant feeding study.

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)

No new studies for determination of residues in processed commodities have been performed. The Applicant refers to data of active ingredient since, the data protection was expired.

7.2.5.1 Available data for all crops under consideration

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

Table 7.2-13: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Enforcement residue definition: Boscalid					
Apples, juice	6	0.08	1.00		PROFile
Apples, wet pomace	6	6.00	1.00		PROFile
Apples, dry pomace	4	18.35	1.00		PROFile
Apples, sauce	4	0.90	1.00		PROFile
Cherries, canned	4	0.52	1.00		EFSA, 2010
Cherries, jam	4	0.11	1.00		EFSA, 2010
Cherries, juice	4	0.39	1.00		EFSA, 2010
Plums, dried (prunes)	4	2.60	1.00		EFSA, 2010
Plums, jam	4	1.40	1.00		EFSA, 2010
Table grapes, dried (raisins)	4	2.40	1.00		DAR, 2002
Wine grapes, juice	4	0.40	1.00		DAR, 2002
Wine grapes, wet pomace	4	2.50	1.00		DAR, 2002
Strawberries, jam	4	0.44	1.00		PROFile
Strawberries, wet pomace	4	0.25	1.00		PROFile
Strawberries, canned	4	0.80	1.00		PROFile
Kiwi, peeled	4	0.06	1.00		PROFile
Carrots, canned	4	0.12	1.00		EFSA, 2010
Carrots, cooked	4	0.12	1.00		EFSA, 2010
Carrots, juice	4	0.12	1.00		EFSA, 2010
Tomatoes, unpeeled and canned	4	0.05	1.00		EFSA, 2010
Tomatoes, peeled and canned	4	0.05	1.00		EFSA, 2010

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
Tomaotes, paste	4	0.30	1.00		EFSA, 2010
Tomatoes, juice	4	0.17	1.00		EFSA, 2010
Gherkins, canned	4	0.56	1.00		EFSA, 2010
Head cabbage, cooked	4	0.07	1.00		EFSA, 2010
Head cabbage, canned	4	0.07	1.00		EFSA, 2010
Head cabbage, sauerkraut	4	0.17	1.00		EFSA, 2010
Head cabbage, sauerkraut juice	4	0.07	1.00		EFSA, 2010
Rape seed, refined oil	4	1.26	1.00		EFSA, 2010
Rape seed, meal/press cake	4	0.56	1.00		EFSA, 2010
Barley, brewing malt	4	0.48	1.00		PROFile
Barley, beer	4	0.02	1.00		PROFile
Barley, pot/pearl	4	0.34	1.00		PROFile
Wheat, whole-meal flour	4	1.21	1.00		PROFile
Wheat, whole-meat bread	4	0.81	1.00		PROFile
Wheat, white flour	4	0.34	1.00		PROFile
Wheat, bran	4	4.32	1.00		PROFile
Peas cooked/canned	1	0.36	1.00		DAR, 2002
Rape seed, crude oil	2	1.1	1.00		EFSA, 2010
Soya bean, refined oil	2	0.40	1.00		EFSA, 2010
Soya bean, meal	2	0.16	1.00		EFSA, 2010

* 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

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

Studies investigating the magnitude of residues in processed commodities of grapes and peas were also reported in the framework of the peer review (DAR, 2002). After Boscalid was included in Annex I to Directive 91/414/EEC, studies investigating the magnitude of residues in processed commodities of apples, cherries, plums, strawberries, kiwi, carrots, tomatoes, gherkins, head cabbage, rape seed, soya bean, barley and wheat were evaluated by EFSA or by the RMS.

It is acknowledged that for most of the studies the exact details on the processing conditions are not available (meaning that the available studies might not be representative for any type of processing). Nevertheless, data are considered acceptable to derive robust processing factors for all processed commodities.

Meanwhile, further processing studies are not required for the time being as they are not expected to affect the outcome of the risk assessment.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Data dealing with magnitude of residues in succeeding crops are available and are summarized hereafter.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

No new studies for determination of residues rotational crops have been performed. The Applicant refers to data of active ingredient since, the data protection was expired.

Available data

No new data submitted in the framework of this application.

Table 7.2-14: 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					
~~Lettuce~~ 1st year: Lettuce & green beans	2.1 kg a.s./ha (2 x 0.3 kg a.s./ha followed by 3 x 0.5 kg a.s./ha)	Cereals	Spring wheat (plant without root, straw, grain)	365, 365, 365 (3-year crop rotation) ~~365, 365, 365 (3 year crop rotation)~~	DAR, 2002 EFSA Journal 2014;12(7):3799 ~~DAR, 2002 EFSA Journal 2014;12(7):3799~~
~~Carrots~~ 2nd year: Carrots & cauliflower	1.7 kg a.s./ha (3 x 0.3 kg a.s/ha followed by 2 x 0.4 kg a.s./ha)	Cereals			
Winter rape	0.25 kg a.s./ha	Cereals	Winter wheat	365	DAR, 2002 EFSA Journal 2014;12(7):3799

Conclusion on rotational crops studies

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:
Occurrence of Boscalid residues in rotational crops was already investigated during the peer review. It is concluded that metabolic patterns in primary and succeeding crops are similar and that a potential for accumulation of Boscalid residues in crops grown in rotation is expected. EFSA is aware that instead of defining risk mitigating measures, risk managers may have the interest to establish MRLs accommodating for the uptake of residues from previously treated soils, EFSA therefore re-calculated the MRL proposals to take into account such residues.

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 SHA 7216 A. Therefore, other special studies are not needed.

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

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

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

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-15: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: Boscalid		
Tree nuts except pistachios, pine nuts and coconuts	0.05	Median residue
Pistachios	0.27	Median residue
Apples, Pears, Quinces	0.42	Median residue
Apricots	0.77	Median residue (tentative)
Cherries	1.51	Median residue
Peaches	0.77	Median residue
Plums	0.29	Median residue
Table and wine grapes	1.42	Median residue
Strawberries	1.90	Median residue
Cane fruits	2.47	Median residue
Other small fruit and berries, except rose hips, mulberries and elderberries	3.60	Median residue
Rose hips, mulberries and elderberries	2.60	Median residue
Kiwi	0.08	Median residue × PF
Bananas	0.05	Median residue
Potatoes, Sweet potatoes, Yams, Arrowroot	0.05	Median residue
Beetroot	0.33	Median residue
Carrots, Horseradish	0.19	Median residue × PF
Celeriac	0.34	Median residue
Jerusalem artichokes	2.00	Median residue

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Parsnips, Parsley root, Salsify, Turnips	0.09	Median residue
Radishes	0.28	Median residue
Garlic, Onions, Shallots	0.20	Median residue
Spring onions	2.30	EU MRL
Tomatoes, Aubergines (egg plants)	0.35	Median residue
Peppers	0.51	Median residue
Cucurbits with edible peel	0.68	Median residue
Cucurbits with inedible peel	0.35	Median residue
Broccoli	1.55	Median residue
Cauliflower	1.55	Median residue
Brussels sprouts	0.30	Median residue
Head cabbage	1.10	Median residue
Chinese cabbage	1.10	Median residue
Kale	1.10	Median residue (tentative)
Kohlrabi	0.04	Median residue
Lettuce and similar	5.60	Median residue
Spinach	5.60	Median residue
Beet leaves (chard)	30.0	Median residue
Witloof	1.16	Median residue
Fresh herbs, except basil	5.60	Median residue
Basil	14.5	Median residue
Beans (fresh, with pods)	0.64	EU MRL
Beans (fresh, without pods)	0.11	Median residue
Peas (fresh, with pods)	0.64	Median residue
Peas (fresh, without pods)	0.11	Median residue
Lentils (fresh)	3.00	Median residue
Asparagus	0.05	Median residue (tentative)
Celery	2.18	Median residue
Fennel	2.18	Median residue
Globe artichokes	1.18	Median residue
Leek	2.30	Median residue
Beans (dry)	0.13	Median residue
Lentils (dry)	0.13	Median residue

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Peas (dry)	0.13	Median residue
Linseed	0.05	Median residue
Peanuts	0.05	Median residue
Poppy seed	0.05	Median residue
Sunflower seed	0.16	Median residue
Rape seed	0.15	Median residue
Soya bean	0.05	Median residue
Mustard seed	0.05	Median residue
Borage	0.05	Median residue
Gold of pleasure	0.05	Median residue
Barley grain, Oats grain	1.07	Median residue
Wheat grain, Rye grain	0.12	Median residue
Herbal infusions (dried, roots)	0.95	Median residue (tentative)
Hops (dried)	24.5	Median residue (tentative)

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-16: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	**398% (NL toddler)** **260% (DE child)** **224% (GEMS/Food G11)** **223% (GEMS/Food G10)** **217% (NL child)** **216% (GEMS/Food G06)** **213% (GEMS/Food G08)** **210% (GEMS/Food G07)** **187% (GEMS/Food G15)** **184% (IE adult)** **168% (SE general)** **145% (IT adult)** **144% (ES adult)** **143% (FR child 3-15 yr)** **140% (ES child)** **131% (IT toddler)** **131% (RO general)** **131% (PT general)** **130% (NL general)** **127% (FR toddler 2-3 yr)** **120% (DE women 14-50 yr)**

	119% (DK child) **115% (DE general)** **112% (FI 3 yr)** **108% (FR adult)** **102% (FR infant)** **102% (UK toddler)**
IEDI (% ADI) according to EFSA PRIMo	85% (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	Not relevant
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

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

Chronic exposure:
The calculation of the TMDI was performed taking into account all the crops to which the Boscalid may be applied. At this scope crops assessed according to EFSA Journal 2014;12(7):3799 have been considered. As a first step, the existing MRLs (Reg. (EU) 2016/156) have been used.

With the current EFSA model the chronic risk assessment ranges from 18 to 398% of ADI. The diet with the highest TMDI is NL toddler population with 398% of ADI. For this diet, the highest contributors are spinaches with 90% of ADI. The second diet with the highest TMDI is DE child population with 260 % of ADI where apples are the major contributor with 85% of ADI. A refinement was necessary as 26 diets lead to an exceedance of ADI.

TMDI based calculations performed with the EFSA "PRIMO" calculation model (Rev. 3) yielded in an exceedance of ADI. Therefore, International Estimated Daily Intake (~~NEDI~~ IEDI) calculations using EU-MRLs and STMR values were performed with the EFSA "PRIMO" model including all crops for which a GAP use of Boscalid is registered in the EU or a registration is sought. NEDI calculations for a refined estimation of the chronic dietary consumer risk were performed using the following scenario:

- EFSA calculation model "PRIMO" (EFSA model for chronic and acute risk assessment - rev. 3, European Food Safety Authority, 2008) which is in accordance with the TMDI methodology of the WHO (1997);
- For more realistic estimations of consumer exposure, STMR values derived for residue according to enforcement definition multiplied for PF have been used, for requested crops;

After refinement calculation, the IEDI/TMDI ranges from 3% to 85% of ADI. The diet with the highest IEDI was NL toddler population with 85% of ADI. For this diet, the highest contributors are apples with 11% of ADI. The second diet with the highest IEDI was DE child population with the 42% of ADI, also for this diet the highest contributors are apples with 13% of ADI. None of diet lead to an exceedance of ADI, no chronic risks for consumers are expected.

The proposed uses of Boscalid in the formulation Boscalid 23.3% + Difenoconazole 6.6% SC do not represent unacceptable chronic risks for the consumer.

zRMS:
Consumer risk assessment has been recalculated (EFSA PRIMo rev.3.1)
The proposed uses of Boscalid in the formulation Boscalid 23.3% + Difenoconazole 6.6% SC do not represent unacceptable chronic risks for the consumer.

TMDI (input values: MRLs (Reg. (EU) 2021/590):

EFSA PRIMo revision 3.1; 2021/01/06

Boscalid

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,04	ARfD (mg/kg bw):	insert valid entry
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 26

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	398%	NL toddler	159,05	90%	Spinaches	54%	Apples	31%	Escaroles/broad-leaved endives		
	260%	DE child	104,12	62%	Apples	25%	Spinaches	20%	Oranges		
	225%	GEMS/Food G11	89,85	34%	Sugar canes	28%	Soyabeans	20%	Potatoes		
	223%	GEMS/Food G10	89,31	41%	Lettuces	24%	Soyabeans	23%	Sugar canes		
	217%	NL child	86,71	31%	Spinaches	29%	Apples	17%	Potatoes		
	216%	GEMS/Food G06	86,49	29%	Sugar canes	27%	Tomatoes	14%	Wheat		
	214%	GEMS/Food G08	85,68	28%	Sugar canes	25%	Lettuces	20%	Potatoes		
	211%	GEMS/Food G07	84,21	30%	Lettuces	27%	Sugar canes	19%	Potatoes		
	187%	GEMS/Food G15	74,87	23%	Sugar canes	18%	Potatoes	14%	Lettuces		
	184%	IE adult	73,47	18%	Sweet potatoes	16%	Wine grapes	16%	Wine grapes		
	168%	SE general	67,17	50%	Lettuces	21%	Potatoes	8%	Spinaches		
	145%	IT adult	57,96	47%	Lettuces	20%	Other lettuce and other salad plants	12%	Spinaches		
	144%	ES adult	57,53	67%	Lettuces	9%	Spinaches	6%	Oranges		
	143%	FR child 3 15 yr	57,27	17%	Oranges	14%	Other lettuce and other salad plants	13%	Spinaches		
	140%	ES child	55,94	52%	Lettuces	11%	Oranges	10%	Spinaches		
	131%	RO general	52,57	21%	Wine grapes	19%	Potatoes	18%	Head cabbages		
	131%	IT toddler	52,33	36%	Lettuces	14%	Other lettuce and other salad plants	13%	Wheat		
	131%	PT general	52,29	31%	Wine grapes	27%	Potatoes	13%	Lettuces		
	130%	NL general	51,97	19%	Spinaches	12%	Escaroles/broad-leaved endives	12%	Potatoes		
	127%	FR toddler 2 3 yr	50,87	20%	Spinaches	16%	Apples	10%	Beans (with pods)		
	120%	DE women 14-50 yr	48,02	14%	Lettuces	13%	Apples	10%	Wine grapes		
	119%	DK child	47,46	18%	Lettuces	16%	Cucumbers	12%	Potatoes		
	115%	DE general	46,05	12%	Apples	12%	Lettuces	10%	Wine grapes		
	112%	FI 3 yr	44,80	24%	Potatoes	10%	Cucumbers	8%	Spinaches		
	108%	FR adult	43,22	29%	Wine grapes	19%	Other lettuce and other salad plants	7%	Spinaches		
	102%	FR infant	40,70	33%	Spinaches	10%	Potatoes	8%	Apples		
	102%	UK toddler	40,62	17%	Potatoes	10%	Oranges	9%	Apples		
	92%	FI 6 yr	36,75	19%	Potatoes	10%	Lettuces	7%	Cucumbers		
	87%	UK infant	34,69	16%	Potatoes	8%	Apples	7%	Carrots		
	82%	UK vegetarian	32,89	18%	Lettuces	10%	Wine grapes	7%	Potatoes		
	68%	UK adult	27,24	15%	Lettuces	14%	Wine grapes	7%	Potatoes		
	67%	PL general	26,89	17%	Potatoes	10%	Apples	7%	Tomatoes		
	66%	DK adult	26,21	12%	Wine grapes	11%	Lettuces	6%	Potatoes		
	63%	FI adult	25,07	18%	Lettuces	6%	Potatoes	4%	Tomatoes		
	60%	LT adult	23,85	16%	Potatoes	9%	Apples	8%	Lettuces		
	18%	IE child	7,23	3%	Potatoes	2%	Wheat	2%	Apples		

Conclusion:

The estimated TMDI/NEDI/IEDI was in the range of 0 % to 397,6 % of the ADI.
For 26 diet(s) the ADI is exceeded.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

TMDI (input values: STMR values - EFSA Journal 2019;17(11):5897)

EFSA PRIMo revision 3.1; 2021/01/06

Boscalid

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,04	ARfD (mg/kg bw):	insert valid entry
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
69%	NL toddler	27,50	10%	Spinaches	10%	Apples	5%	Table grapes		
49%	DE child	19,45	12%	Apples	5%	Table grapes	3%	Spinaches		
38%	NL child	15,03	5%	Apples	4%	Table grapes	4%	Spinaches		
35%	GEMS/Food G08	14,14	4%	Wine grapes	3%	Potatoes	3%	Onions		
34%	GEMS/Food G06	13,76	4%	Onions	4%	Table grapes	4%	Tomatoes		
34%	GEMS/Food G10	13,65	5%	Lettuces	3%	Onions	2%	Potatoes		
34%	GEMS/Food G07	13,51	5%	Wine grapes	3%	Lettuces	3%	Potatoes		
33%	GEMS/Food G15	13,31	4%	Wine grapes	3%	Onions	3%	Potatoes		
32%	IE adult	12,95	4%	Wine grapes	2%	Potatoes	2%	Spinaches		
32%	GEMS/Food G11	12,95	4%	Wine grapes	3%	Potatoes	2%	Barley		
30%	SE general	11,88	6%	Lettuces	3%	Potatoes	3%	Onions		
29%	RO general	11,72	6%	Wine grapes	4%	Onions	4%	Head cabbages		
27%	PT general	10,71	9%	Wine grapes	4%	Potatoes	2%	Onions		
24%	FR child 3 15 yr	9,72	2%	Wheat	2%	Apples	2%	Other lettuce and other salad plant		
23%	DK child	9,21	3%	Cucumbers	2%	Rye	2%	Apples		
22%	NL general	8,99	2%	Spinaches	2%	Wine grapes	2%	Potatoes		
22%	FR toddler 2 3 yr	8,82	3%	Apples	2%	Spinaches	2%	Leeks		
22%	FI 3 yr	8,74	4%	Potatoes	2%	Onions	2%	Cucumbers		
22%	IT adult	8,60	5%	Lettuces	2%	Other lettuce and other salad plants	2%	Wheat		
21%	DE women 14-50 yr	8,57	3%	Wine grapes	2%	Apples	2%	Lettuces		
21%	DE general	8,56	3%	Wine grapes	2%	Apples	1%	Barley		
21%	ES adult	8,46	7%	Lettuces	1%	Wine grapes	1%	Barley		
21%	FR adult	8,44	8%	Wine grapes	2%	Other lettuce and other salad plants	0,9%	Wheat		
21%	IT toddler	8,21	4%	Lettuces	3%	Wheat	2%	Other lettuce and other salad plant		
20%	ES child	8,04	6%	Lettuces	2%	Wheat	1%	Potatoes		
18%	UK toddler	7,22	3%	Potatoes	2%	Wheat	2%	Apples		
18%	FR infant	7,08	4%	Spinaches	2%	Apples	2%	Leeks		
17%	UK infant	6,98	3%	Potatoes	2%	Milk: Cattle	1%	Apples		
17%	FI 6 yr	6,77	3%	Potatoes	2%	Onions	1%	Strawberries		
15%	UK vegetarian	5,97	3%	Wine grapes	2%	Lettuces	1%	Onions		
14%	PL general	5,53	3%	Potatoes	2%	Apples	2%	Onions		
13%	DK adult	5,30	3%	Wine grapes	1%	Lettuces	1,0%	Potatoes		
13%	UK adult	5,21	4%	Wine grapes	2%	Lettuces	1%	Potatoes		
12%	FI adult	4,65	2%	Lettuces	1%	Wine grapes	0,9%	Potatoes		
11%	LT adult	4,21	2%	Potatoes	2%	Apples	1%	Head cabbages		
4%	IE child	1,56	0,5%	Wheat	0,5%	Potatoes	0,3%	Onions		

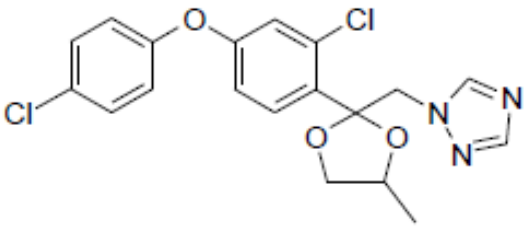
Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Boscalid 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.

7.3 Difenoconazole

General data on Difenoconazole are summarized in the table below (last updated 2018/11/16)

Table 7.3-1: General information on Difenoconazole

Active substance (ISO Common Name)	Difenoconazole
IUPAC	3-chloro-4-[(2*RS*,4*RS*;2*RS*,4*SR*)-4-methyl-2-(1*H*-1,2,4-triazol- 1-ylmethyl)-1,3-dioxolan-2-yl] phenyl 4-chlorophenyl ether
Chemical structure	
Molecular formula	$C_{19}H_{17}Cl_2N_3O_3$
Molar mass	406.3 g/mol
Chemical group	Triazole
Mode of action (if available)	It acts by interfering with the ergosterol biosynthesis in target fungi by inhibition of the C-14-demethylation of sterols
Systemic	Yes
Company	Syngenta Limited
Rapporteur Member State (RMS)	Original RMS: Sweden RMS: Spain Co-RMS: UK
Approval status	Approved Date of (01/01/2009) and reference to decision (COMMISSION DIRECTIVE 2008/69/EC - REGULATION (EU) No 1100/2011) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008L0069&from=EN https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R1100&from=EN
Restriction	Only uses as fungicide may be authorised.
Review Report	SANCO/830/08 – rev. 3 13/12/2013, 18 May 2020
Current MRL regulation	~~Regulation (EC) No 2018/832~~ Reg. (EU) 2019/552
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	No
EFSA Journal: Conclusion on the peer review	Yes (EFSA Journal 2011;9(1):1967)
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	EFSA-Q-2009-00103 (EMS) All commodities Status: In progress

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Potato, wheat	High protein/starch content	24 months	EFSA Journal 2011;9(1):1967
Tomato	High water content	24 months	EFSA Journal 2011;9(1):1967
Cotton	High oil content	24 months	EFSA Journal 2011;9(1):1967
Lettuce, banana	High water content	12 months	EFSA Journal 2011;9(1):1967
Soybean	High oil content	12 months	EFSA Journal 2011;9(1):1967
Animal Products			
Difenoconazole: storage frozen at -20°C			
Ruminant	Liver	12 months	EFSA Journal 2011;9(1):1967
Ruminant	Milk	12 months	EFSA Journal 2011;9(1):1967
Poultry	Breast	12 months	EFSA Journal 2011;9(1):1967
Poultry	Eggs	12 months	EFSA Journal 2011;9(1):1967
Difenoconazole and Difenoconazole alcohol (CGA 205375): storage frozen at -18°C			
Ruminant	Milk	10 months	EFSA Journal 2011;9(1):1967
Ruminant	Liver	10 months	EFSA Journal 2011;9(1):1967
Ruminant	Kidney	10 months	EFSA Journal 2011;9(1):1967
Ruminant	Fat	10 months	EFSA Journal 2011;9(1):1967
Ruminant	Muscle	10 months	EFSA Journal 2011;9(1):1967
1,2,4-Triazole			
Apples, tomatoes, mustard, leaves, wheat forage, radishes tops/roots, turnips roots, sugar beet roots, cabbages, lettuces	High water content	6 months	EFSA Journal 2018;16(7):5376
Barley, wheat	High starch content	12 months	EFSA Journal 2018;16(7):5376
Soya beans	High oil content	12 months	EFSA Journal 2018;16(7):5376
Barley wheat straw	Cereal straw	12 months	EFSA Journal 2018;16(7):5376
Ruminant	Milk	18 months	EFSA Journal 2018;16(7):5376
	Eggs, liver, muscle, fat	12 months	EFSA Journal 2018;16(7):5376
TA			

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Apples, tomatoes, mustard, leaves, wheat forage, radishes tops/roots, turnips roots, sugar beet roots, cabbages, lettuces	High water content	53 months	EFSA Journal 2018;16(7):5376
Barley, wheat	High starch content	26 months	EFSA Journal 2018;16(7):5376
Soya beans	High oil content	26 months	EFSA Journal 2018;16(7):5376
Peas, dry; Navy beans	High protein content	15 months	EFSA Journal 2018;16(7):5376
Barley wheat straw	Cereal straw	53 months	EFSA Journal 2018;16(7):5376
TAA			
Apples, tomatoes, mustard, leaves, wheat forage, radishes tops/roots, turnips roots, sugar beet roots, cabbages, lettuces	High water content	53 months	EFSA Journal 2018;16(7):5376
Barley, wheat	High starch content	26 months	EFSA Journal 2018;16(7):5376
Rapeseeds, soya beans	High oil content	53 months	EFSA Journal 2018;16(7):5376
Peas, dry; Navy beans	High protein content	25 months	EFSA Journal 2018;16(7):5376
Barley wheat straw	Cereal straw	40 months	EFSA Journal 2018;16(7):5376
TLA			
Lettuce	High water content	48 months	EFSA Journal 2018;16(7):5376
Barley, wheat	High starch content	48 months	EFSA Journal 2018;16(7):5376
Rapeseeds, soya beans	High oil content	48 months	EFSA Journal 2018;16(7):5376
Peas, dry; Navy beans	High protein content	48 months	EFSA Journal 2018;16(7):5376
Oranges	High acid content	48 months	EFSA Journal 2018;16(7):5376

Conclusion on stability of residues during storage

Conclusions drawn in EFSA Journal 2011; 9(1):1967 are reported below:
These residue data are supported by the storage stability study showing difenoconazole residues to be stable up to 2 years in various plant matrices when stored at -20°C.
Difenoconazole stable when stored frozen at -20°C, up to:

- *24 months in potato, tomato, cotton (cottonseed oil) and wheat (straw, forage and grain)*
- *12 months in lettuce (head), soybean (beans) and banana.*

Difenoconazole stable at least 12 months in animal matrices (Eggs, milk, poultry breast and beef liver) when stored frozen at -20°C.
Difenoconazole and difenoconazole alcohol (CGA 205375) stable at least 10 months in animal matrices (milk, liver, kidney, fat and muscle) when stored frozen at -18 °C.

Residues of triazole metabolite compounds are stable for at least 6 months in high water commodities, and at least 12 months in high starch or oily matrices.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No data was submitted and required at EU level during the EU Review of Difenoconazole.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Grape	^{14}C-phenyl ^{14}C-triazole	foliar treatment, F	247 g a.s./ha	5	20	First application: BBCH 75, then 14, 28, 14- and 15-days interval thereafter.	DAR, 2006; EFSA Journal 2011;9(1):1967
	Tomato	^{14}C-phenyl ^{14}C-triazole	foliar treatment, G	123.5 g a.s./ha	6	7, 16	Applications 55, 62, 69, 76, 83 and 90 days after planting.	DAR, 2006; EFSA Journal 2011;9(1):1967
		^{14}C-phenyl ^{14}C-triazole	foliar treatment, G	247 g a.s./ha	3	40	Applications 63, 77 and 91 days after planting.	DAR, 2006; EFSA Journal 2011;9(1):1967
		^{14}C-phenyl ^{14}C-triazole	foliar treatment, G	123 g a.s./ha	6	7, 34	Applications 62, 69, 76, 83,9. And 97 after planting.	DAR, 2006; EFSA Journal 2011;9(1):1967
Root and tuber vegetables	Potatoes	^{14}C-phenyl ^{14}C-triazole	foliar treatment, G	123.5 g a.s./ha	6	11	First application: 2 months after planting and the subsequent at 7 days inter-	DAR, 2006; EFSA Journal 2011;9(1):1967

							vals.	
Pulses and oilseeds	Oilseed rape	^{14}C-phenyl ^{14}C-triazole	Foliar treatment, F	125 g a.s./ha	2	39	Applications 78 days after sowing and 14 days after the first applica-tion.	DAR, 2006; EFSA Journal 2011;9(1):1967
Cereals	Spring wheat	^{14}C-phenyl ^{14}C-triazole	Seed treatment, outdoor	24 g a.s./100 kg seed	1	Wheat foliage: 31-34 and 48-62 Wheat straw: 59, 83	-	DAR, 2006; EFSA Journal 2011;9(1):1967
		^{14}C-phenyl ^{14}C-triazole	Seed treatment, G	24 g a.s./100 kg seed	1	Wheat foliage: 40, 72 Wheat straw: 236	-	DAR, 2006; EFSA Journal 2011;9(1):1967
		^{14}C-phenyl ^{14}C-triazole	Foliar spray, G	247 g a.s./ha	4	29	Applications 43, 50, 58 and 65 days after plant-ing.	DAR, 2006; EFSA Journal 2011;9(1):1967

Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2011;9(1):1967 are reported below:
Metabolism in plant was investigated in four plant groups: fruit crops (tomato, grape), cereals (wheat), tuber/root crops (potato) and on oilseeds/pulses crops (oilseed rape), using ^{14}C-difenoconazole labelled in the phenyl or the triazole ring and foliar applications with a total of 2 to 6 treatments. Samples were collected for analysis at interim intervals and 6 to 40 days after the final application. In addition, metabolism was also considered in cereals following seed application. The metabolism was seen to be similar in all four crop types. The parent difenoconazole remained the major component of the residues in the majority of the plant parts (mostly >40 % TRR), with the exception of the cereal grains, potato tubers and rape seeds, where it accounted for less than 10 – 15 % of the TRR. In these crops, and for the triazole labelling, TRRs are mainly composed of the triazole derivative metabolites (TDM): triazole alanine (56 % and 79 % TRR in rape seeds and potato tubers) and triazole acetic acid (20 % TRR in cereal grain). In addition, triazole alanine was detected up to 42 % TRR in tomato fruits and 1,2,4-triazole up to 12 % in grape. TDM were also the major components of the residues in cereal grains following seed treatment and the major metabolites in the succeeding crop studies. Metabolites CGA 205374 (ketone), CGA 205375 (alcohol) and CGA 189138 (benzoic acid) were also identified in low proportions (below 5 % TRR). Based on the different structures identified, the following metabolic pathway in plants was proposed. As a first step, the metabolism involves hydrolysis of the dioxolane ring to form the ketone metabolite which is then reduced to the corresponding alcohol. Further oxidation of the difenoconazole-alcohol metabolite results in the cleavage of the alkyl bridge to form the difenoconazole-benzoic acid metabolite and the 1,2,4-triazole which is further metabolised to triazole alanine and triazole acetic acid.

Conclusion on metabolism in primary crops

Conclusions drawn from EFSA Journal 2011;9(1):1967 are reported below:
Based on these data, the residue for monitoring was defined as the parent compound difenoconazole. For risk assessment, considering that TDM are toxicologically relevant metabolites present in significant

proportions in primary and rotational crops, two separate plant residue definitions were proposed:
1) difenoconazole and
2) provisionally, Triazole Derivative Metabolites.
No final definition can be proposed for TDM at this stage, since a global and harmonized approach is needed for all compounds of the triazole chemical class.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	^{14}C-phenyl ^{14}C-triazole	Bare soil treatment, G	1 x 125 g a.s./ha	98	126, 151	-	DAR, 2006; EFSA Journal 2011;9(1):1967
	Spinach	-	Barel soil treatment, F	1 x 750 g a.s./ha	31	62, 70, 77	-	DAR, 2006; EFSA Journal 2011;9(1):1967
Root and tuber vegetables	Sugarbeet	^{14}C-phenyl ^{14}C-triazole	Bare soil treatment, G	1 x 125 g a.s./ha	369	427, 473, 488	-	DAR, 2006; EFSA Journal 2011;9(1):1967
	Turnip	^{14}C-phenyl	Bare soil treatment, F	1 x 32.4 g a.s./ha	30 33	137 129	32.4 g a.s./ha applied in methanol solution.	DAR, 2006; EFSA Journal 2011;9(1):1967
	Carrot	-	Bare soil treatment, F	1 x 750 g a.s./ha	30	97, 114, 136	-	DAR, 2006; EFSA Journal 2011;9(1):1967
Pulses and oilseeds	Mustard	^{14}C-phenyl	Bare soil treatment, F	1 x 32.4 g a.s./ha	30 33	137 129	32.4 g a.s./ha applied in methanol solution.	DAR, 2006; EFSA Journal 2011;9(1):1967
Cereals	Winter wheat	^{14}C-phenyl ^{14}C-triazole	Bare soil treatment, G	1 x 125 g a.s./ha	126	167, 342, 369, 418	-	DAR, 2006; EFSA Journal 2011;9(1):1967
	Maize	^{14}C-phenyl ^{14}C-triazole	Bare soil treatment, G	1 x 125 g a.s./ha	342	398, 427, 488	-	DAR, 2006; EFSA Journal 2011;9(1):1967

	Spring wheat	^{14}C-phenyl	Bare soil treatment, F	1 x 32.4 g a.s./ha	30 33	218 175 179 (straw)	32.4 g a.s./ha applied in methanol solution.	DAR, 2006; EFSA Journal 2011;9(1):1967

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

Summary of plant metabolism studies reported in the EU

Conclusions drawn in the DAR, 2006 are reported below:
In five available studies, total radioactive residues in rotational crops (wheat, sugar beet, maize, lettuce, turnips and mustard) planted 62 to 488 days after one application of difenoconazole applied to bare ground at rates of 32.4, 125 and 750 g a.i./ha ranged from < 0.0001 to 0.34 mg difenoconazole equivalents/kg.

Conclusions drawn from EFSA Journal 2011;9(1):1967 are reported below:
Cold rotational crop studies were provided where difenoconazole was applied to the bare soil at a rate of 750 g/ha (2N) one month prior to planting and samples were analysed for difenoconazole and triazole alanine.

Conclusion on metabolism in rotational crops

Conclusions drawn from EFSA Journal 2011;9(1):1967 are reported below:
For risk assessment, considering that TDM are toxicologically relevant metabolites present in significant proportions in primary and rotational crops, two separate plant residue definitions were proposed:
1) difenoconazole and
2) provisionally, Triazole Derivative Metabolites.
No final definition can be proposed for TDM at this stage, since a global and harmonized approach is needed for all compounds of the triazole chemical class.
The peer review concluded that the metabolic pathway in primary and rotational crops is partially similar.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Difenoconazole (95.6%)	DAR, 2006; EFSA Journal 2011;9(1):1967
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Difenoconazole (98.1%)	DAR, 2006; EFSA Journal 2011;9(1):1967
Sterilisation (20 minutes, 120°C, pH 6)	Difenoconazole (98.6%)	DAR, 2006; EFSA Journal 2011;9(1):1967

Conclusion on nature of residues in processed commodities

Conclusions drawn from EFSA Journal 2011;9(1):1967 are reported below:
Difenoconazole was found to be stable under standard hydrolysis conditions simulating pasteurisation,

baking and sterilisation.

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

Table 7.3-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	**Foliar treatment:** Cereals (spring wheat) Root vegetables (potato) Fruits (tomato, grape) Pulses/oilseeds (oilseed rape) **Seed treatment:** Cereals (spring wheat)
Rotational crops covered	Leafy vegtables (lettuce, spinach) Root vegetable (carrot, sugarbeet, turnip) Cereals (spring and winter wheat, maize) Oilseeds (mustard)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes, in part. No residues of parent difenoconazole were found. Residue mainly composed of TDM metabolites: triazole analine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA).
Processed commodities	Difenoconazole stable under standard hydrolysis conditions representative of pasteurisation/baking/sterilisation (more than 96% TRR consisted of parent difenoconazole)
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Difenoconazole (Regulation (EU) No. 2018/832)
Plant residue definition for risk assessment	~~Two separate residue definitions:~~ ~~1) Difenoconazole~~ ~~2) Triazole derivative metabolites (TDM) (provisioonal, pending the definition of a common and harmonised approach for all the active substances of th triazole chemical class)~~ ~~(EFSA Journal 2011;9(1):1967)~~ Four separate residue definitions: 1) Difenoconazole and any other relevant metabolite exclusively linked to the parent compound. (EFSA Journal 2018;16(7):5376) 2) TA and TLA (EFSA Journal 2018;16(7):5376) 3) TAA (EFSA Journal 2018;16(7):5376) 4) 1,2,4-T (EFSA Journal 2018;16(7):5376)
Conversion factor from enforcement to RA	None

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

Available data

No new data submitted in the framework of this application.

Table 7.3-7: 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	^{14}C-phenyl ^{14}C-triazole	2	5 mg/kg feed/day	10	Milk	daily	DAR, 2006
						Urine and faeces	daily	
						Blood	Days 1, 2, 4, 5, 6, 9 and 10	
						Tissues	at sacrifice	
			4	100 mg/kg feed/day	3	Milk	Twice daily	DAR, 2006
						Urine and faeces	Daily	
						Blood and tissues	At sacrifice	
		^{14}C-phenyl	2	100 mg/kg feed/day	4	Milk	Twice daily	DAR, 2006
						Urine and faeces	Daily	
						Blood and tissues	At sacrifice	
Laying poultry	Hens	^{14}C-phenyl ^{14}C-triazole	4	5 mg/kg feed/day	14	Eggs	Daily	DAR, 2006
						Excreta	Daily	
						Tissues	At sacrifice	
			20	68 mg/kg feed/day	3	Eggs	Daily	DAR, 2006
						Excreta	Daily	
						Tissues	At sacrifice	
		^{14}C-triazole	5	121 mg/kg feed/day	4	Eggs	Daily	DAR, 2006
						Excreta	Daily	
						Tissues	At sacrifice	

Summary of plant metabolism studies reported in the EU

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-^{14}C] and [triazole-^{14}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.

Conclusion on metabolism in livestock

Conclusions drawn from EFSA Journal 2011;9(1):1967 are reported below:
Several metabolism studies on goats and laying hens were submitted where animals were fed with ^{14}C-difenoconazole labelled on the phenyl and triazole ring. Difenoconazole was more extensively metabolised in animals than in plants, occurring at less than 10 % TRR in nearly all matrices. Difenoconazole-alcohol (CGA 205375) was by far the most abundant metabolite detected, up to 60 – 90 % TRR in goat and poultry fat. Beside CGA 205375, the metabolite 1,2,4-triazole resulting from cleavage of the parent structure was also observed in significant proportions in milk (46 % TRR) and eggs (32 – 75 % TRR). Based on these studies, the residue definition for monitoring was limited to the metabolite difenoconazole-alcohol only. For risk assessment, as for plants, two separate residue definitions are proposed: 1) difenoconazole-alcohol expressed as difenoconazole and 2) provisionally, Triazole Derivative Metabolites. Only 1,2,4-triazole was detected in the animal metabolism studies, but the presence of the other TDM (CGA 131013, CGA 142586 and CGA 205369) in animal feed was not considered. Their transfer to the animal products cannot be excluded and the definition for TDM can not be limited to the 1,2,4-triazole only. As for plants, no final residue definition can be proposed for TDM, since the fate of CGA 131013, CGA 142586 and CGA 205369 were not investigated and a global and harmonized approach is needed for all compounds of the triazole chemical class.

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

Table 7.3-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Ruminant (goat), poultry (hen)
Time needed to reach a plateau concentration	48 hours: in milk [^{14}C-phenyl]-difenoconazole 144 hours: in milk [^{14}C-triazole]-difenoconazole 168 hours: in egg yolk [^{14}C-pheynl] and [^{14}C-triazole] 120 hours: in eggs white [^{14}C-triazole]-difenoconazole
Animal residue definition for monitoring	Difenoconazole alcohol (CGA 205375) expressed as Difenoconazole (EFSA Journal 2011;9(1):1967) Difenoconazole (Regulation (EU) No. 2018/832)
Animal residue definition for risk assessment	~~Two separate residue definitions:~~ ~~3) Difenoconazole~~ ~~4) Triazole derivative metabolites (TDM) (provisioonal, pending the definition of a common and harmonised approach for all the active substances of th triazole chemical class)~~ ~~(EFSA Journal 2011;9(1):1967)~~ Four separate residue definitions: 5) Difenoconazole and any other relevant metabolite exclusively linked to the parent compound. (EFSA Journal

	2018;16(7):5376) 6) TA and TLA (EFSA Journal 2018;16(7):5376) 7) TAA (EFSA Journal 2018;16(7):5376) 1,2,4-T (EFSA Journal 2018;16(7):5376)
Conversion factor	Not concluded
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

Comparison of critical GAPs for Wheat

Crop	Type of GAP	Number of applications	Application rate per treatment (kg/ha)	Interval between application	Growth stage at last application	PHI (days)
Wheat	DAR (2006) NEU & SEU	1 (seed treatment)	12 g a.s./ha	-	BBCH 00	n.a.
	Intended NEU SHA7216A	2	100 g a.s./ha	14	BBCH 30-59	n.a.

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of SHA 7216 A and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Wheat grain	New trials	N-EU	GAP: 2x 0~~,~~.1 kg Difenoconazole/ha, Interval= 14 days, last application: BBCH 69-75; PHI= 42, outdoor. 2x<0.01, 0.011, 0.013, 0.015, 0.018, 0.024, 0.093	N/A				
	Overall supporting data for cGAP	EU	~~2x<0.01, 0.011, 0.013, 0.015, 0.018, 0.024, 0.093~~ 2x<0.01, 2x 0.01, 3x 0.02, 0.09	~~0.014~~ 0.02	0.09~~3~~	0~~,~~.13	0.1	Yes
Wheat straw	New trials	N-EU	0.19, 0.25, 0.30, 0.63, 0.87, 0.95, 1.23, 2.14	N/A				
	Overall supporting data for cGAP	EU	0.19, 0.25, 0.30, 0.63, 0.87, 0.95, 1.23, 2.14	0.75	2.14		NR	NR

Wheat grain (TA metabolite)	New trials informative data not included in the assessment	N-EU	GAP: 2x 0~~,~~.1 kg Difenoconazole/ha, Interval= 14 days, last application: BBCH 69-75; PHI= 42, outdoor. 6 x n.d. (<0.003), 0.089, 0.14	N/A				
	TDM Confirmatory, 2018	N-EU	GAP: 1 x 0.125 kg Difenoconazole/ha, BBCH 69, PHI 39-64 d, outdoor, foliar application 2 x 0.05, 0.06, 0.1, 0.13, 2 x 0.16, 0.18					
	Overall supporting data for cGAP	EU	6 x n.d. (<0.003), 2 x 0.05, 0.06, 0.089, 0.1, 0.13, 0.14, 2 x 0.16, 0.18	~~0.01~~ 0.05	~~0.14~~ 0.18	~~0.244~~ 0.327	NA	NA
Wheat straw (TA metabolite)	New trials informative data not included in the assessment	N-EU	GAP: 2x 0~~,~~.1 kg Difenoconazole/ha, Interval= 14 days, last application: BBCH 69-75; PHI= 42, outdoor. 8 x n.d. (<0.003)	N/A				
	TDM Confirmatory, 2018	N-EU	GAP: 1 x 0.125 kg Difenoconazole/ha, BBCH 69, PHI 39-64 d, outdoor, foliar application 6 x <0.01, 0.01, 0.02					
	Overall supporting data for cGAP	EU	8 x n.d. (<0.003), 6 x <0.01, 0.01, 0.02	0.01	~~0.01~~ 0.02	~~0.01~~ 0.021	NA	NA
Wheat grain (TLA metabolite)	New trials informative data not included in the assessment	N-EU	GAP: 2x 0~~,~~.1 kg Difenoconazole/ha, Interval= 14 days, last application: BBCH 69-75; PHI= 42, outdoor. 8 x n.d. (<0.003)	N/A				
	TDM Confirmatory, 2018	N-EU	GAP: 1 x 0.125 kg Difenoconazole/ha, BBCH 69, PHI 39-64 d, outdoor, foliar application 8 x <0.01					
	Overall	EU	8 x n.d. (<0.003), 8 x <0.01	0.01	0.01	0.01	NA	NA

	supporting data for cGAP							
Wheat straw (TLA metabolite)	New trials informative data not included in the assessment	N-EU	GAP: 2x 0~~,~~.1 kg Difenoconazole/ha, Interval= 14 days, last application: BBCH 69-75; PHI= 42, outdoor. 8 x n.d. (<0.003)	N/A				
	TDM Confirmatory, 2018	N-EU	GAP: 1 x 0.125 kg Difenoconazole/ha, BBCH 69, PHI 39-64 d, outdoor, foliar application 5 x <0.01, 2 x 0.03, 0.04					
	Overall supporting data for cGAP	EU	8 x n.d. (<0.003), 5 x <0.01, 2 x 0.03, 0.04	0.01	~~0.01~~ 0.04	~~0.01~~ 0.053	NA	NA
Wheat grain (TAA metabolite)	New trials informative data not included in the assessment	N-EU	GAP: 2x 0~~,~~.1 kg Difenoconazole/ha, Interval= 14 days, last application: BBCH 69-75; PHI= 42, outdoor. 6 x n.d. (<0.003), <0.01 (<LOQ), 0.013	N/A				
	TDM Confirmatory, 2018	N-EU	GAP: 1 x 0.125 kg Difenoconazole/ha, BBCH 69, PHI 39-64 d, outdoor, foliar application 0.01, 0.02, 2 x 0.03, 2 x 0.08, 0.10, 0.14					
	Overall supporting data for cGAP	EU	6 x n.d. (<0.003), <0.01 (<LOQ), 0.01, 0.013, 0.02, 2 x 0.03, 2 x 0.08, 0.10, 0.14	0.01	~~0.013~~ 0.14	~~0.021~~ 0.199	NA	NA
Wheat straw (TAA metabolite)	New trials informative data not included in the assessment	N-EU	GAP: 2x 0~~,~~.1 kg Difenoconazole/ha, Interval= 14 days, last application: BBCH 69-75; PHI= 42, outdoor. 8 x n.d. (<0.003)	N/A				
	TDM Confirmatory, 2018	N-EU	GAP: 1 x 0.125 kg Difenoconazole/ha, BBCH 69, PHI 39-64 d, outdoor, foliar application					

			<0.01, 0.01, 2 x 0.02, 0.03, 0.04, 2 x 0.06					
	Overall supporting data for cGAP	EU	8 x n.d. (<0.003), <0.01, 0.01, 2 x 0.02, 0.03, 0.04, 2 x 0.06	0.01	~~0.01~~ 0.06	~~0.01~~ 0.091	NA	NA
Wheat grain (1,2,4-T metabolite)	New trials informative data not included in the assessment	N-EU	GAP: 2x 0~~,~~.1 kg Difenoconazole/ha, Interval= 14 days, last application: BBCH 69-75; PHI= 42, outdoor. 0.24, 0.13, 0.11, 0.11, 0.13, 0.09, 0.57, 0.098	N/A				
	TDM Confirmatory, 2018	N-EU	GAP: 1 x 0.125 kg Difenoconazole/ha, BBCH 69, PHI 39-64 d, outdoor, foliar application 8 x <0.01					
	Overall supporting data for cGAP	EU	8 x <0.01, 0.09, 0.098, 2 x 0.11, 2 x 0.13, 0.24, 0.57	~~0.12~~ 0.05	0.57	~~0.835~~ 0.670	NA	NA
Wheat ~~grain~~ straw (1,2,4-T metabolite)	New trials informative data not included in the assessment	N-EU	GAP: 2x 0~~,~~.1 kg Difenoconazole/ha, Interval= 14 days, last application: BBCH 69-75; PHI= 42, outdoor. 8 x n.d. (<0.003)	N/A				
	TDM Confirmatory, 2018	N-EU	GAP: 1 x 0.125 kg Difenoconazole/ha, BBCH 69, PHI 39-64 d, outdoor, foliar application 8 x <0.01					
	Overall supporting data for cGAP	EU	8 x n.d. (<0.003), 8 x <0.01	0.01	0.01	0.01	NA	NA

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

7.3.3.2 Conclusion on the magnitude of residues in plants

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

The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

Therefore, it is possible assume that for proposed uses no exceedance of the MRL will occur.

zRMS note:
zRMS is of the opinion that the residues arising from the proposed uses will not exceed the MRL for Difenoconazole established for cereals (0.1 mg/kg; Reg. (EU) 2019/552).
The value of 0.093 mg/kg can be considered an outlier. Additionally, in the study, the last application was performed at a later BBCH stage (69-75) than the proposed one (till 59).
TMDs:
Results from Sharda field trials were not used in the risk assessment calculations and can be considered as additional.
Applicant's statement: Time between sampling and extraction varies from 28 to 39 months. Such long period has been a result of hard-to-reach situation with TDMs standards on the market at the time of performing study. Therefore applicant wants to refer to Confirmatory Data on Triazole Derivative Metabolites and its addendum (February 2018) already evaluated and accepted at EU level.
The sufficient data submitted for residues TMDs in wheat are available and presented in EFSA Journal 2018;16(7):5376. Proposed GAP is within acceptable range with respect to trials GAP (±25%).

7.3.4 0.75Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

Table 7.3-10: Input values for the dietary burden calculation (considering the uses in EFSA and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Difenoconazole (provisional)				
Cereals grain	0.02	HR (Addendum to the DAR, 2010)	0.02	HR (Addendum to the DAR, 2010)
Cereal straw	0.05	HR (Addendum to the DAR, 2010)	0.05	HR (Addendum to the DAR, 2010)

Table 7.3-11: Results of the dietary burden calculation

New data requirements	Regulation (EU) No 283/2013)								
									Column to be deleted if not relevant
Relevant groups	**Dietary burden expressed in**				**Most critical diet (a)**	**Most critical commodity (b)**		Trigger exceeded (Yes/No)	Previous assessment
	mg/kg bw per day		mg/kg DM					0.004	Max burden
	Median	Maximum	Median	Maximum				mg/kg bw	mg/kg bw
Cattle (all diets)	0,003	0,003	0,07	0,07	Dairy cattle	Wheat	milled bypdts	No	
Cattle (dairy only)	0,003	0,003	0,07	0,07	Dairy cattle	Wheat	milled bypdts	No	
Sheep (all diets)	0,004	0,004	0,10	0,10	Lamb	Wheat	milled bypdts	Yes	
Sheep (ewe only)	0,003	0,003	0,09	0,09	Ram/Ewe	Wheat	milled bypdts	No	
Swine (all diets)	0,003	0,003	0,09	0,09	Swine (finishing)	Wheat	milled bypdts	No	
Poultry (all diets)	0,004	0,004	0,05	0,05	Poultry layer	Wheat	milled bypdts	No	
Poultry (layer only)	0,004	0,004	0,05	0,05	Poultry layer	Wheat	milled bypdts	No	
(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"									
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".									

zRMS

Below is a calculation (animal model 2017) using the input data from the EFSA Journal 2021 as input; 19 (2): 64 except for wheat.

Input data for wheat (residue trials):

Grain

STMR – 0.02

Straw

STMR – 0.75; HR – 2.14

Relevant groups	**Dietary burden expressed in**				**Most critical diet (a)**	**Most critical commodity (b)**		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,241	0,372	8,09	11,88	Dairy cattle	Kale	leaves	Yes
Cattle (dairy only)	0,241	0,372	6,27	9,66	Dairy cattle	Kale	leaves	Yes
Sheep (all diets)	0,249	0,319	7,47	9,56	Ram/Ewe	Kale	leaves	Yes
Sheep (ewe only)	0,249	0,319	7,47	9,56	Ram/Ewe	Kale	leaves	Yes
Swine (all diets)	0,097	0,150	4,21	6,51	Swine (breeding)	Kale	leaves	Yes
Poultry (all diets)	0,076	0,090	1,08	1,27	Poultry broiler	Rice	bran/pollard	Yes
Poultry (layer only)	0,057	0,081	0,83	1,19	Poultry layer	Potato	dried pulp	Yes

TDMs assessment

Table 7.3-12: Input values for the maximum dietary burden calculation (considering the uses in EFSA and the uses under consideration)

Crop	**Source of data**	**HR or STMR*PF**	**1,2,4-T**	**TA**	**TAA**	**TLA**
Alfalfa forage	Wheat or barley plant	HR	0.06	0.524	0.434	1.43

Alfalfa hay	Wheat or barley plant	HR * default PF (2.5)	0.15	1.31	1.085	3.58
Alfalfa meal	Wheat or barley plant	HR * default PF (2.5)	0.15	1.31	1.085	3.58
Alfalfa silage	Wheat or barley plant	HR * default PF (1.1)	0.066	0.576	0.477	1.57
Beet, mangel fodder	HR of beet leaves or root	HR	0.12	0.239	0.05	0.14
Beet tops	Sugar beet leaves	HR	0.12	0.218	0.02	0.14
Cabbage heads	brassica	HR	0.113	0.5	0.01	0.01
Clover forage	Wheat or barley plant	HR	0.06	0.524	0.434	1.43
Clover hay	Wheat or barley plant	HR * default PF (3)	0.18	1.57	1.3	4.29
Clover silage	Wheat or barley plant	HR * default PF (1)	0.06	0.524	0.434	1.43
Grass forage	Wheat or barley plant	HR	0.06	0.524	0.434	1.43
Grass hay	Wheat or barley plant	HR * default PF (3.5)	0.21	1.83	1.5	5.0
Grass silage	Wheat	HR * default PF (1.6)	0.096	0.838	0.694	2.3
Kale	Brassica	HR	0.113	0.5	0.01	0.01
Rape forage	Oilseed rape plant	HR	0.023	0.913	0.034	0.04
Cereal straws/stover	Cereal data	HR	0.05	0.65	0.78	1.1
Turnip leaves	Sugar beet leaves data	HR	0.12	0.218	0.02	0.14
Carrot	Root vegetable	HR	0.06	0.239	0.05	0.13
Potato	Root vegetable	HR	0.06	0.239	0.05	0.13
Swede	Root vegetable	HR	0.06	0.239	0.05	0.13
Turnip	Root vegetable	HR	0.06	0.239	0.05	0.13
All cereal grains	Cereal data	STMR	0.05	0.621	0.79	0.02
Pulses	Pulse data	STMR	0.05	0.17	0.05	0.01
By products						
Apple pomace	Citrus or apple	STMR-P	0.25 (STMR* default PF (5))	0.167 (STMR*PF) (0.32*0.52)	0.25 (STMR* default PF (5))	0.1 (STMR*PF) (0.04*2.5)

Beet sugar dried pulp	Sugar beet root data	STMR* default PF (18)	0.9	3.3	0.9	0.38
Beet, sugar, ensiled pulp	Sugar beet root data	STMR* default PF (3)	0.15	0.55	0.15	0.06
Beet, sugar molasses	Sugar beet root data	STMR* default PF (28)	1.4	5.1	1.4	0.59
Brewer's grain	Cereal grain data	STMR* default PF (3.3)	0.165	2.0	2.6	0.073
Canola	Oilseed rape data	STMR* PF	0.1 (STMR* default PF (2))	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Citrus pomace	Citrus or apple	STMR-P	0.5 (STMR* default PF (10))	0.167 (STMR*PF) (0.32*0.52)	0.5 (STMR* default PF (10))	0.1 (STMR*PF) (0.04*2.5)
Corn, field milled by-products	Cereal grain data	STMR* default PF (1)	0.05	0.621	0.79	0.02
Corn, field, hominy meal	Cereal grain data	STMR* default PF (6)	0.3	3.73	4.74	0.13
Corn, field gluten feed	Cereal grain data	STMR* default PF (2.5)	0.125	1.55	1.98	0.06
Corn field, gluten meal	Cereal grain data	STMR* default PF (1)	0.05	0.621	0.79	0.02
Cotton meal	Oilseed data	STMR* PF	0.065 (STMR* default PF (1.3)) (0.05* 1.3)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Distiller's grain	Cereal grain data	STMR* default PF (3.3)	0.165	2.0	2.6	0.073
Flaxseed/linseed meal	Oilseed rape data	STMR* PF	0.1 (STMR * default PF (2)) (0.05* 2)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Lupin seed meal	Pulse data	STMR* default PF (1.1)	0.055	0.187	0.055	0.01
Potato process waste	Root vegetable	STMR* default PF (20)	1	3.68	1	0.42
Potato dried pulp	Root vegetable	STMR* default PF (38)	1.9	6.99	1.9	0.80

Rape meal	Oilseed rape data	STMR* PF	0.1 (STMR * default PF (2)) (0.05* 2)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Safflower meal	Oilseed rape data	STMR* PF	0.1 (STMR * default PF (2)) (0.05* 2)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Soybean meal	Oilseed rape data	STMR* PF	0.065 (STMR * default PF (1.3)) (0.05*1.3)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Soybean hulls	Oilseed rape data	STMR* default PF (13)	0.65	13.5	1.56	0.85
Sugarcane molasses	Sugar plant data	STMR* default PF (32)	1.6	5.89	1.6	0.67
Sunflower meal	Oilseed rape data	STMR* PF	0.1 (STMR * default PF (2)) (0.05* 2)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Wheat gluten meal	Cereal data	STMR* default PF (1.8)	0.09	1.11	1.42	0.04
Wheat milled by products	Cereal data	STMR* default PF (7)	0.035	4.35	5.53	0.15

Table 7.3-13: Input values for the median dietary burden calculation (considering the uses in EFSA and the uses under consideration)

Crop	**Source of data**	**STMR or STMR*PF**	**1,2,4-T**	**TA**	**TAA**	**TLA**
Alfalfa forage	Wheat or barley plant	STMR	0.05	0.16	0.1	0.4
Alfalfa hay	Wheat or barley plant	HR * default PF (2.5)	0.3	0.4	0.25	1
Alfalfa meal	Wheat or barley plant	HR * default PF (2.5)	0.3	0.4	0.25	1
Alfalfa silage	Wheat or barley plant	HR * default PF (1.1)	0.06	0.18	0.11	0.44
Beet, mangel fodder	HR of beet leaves or root	STMR	0.05	0.18	0.05	0.05
Beet tops	Sugar beet leaves	STMR	0.03	0.04	0.01	0.05
Cabbage heads	brassica	STMR	0.04	0.17	0.01	0.01

Clover forage	Wheat or barley plant	STMR	0.05	0.16	0.1	0.4
Clover hay	Wheat or barley plant	STMR * default PF (3)	0.15	0.48	0.3	1.2
Clover silage	Wheat or barley plant	STMR * default PF (1)	0.05	0.16	0.1	0.4
Grass forage	Wheat or barley plant	STMR	0.05	0.16	0.1	0.4
Grass hay	Wheat or barley plant	STMR * default PF (3.5)	0.18	0.56	0.35	1.4
Grass silage	Wheat or barley plant	STMR * default PF (1.6)	0.08	0.26	0.16	0.64
Kale	brassica	STMR	0.04	0.17	0.01	0.01
Rape forage	Oilseed rape plant	STMR	0.01	0.10	0.01	0.04
Cereal straws	Cereal data	STMR	0.05	0.12	0.24	0.37
Turnip leaves	Sugar beet leaf data	STMR	0.03	0.04	0.01	0.05
Root and tubers						
Carrot	Root vegetable	STMR	0.05	0.18	0.05	0.02
Potato	Root vegetable	STMR	0.05	0.18	0.05	0.02
Swede	Root vegetable	STMR	0.05	0.18	0.05	0.02
Turnip	Root vegetable	STMR	0.05	0.18	0.05	0.02
Cereal grains/ crop seeds						
All cereal grains	Cereal data	STMR	0.05	0.62	0.79	0.022
Pulses	Pulse data	STMR	0.05	0.17	0.05	0.01
By products						
Apple pomace	Citrus or apple	STMR-P	0.3 (STMR* default PF (5))	0.17 (STMR*PF) (0.32*0.52)	0.13 (STMR*PF) (0.05*2.5	0.1 (STMR*PF) (0.04*2.5)
Beet sugar dried pulp	Sugar beet root data	STMR* default PF (18)	0.9	3.3	0.9	0.38
Beet, sugar, ensiled pulp	Sugar beet root data	STMR* default PF (3)	0.15	0.55	0.15	0.06

Beet, sugar molasses	Sugar beet root data	STMR* default PF (28)	1.4	5.1	1.4	0.59
Brewer's grain	Cereal grain	STMR* default PF (3.3)	0.17	2.0	2.6	0.073
Canola	Oilseed rape data	STMR* PF	0.1 (STMR* default PF (2))	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Citrus pomace		STMR-P	0.5 (STMR* default PF (10))	0.17 (STMR*PF) (0.32*0.52)	0.13 (STMR*PF) (0.05*2.5	0.1 (STMR*PF) (0.04*2.5)
Corn, field milled by-products	Cereal grain data	STMR* default PF (1)	0.05	0.62	0.79	0.02
Corn, field, hominy meal	Cereal grain data	STMR* default PF (6)	0.3	3.7	4.74	0.13
Corn, field gluten feed	Cereal grain data	STMR* default PF (2.5)	0.13	1.6	1.98	0.06
Corn field, gluten meal	Cereal grain data	STMR* default PF (1)	0.05	0.62	0.79	0.02
Cotton meal	Oilseed data	STMR* PF	0.07 (STMR* default PF (1.3)) (0.05* 1.3)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Distiller's grain	Cereal grain data	STMR* default PF (3.3)	0.17	2.0	2.6	0.073
Flaxseed/linsee	Oilseed rape data	STMR*PF	0.1 (STMR * default PF (2)) (0.05* 2)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Lupin seed meal	Pulse data	STMR* default PF (1.1)	0.06	0.19	0.06	0.01
Potato process waste	Root vegetable	STMR* default PF (20)	1	3.7	1	0.42
Potato dried pulp	Root vegetable	STMR* default PF (38)	1.9	6.99	1.9	0.80
Rape meal	Oilseed rape data	STMR* PF	0.1 (STMR * default PF (2)) (0.05* 2)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Safflower meal	Oilseed rape data	STMR* PF	0.1 (STMR *	1.45 (STMR*PF)	0.24 (STMR*PF)	0.13 (STMR*PF)

			default PF (2)) (0.05* 2)	(1.039*1.4)	(0.12*2)	(0.065*2)
Soybean meal	Oilseed rape data	STMR* PF	0.07 (STMR * default PF (1.3)) (0.05* 1.3)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Soybean hulls	Oilseed rape data	STMR* default PF (13)	0.7	13.5	1.56	0.85
Sugarcane molasses	Sugar plant data	STMR* default PF (32)	1.6	5.89	1.6	0.67
Sunflower meal	Oilseed rape data	STMR* PF	0.1 (STMR * default PF (2)) (0.05* 2)	1.45 (STMR*PF) (1.039*1.4)	0.24 (STMR*PF) (0.12*2)	0.13 (STMR*PF) (0.065*2)
Wheat gluten meal	Cereal data	STMR* default PF (1.8)	0.09	1.11	1.42	0.04
Wheat milled by products	Cereal data	STMR* default PF (7)	0.35	4.35	5.53	0.15

Table 7.3-14: Results of the dietary burden calculation for TDMs

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)
TA					
Cattle (all diets)	0.376	0.405	Potato process waste	13.63	Y
Cattle (dairy only)	0.376	0.405	Potato process waste	10.52	Y
Sheep (all diets)	0.424	0.454	Potato process waste	13.63	Y
Sheep (ewe only)	0.424	0.454	Potato process waste	13.63	Y
Swine (all diets)	0.163	0.178	Potato process waste	7.71	Y
Poultry (all diets)	0.158	0.165	Potato dried pulp	2.34	Y
Poultry (layer only)	0.130	0.149	Potato dried pulp	2.18	Y
TLA					
Cattle (all diets)	0.078	0.177	Grass forage (fresh)	4.61	Y
Cattle (dairy only)	0.078	0.177	Grass forage (fresh)	4.61	Y
Sheep (all diets)	0.079	0.187	Grass forage (fresh)	5.61	Y
Sheep (ewe only)	0.079	0.187	Grass forage (fresh)	5.61	Y
Swine (all diets)	0.026	0.055	Grass forage (fresh)	2.37	Y

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)
Poultry (all diets)	0.021	0.052	Clover hay	0.77	Y
Poultry (layer only)	0.021	0.052	Clover hay	0.77	Y
TAA					
Cattle (all diets)	0.118	0.140	Potato process waste	4.29	Y
Cattle (dairy only)	0.118	0.140	Potato process waste	3.63	Y
Sheep (all diets)	0.153	0.170	Wheat milled bypdts	4.37	Y
Sheep (ewe only)	0.127	0.146	Potato process waste	4.37	Y
Swine (all diets)	0.108	0.109	Wheat milled bypdts	3.76	Y
Poultry (all diets)	0.138	0.140	Wheat milled bypdts	2.05	Y
Poultry (layer only)	0.135	0.140	Wheat milled bypdts	2.05	Y
1,2,4-T					
Cattle (all diets)	0.104	0.109	Potato process waste	3.75	Y
Cattle (dairy only)	0.104	0.109	Potato process waste	2.83	Y
Sheep (all diets)	0.118	0.121	Potato process waste	3.63	Y
Sheep (ewe only)	0.118	0.121	Potato process waste	3.63	Y
Swine (all diets)	0.045	0.047	Potato process waste	2.04	Y
Poultry (all diets)	0.037	0.038	Potato dried pulp	0.53	Y
Poultry (layer only)	0.029	0.032	Potato dried pulp	0.46	Y

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

Table 7.3-15: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	Calculated MRL (mg/kg)	CF for RA[d]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[a]	No	Result for enforce-ment		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (addendum to the DAR, 2006; EFSA, 2011)												
Enforcement residue definition: Difenoconazole alcohol (CGA 205375) expressed as difenoconazole												
Difenoconazole												
Ruminant meat	0.0005	< 0.001	1	9	< 0.01	< 0.01	n.r.	n.r.	< 0.01	< 0.01	n.r.	n.r.
			3	9	< 0.01	< 0.01	n.r.	n.r.				
			10	9	< 0.01	< 0.01	n.r.	n.r.				
Ruminant fat			1	9	< 0.01	< 0.01	n.r.	n.r.	< 0.01	< 0.01	n.r.	n.r.
			3	9	< 0.01	< 0.01	n.r.	n.r.				
			10	9	< 0.01	< 0.01	n.r.	n.r.				
Ruminant liver			1	9	< 0.01	< 0.01	n.r.	n.r.	< 0.01	0.02	n.r.	n.r.
			3	9	< 0.01	< 0.01	n.r.	n.r.				
			10	9	0.014	0.020	n.r.	n.r.				
Ruminant kidney			1	9	< 0.01	< 0.01	n.r.	n.r.	< 0.01	< 0.01	n.r.	n.r.
			3	9	< 0.01	< 0.01	n.r.	n.r.				
			10	9	< 0.01	< 0.01	n.r.	n.r.				
Milk	0.0008	0.001	1	9	< 5 [e]	N/A	n.r.	n.r.	< 5	< 5	n.r.	n.r.
			3	9	< 5	N/A	n.r.	n.r.				
			10	9	< 5	N/A	n.r.	n.r.				

Difenoconazole alcohol (CGA 205375)												
Ruminant meat	0.0005	< 0.001	1	9	< 0.01	< 0.01	n.r.	n.r.	-	0.024	n.r.	n.r.
			3	9	0.011	0.012	n.r.	n.r.				
			10	9	0.022	0.024	n.r.	n.r.				
Ruminant fat			1	9	< 0.01	< 0.01	n.r.	n.r.	-	0.095	n.r.	n.r.
			3	9	0.027	0.033	n.r.	n.r.				
			10	9	0.077	0.095	n.r.	n.r.				
Ruminant liver			1	9	0.039	0.044	n.r.	n.r.	-	0.35	n.r.	n.r.
			3	9	0.12	0.13	n.r.	n.r.				
			10	9	0.30	0.35	n.r.	n.r.				
Ruminant kidney			1	9	< 0.01	< 0.01	n.r.	n.r.	-	0.052	n.r.	n.r.
			3	9	0.017	0.018	n.r.	n.r.				
			10	9	0.044	0.052	n.r.	n.r.				
Milk	0.0008	0.001	1	9	< 5 [(e)]	N/A	n.r.	n.r.	< 5	< 5	n.r.	n.r.
			3	9	< 5	N/A	n.r.	n.r.				
			10	9	< 5	N/A	n.r.	n.r.				

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 (European comission 7031/VI/95 rev.4)
(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 0 until day 28 (11 cows).

			3	9	< 5	N/A	n.r.	n.r.				
			10	9	< 5	N/A	n.r.	n.r.				

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.

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

7.3.5.1 Available data for all crops under consideration

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

Table 7.3-16: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Enforcement residue definition: difenoconazole					
Apple, washed fruit	2	0.78	1.0		EFSA Journal 2011;9(1):1967
Apple, wet pomace	4	4.3	1.0		EFSA Journal 2011;9(1):1967
Apple, dry pomace	1	16	1.0		EFSA Journal 2011;9(1):1967
Apple, juice (before/after pasteurisation)	1[a]	0.02	1.0		EFSA Journal 2011;9(1):1967
Apple, puree	1	0.14	1.0		EFSA Journal 2011;9(1):1967
TA					
Wheat husk	4	0.75	1.0		TDMs Addendum – Confirmatory Data, UK, 2018
Coarse bran	4	2.05	1.0		
Wheat straight flour	8	0.6	1.0		
Fine bran	8	2.05	1.0		
Middlings	5	0.6	1.0		
Shorts	5	1.4	1.0		
Germ	5	2.5	1.0		
Low grade meal	4	0.85	1.0		
Flour type 550	4	0.55	1.0		
Wheat wholemeal flour	5	0.9	1.0		
Wheat wholemeal bread	4	0.6	1.0		
TAA					
Wheat husk	4	1.0	1.0		TDMs Addendum – Confirmatory Data,
Coarse bran	4	1.2	1.0		

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
Wheat straight flour	8	0.95	1.0		UK, 2018
Fine bran	8	1.25	1.0		
Middlings	5	0.9	1.0		
Shorts	5	1.0	1.0		
Germ	5	1.2	1.0		
Low grade meal	4	0.95	1.0		
Flour type 550	4	0.85	1.0		
Wheat wholemeal flour	5	0.8	1.0		
Wheat wholemeal bread	4	0.75	1.0		

a 4 studies available for apple juice, but 3 studies disregarded as residue in RAC and juice at/close to the LOQ
* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
** The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

7.3.5.2 Conclusion on processing studies

Conclusions drawn in the DAR, 2006 are reported below:
In studies to determine the effect of processing on residue levels, residues of difenoconazole in apple were reduced by washing (mean transfer factor 0.8) and were not concentrated in juice. Residues of difenoconazole were concentrated in wet pomace (mean transfer factor 4.5) and in dry pomace (mean transfer factor 15.7).
RMS:
Further processing studies are not required as they are not expected to affect the outcome of the risk assessment.
According to the trials studies, the highest value for difenoconazole in grain is 0.09 mg/kg which is below the trigger value of 0.1 mg/kg.
Contribution of wheat (IEDI (% ADI) according to EFSA PRIMo 3.1) is very low: max. 1.01% (GEMS Food).
IESTI is below 10% of the ARfD.

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Conclusion on rotational crops studies

Conclusions drawn in DAR, 2006 are reported below:

In five available studies, total radioactive residues in rotational crops (wheat, sugar beet, maize, lettuce, turnips and mustard) planted 62 to 488 days after one application of difenoconazole applied to bare ground at rates of 32.4, 125 and 750 g a.i./ha ranged from < 0.0001 to 0.34 mg difenoconazole eq./kg. Following application equivalent to twice the maximum recommended rate for carrots in Northern and Southern Europe (3 x 125 g a.i./ha), residues of difenoconazole were below the LOD (< 0.02 and < 0.05 mg/kg). Although the PHI was not within 25% of the critical GAP in Northern and Southern Europe (14 vs. 30), the exaggerated application rate of 750 g a.i./he represents a worst-case for residues of difenoconazole in rotational crops and in commercial practice residues of difenoconazole will not be expected in succeeding crops.

TDMs Assessment

Rotational crop study was performed on three crop groups (barley, lettuce and carrot). The crops were planted 30 – 375 days after one application of difenoconazole applied to bare soil at a dose of 375 g a.s./ha. Results of the study is summarized below:

Commodity	Application to	No of Trials	STMR (mg/kg)				HR (mg/kg)			
			T	TA	TAA	TLA	T	TA	TAA	TLA
Barley plant	Bare soil PBI 30-36 days	4	<0.01	0.06	0.03	0.14	<0.01	0.09	0.04	0.20
	Bare soil PBI 60-61 days	4	<0.01	0.06	0.04	0.12	<0.01	0.14	0.09	0.42
	Bare soil PBI 322-375 days	4	<0.01	0.09	0.02	0.13	<0.01	0.12	0.05	0.19
Barley (plant) worst case			<0.01	0.09	0.04	0.14	<0.01	0.14	0.09	0.42
Barley grain	Bare soil PBI 30-36 days	3	<0.01	0.18	0.16	0.01	<0.01	0.54	0.57	0.01
	Bare soil PBI 60-61 days	3	<0.01	0.23	0.22	<0.01	<0.01	0.31	0.33	<0.01
	Bare soil PBI 322-375 days	4	<0.01	0.28	0.27	0.01	<0.01	0.40	0.35	0.02
Barley (grain) worst case			<0.01	0.28	0.27	0.01	<0.01	0.54	0.57	0.02
Barley straw	Bare soil PBI 30-36 days	4	<0.01	0.11	0.13	0.07	<0.01	0.22	0.17	0.24
	Bare soil PBI 60-61 days	3	<0.01	0.05	0.16	0.07	<0.01	0.19	0.24	0.42
	Bare soil PBI 322-375 days	4	<0.01	0.04	0.13	0.07	<0.01	0.08	0.23	0.10
Barley (straw) worst case			<0.01	0.11	0.16	0.07	<0.01	0.22	0.24	0.42
Carrot tops	Bare soil PBI 30-36 days	4	<0.01	<0.01	<0.01	0.09	<0.01	0.01	<0.01	0.29
	Bare soil PBI 60-61 days	4	<0.01	<0.01	<0.01	0.06	<0.01	<0.01	<0.01	0.09
	Bare soil PBI 322-375 days	4	<0.01	<0.01	<0.01	0.06	<0.01	0.01	<0.01	0.07
Carrot (tops) worst case			<0.01	<0.01	<0.01	0.09	<0.01	0.01	<0.01	0.29
Carrot root	Bare soil PBI 30-36 days	4	<0.01	0.06	<0.01	0.01	<0.01	0.07	<0.01	0.03

	Bare soil PBI 60-61 days	4	<0.01	0.05	<0.01	<0.01	<0.01	0.05	<0.01	0.01
	Bare soil PBI 322-375 days	4	<0.01	0.03	<0.01	<0.01	<0.01	0.04	<0.01	0.01
Carrot (root) worst case			<0.01	0.06	<0.01	0.01	<0.01	0.07	<0.01	0.03
Lettuce	Bare soil PBI 29-36 days	4	<0.01	0.01	<0.01	0.03	<0.01	0.02	<0.01	0.05
	Bare soil PBI 60-61 days	4	<0.01	0.01	<0.01	0.03	<0.01	0.02	<0.01	0.08
	Bare soil PBI 322-375 days	4	<0.01	<0.01	<0.01	0.03	<0.01	0.02	<0.01	0.08
Lettuce worst case			<0.01	0.01	<0.01	0.03	<0.01	0.03	<0.01	0.08

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of SHA 7216 A. Therefore, other special studies are not needed.

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

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

7.3.8.1 Input values for the consumer risk assessment

Table 7.3-17: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: Difenoconazole		
Barley	0.02	STMR
Apricots	0.17	STMR
Strawberries	0.14	STMR
Brussels sprouts	0.09	STMR
Head cabbages	0.02	STMR
Lettuce and salad plants including Brassicacea, excluding Roman rocket/rucola and Lamb's lettuce	0.52	STMR
Scaroles/broad-leaved endives [(a)]	0.52	STMR (lettuce) (scenario 1)
	0.18	STMR (lettuce) (scenario 2)
Beet leaves (chard)	0.52	STMR (lettuce)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Herbs and edible flowers (excluding chervil, parsley, celery leaves, basil)	0.52	STMR (lettuce)
Celeries	1.22	STMR
Cardoons	1.22	STMR (celery)
Rhubarbs	0.12	STMR (celery stems)
Leeks	0.13	STMR
Pulses, except peas	0.02	STMR
Root and rhizome (spices)	0.64	STMR (carrot) x PF (8)
Citrus, pome fruit	0.16	STMR (FAO, 2013)
Peaches	0.15	STMR (EFSA, 2010)
Grapes (table and wine)	0.52	STMR (FAO, 2013)
Blackberries, raspberries	0.04	STMR (EFSA, 2012)
Olives (table and oil)	0.48	STMR (EFSA, 2010)
Avocados	0.05	STMR (FAO, 2015)
Papaya	0.01	STMR-peel (EFSA, 2013)
Beetroots	0.08	STMR (EFSA, 2013)
Carots	0.08	STMR (EFSA, 2013)
Horseradish	0.08	STMR (EFSA, 2013)
Jerusalem artichoke	0.08	STMR (EFSA, 2013)
Parsnip	0.08	STMR (EFSA, 2013)
Parsley root	0.08	STMR (EFSA, 2013)
Radish	0.08	STMR (EFSA, 2013)
Salsify	0.08	STMR (EFSA, 2013)
Swedes, turnips	0.08	STMR (EFSA, 2013)
Garlic	0.01	STMR (EFSA, 2013)
Onion (bulb)	0.01	STMR (EFSA, 2013)
Shallots	0.01	STMR (EFSA, 2013)
Spring onions	2.8	STMR (FAO, 2013)
Tomatoes	0.72	STMR (EFSA, 2010)
Peppers	0.17	STMR (EFSA, 2014a)
Aubergines	0.18	STMR (EFSA, 2014a)
Cucumbers, gherkins, courgettes	0.01	STMR (EFSA, 2012)
Melons	0.01	STMR-peel (EFSA, 2013)
Pumpkin, watermelon	0.01	STMR (EFSA, 2013)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Broccoli	0.13	STMR (EFSA, 2011b)
Lamb's lettuces	1.45	STMR (EFSA, 2014b)
Rucola, rocket	0.44	STMR (EFSA, 2014b)
Witloof	0.01	STMR (EFSA, 2013)
Parsley, chervil, celery leaves	4.65	STMR (EFSA, 2009)
Basil (mint)	4.65	STMR (EFSA, 2014b)
Fennel	1.66	STMR (EFSA, 2009)
Globe artichoke	0.36	STMR (EFSA, 2013)
Soya bean	0.01	STMR (FAO, 2015)
Rice	0.88	STMR (EFSA, 2013)
Chicory roots	0.20	STMR (EFSA, 2013)
Wheat, rye	0.02	STMR (EFSA, 2010)
	Acute risk assessment	
Wheat	0.02	STMR (EFSA, 2010)

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-18: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	**351,3% NL toddler** **282,4% DE child** **240,7% GEMS/Food G06** **195,0% NL child** **188,2% GEMS/Food G11** **182,9% GEMS/Food G10** **182,5% GEMS/Food G07** **179,8% PT general** **177,2% GEMS/Food G08** **175,5% IE adult** **155,2% GEMS/Food G15** **155,1% RO general** **149,6% FR child 3 15 yr** **136,4% DE women 14-50 yr** **135,1% FR adult** **128,9% FR toddler 2 3 yr** **125,6% DE general** **124,6% ES child** **115,0% SE general** **111,1% ES adult** **107,7% NL general** **105,3% UK toddler** **103,4% IT toddler** **100,4% IT adult**

IEDI (% ADI) according to EFSA PRIMo 3.1	53,3% GEMS/Food G06 tomatoes 32,2% GEMS/Food G10 Rice
IESTI (% ARfD) according to EFSA PRIMo*	**Unprocessed commodities:** Wheat: 0.2% (based on children) Wheat: 0.1% (based on adult) **Processed commodities:** Wheat/milling (flour): 0.2% (based on children) Wheat/bread/pizza: 0.1% (based on adult) **Calculation using MRL value:** **Unprocessed commodities:** Wheat: 0.9% (based on children) Wheat: 0.5% (based on adult) **Processed commodities:** Wheat/milling (flour): 0.8% (based on children) Wheat/bread/pizza: 0.3% (based on adult)
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

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

The proposed uses of Difenoconazole in the formulation Boscalid 23.3% + Difenoconazole 6.6% SC do not represent unacceptable acute risks for the consumer.

All input values for difenoconazole is based on EFSA, 2021. Modification of the existing maximum residue levels for difenoconazole in leafy brassica. EFSA Journal 2021;19(2):6407 except for wheat, where the results of the new study were applied.

Input values

Code number	Commodity	Chronic risk assessment (IEDI)	
		Input value (mg/kg)	Comment
0243000	. (c) leafy brassica	0.83	proposed STMR (this submission)
0110000	Citrus fruits	0.16	STMR (FAO, 2013)
0130000	Pome fruits	0.16	STMR (FAO, 2013)
0140010	. Apricots	0.17	STMR (EFSA, 2017a)
0140020	. Cherries (sweet)	0.3	EU MRL Reg (EU) 2019/552
0140030	. Peaches	0.15	STMR (EFSA, 2010)
0140040	. Plums	0.5	EU MRL Reg (EU) 2019/552
0151010	. Table grapes	0.52	STMR (FAO, 2013)
0151020	. Wine grapes	0.52	STMR (FAO, 2013)
0152000	. (b) strawberries	0.42	STMR (FAO, 2017)
0153010	. Blackberries	0.04	STMR (EFSA, 2012)
0153020	. Dewberries	0.1	EU MRL Reg (EU) 2019/552
0153030	. Raspberries (red and yellow)	0.04	STMR (EFSA, 2012)
0154010	. Blueberries	1.0	STMR (FAO, 2017)
0154020	. Cranberries	0.1	EU MRL Reg (EU) 2019/552
0154030	. Currants (black, red and white)	0.2	EU MRL Reg (EU) 2019/552
0154040	. Gooseberries (green, red & yellow)	0.1	EU MRL Reg (EU) 2019/552

Code number	Commodity	Chronic risk assessment (IEDI)	
		Input value (mg/kg)	Comment
0154050	. Rose hips	0.1	EU MRL Reg (EU) 2019/552
0154060	. Mulberries (black and white)	0.1	EU MRL Reg (EU) 2019/552
0154070	. Azaroles/Mediterranean medlars	0.16	STMR (FAO, 2013)
0154080	. Elderberries	0.1	EU MRL Reg (EU) 2019/552
0161010	. Dates	0.1	EU MRL Reg (EU) 2019/552
0161020	. Figs	0.1	EU MRL Reg (EU) 2019/552
0161030	. Table olives	0.47	STMR (EFSA, 2010)
0161040	. Kumquats	0.16	STMR (FAO, 2013)
0161050	. Carambolas	0.1	EU MRL Reg (EU) 2019/552
0161060	. Kaki/Japanese persimmons	0.16	STMR (FAO, 2013)
0161070	. Jambuls/jambulans	0.1	EU MRL Reg (EU) 2019/552
0162010	. Kiwi fruits (green, red, yellow)	0.1	EU MRL Reg (EU) 2019/552
0162020	. Litchis/lychees	0.1	EU MRL Reg (EU) 2019/552
0162030	. Passionfruits/maracujas	0.1	EU MRL Reg (EU) 2019/552
0162040	. Prickly pears/cactus fruits	0.034	STMR (FAO, 2017)
0162050	. Star apples/cainitos	0.1	EU MRL Reg (EU) 2019/552
0162060	. American persimmon/ Virginia kaki	0.1	EU MRL Reg (EU) 2019/552
0163010	. Avocados	0.05	STMR (FAO, 2015)
0163020	. Bananas	0.1	EU MRL Reg (EU) 2019/552
0163030	. Mangoes	0.1	EU MRL Reg (EU) 2019/552
0163040	. Papayas	0.01	STMR -peel (EFSA, 2013)
0163050	. Granate apples/ pomegranates	0.1	EU MRL Reg (EU) 2019/552
0163060	. Cherimoyas	0.1	EU MRL Reg (EU) 2019/552
0163070	. Guavas	0.1	EU MRL Reg (EU) 2019/552
0163080	. Pineapples	0.1	EU MRL Reg (EU) 2019/552
0163090	. Breadfruits	0.1	EU MRL Reg (EU) 2019/552
0163100	. Durians	0.1	EU MRL Reg (EU) 2019/552
0163110	. Soursops/guanabanas	0.1	EU MRL Reg (EU) 2019/552
0211000	. (a) potatoes	0.1	EU MRL Reg (EU) 2019/552
0212000	. (b) tropical root and tuber vegetables	0.1	EU MRL Reg (EU) 2019/552
0213010	. Beetroots	0.08	STMR (carrot) (EFSA, 2013)
0213020	. Carrots	0.08	STMR (carrot) (EFSA, 2013)
0213030	. Celeriacs/ turnip rooted celeries	2.0	EU MRL Reg (EU) 2019/552
0213040	. Horseradishes	0.08	STMR (carrot) (EFSA, 2013)
0213050	. Jerusalem artichokes	0.08	STMR (carrot) (EFSA, 2013)
0213060	. Parsnips	0.08	STMR (carrot) (EFSA, 2013)
0213070	. Parsley roots/ Hamburg roots parsley	0.08	STMR (carrot) (EFSA, 2013)
0213080	. Radishes	0.08	STMR (carrot) (EFSA, 2013)

Code number	Commodity	Chronic risk assessment (IEDI)	
		Input value (mg/kg)	Comment
0213090	. Salsifies	0.08	STMR (carrot) (EFSA, 2013)
0213100	. Swedes/rutabagas	0.08	STMR (carrot) (EFSA, 2013)
0213110	. Turnips	0.08	STMR (carrot) (EFSA, 2013)
0220010	. Garlic	0.01	STMR (EFSA, 2013)
0220020	. Onions	0.01	STMR (EFSA, 2013)
0220030	. Shallots	0.01	STMR (EFSA, 2013)
0220040	. Spring onions/green onions and Welsh onions	2.8	STMR (FAO, 2013)
0231010	. Tomatoes	0.72	STMR (EFSA, 2010)
0231020	. Sweet peppers/bell peppers	0.17	STMR (EFSA, 2014)
0231030	. Aubergines/ eggplants	0.18	STMR (EFSA, 2014)
0231040	. Okra/lady's fingers	0.14	STMR (FAO, 2013/FAO 2017)
0232010	. Cucumbers	0.01	STMR (EFSA, 2012)
0232020	. Gherkins	0.01	STMR (EFSA, 2012)
0232030	. Courgettes	0.01	STMR (EFSA, 2012)
0233010	. Melons	0.01	STMR -p (EFSA, 2013)
0233020	. Pumpkins	0.01	STMR -p (EFSA, 2013)
0233030	. Watermelons	0.01	STMR -p (EFSA, 2013)
0241010	. Broccoli	0.13	STMR (EFSA, 2011a)
0241020	. Cauliflowers	0.2	EU MRL Reg (EU) 2019/552
0241990	. Others	0.01	STMR (EFSA, 2018a)
0242010	. Brussels sprouts	0.07	STMR (EFSA, 2018a)
0242020	. Head cabbages	0.02	STMR (EFSA, 2017b)
0251010	. Lamb's lettuces/ corn salads	1.45	STMR (EFSA, 2014a)
0251020	. Lettuces	0.52	STMR (lettuce) (EFSA, 2017a)
0251030	. Escaroles/broad-leaved endives	0.33	STMR (EFSA, 2018a)
0251040	. Cresses and other sprouts and shoots	0.52	STMR (lettuce) (EFSA, 2017a)
0251050	. Land cresses	0.52	STMR (lettuce) (EFSA, 2017a)
0251060	. Roman rocket/ rucola	0.33	STMR (EFSA, 2018a)
0251070	. Red mustards	0.52	STMR (lettuce) (EFSA, 2017a)
0251080	. Baby leaf crops (including brassica species)	0.52	STMR (lettuce) (EFSA, 2017a)
0252010	. Spinaches	0.33	STMR (EFSA, 2018a)
0252020	. Purslanes	0.33	STMR (EFSA, 2018a)
0252030	. Chards/beet leaves	0.52	STMR (EFSA, 2017a)
0254000	. (d) watercresses	0.5	EU MRL Reg (EU) 2019/552
0255000	. (e) witloofs/ Belgian endives	1.3	STMR (EFSA, 2018a)
0256010	. Chervil	4.65	STMR (EFSA, 2014a)
0256020	. Chives	0.52	STMR (lettuce) (EFSA, 2017a)
0256030	. Celery leaves	4.65	STMR (EFSA, 2014a)
0256040	. Parsley	4.65	STMR (EFSA, 2014a)

Code number	Commodity	Chronic risk assessment (IEDI)	
		Input value (mg/kg)	Comment
0256050	. Sage	0.52	STMR (lettuce) (EFSA, 2017a)
0256060	. Rosemary	0.52	STMR (lettuce) (EFSA, 2017a)
0256070	. Thyme	0.52	STMR (lettuce) (EFSA, 2017a)
0256080	. Basil and edible flowers	4.65	STMR (EFSA, 2014a)
0256090	. Laurel/bay leave	0.52	STMR (lettuce) (EFSA, 2017a)
0256100	. Tarragon	0.52	STMR (lettuce) (EFSA, 2017a)
0260010	. Beans (with pods)	1	EU MRL Reg (EU) 2019/552
0260020	. Beans (without pods)	1	EU MRL Reg (EU) 2019/552
0260030	. Peas (with pods)	1	EU MRL Reg (EU) 2019/552
0260040	. Peas (without pods)	1	EU MRL Reg (EU) 2019/552
0270020	. Cardoons	1.22	STMR (EFSA, 2017a)
0270030	. Celeries	1.22	STMR (EFSA, 2017a)
0270040	. Florence fennels	1.66	STMR (EFSA, 2009)
0270050	. Globe artichokes	0.36	STMR (EFSA, 2013)
0270060	. Leeks	0.13	STMR (EFSA, 2017a)
0270070	. Rhubarbs	0.7	STMR (EFSA, 2018a)
0300010	. Beans	0.02	STMR (EFSA, 2017a)
0300020	. Lentils	0.02	STMR (EFSA, 2017a)
0300030	. Peas	0.028	STMR (FAO, 2017)
0300040	. Lupins/lupini beans	0.02	STMR (EFSA, 2017a)
0401010	. Linseeds	0.2	EU MRL Reg (EU) 2019/552
0401020	. Peanuts/groundnuts	0.01	CXL (FAO, 2016)
0401060	. Rapeseeds/canola seeds	0.02	STMR (Spain, 2019)
0401070	. Soyabeans	0.01	STMR (FAO, 2015)
0401080	. Mustard seeds	0.2	EU MRL Reg (EU) 2019/552
0402010	. Olives for oil production	0.47	STMR (EFSA 2010)
0500010	. Barley	0.02	STMR (EFSA, 2017a)
0500060	. Rice	0.88	STMR (EFSA, 2013)
0500070	. Rye	0.02	STMR (EFSA, 2010)
0500090	**. Wheat**	**0.014**	**STMR (new study)**
0630000	Herbal infusions from	20	EU MRL Reg (EU) 2019/552
0810000	. Seed spices	0.3	EU MRL Reg (EU) 2019/552
0820000	Fruit spices	0.3	EU MRL Reg (EU) 2019/552
0830000	Bark spices	0.3	EU MRL Reg (EU) 2019/552
0840000	Root and rhizome spices	0.64	STMR (carrot) x PF (8) (EFSA, 2017a)
0850000	Bud spices	0.3	EU MRL Reg (EU) 2019/552
0860000	Flower pistil spices	0.3	EU MRL Reg (EU) 2019/552
0900010	. Sugar beet roots	0.02	STMR (FAO, 2008)
0900030	. Chicory roots	0.2	STMR (EFSA, 2013)

1000000	PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS		
1010000	Tissues from		
1011000	. (a) swine		
1011010	. Muscle	0.01	STMR (FAO, 2011)
1011020	. Fat tissue	0.012	STMR (FAO, 2011)
1011030	. Liver	0.04	STMR (FAO, 2011)
1011040	. Kidney	0.04	STMR (FAO, 2011)
1011050	. Edible offals (other than liver & kidney)	0.04	STMR (FAO, 2011)
1011990	. Others	0.1	EU MRL Reg (EU) 2019/552
1012000	. (b) bovine		
1012010	. Muscle	0.01	STMR (FAO, 2011)
1012020	. Fat tissue	0.012	STMR (FAO, 2011)
1012030	. Liver	0.04	STMR (FAO, 2011)
1012040	. Kidney	0.04	STMR (FAO, 2011)
1012050	. Edible offals (other than liver & kidney)	0.04	STMR (FAO, 2011)
1012990	. Others	0.1	EU MRL Reg (EU) 2019/552
1013000	. (c) sheep		
1013010	. Muscle	0.01	STMR (FAO, 2011)
1013020	. Fat tissue	0.012	STMR (FAO, 2011)
1013030	. Liver	0.04	STMR (FAO, 2011)
1013040	. Kidney	0.04	STMR (FAO, 2011)
1013050	. Edible offals (other than liver & kidney)	0.04	STMR (FAO, 2011)
1013990	. Others	0.1	EU MRL Reg (EU) 2019/552
1014000	. d) goat		
1014010	. Muscle	0.01	STMR (FAO, 2011)
1014020	. Fat tissue	0.012	STMR (FAO, 2011)
1014030	. Liver	0.04	STMR (FAO, 2011)
1014040	. Kidney	0.04	STMR (FAO, 2011)
1014050	. Edible offals (other than liver & kidney)	0.04	STMR (FAO, 2011)
1014990	. Others	0.1	EU MRL Reg (EU) 2019/552
1015000	. (e) equine		
1015010	. Muscle	0.01	STMR (FAO, 2011)
1015020	. Fat tissue	0.012	STMR (FAO, 2011)
1015030	. Liver	0.04	STMR (FAO, 2011)
1015040	. Kidney	0.04	STMR (FAO, 2011)
1015050	. Edible offals (other than liver & kidney)	0.04	STMR (FAO, 2011)
1015990	. Others	0.1	EU MRL Reg (EU) 2019/552
1016000	. (f) poultry		
1016010	. Muscle	0.1	EU MRL Reg (EU) 2019/552
1016020	. Fat tissue	0.1	EU MRL Reg (EU) 2019/552
1016030	. Liver	0.1	EU MRL Reg (EU) 2019/552
1016040	. Kidney	0.1	EU MRL Reg (EU) 2019/552
1016050	. Edible offals (other than liver &	0.1	EU MRL Reg (EU) 2019/552

	kidney)		
1016990	. Others	0.1	EU MRL Reg (EU) 2019/552
1017000	. (g) Other farmed terrestrial animals		
1017010	. Muscle	0.1	EU MRL Reg (EU) 2019/552
1017020	. Fat tissue	0.1	EU MRL Reg (EU) 2019/552
1017030	. Liver	0.2	EU MRL Reg (EU) 2019/552
1017040	. Kidney	0.2	EU MRL Reg (EU) 2019/552
1017050	. Edible offals (other than liver & kidney)	0.2	EU MRL Reg (EU) 2019/552
1017990	. Others	0.1	EU MRL Reg (EU) 2019/552
1020000	Milk		
1020010	. Milk: Cattle	0.005	LOQ Reg (EU) 2019/552
1020020	. Milk: Sheep	0.005	LOQ Reg (EU) 2019/552
1020030	. Milk: Goat	0.005	LOQ Reg (EU) 2019/552
1020040	. Milk: Horse	0.005	LOQ Reg (EU) 2019/552
1020990	. Milk: Others	0.005	LOQ Reg (EU) 2019/552
1030000	Birds eggs		LOQ Reg (EU) 2019/552
1030010	. Eggs: Chicken	0.05	LOQ Reg (EU) 2019/552
1030020	. Eggs: Duck	0.05	LOQ Reg (EU) 2019/552
1030030	. Eggs: Goose	0.05	LOQ Reg (EU) 2019/552
1030040	. Eggs: Quail	0.05	LOQ Reg (EU) 2019/552
1030990	. Eggs: Others	0.05	LOQ Reg (EU) 2019/552
1040000	Honey and other apiculture products	0.05	LOQ Reg (EU) 2019/552
1050000	Amphibians and reptiles	0.05	LOQ Reg (EU) 2019/552
1060000	Terrestrial invertebrate animals	0.05	LOQ Reg (EU) 2019/552
1070000	Wild terrestrial vertebrate animals	0.05	LOQ Reg (EU) 2019/552

EFSA PRIMo revision 3.1; 2019/03/19

Difenoconazole

LOQs (mg/kg) range from: 0,005 to: 0,05

Toxicological reference values

ADI (mg/kg bw/day):	0,01	ARfD (mg/kg bw):	0,16
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2011	Year of evaluation:	2011

Input values

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	93%	NL toddler	9,33	17%	Apples	8%	Beans (with pods)	8%	Table grapes	3%	0,5%
	75%	DE child	7,49	20%	Apples	7%	Tomatoes	7%	Table grapes	2%	0,2%
	69%	GEMS/Food G06	6,89	26%	Tomatoes	14%	Rice	5%	Table grapes	0,1%	0,5%
	53%	IE adult	5,31	7%	Wine grapes	4%	Sweet potatoes	3%	Tomatoes	0,4%	2%
	53%	GEMS/Food G11	5,29	7%	Tomatoes	6%	Celeriacs/turnip rooted celeries	5%	Wine grapes	0,4%	
	50%	GEMS/Food G10	5,03	11%	Rice	10%	Tomatoes	3%	Potatoes	0,3%	1%
	49%	GEMS/Food G07	4,89	8%	Tomatoes	8%	Wine grapes	4%	Potatoes	0,3%	
	49%	NL child	4,88	9%	Apples	5%	Table grapes	4%	Tomatoes	1%	0,6%
	48%	PT general	4,84	13%	Wine grapes	7%	Rice	6%	Tomatoes		2%
	46%	GEMS/Food G08	4,57	8%	Tomatoes	5%	Wine grapes	4%	Potatoes	0,3%	
	44%	FR child 3 15 yr	4,41	6%	Tomatoes	5%	Oranges	5%	Beans (with pods)	2%	0,1%
	44%	GEMS/Food G15	4,40	9%	Tomatoes	5%	Wine grapes	4%	Potatoes	0,4%	
	42%	RO general	4,23	14%	Tomatoes	9%	Wine grapes	4%	Potatoes	0,9%	
	41%	FR toddler 2 3 yr	4,11	8%	Beans (with pods)	5%	Rice	5%	Apples	2%	0,1%
	36%	ES child	3,62	7%	Tomatoes	4%	Rice	3%	Oranges	1%	
	36%	SE general	3,58	6%	Tomatoes	4%	Potatoes	4%	Rice	1%	2%
	34%	DE women 14-50 yr	3,44	5%	Tomatoes	4%	Wine grapes	4%	Apples	0,8%	0,1%
	33%	UK infant	3,26	6%	Peas (without pods)	6%	Rice	3%	Potatoes	3%	
	32%	UK toddler	3,23	5%	Rice	4%	Tomatoes	3%	Potatoes	1%	
	31%	DE general	3,15	5%	Tomatoes	4%	Wine grapes	4%	Apples	0,8%	0,1%
	31%	FR adult	3,14	12%	Wine grapes	3%	Tomatoes	2%	Beans (with pods)	0,5%	0,1%
	29%	ES adult	2,88	6%	Tomatoes	3%	Lettuces	2%	Beans (with pods)	0,5%	
	28%	NL general	2,84	3%	Wine grapes	3%	Tomatoes	2%	Beans (with pods)	0,6%	0,6%
	28%	IT toddler	2,82	10%	Tomatoes	2%	Rice	2%	Lettuces		0,2%
	26%	IT adult	2,63	8%	Tomatoes	2%	Lettuces	2%	Florence fennels		0,2%
	26%	DK child	2,57	4%	Tomatoes	4%	Apples	3%	Rice	1%	0,1%
	26%	FI 3 yr	2,56	5%	Rice	5%	Potatoes	4%	Tomatoes	0,0%	0,2%
	23%	UK vegetarian	2,33	4%	Tomatoes	4%	Wine grapes	3%	Rice	0,3%	0,0%
	21%	UK adult	2,11	6%	Wine grapes	3%	Rice	3%	Tomatoes	0,3%	0,0%
	20%	FR infant	2,05	5%	Beans (with pods)	3%	Apples	2%	Potatoes	0,9%	
	20%	PL general	2,02	6%	Tomatoes	3%	Potatoes	3%	Apples		0,2%
	20%	FI 6 yr	1,99	4%	Potatoes	4%	Rice	3%	Tomatoes	0,0%	0,3%
	20%	DK adult	1,99	5%	Wine grapes	4%	Tomatoes	2%	Apples	0,4%	0,0%
	16%	LT adult	1,60	4%	Tomatoes	3%	Potatoes	3%	Apples	0,4%	
	14%	FI adult	1,38	4%	Tomatoes	2%	Wine grapes	1%	Potatoes		0,1%
	7%	IE child	0,75	3%	Rice	0,9%	Beans (without pods)	0,6%	Potatoes	0,3%	

Conclusion:

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

Results:

IEDI (% ADI) according to EFSA PRIMo 3.1	93 % 17%	NL toodlers, highest contributor to MS diet: apple

Contribution of wheat is very low: max. 1.01% (GEMS Food)

The proposed uses of Difenoconazole in the formulation Boscalid 23.3% + Difenoconazole 6.6% SC do not represent unacceptable acute risks for the consumer.

TDMs

Table 7.3-19: Input values for the consumer risk assessment

	Residue (mg/kg)							
	1,2,4-T		TA		TAA		TLA	
	STMR	HR	STMR	HR	STMR	HR	STMR	HR
Citrus fruit	0.050	0.050	0.320	0.628	0.050	0.100	0.040	0.140
Pome fruit	0.010	0.021	0.039	0.530	0.030	0.060	0.030	0.110
Stone fruit	0.010	0.010	0.320	0.628	0.020	0.034	0.038	0.138
Berries	0.010	0.026	0.060	0.100	0.050	0.100	0.040	0.140
Banana	0.050	0.050	0.050	0.070	0.050	0.050	n.a	n.a
Root & tuber vegetables	0.01	0.016	0.184	0.239	0.010	0.010	0.021	0.131
Bulb vegetables	0.010	0.010	0.060	0.260	0.010	0.010	0.010	0.270
Fruiting vegetables	0.010	0.030	0.21	0.46	0.010	0.020	0.030	0.110
Brassica vegetables	0.039	0.113	0.170	0.500	0.010	0.010	0.010	0.010
Leafy vegetables	0.015	0.020	0.047	0.091	0.023	0.036	0.080	0.140
Legume vegetables	0.010	0.010	0.090	0.340	0.010	0.030	0.010	0.040
Stem vegetables	0.010	0.010	0.090	0.114	0.020	0.030	0.010	0.030
Pulses	0.050	0.050	0.170	3.700	0.050	0.052	0.010	0.060
Oilseeds	0.050	0.100	1.039	2.826	0.120	0.680	0.065	0.192
Oilfruits	0.050	0.100	1.039	2.826	0.120	0.680	0.065	0.192
Cereals	0.050	0.080	0.621	2.200	0.790	1.730	0.022	0.160
Sugar	0.050	0.060	0.050	0.078	0.050	0.050	0.010	0.010

plants								
Ruminant meat	0.27	0.31	0.46	0.62	0.04	0.04	0.04	0.04
Ruminant fat	0.18	0.24	0.22	0.34	0.05	0.08	0.07	0.1
Ruminant liver	0.31	0.36	1.01	1.36	0.05	0.05	0.04	0.04
Ruminant kidney	0.32	0.34	0.49	0.58	0.15	0.22	0.09	0.13
Ruminant milk	0.30	0.35	0.04	0.04	0.04	0.04	0.04	0.04
Sheep meat	0.29	0.33	0.51	0.68	0.04	0.04	0.04	0.04
Sheep fat	0.19	0.26	0.23	0.38	0.06	0.08	0.07	0.11
Sheet liver	0.34	0.39	1.13	1.80	0.05	0.05	0.04	0.04
Sheep kidney	0.34	0.37	0.55	0.65	0.18	0.25	0.09	0.13
Sheep milk	0.32	0.37	0.04	0.04	0.04	0.04	0.04	0.04
Swine meat	0.13	0.17	0.21	0.27	0.04	0.04	0.04	0.04
Swine fat	0.10	0.13	0.09	0.14	0.04	0.05	0.07	0.08
Swine liver	0.13	0.17	0.50	0.61	0.04	0.05	0.04	0.04
Swine kidney	0.14	0.20	0.22	0.27	0.11	0.14	0.05	0.08
Poultry meat	0.04	0.04	0.11	0.12	0.04	0.04	0.04	0.04
Poultry fat	0.04	0.04	0.10	0.11	0.04	0.04	0.04	0.04
Poultry liver	0.04	0.04	0.27	0.31	0.05	0.05	0.04	0.04
Poultry Eggs	0.04	0.04	0.06	0.06	0.04	0.04	0.04	0.04

TA

Table 7.3-20: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	**6% NL toddler**
IEDI (% ADI) according to EFSA PRIMo 3.1	-
IESTI (% ARfD) according to EFSA PRIMo*	**Unprocessed commodities:** Wheat: 3% (based on children) Wheat: 2% (based on adult)

	Processed commodities: **Based on children** Wheat/milling (flour): 3% Wheat/milling (wholemeal): 1% **Based on adults** Wheat/bread/pizza: 0.9% Wheat/pasta: 0.8% Wheat/bread: 0.7%
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

TLA

Table 7.3-21: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	**1% NL toddler**
IEDI (% ADI) according to EFSA PRIMo 3.1	-
IESTI (% ARfD) according to EFSA PRIMo*	**Unprocessed commodities:** Wheat: 0.1% (based on children) Wheat: 0.06% (based on adult) **Processed commodities:** **Based on children** Wheat/milling (flour): 0.1% Wheat/milling (wholemeal): 0.04% **Based on adults** Wheat/bread/pizza: 0.03% Wheat/pasta: 0.03% Wheat/bread: 0.03%
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

TAA

Table 7.3-22: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	**1% NL toddler**
IEDI (% ADI) according to EFSA PRIMo 3.1	-
IESTI (% ARfD) according to EFSA PRIMo*	**Unprocessed commodities:** Wheat: 1% (based on children) Wheat: 0.7% (based on adult) **Processed commodities:** **Based on children** Wheat/milling (flour): 1% Wheat/milling (wholemeal): 0.44% **Based on adults** Wheat/bread/pizza: 0.35% Wheat/pasta: 0.3% Wheat/bread: 0.3%

NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

1,2,4-T

Table 7.3-23: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	**~~93%~~ 88% NL toddler**
IEDI (% ADI) according to EFSA PRIMo 3.1	-
IESTI (% ARfD) according to EFSA PRIMo*	**Unprocessed commodities:** Wheat: 0.7% (based on children) Wheat: 0.4% (based on adult) **Processed commodities:** **Based on children** Wheat/milling (flour): ~~6%~~ 0.6% Wheat/milling (wholemeal): 0.28% **Based on adults** Wheat/bread/pizza: 0.22% Wheat/pasta: 0.2% Wheat/bread: 0.2%
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

The proposed uses of Difenoconazole in the formulation Boscalid 23.3% + Difenoconazole 6.6% SC do not represent unacceptable acute risks for the consumer.

7.4 Combined exposure and risk assessment

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

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

7.5 References

Boscalid:

DAR, 2002. Draft Assessment Report of Boscalid. 8 November 2002.

European Commission, 2008. Review report for the active substance Boscalid. SANCO/3919/2007-rev. 5, 21 January 2008

EFSA (European Food Safety Authority), 2014. Review of the existing Maximum Residue Levels (MRLs) for Boscalid according to Article 12 of Regulation 396/2005. (EFSA Journal 2014;12(7):3799)

Difenoconazole:

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

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

DAR, 2006. Draft assessment Report on Difenoconazole. May 2006.

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

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
KCP 8.3.1.1	Zsolt Limp	2019	Determination of the residues of boscalid in/on wheat after two applications of boscalid 50 % WG in Northern Europe- Hungary in 2019 Study number: 034SRHU19R20 SynTech Research Hungary GLP Unpublished	N	Sharda
KCP 8.3.1.2	Grzegorz Paszek	2020	Determination of the residue of boscalid in/on wheat after two applications of boscalid 50 % WG un Northern Europe- Hungary in 2019 Study number: DPL/142/2019 SGS Polska Sp. z o.o. GLP Unpublished	N	Sharda
KCP 8.3.1.3	Kathrin Rump	2019	Determination of residues at decline and harvest of boscalid in wheatm following two broadcast applications of boscalid 50 % WDG, under open field conditions. Germany – 2019 Study number: FRS 155/19 Field Research Support GLP Unpublished	N	Sharda
KCP 8.3.1.4	Grzegorz Paszek	2020	Determination of residues at decline and harvest of boscalid in wheat, following two broadcast applications of boscalid 50 % WG, under open field conditions. Germany – Season 2019	N	Sharda

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
			Study number: DPL/143/2019 SGS Polska Sp. z o.o. GLP Unpublished		
KCP 8.3.2.1	K. Rump	2016	Determination of residues at harvest and decline of Difenoconazole in Wheat, following broadcast applications of DIFENOCONAZOLE 25% EC, under open field conditions Central Europe - Season 2016. Study number: FRS 065/16 Field Research Support GLP Unpublished	N	Sharda
KCP 8.3.2.2	Kathryn Sherratt	2017	Field residue trials to determine levels of difenoconazole 25 % EC in wheat, for Northern Europe. UK-2017 Study number: SHA006-17-RES011 SGS UK GLP Unpublished	N	Sharda
KCP 8.3.2.3	Serena Kull	2017	Residue study (harvest and decline) in wheat following two applications with difenoconazole 25 % EC in Germany 2017 – field part Study number: CT17-1-57 CropTrials GmbH GLP Unpublished	N	Sharda
KCP 8.3.2.4	Grzegorz Paszek	2017	Determination of magnitude of residue of difenoconazole in/on wheat after applications of difenoconazole 25 % funguicide. Germany/ United Kingdom - 2017 Study number: DPL/44/2019 SGS Polska Sp. Z o.o. GLP Unpublished	N	Sharda
KCP	Sandra Romero	2020	Magnitude of residue of difenoconazole and triazole derivate metabolites (1,2,4-triazol, triazol alanine,	N	Sharda

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
8.3.2.5			triazol acetic acid and triazol acid) in wheat raw agricultural commodity after two applications of difeno-conazole 25 % EC under field conditions – 1 harvest trial and 1 decline trial. Poland 2018 Study number: BPL 18-030 BIOTEK Agriculture España SL GLP Unpublished		
KCP 8.3.2.5	Sabina Niewelt	2020	Magnitude of residue of difenoconazole in wheat raw agricultural commodity after two applications of difenoconazole 25 % EC under field conditions - 1 harvest trial and 1 decline trial Study number: BPL 18-030 SGS Polska Sp. Z o.o GLP Unpublished	N	Sharda
KCP 8.3.2.6	G. Paszek	2019	Determination of residue of Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA) in/on wheat after applications of Difenoconazole 25% EC fungicide. Report No. DPL/45/2019 SGS Polska Sp. Z o.o GLP Unpublished	N	Sharda
KCP 8.3.2.7	S. Romero/S. Niewelt	2019	Magnitude of residues of Triazole Derivative Metabolites (1,2,4-triazol, triazol alanine, triazol acetic acid and triazol lactic acid) in wheat Raw Agricultural Commodity after two applications of Difenoconazole 25% EC under field conditions – 1 harvest trial and 1 decline trial. Analytical phase Report No. DPL/43/2019 SGS Polska Sp. Z o.o GLP Unpublished	N	Sharda

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
Boscalid					
	Funk, Horst; Mackenroth, Christiane	2001	Investigation of the Stability of Residues of BAS 510 F in Plant Matrices under Storge Conditions. 2001/1015028 GLP, unpublished RIP2002-192	N	BASF
	Rabe, U.; Schlüter, H.	2001	Metabolism of BAS 510 F in Grapevine. BASF DocID: 2000/1014860 GLP, unpublished RIP2001-327	N	BASF
	Hamm, R.T.	1999	Metabolism of BAS 510 F in Lettuce. BASF DocID: 1999/11240 GLP, unpublished RIP2001-328	N	BASF
	Veit, P.	2001	Metabolism of 14C-BAS 510 F in Beans. BASF DocID: 2000/1014861 GLP, unpublished RIP2001-329	N	BASF
	xxxxxxxx	2001	The Metabolism of 14C-BAS 510F in Lactaing Goat. xxxxxxxxxx DocID: 2000/1017221 GLP, unpublished RIP2001-331	Y	BASF
	xxxxxxxx	2000	14C-BAS 510 F- Absorption, Distribution and Excretion after Repeated Oral Administration in Lactating Goats. xxxxxxx DocID: 2000/1012353 GLP, unpublished RIP2001-330	Y	BASF

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
	xxxxxxxxx	2000	Nature of Residues of 14C-BAS 510 F in Laying Hens. xxxxxx Doc No.: 2000/5154 GLP, unpublished RIP2001-332	Y	BASF
	xxxxxxxxx	2001	Investigation of the Stability of Residues of BAS 510 F and M510F01 in Sample Material of Animal Origin under Usual Storage Conditions. xxxxxx DocID: 2000/1017229 GLP, unpublished RIP2001-354	Y	BASF
	xxxxxxxxx	2001	Residues in Milk and Edible Tissues Following Oral Administration of BAS 510 F to Lactating Dairy Cattle. xxxxxx DocID: 2000/1017228 GLP, unpublished RIP2001-352	Y	BASF
	Scharf, J.	1998	Hydrolysis of BAS 510 F at 90°C, 100°C, and 120°C. BASF Doc.: 1998/10878 GLP, unpublished RIP2001-355	N	BASF
	Funk, H.; Mackenroth, C.	2001	Determination of the residues of BAS 510 F in wheat obtained from the trial year 2000. BASF DocID.: 2000/1000989 GLP, unpublished RIP2001-375	N	BASF
	Funk, H.; Mackenroth C.	2000	Determination of the residues of BAS 510 F in wheat obtained from the trial year 2000. BASF DocID.: 2000/1014853 GLP, unpublished RIP2001-374	N	BASF
	Hamm, T.R.; Veit, P.	2001	Confined Rotational Crop Study with 14CBAS 510 F. BASF DocID.: 2000/1014862 GLP, unpublished	N	BASF

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
			RIP2001-373		
JMPR					
	Schulz H.	2003	Boscalid: Determination of the residues of Epoxiconazole and BAS 510 F in barley and processed products following treatment with BAS 549 KA F under field conditions in Germany 2002. Institut Fresenius, Chemische und Biologische Laboratorien GmbH; Taunusstein; Germany Fed. Rep. BASF unpublished report IF-02/00006864, issued 25.06.2003. 2003/1000946	N	BASF
	Renner G.	2003	Boscalid: Determination of the residues of BAS 510 F and Epoxiconazole in winter wheat processing products following double application of BAS 549 KA F in Germany. BioChem Agrar; Gerichshain; Germany Fed. Rep. BASF unpublished report 02 10 47 003, issued 26.06.2003. 2003/1000945	N	BASF
	Raunft E et al.	2003	Boscalid: Study on the residue behaviour of Boscalid (proposed) and Epoxiconazole in cereals after application of BAS 549 00 F under field conditions in France, Germany, the Netherlands and United Kingdom, 2003. BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. BASF unpublished report 164047, issued 17.12.2003. 2003/1009783	N	BASF
	Leonard R C.	2005	Boscalid: Study on the residue behavior of Boscalid and Epoxiconazole in cereals after treatment with BAS 549 00 F under field conditions in Denmark, Belgium, United Kingdom, Northern and Southern France and Germany, 2005. BASF Agro Research RTP; Research Triangle Park, NC 27709, USA. BASF unpublished report 164104, issued 14.09.2005. 2005/5000151	N	BASF

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Boscalid

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

A 2.1.1.1.2 Storage stability of residues in animal products

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

A 2.1.2.1.2 Nature of residue in rotational crops

A 2.1.2.1.3 Nature of residues in processed commodities

A 2.1.2.2 Nature of residues in livestock

A 2.1.3 Magnitude of residues in plants

WHEAT country, year (variety)	Application [a] Form	kg ai/ha	water (L/ha)	no.	BBCH stage	PHI days	Commodity	Residues, mg/kg Difenoconazole	Ref
Denmark, 1989 (Sleipner)	EC	0.13	300	1	BBCH 54	75	wheat grain	< 0.02	2060/89
Denmark, 1990 (Kraka)	EC	0.13	250	1	BBCH 60	58	wheat grain	< 0.02	2047/90
Denmark, 1990 (Kraka)	EC	0.13	250	1	BBCH 60	57	wheat grain	< 0.02	2048/90
France, 1988 (Festival)	SC includes CGA 18251	0.13	450	1	BBCH 66-76	51	wheat grain	< 0.02	53/88
France, 1989 (Garant)	SC includes CGA 18251	0.13	500	1	BBCH 61	57	wheat grain	< 0.02	08/90
France, 1989 (Garant)	SC includes CGA 18251	0.13	500	1	BBCH 55-57	63	wheat grain	< 0.02	09/90
France, 1989 (Goeland)	SC includes CGA 18251	0.13	500	1	BBCH 61	52	wheat grain	< 0.02	07/90
France, 1989 (Tango)	SC includes CGA 18251	0.13	500	1	ripen-ing	57	wheat grain	< 0.02	06/90
France, 1993 (Capitaine)	GL includes CGA 18251	0.13	400	1	BBCH 83	31	wheat grain	< 0.02	OF93148
France, 1993 (Recital)	GL includes CGA 18251	0.13	400	1	BBCH 87	39	wheat grain	< 0.02	OF93148
France, 1993 (Soisson)	GL includes CGA 18251	0.13	400	1	BBCH 77	42	wheat grain	< 0.02	OF93148
France, 1998 (Arstar)	GL includes carbendazim	0.13	400	1	BBCH 65	47	wheat grain	< 0.02	9813303
France, 1998 (Excalibur)	GL includes carbendazim	0.13	400	1	BBCH 69	49	wheat grain	< 0.02	9813302
France, 1998 (Primadur)	GL includes carbendazim	0.12	400	1	BBCH 65	45	wheat grain	< 0.02	9813304
France, 1998 (Rubbens)	GL includes carbendazim	0.14	430	1	BBCH 61-65	47	wheat grain	< 0.02	9813301
Switzerland, 1989 (Remia)	EC	0.13	500	1	BBCH 59	45	wheat grain	< 0.02 [b] < 0.02	2031/89
UK (Cambs), 1989 (Brock)	EC	0.15	200	1	BBCH 64-65	49	wheat grain	< 0.02	R/0157/01
UK (Cambs), 1989 (Mercia)	EC	0.15	200	1	BBCH 61-63	65	wheat grain	< 0.02	R/0157/01
UK (Essex), 1989 (Galahad)	EC	0.15	200	1	BBCH 65	55	wheat grain	< 0.02	R/0157/01
UK (Gt Halingbury), 1989 (Hornet)	EC	0.15	200	1	BBCH 65	57	wheat grain	< 0.02	R/0157/01
UK(Bulbeck), 1989 (Mercia)	EC	0.15	200	1	BBCH 64-65	57	wheat grain	< 0.02	R/0157/01
UK, 1985 (Avalon)	?	0.13	200	1	BBCH 65	59	wheat grain	< 0.02	2229/85
UK, 1985 (Norman)	?	0.13	200	1	BBCH 65	67	wheat grain	< 0.02	2230/85

Reviewer's comment:
the following studies are acceptable

Reference: KCP 8.3.1.1

Field report: Determination of the residues of boscalid in/on wheat after two applications of boscalid 50 % WG in Northern Europe- Hungary in 2019
Zsolt Limp, 2019
Study number: 034SRHU19R20

Guideline(s):	Yes Regulations (EC) No 283/2013 and 284/2013 implementing regularion (EC) No 1107/2009 Commission working document 7029/VI/95 Rev.5
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Reference:	KCP 8.3.1.2
Analytical report	Determination of the residue of boscalid in/on wheat after two applications of boscalid 50 % WG un Northern Europe- Hungary in 2019 Grzegorz Paszek, 2020 Study number: DPL/142/2019
Guideline(s):	Yes Regulation (EC) No 1107/2009 repealing council directives 79/117/EEC and 91/414/EEC Directive 91/414/EEC, Annex II, (section 4 of Part A) and Annex III (section 5 of part A). EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods:

During the growing season of 2019, a total of four harvest trial were conducted in peaches in Northern Europe (Hungary) to determine the magnitude of residues of boscalid in or on raw agricultural commodities (RAC).

The field part of this study was conducted by SynTech Research Hungary in Hungary. The analytical part of the study was conducted by SGS Polska Sp.z o.O, Poland.

The trials performed in Northen Europe (Greece) consisted of two plots: one untreated plot (control) and one plot treated once with boscalid 50 % WG at a target rate of 2x350 g boscalid /ha.

First application to plot 2 was made at BBCH 39-41, second application was made at BBCH 55. For the analysis samples were taken at normal harvest, and at normal harvest and 20 and 10 days before harvest for decline trials, and were stored deep frozen until shipment.

The determination of boscalid residues has been performed by LC-MS/MS according to SANCO/3029/99,rev. 4 and SANCO/825/00, rev. 8.1 The residues of boscalid are extracted with water and acetonitrile in the presence of magnesium sulphate and Sodium chloride, trisodium citrate dehydrate and disodium hydrogencytrate sesquigydrate. The extract obtained after centrifugation is analysed by LC-MS/MS.
The caracteristics ot the analytical method was as follows:

Table IIIA 8.3-12: Characteristics of the analytical method

LOQ on wheat:	0.01 mg/kg
Fortification level(s):	0.01 mg/kg, 0.10 mg/kg
Quantification Trace 343.00 > 140.00 m/z)	
Confirmation Trace 343.00 > 307.00 m/z	
Mean recovery: (grain) 0.01 mg/kg	80.0 %
Mean recovery: (grain) 0.10 mg/kg	87.2 %
Mean recovery: (plant) 0.01 mg/kg	85.3 %
Mean recovery: (plant) 0.10 mg/kg	77.8 %
Mean recovery: (straw) 0.01 mg/kg	94.7 %
Mean recovery: (straw) 0.10 mg/kg	79.5 %

Results and conclusion:

No residue above the LOQ were detected in the control samples. The analytical results in mg of lambda-cyhalothrin per kg are summarized in Table 8.3-13:

Table IIIA 8.3-13: Residues of boscalid after two application on wheat

Trial N°	**Matrix**	**boscalid (mg/kg)**
		49-53 DALA
SRHU19-135-034FR	Seed	<LOQ
SRHU19-135-034FR	straw	1.38
SRHU19-136-034FR	Seed	<LOQ
SRHU19-136-034FR	Straw	1.44
SRHU19-137-034FR	Grain	<LOQ
SRHU19-137-034FR	Straw	1.48
SRHU19-138-034FR	Grain	<LOQ
SRHU19-138-034FR	Straw	1.52
Trial N°	**Matrix**	**boscalid (mg/kg)**
		39 DALA
SRHU19-137-034FR	Wheat (whole plant)	0.74
SRHU19-138-034FR	Wheat (whole plant)	1.63
Trial N°	**Matrix**	**boscalid (mg/kg)**
		30 DALA
SRHU19-137-034FR	Wheat (whole plant)	1.04
SRHU19-138-034FR	Wheat (whole plant)	0.90

DALA = days after last application
n.d. = not detectable

The residue data clearly indicates that residues in seeds graisn are lower than the current EU MRL (0.8 mg/kg), after 2 applications at a 350 g a.i./ha dose rate and a PHI of 46 days.

Reference: KCP 8.3.1.3

Field report: Determination of residues at decline and harvest of boscalid in wheatm following two broadcast applications of boscalid 50 % WDG, under open field conditions. Germany - 2019
Kathrin Rump, 2019
Study number: FRS 155/19

Guideline(s): Yes
Directive 91/414/EEC
ENV/JM/MONO(99)22
EC Commission Directive 2004/10/EC

Deviations: No

GLP: Yes

Acceptability: Yes

Reference: KCP 8.3.1.4

Analytical report: Determination of residues at decline and harvest of boscalid in wheat, following two broadcast applications of boscalid 50 % WG, under open

field conditions. Germany – Season 2019
Grzegorz Paszek, 2020
Study number: DPL/143/2019

Guideline(s): Yes
Regulation (EC) No 1107/2009 repealing council directives 79/117/EEC and 91/414/EEC
Directive 91/414/EEC, Annex II, (section 4 of Part A) and Annex III (section 5 of part A).
EU Guidance Document SANCO/3029/99 rev. 4
EU Guidance Document SANCO/825/00 rev. 8.1

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods:

During the growing season of 2019, a total of four harvest trial were conducted in peaches in Northern Europe (Germany) to determine the magnitude of residues of boscalid in or on raw agricultural commodities (RAC).

The field part of this study was conducted by Field Research Support in Germany. The analytical part of the study was conducted by SGS Polska Sp.z o.O, Poland.

The trials performed in Northen Europe (Germany) consisted of two plots: one untreated plot (control) and one plot treated once with boscalid 50 % WG at a target rate of 2x350 g boscalid /ha.

First application to plot 2 was made at BBCH 39, second application was made at BBCH 59. For the analysis samples were taken at normal harvest, and at normal harvest and 20 and 10 days before harvest for decline trials, and were stored deep frozen until shipment.

The determination of boscalid residues has been performed by LC-MS/MS according to SANCO/3029/99,rev. 4 and SANCO/825/00, rev. 8.1 The residues of boscalid are extracted with water and acetonitrile in the presence of magnesium sulphate and Sodium chloride, trisodium citrate dehydrate and disodium hydrogencytrate sesquigydrate. The extract obtained after centrifugation is analysed by LC-MS/MS.
The caracteristics ot the analytical method was as follows:

Table IIIA 8.3-12: Characteristics of the analytical method

LOQ on wheat:	0.01 mg/kg
Fortification level(s):	0.01 mg/kg, 0.10 mg/kg
Quantification Trace 343.00 > 140.00 m/z)	
Confirmation Trace 343.00 > 307.00 m/z	
Mean recovery: (grain) 0.01 mg/kg	80.3 %
Mean recovery: (grain) 0.10 mg/kg	77.7 %
Mean recovery: (plant) 0.01 mg/kg	91.8 %
Mean recovery: (plant) 0.10 mg/kg	100.0 %
Mean recovery: (straw) 0.01 mg/kg	106.7 %
Mean recovery: (straw) 0.10 mg/kg	97.1 %

Results and conclusion:

No residue above the LOQ were detected in the control samples. The analytical results in mg of lambda-cyhalothrin per kg are summarized in Table 8.3-13:

Table IIIA 8.3-13: Residues of boscalid after two application on wheat

Trial N°	**Matrix**	**boscalid (mg/kg)**
		40-53 DALA
FRS 155/19-V1	Seed	0.013
FRS 155/19-V1	straw	3.27
FRS 155/19-V2	Seed	<LOQ
FRS 155/19-V2	Straw	1.19
FRS 155/19-V3	Grain	0.015
FRS 155/19-V3	Straw	5.08
FRS 155/19-V4	Grain	0.017
FRS 155/19-V4	Straw	4.97
Trial N°	**Matrix**	**boscalid (mg/kg)**
		43 DALA
FRS 155/19-V3	Wheat (whole plant)	4.92
FRS 155/19-V4	Wheat (whole plant)	2.10
Trial N°	**Matrix**	**boscalid (mg/kg)**
		33 DALA
FRS 155/19-V3	Wheat (whole plant)	2.33
FRS 155/19-V4	Wheat (whole plant)	1.89

DALA = days after last application
n.d. = not detectable

The residue data clearly indicates that residues in seeds graisn are lower than the current EU MRL (0.8 mg/kg), after 2 applications at a 350 g a.i./ha dose rate and a PHI of 46 days.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Analyte 1		

SRHU19-135-034FR Csõnge - Hungary NEU 2019	Wheat	1) 20.09.2018 2) May 2019 3) 01.07.2019	358.971 325.912	307.7 279.3	117 117	29/04/2019 13/05/2019	BBCH 39 BBCH 55	Seeds Straw	<LOQ 1.38	53 53	Analytical method: DPL/142/2019 QuEChERS, LC-MS/MS LOQ: 0.01 mg/kg LOD: 0.003 mg/kg
SRHU19-136-034FR Nemesszentandrás - Hungary NEU 2019	Wheat	1) 05.11.2018 2) May 2019 3)12.06.2019	365.193 353.137	313.0 302.7	117 117	29/04/2019 13/05/2019	BBCH 41 BBCH 59	Seeds Straw	<LOQ 1.44	49 49	Analytical method: DPL/142/2019 QuEChERS, LC-MS/MS LOQ: 0.01 mg/kg LOD: 0.003 mg/kg
SRHU19-137-034FR Szombathely - Hungary NEU 2019	Wheat	1) 15.10.2018 2) May 2019 3)02.07.2019	376.834 369.055	323.0 316.3	117 117	29/04/2019 13/05/2019	BBCH 39 BBCH 59	Whole plant Seeds Straw	1.04 0.74 <LOQ 1.48	30 39 50 50	Analytical method: DPL/142/2019 QuEChERS, LC-MS/MS LOQ: 0.01 mg/kg LOD: 0.003 mg/kg
SRHU19-138-034FR Kám - Hungary NEU 2019	Wheat	1) 16.10.2018 2) May 2019 3)01.07.2019	368.862 361.862	316.2 310.2	117 117	29/04/2019 13/05/2019	BBCH 39 BBCH 55	Whole plant Seeds Straw	0.90 1.63 <LOQ 1.52	30 39 49 49	Analytical method: DPL/142/2019 QuEChERS, LC-MS/MS LOQ: 0.01 mg/kg LOD: 0.003 mg/kg
FRS 155/19-V1 Hannover - Germany NEU 2019	Wheat	1) 01.10.2018 2) 12.06.2019 3) 17.07.2019	350 350	200 200	175 175	24/05/2019 07/06/2019	BBCH 39 BBCH 59	Seeds Straw	0.013 3.27	40 40	Analytical method: DPL/143/2019 QuEChERS, LC-MS/MS LOQ: 0.01 mg/kg LOD: 0.003 mg/kg
FRS 155/19-V2 Wittingen-Vorhop Germany NEU 2019	Wheat	1) 27.10.2018 2) 20.05.2019 3) 17.07.2019	350 350	200 200	175 175	24/05/2019 07/06/2019	BBCH 39 BBCH 59	Seeds Straw	<LOQ 1.19	40 40	Analytical method: DPL/143/2019 QuEChERS, LC-MS/MS LOQ: 0.01 mg/kg LOD: 0.003 mg/kg
FRS 155/19-V3 Barsinghausen-Hohenbostel - Germany NEU 2019	Wheat	1) 05.10.2018 2) 12.06.2019 3) 29.07.2019	350 350	200 200	175 175	23/05/2019 06/06/2019	BBCH 39 BBCH 59	Whole plant Seeds Straw	2.33 4.92 0.015 5.08	33 43 53 53	Analytical method: DPL/143/2019 QuEChERS, LC-MS/MS LOQ: 0.01 mg/kg LOD: 0.003 mg/kg
FRS 155/19-V4 Germany NEU 2019	Wheat	1) 25.10.2018 2) 11.06.2019 3) 29.07.2019	350 350	200 200	175 175	23/05/2019 06/06/2019	BBCH 39 BBCH 59	Whole plant Seeds Straw	1.89 2.10 0.017 4.97	33 43 53 53	Analytical method: DPL/143/2019 QuEChERS, LC-MS/MS LOQ: 0.01 mg/kg LOD: 0.003 mg/kg

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

A 2.1.4.1.1 Livestock feeding study 1

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

A 2.1.5.1 Distribution of the residue in peel/pulp

A 2.1.5.2 Processing studies on a core set of representative processes

A 2.1.6 Magnitude of residues in representative succeeding crops

A 2.1.7 Other/Special Studies

A 2.2 Difenoconazole

A 2.2.1 Stability of residues

A 2.2.1.1 Stability of residues during storage of samples

A 2.2.1.1.1 Storage stability of residues in plant products

A 2.2.1.1.2 Storage stability of residues in animal products

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

A 2.2.2.1 Nature of residue in plants

A 2.2.2.1.1 Nature of residue in primary crops

A 2.2.2.1.2 Nature of residue in rotational crops

A 2.2.2.1.3 Nature of residues in processed commodities

A 2.2.2.2 Nature of residues in livestock

A 2.2.3 Magnitude of residues in plants

Reviewer's comment: the following studies are acceptable

Reference:	KCP 8.3.2.1
Field report	Determination of residues at harvest and decline of Difenoconazole in Wheat, following broadcast applications of DIFENOCONAZOLE 25% EC, under open field conditions Central Europe - Season 2016. K. Rump, 2016 Study number: FRS 065/16
Guideline(s):	Yes

	EC Commission Directive 2004/10/EC of 11 February 2004 (Official Journal No L 50/44). OECD Principles of Good Laboratory Practice (as revised in 1997) and Compliance Monitoring No 1, ENV/MC/CHEM(98)17. The application of the GLP Principles to Field Studies, Compliance Monitoring No. 6, ENV/JM/MONO(99)22.
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes
Reference:	KCP 8.3.2.2
Field report	Field residue trials to determine levels of difenoconazole 25 % EC in wheat, for Northern Europe. UK- 2017 Kathryn Sherratt - 2017 Study number: SHA006-17-RES011
Guideline(s):	Yes Regulation (EC) No 1107/2009 Directives 93/71/EEC and 91/414/EC Directive 2004/9/EC ENV/MC/CHEM(98)17 ENV/JM/MONO(99)22 ENV/JM/MONO(99)24
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Reference:	KCP 8.3.2.3
Field report	Residue study (harvest and decline) in wheat following two applications with difenoconazole 25 % EC in Germany 2017 – field part Serena Kull - 2017 Study number: CT17-1-57
Guideline(s):	Yes

	Regulation (EC) No 7029/V1/95 rev. 5, 1997, Appendix B working document 1607/V1/97 rev. 2, 1999 ENV/MC/CHEM(1999)20 ENV/JM/MONO(1999)22 ENV/JM/MONO(2002)29
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes
Reference:	KCP 8.3.2.4
Analytical report	Determination of magnitude of residue of difenoconazole in/on wheat after applications of difenoconazole 25 % fungicide. Germany/ United Kingdom - 2017 Grzegorz Paszek - 2017 Study number: DPL/44/2019
Guideline(s):	Yes Regulation (EC) No 1107/2009 repealing directives 79/117/EEC and 91/414/EC Annex 2 (part A, section 4) and Annex 3 (part A, section 4) of directive 91/414 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods:

During the growing season of 2017, a total of two trials (harvest and decline) were conducted in wheat in Northern Europe (Germany) Two more trials and (harvest and decline) trials were conducted during the growing season of 2017 in Northern Europe (United Kingdom) to determine the magnitude of residues of difenoconazole in or on raw agricultural commodities (RAC).

The field part of this study was conducted by CropTrials GmbH in Germany and by SGS United Kingdom Ltd in United Kingdom. The analytical part of the study was conducted by SGS Polska Sp.z o.O, Poland

The trials performed in Northern Europe (Germany and United Kingdom) consisted of two plots: one untreated plot (control) and one plot treated once with difenoconazole 25 % EC at a target rate of 2x100 g difenoconazole /ha.

In Germany trail, first application to plot 2 was made 14 days before (at BBCH 61) the second application, that was made after at BBCH 69. In United Kingdom trail, first application was made 14 days before the second application, and second application at BBCH 69. For the analysis samples were taken at normal haverst for harvest trials, and at normal harvest and 0, 7, 14 and 28 days after application.

The determination of difenoconazole residues has been performed by LC-MS/MS according to SANCO/3029/99,rev. 4 and SANCO/825/00, rev. 8.1 The residues of difenoconazole are extracted with water and acetonitrile in the presence of magnesium sulphate and Sodium chloride, trisodium citrate dehydrate and disodium hydrogencytrate sesquigydrate. The extract obtained after centrifugation is analysed by LC-MS/MS.
The caracteristics ot the analytical method was as follows:

Table IIIA 8.3-12: Characteristics of the analytical method

LOQ on wheat:	0.01 mg/kg
Fortification level(s):	0.01 mg/kg, 0.10 mg/kg
Quantification Trace 406.00 > 250.90 m/z)	
Confirmation Trace 406.00 > 337.00 m/z Confirmation Trace 406.00 > 187.90 m/z	
Mean recovery: (grain) 0.01 mg/kg	92.8 %
Mean recovery: (grain) 0.10 mg/kg	96.8 %
Mean recovery: (straw) 0.01 mg/kg	106 %
Mean recovery: (straw) 0.10 mg/kg	94.2 %
Mean recovery: (plant) 0.01 mg/kg	97.5 %
Mean recovery: (plant) 0.10 mg/kg	99.1 %

Results and conclusion:

No residue above the LOQ were detected in the control samples. The analytical results in mg of difenoconaole per kg are summarized in Table 8.3-11:

Table IIIA 8.3-13: Residues of difenoconazole after two application on wheat		
Trial N°	**Matrix**	**difenoconazole (mg/kg)**

		0-1 DALA
FRS065/16-V2	Whole plant	1.96
SHA006-17-RES011-02	Whole plant	2.70
SH-1T/CT17-1-57DE2	Whole plant	2.45
Trial N°	**Matrix**	**difenoconazole (mg/kg)**
		7-11 DALA
FRS065/16-V2	Whole plant	1.38
SHA006-17-RES011-02	Whole plant	3.11
SH-2T/CT17-1-57DE2	Whole plant	0.49
Trial N°	**Matrix**	**difenoconazole (mg/kg)**
		14-19 DALA
FRS065/16-V2	Whole plant	1.10
SHA006-17-RES011-02	Whole plant	1.99
SH-3T/CT17-1-57DE2	Whole plant	0.26
Trial N°	**Matrix**	**difenoconazole (mg/kg)**
		28-29 DALA
FRS065/16-V2	Whole plant	0.84
SHA006-17-RES011-02	Whole plant	1.17
SH-4T-CT17-1-57DE2	Whole plant	0.39
Trial N°	**Matrix**	**difenoconazole (mg/kg)**
		42±2 DALA
FRS065/16-V1	Grain	0.093
FRS065/16-V1	Straw	0.19
FRS065/16-V2	Grain	0.015
FRS065/16-V2	Straw	0.95
SHA006-17RES011-01	Grain	0.011
SHA006-17RES011-01	Straw	0.63
SHA006-17-RES011-02	Grain	0.018
SHA006-17-RES011-02	Straw	1.23
GR-1T/CT17-1-	Grain	0.013

57DE1		
SW-1T/CT17-1-57DE1	Straw	0.30
GR-5T/CT17-1-57DE2	Grain	<LOQ
SW-5T/CT17-1-57DE2	Straw	0.25

DALA = days after last application
n.d. = not detectable

The residue data clearly indicates that residues in wheat grain are lower than the current EU MRL (0.10 mg/kg), after 2 applications at a 100 g a.i./ha dose rate and a PHI of 40-42 days.

Reference:	KCP 8.3.2.5
Field report	Magnitude of residue of difenoconazole and triazole derivate metabolites (1,2,4-triazol, triazol alanine, triazol acetic acid and triazol acid) in wheat raw agricultural commodity after two applications of difenoconazole 25 % EC under field conditions – 1 harvest trial and 1 decline trial. Poland 2018 Sandra Romero Study number: BPL 18-030
Guideline(s):	Yes Annex II (part A, section 4) and Annex III (part A, section 5) of Directive 91/414, SANCO 3029/99 rev 4. SANCO/825/00 rev 8.1 Regulation (EC) Nº 1107/2009 repealing council directives 19/117/EEC and 91/414/EEC Commission Regulation (EU) 2019/552
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Reference:	KCP 8.3.2.5
Analytical report	Magnitude of residue of difenoconazole in wheat raw agricultural commodity after two applications of difenoconazole 25 % EC under field conditions - 1 harvest trial and 1 decline trial Sabina Niewelt - 2018

	Study number: BPL 18-030
Guideline(s):	Yes Regulation (EC) No 1107/2009 repealing directives 79/117/EEC and 91/414/EC Annex 2 (part A, section 4) and Annex 3 (part A, section 4) of directive 91/414 EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods:

During the growing season of 2018, a total of two trials (harvest and decline) were conducted in wheat in Northern Europe (Poland) to determine the magnitude of residues of difenoconazole in or on raw agricultural commodities (RAC).

The field part of this study was conducted by BIOTEK agriculture Polska in Poland. The analytical part of the study was conducted by SGS Polska Sp.z o.O, Poland

The trials performed in Northern Europe (Poland) consisted of two plots: one untreated plot (control) and one plot treated once with difenoconazole 25 % EC at a target rate of 2x100 g difenoconazole /ha.

In Poland trail, first application to plot 2 was made 14 days before (at BBCH 61) the second application, that was made after at BBCH 69. For the analysis samples were taken at normal haverst for harvest trials, and at normal harvest and 0, 7, 14 and 28 days after application.

The determination of difenoconazole residues has been performed by LC-MS/MS according to SANCO/3029/99,rev. 4 and SANCO/825/00, rev. 8.1 The residues of difenoconazole are extracted with water and acetonitrile in the presence of magnesium sulphate and Sodium chloride, trisodium citrate dehydrate and disodium hydrogencytrate sesquigydrate. The extract obtained after centrifugation is analysed by LC-MS/MS.

The caracteristics ot the analytical method was as follows:

Table IIIA 8.3-12: Characteristics of the analytical method

LOQ on wheat:	0.01 mg/kg
Fortification level(s):	0.01 mg/kg, 0.10 mg/kg
Quantification Trace 406.00 > 250.90 m/z)	
Confirmation Trace 406.00 > 337.00 m/z Confirmation Trace 406.00 > 187.90 m/z	
Mean recovery: (grain) 0.01 mg/kg	98.4 %
Mean recovery: (grain) 0.10 mg/kg	99 %
Mean recovery: (straw) 0.01 mg/kg	96.4 %
Mean recovery: (straw) 0.10 mg/kg	104.8 %
Mean recovery: (plant) 0.01 mg/kg	101.6 %
Mean recovery: (plant) 0.10 mg/kg	102.2 %

Results and conclusion:

No residue above the LOQ were detected in the control samples. The analytical results in mg of difenoconaole per kg are summarized in Table 8.3-11:

Table IIIA 8.3-13: Residues of difenoconazole after two application on wheat

Trial N°	**Matrix**	**difenoconazole (mg/kg)**
		0 DALA
BPL 18-030-02	Whole plant	1.93
Trial N°	**Matrix**	**difenoconazole (mg/kg)**
		7 DALA
BPL 18-030-02	Whole plant	0.58
Trial N°	**Matrix**	**difenoconazole (mg/kg)**
		14 DALA
BPL 18-030-02	Whole plant	0.58
Trial N°	**Matrix**	**difenoconazole (mg/kg)**
		28 DALA
BPL 18-030-02	Whole plant	0.51
Trial N°	**Matrix**	**difenoconazole (mg/kg)**
		43 DALA
BPL 18-030-01	Grain	0.024
BPL 18-030-01	Straw	2.14
BPL 18-030-02	Grain	<LOQ
BPL 18-030-02	Straw	0.87

DALA = days after last application
n.d. = not detectable

The residue data clearly indicates that residues in wheat grain are lower than the

current EU MRL (0.10 mg/kg), after 2 applications at a 100 g a.i./ha dose rate and a PHI of 43 days.

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				Analyte 1		
FRS065/16-V1 Ronnenberg Germany NEU 2017	Wheat	1) 09.10.2015 2) June 3) 03.08.2016	100 100	200 200	50 50	07.06.2016 22.06.2016	BBCH 61 BBCH 75	Grain Straw	0.093 0.19	42 42	Analytical method: QuEChERS, LC-MS/MS LOQ: 0.01 mg/kg LOD: 0.003 mg/kg
FRS065/16/V2 Wunstorf-Kolenfeld Germany NEU 2017	Wheat	1) 05.10.2015 2) June 3) 11.08.2016	100 100	200 200	50 50	14.06.2016 30.06.2016	BBCH 65 BBCH 75	Whole plant Whole plant Whole plant Whole plant Grain Straw	1.96 1.38 1.10 0.84 0.015 0.95	1 11 19 29 42 42	Analytical method: QuEChERS, LC-MS/MS LOQ: 0.01 mg/kg LOD: 0.003 mg/kg
SHA006-17-RES011-01 Oxfordshire - United Kingdom NEU 2017	Wheat	1) 13.10.2016 2) June 3) August.2017	105 102	316.6 306.6	33 33	20.06.2017 04.07.2017	BBCH 65 BBCH 69	Grain Straw	0.011 0.63	42 42	Analytical method: QuEChERS, LC-MS/MS LOQ: 0.01 mg/kg LOD: 0.003 mg/kg
SHA006-17-RES011-02 Oxfordshire - United Kingdom NEU 2017	Wheat	1) 13.10.2016 2) June 3) 01.08.2017-11.08.2017	101 105	304 313.3	33 34	20.06.2017 04.07.2017	BBCH 65 BBCH 69	Whole plant Whole plant Whole plant Whole plant Grain Straw	2.70 3.11 1.99 1.17 0.018 1.23	0 7 14 28 42 42	Analytical method: QuEChERS, LC-MS/MS LOQ: 0.01 mg/kg LOD: 0.003 mg/kg
CT17-1-57DE1 Neidenstein - Germany NEU 2017	Wheat	1) 15.10.2016 2) NA 3) 3.08.2017	93.5 102.5	400 400	23 26	09.06.2017 23.07.2017	BBCH 61 BBCH 69	Grain Straw	0.013 0.30	42 42	Analytical method: QuEChERS, LC-MS/MS LOQ: 0.01 mg/kg LOD: 0.003 mg/kg
CT17-1-57DE2 Isherhagen - Germany NEU 2017	Wheat	1) 25.09.2016 2) NA 3) 14.08.2017	102.5 105.8	300 300	34 35	09.06.2017 23.06.2017	BBCH 61 BBCH 69	Whole plant Whole plant Whole plant Whole plant Grain Straw	2.45 0.49 0.26 0.39 <LOQ 0.25	0 7 14 28 42 42	Analytical method: QuEChERS, LC-MS/MS LOQ: 0.01 mg/kg LOD: 0.003 mg/kg
BPL 19-030-01 Wieluń - Poland NEU 2018	Wheat	1) 21.09.2017 2) NA 3) 21.07.2018	99.9 99.4	305 303	33 33	25.05.2018 08.06.2018	BBCH 61 BBCH 69	Grain Straw	0.024 2.14	43 43	Analytical method: QuEChERS, LC-MS/MS LOQ: 0.01 mg/kg LOD: 0.003 mg/kg

BPL 19-030-02 Prusice - Poland NEU 2018	Wheat	1) 23.10.2017 2) NA 3) 20.07.18	99.1 98.7	302 301	33 33	25.05.2018 07.06.2018	BBCH 61 BBCH 69	Whole plant Whole plant Whole plant Whole plant Grain Straw	1.93 0.58 0.58 0.51 <LOQ 0.87	0 7 14 28 43 43	Analytical method: QuEChERS, LC-MS/MS LOQ: 0.01 mg/kg LOD: 0.003 mg/kg

Comments of zRMS:	Analytical method is acceptable. Validation was conducted according to SANCO/3029/99 rev. 4. The limit of quantification (LOQ) was 0.01 mg/kg and the limit of detection (LOD) was 0.003 mg/kg for difenoconazole and triazole derivative metabolites. Trials are independent. Data gaps: The samples were analyses in November 2019. Therefore, trials conducted in Germany (2016) could not be accepted due to lack of stability data of TMDs over time from sampling to analysis. The available data does not cover this time. Time from sampling to analysis of 1,2,4-T is more than 12 months in all other trials. The applicant should provide data to document the stability of 1,2,4-T in the test samples.

Reference:	KCP 8.3.2.6
Report	Determination of residues of Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA) in/on wheat after applications of Difenoconazole 25% EC fungicide. G. Paszek, 2019, Report No. DPL/45/2019
Guideline(s):	SANCO/3029/99 rev. 5
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The aim of the study is to evaluate of residues of Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA) in/on wheat after applications of Difenoconazole 25% EC fungicide. Specimen extraction and determination of residues of Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA0 in wheat were performed according to the multi-residue QuPPe method.

Extraction
5 g (plant, grain), 2g (straw) of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of water and 10 mL of acidified methanol (1%

HCOOH) was added together with 100 µL of internal standard solution, and the mixture was shaken vigorously by hand for one minute, then centrifuged at 4700 rpm for 10 min for phase separation. After that, extract was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis.
The extracts were analyzed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day). Data acquisition was carried out in MRM mode. The analysis was performed using internal standard addition.
For each analyte, two mass transitions were evaluated and used for quantification.

Table A 1: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				TAA	TA	TLA	1,2,4-T		
FRS065/16-V1/N-EU/Germany/ 2016 30952 Ronnenberg	Wheat/Tobak	09/10/2015 June 2016 03/08/2016	100 100	200 200	50 50	07/06/2016 22/06/2016	BBCH 61 BBCH 75	Grain Straw	n.d. n.d.	n.d. n.d.	n.d. n.d.	0.24 n.d.	42 42	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Analytical phase: DPL/45/2019
FRS065/16-V2/N-EU/Germany/ 2016 31515 Wunstorf- Kolen-feld	Wheat/Lear	05/10/16 June 2016 11/08/2016	100 100	200 200	50 50	14/06/2016 30/06/2017	BBCH 65 BBCH 75	Whole plant Whole plant Whole plant Whole plant Grain Straw	n.d. n.d. n.d. n.d. n.d. n.d.	n.d. n.d. n.d. n.d. n.d. n.d.	n.d. n.d. n.d. n.d. n.d. n.d.	0.32 0.17 0.09 n.d. 0.13 n.d.	1 11 19 29 42 42	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Analytical phase: DPL/45/2019
SHA006-17-RES011-01/N-EU/UK/2017 Oxfordshire	Wheat/Gallant	13/10/2016 30/06/2017 31/08/2017	100 100	300 300	33 33	20/01/2017 04/07/2017	BBCH 65 BBCH 69	Grain Straw	n.d. n.d.	n.d. n.d.	n.d. n.d.	0.11 n.d.	42 42	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Analytical phase: DPL/45/2019
SHA006-17-RES011-02/N-EU/UK/2017 Oxfordshire	Wheat/CV Gallant	13/08/2016 04/07/2017 11/08/2017	100 100	300 300	33 33	20/01/2017 04/07/2017	BBCH 65 BBCH 69	Whole plant Whole plant Whole plant Whole plant Grain Straw	n.d. n.d. n.d. n.d. n.d. n.d.	n.d. n.d. n.d. n.d. n.d. n.d.	n.d. n.d. n.d. n.d. n.d. n.d.	0.60 0.34 0.17 0.12 0.11 n.d.	0 6 13 27 42 42	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Analytical phase: DPL/45/2019
CT17-1-57DE1/N-EU/Germany/2017 Southern Germany	Wheat/Pamier	15/10/2016 15/11/2016 03/08/2017	100 100	400 400	25 25	09/06/2017 23/06/2017	BBCH 61 BBCH 69	Grain Straw	n.d. n.d.	n.d. n.d.	n.d. n.d.	0.13 n.d.	34	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Analytical phase: DPL/45/2019

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: g a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): TAA	Residues (mg/kg): TA	Residues (mg/kg): TLA	Residues (mg/kg): 1,2,4-T	PHI (days) (d)	Details on trial (e)
CT17-1-57DE2/N-EU/Germany/2017 Northern Germany	Wheat/Elixier	25/09/2016 07/10/2016 14/08/2017	100 100	300 300	33 33	09/06/2017 23/06/2017	BBCH 61 BBCH 69	Whole plant Whole plant Whole plant Whole plant Grain Straw	n.d. n.d. n.d. n.d. n.d. n.d.	n.d. n.d. n.d. n.d. n.d. n.d.	n.d. n.d. n.d. n.d. n.d. n.d.	0.98 0.40 0.96 0.11 0.09 n.d.	0 7 14 28 42 42	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Analytical phase: DPL/45/2019

Comments of zRMS:	Two field trials (one harvest and one decline) were conducted in Poland (Northern Europe). Study is valid with regard to storage stability data with the exception of 1,2,4-Triazole. Time from sampling to analysis is more than 12 months. The applicant should prove the stability of this compound in this study. Trials are independent. Preharvest interval was 43 days. Analytical method is acceptable. Validation is conducted according to SANCO/3029/99 rev. 4. The limit of quantification (LOQ) was 0.01 mg/kg and the limit of detection (LOD) was 0.003 mg/kg for difenoconazole and triazole derivative metabolites.

Reference:	KCP 8.3.2.7
Report	Magnitude of residues of Triazole derivative Metabolites (1,2,4-triazol, triazol alanine, triazol acetic acid and triazol lactic acid) in wheat Raw Agricultural Commodity after two applications of Difenoconazole 25% EC under field conditions – 1 harvest trial and 1 decline trial. S. Romero, 2019, Report No. BPL18-030, Analytical phase: DPL/43/2019
Guideline(s):	SANCO/3029/99 rev. 5
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Two field trials were conducted in Poland (Northern Europe). The trials were on representative varieties of wheat.
Each trial was comprised of one untreated control plot and one plot treated with Difenoconazole 25% EC (difenoconazole 250 g/l).

Two applications were performed with 13-14 days interval, being the second application 43 days preharvest interval, and at a dose rate 0.40 to 0.41 l/ha of test item; corresponding to a total dose of active ingredient between 98.7 to 99.9 g/ha.
One trial was performed to gain specimens at harvest timing BBCH 891 (raw agricultural commodities) of wheat grain and straw.
Another trial was conducted to study the decline curve of the active ingredient and triazole derivative metabolites (1,2,4-traizole, triazole alanine, triazole acetic and triazole lactic acid) in whole plants without roots and Raw Agricultural Commodities (grain and straw) generated at ±0, 7, 14 and 28 DALA. At 43 DALA, harvest timing BBCH 89 , specimens of raw agricultural commodities of wheat grain and straw were generated.

Analytical phase
Specimen extraction and determination of residues of Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA in wheat were performed according to the multi-residue QuPPe method.

Extraction
5 g (plant, grain), 2g (straw) of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of water and 10 mL of acidified methanol (1% HCOOH) was added together with 100 µL of internal standard solution, and the mixture was shaken vigorously by hand for one minute, then centrifuged at 4700 rpm for 10 min for phase separation. After that, extract was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis.
The extracts were analyzed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day). Data acquisition was carried out in MRM mode. The analysis was performed using internal standard addition.
For each analyte, two mass transitions were evaluated and used for quantification.

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				Difenoconazole	TAA	TA	TLA	1,2,4-T		

Trial No./ Location/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ ha	Water (l/ha)	g a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): Difenoconazole	TAA	TA	TLA	1,2,4-T	PHI (days) (d)	Details on trial (e)
BPL18-030-01/N-EU/Poland/2018 Wieluń– POLAND	Wheat/Mewa	21/09/2017 08/06/2018 21/07/2018	100 100	300 300	33 33	25/05/2018 08/06/2018	BBCH 61 BBCH 69	Grain Straw	0.024 2.14	0.013 n.d.	0.14 n.d.	n.d n.d..	0.57 n.d.	43 43	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Analytical phase: DPL/43/2019
BPL18-030-01/N-EU/Poland/2018 , Prusice, Dolny Śląsk – POLAND	Wheat/Hondia	23/10/2017 07/06/2018 20/07/2018	100 100	300 300	33 33	25/05/2018 07/06/2018	BBCH 61 BBCH 69	Whole plant Whole plant Whole plant Whole plant Grain Straw	1.93 0.58 0.58 0.51 <0.01 (<LOQ) 0.87	n.d. n.d. n.d. n.d. <0.01 n.d.	n.d. n.d. n.d. n.d. 0.089 n.d.	n.d. n.d. n.d. n.d. n.d. n.d.	0.65 0.36 0.30 0.060 0.098 n.d.	0 7 14 28 43 43	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg Analytical phase: DPL/43/2019

Table A 2: Summary of the studies in N-EU

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

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				1,2,4-T	TA	TAA	TLA		
S09-01485-01/N-EU/France/2009	Winter wheat/Campero	-	125	200	62.5	1	BBCH 71	Grain Straw	<0.01 <0.01	0.1 <0.01	0.08 0.03	<0.01 0.03	40 40	
S09-01485-02/N-EU/France	Spring wheat/Triso	-	125	300	41.67	1	BBCH 69	Plant Plant Plant Plant Plant Plant Grain Straw	NA <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	NA 0.03 0.04 0.02 0.03 0.08 0.18 0.02	NA 0.02 0.02 0.02 0.02 0.04 0.10 0.06	NA 0.02 0.02 0.01 0.01 <0.01 <0.01 0.01	0- 0+ 7 14 20 29 40 40	
S09-01485-03/N-EU/Germany	Winter wheat/Brilliant	-	125	200	62.5	1	BBCH 69	Grain Straw Grain Straw	<0.01 <0.01 <0.01 <0.01	0.16 <0.01 0.16 <0.01	0.12 0.04 0.14 0.06	<0.01 0.03 <0.01 0.04	39 39 46 46	
S09-01485-04/N-EU/Germany	Winter wheat/Impression	-	125	300	41.67	1	BBCH 69	Plant Plant Plant Plant Plant Plant Grain Straw Grain Straw	NA <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	NA <0.01 <0.01 0.02 0.02 0.05 0.13 0.01 0.12 0.01	NA <0.01 <0.01 0.01 <0.01 0.02 0.04 0.01 0.04 0.02	NA <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.02	0- 0+ 7 13 20 26 44 44 58 58	
S10-00958-02/N-EU/France	Winter wheat/Cezanne	-	125	300	41.67	1	BBCH 69	Plant Plant Plant Plant Plant Grain Straw Grain Straw	NA <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	NA 0.03 0.03 0.02 0.03 0.16 <0.01 0.12 <0.01	NA 0.03 0.03 0.02 0.02 0.08 0.02 0.06 0.05	NA 0.02 0.02 0.02 0.02 <0.01 0.03 <0.01 0.04	0- 0+ 14 21 28 40 40 55 55	
S10-00958-03/N-EU/France	Winter wheat/Mercato	-	125	200	62.5	1	BBCH 69	Grain Straw	<0.01 <0.01	0.36 0.02	0.21 0.09	<0.01 0.18	40 40	
S10-00958-04/N-EU/UK	Winter wheat/Alchemy	-	125	200	62.5	1	BBCH 69	Grain Straw	<0.01 <0.01	0.05 <0.01	0.03 0.02	<0.01 <0.01	39 39	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat-ments and last date	Growth stage at last treat-ment or date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl				1,2,4-T	TA	TAA	TLA		
								Grain Straw	<0.01 <0.01	0.05 <0.01	0.02 0.02	<0.01 <0.01	44 44	
S10-00958-05/N-EU/Germany	Winter wheat/Tabasco	-	125	300	41.67	1	BBCH 69	Plant Plant Plant Plant Plant Grain Straw	NA <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	NA <0.01 <0.01 <0.01 0.01 0.06 <0.01	NA <0.01 <0.01 <0.01 0.01 0.02 0.04	NA <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0- 0+ 14 21 28 42 42	
S11-00557-01/N-EU/Germany	Winter wheat/Hermann	-	125	200	62.5	1	BBCH 69	Plant Plant Plant Plant Plant Ear Straw Grain Straw	NA <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	NA <0.01 <0.01 <0.01 0.01 0.03 <0.01 0.05 <0.01	NA <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.01 <0.01	NA <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0- 0+ 14 22 27 41 41 64 64	

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

A 2.2.4.1.1 Livestock feeding study 1

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

A 2.2.5.1 Distribution of the residue in peel/pulp

A 2.2.5.2 Processing studies on a core set of representative processes

A 2.2.6 Magnitude of residues in representative succeeding crops

A 2.2.7 Other/Special Studies

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 Boscalid

A 3.1.1 TMDI calculations

European Food Safety Authority
EFSA PRIMo revision 3.0; 2017/12/11

Boscalid

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw/day):	0.04	ARfD (mg/kg bw):	not necessary
Source of ADI:	EC	Source of ARfD:	
Year of evaluation:	2008	Year of evaluation:	

Input values
Details - chronic risk assessment
Supplementary results - chronic risk assessment
Details - acute risk assessment/children
Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 26

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
398%	NL toddler	159.05	30%	Spinaches	54%	Apples	31%	Escaroles/broad-leaved endives	0.2%	398%
260%	DE child	104.03	62%	Apples	25%	Spinaches	20%	Oranges	0.1%	260%
224%	GEMS/Food G11	89.56	34%	Sugar canes	28%	Soyabeans	20%	Potatoes	0.2%	224%
223%	GEMS/Food G10	89.14	41%	Lettuces	24%	Soyabeans	23%	Sugar canes	0.2%	223%
217%	NL child	86.71	31%	Spinaches	29%	Apples	17%	Potatoes	0.2%	217%
216%	GEMS/Food G06	86.26	29%	Sugar canes	27%	Tomatoes	14%	Wheat	0.1%	216%
213%	GEMS/Food G08	85.36	28%	Sugar canes	25%	Lettuces	20%	Potatoes	0.2%	213%
210%	GEMS/Food G07	83.95	30%	Lettuces	27%	Sugar canes	19%	Potatoes	0.2%	210%
187%	GEMS/Food G15	74.87	23%	Sugar canes	18%	Potatoes	14%	Lettuces	0.1%	187%
184%	IE adult	73.47	18%	Sweet potatoes	16%	Wine grapes	16%	Wine grapes	0.1%	184%
168%	SE general	67.16	50%	Lettuces	21%	Potatoes	8%	Spinaches	0.1%	168%
145%	IT adult	57.95	47%	Lettuces	20%	Other lettuce and other salad plants	12%	Spinaches	0.0%	145%
144%	ES adult	57.49	67%	Lettuces	9%	Spinaches	6%	Oranges	0.1%	144%
143%	FR child 3 15 yr	57.26	17%	Oranges	14%	Other lettuce and other salad plants	13%	Spinaches	0.2%	143%
140%	ES child	55.92	52%	Lettuces	11%	Oranges	10%	Spinaches	0.2%	140%
131%	RO general	52.57	21%	Wine grapes	19%	Potatoes	18%	Head cabbages	0.1%	131%
131%	IT toddler	52.32	36%	Lettuces	14%	Other lettuce and other salad plants	13%	Wheat	0.0%	131%
131%	PT general	52.28	31%	Wine grapes	27%	Potatoes	13%	Lettuces	0.0%	131%
130%	NL general	51.97	19%	Spinaches	12%	Escaroles/broad-leaved endives	12%	Potatoes	0.2%	130%
127%	FR toddler 2 3 yr	50.85	20%	Spinaches	16%	Apples	10%	Beans (with pods)	0.1%	127%
120%	DE women 14-50 yr	48.02	14%	Lettuces	13%	Apples	10%	Wine grapes	0.1%	120%
119%	DK child	47.46	18%	Lettuces	16%	Cucumbers	12%	Potatoes	0.1%	119%
115%	DE general	46.04	12%	Apples	12%	Lettuces	10%	Wine grapes	0.1%	115%
112%	FI 3 yr	44.80	24%	Potatoes	10%	Cucumbers	8%	Spinaches	0.0%	112%
108%	FR adult	43.21	29%	Wine grapes	19%	Other lettuce and other salad plants	7%	Spinaches	0.1%	108%
102%	FR infant	40.70	33%	Spinaches	10%	Potatoes	8%	Apples	0.0%	102%
102%	UK toddler	40.60	17%	Potatoes	10%	Oranges	9%	Apples	0.1%	102%
92%	FI 6 yr	36.75	19%	Potatoes	10%	Lettuces	7%	Cucumbers	0.0%	92%
87%	UK infant	34.62	16%	Potatoes	8%	Apples	7%	Carrots	0.1%	87%
82%	UK vegetarian	32.87	18%	Lettuces	10%	Wine grapes	7%	Potatoes	0.0%	82%
68%	UK adult	27.22	15%	Lettuces	14%	Wine grapes	7%	Potatoes	0.0%	68%
67%	PL general	26.89	17%	Potatoes	10%	Apples	7%	Tomatoes	0.0%	67%
66%	DK adult	26.21	12%	Wine grapes	11%	Lettuces	6%	Potatoes	0.1%	66%
63%	FI adult	25.07	18%	Lettuces	6%	Potatoes	4%	Tomatoes	0.1%	63%
60%	LT adult	23.85	16%	Potatoes	9%	Apples	8%	Lettuces	0.1%	60%
18%	IE child	7.23	3%	Potatoes	2%	Wheat	2%	Apples	0.0%	18%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 397.6 % of the ADI.
For 26 diet(s) the ADI is exceeded.

A 3.1.2 IEDI calculations

European Food Safety Authority
EFSA PRIMo revision 3.0; 2017/12/11

Boscalid

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw/day):	0.04	ARfD (mg/kg bw):	not necessary
Source of ADI:	EC	Source of ARfD:	
Year of evaluation:	2008	Year of evaluation:	

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
85%	NL toddler	33.96	11%	Apples	11%	Oranges	10%	Spinaches	0.2%	85%
68%	GEMS/Food G11	27.24	34%	Sugar canes	4%	Oranges	4%	Wine grapes	0.2%	68%
67%	DE child	26.89	20%	Oranges	13%	Apples	5%	Table grapes	0.1%	67%
65%	GEMS/Food G06	26.02	29%	Sugar canes	5%	Oranges	4%	Table grapes	0.1%	65%
63%	GEMS/Food G07	25.24	27%	Sugar canes	7%	Oranges	5%	Wine grapes	0.2%	63%
59%	GEMS/Food G08	23.68	28%	Sugar canes	4%	Wine grapes	3%	Lettuces	0.2%	59%
55%	GEMS/Food G10	22.14	23%	Sugar canes	6%	Oranges	5%	Lettuces	0.2%	55%
53%	NL child	21.25	8%	Sugar beet roots	7%	Oranges	6%	Apples	0.2%	53%
52%	GEMS/Food G15	20.78	23%	Sugar canes	4%	Wine grapes	3%	Oranges	0.1%	52%
43%	IE adult	17.15	5%	Oranges	4%	Wine grapes	4%	Other leafy brassica	0.1%	43%
42%	FR child 3 15 yr	16.78	17%	Oranges	4%	Sugar beet roots	2%	Apples	0.2%	42%
36%	DE women 14-50 yr	14.60	10%	Oranges	5%	Sugar beet roots	3%	Wine grapes	0.1%	36%
34%	DE general	13.56	8%	Oranges	4%	Sugar beet roots	3%	Wine grapes	0.1%	34%
34%	ES child	13.46	11%	Oranges	6%	Chards/beet leaves	6%	Lettuces	0.2%	34%
33%	FR toddler 2 3 yr	13.35	7%	Oranges	4%	Mandarins	3%	Apples	0.1%	33%
31%	ES adult	12.46	7%	Lettuces	6%	Oranges	6%	Chards/beet leaves	0.1%	31%
29%	SE general	11.53	6%	Lettuces	4%	Oranges	2%	Mandarins	0.1%	29%
28%	UK toddler	11.20	10%	Oranges	3%	Sugar beet roots	2%	Apples	0.1%	28%
28%	NL general	11.14	5%	Oranges	3%	Sugar beet roots	2%	Spinaches	0.2%	28%
26%	IT adult	10.49	5%	Lettuces	5%	Chards/beet leaves	2%	Other lettuce and other salad plan	0.0%	26%
25%	IT toddler	10.18	5%	Chards/beet leaves	4%	Lettuces	2%	Oranges	0.0%	25%
25%	RO general	9.86	6%	Wine grapes	4%	Head cabbages	2%	Tomatoes	0.1%	25%
24%	FR adult	9.69	8%	Wine grapes	3%	Oranges	2%	Other lettuce and other salad plan	0.1%	24%
23%	PT general	9.31	9%	Wine grapes	3%	Oranges	1%	Lettuces	0.0%	23%
21%	UK infant	8.59	6%	Oranges	2%	Milk: Cattle	2%	Apples	0.1%	21%
20%	FR infant	8.12	4%	Spinaches	2%	Chards/beet leaves	2%	Apples	0.0%	20%
19%	DK child	7.75	3%	Cucumbers	2%	Apples	2%	Lettuces	0.1%	19%
19%	FI 3 yr	7.43	2%	Mandarins	2%	Cucumbers	2%	Strawberries	0.0%	19%
18%	UK vegetarian	7.08	4%	Oranges	3%	Wine grapes	2%	Lettuces	0.0%	18%
15%	UK adult	5.88	4%	Wine grapes	3%	Oranges	2%	Lettuces	0.0%	15%
15%	FI 6 yr	5.81	2%	Mandarins	1%	Strawberries	1%	Cucumbers	0.0%	15%
12%	FI adult	4.97	2%	Oranges	2%	Lettuces	1%	Wine grapes	0.7%	12%
12%	DK adult	4.89	3%	Wine grapes	1%	Lettuces	1%	Apples	0.1%	12%
10%	PL general	3.87	2%	Apples	1%	Table grapes	1%	Head cabbages	0.0%	10%
9%	LT adult	3.45	2%	Apples	1%	Head cabbages	0.9%	Lettuces	0.1%	9%
3%	IE child	1.33	0.4%	Oranges	0.3%	Wheat	0.3%	Apples	0.0%	3%

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

A 3.1.3 IESTI calculations - Raw commodities

Not relevant.

A 3.1.4 IESTI calculations - Processed commodities

Not relevant.

A 3.2 Difenoconazole

A 3.2.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

DIFENOCONAZOLE

LOQs (mg/kg) range from:	0,005	to:	0,05
Toxicological reference values			
ADI (mg/kg bw/day):	0,01	ARfD (mg/kg bw):	0,16
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2011	Year of evaluation:	2011

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 24

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	351%	NL toddler	35,13	86%	Apples	46%	Table grapes	35%	Pears	8%	
	282%	DE child	28,24	100%	Apples	41%	Table grapes	24%	Oranges	2%	
	241%	GEMS/Food G06	24,07	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	18,25	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	17,55	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%	
	136%	DE women 14-50 yr	13,64	25%	Wine grapes	21%	Apples	15%	Tomatoes	1%	
	135%	FR adult	13,51	70%	Wine grapes	9%	Tomatoes	6%	Apples	1%	
	129%	FR toddler 2 3 yr	12,89	25%	Apples	18%	Rice	10%	Tomatoes	2%	
	126%	DE general	12,56	25%	Wine grapes	19%	Apples	13%	Tomatoes	1%	
	125%	ES child	12,46	20%	Tomatoes	17%	Lettuces	15%	Olives for oil production	2%	
	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	6,82	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	5,69	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%	

Conclusion:
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 3.2.2 IEDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

DIFENOCONAZOLE

LOQs (mg/kg) range from:	0,005	to:	0,05
Toxicological reference values			
ADI (mg/kg bw/day):	0,01	ARfD (mg/kg bw):	0,16
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2011	Year of evaluation:	2011

Input values

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

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

Comments:

Refined calculation mode

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)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	53%	GEMS/Food G06	5,33	26%	Tomatoes	14%	Rice	5%	Table grapes		53%
	32%	GEMS/Food G10	3,22	11%	Rice	10%	Tomatoes	2%	Wine grapes		32%
	32%	PT general	3,16	13%	Wine grapes	7%	Rice	6%	Tomatoes		32%
	29%	RO general	2,91	14%	Tomatoes	9%	Wine grapes	2%	Rice		29%
	29%	GEMS/Food G08	2,88	8%	Tomatoes	5%	Wine grapes	4%	Olives for oil production		29%
	28%	GEMS/Food G07	2,83	8%	Tomatoes	8%	Wine grapes	3%	Rice		28%
	27%	GEMS/Food G11	2,73	7%	Tomatoes	5%	Wine grapes	3%	Celeries		27%
	27%	NL toddler	2,68	8%	Table grapes	7%	Tomatoes	6%	Rice		27%
	25%	GEMS/Food G15	2,47	9%	Tomatoes	5%	Wine grapes	3%	Rice		25%
	24%	DE child	2,44	7%	Tomatoes	7%	Table grapes	2%	Rice		24%
	22%	IE adult	2,18	7%	Wine grapes	3%	Tomatoes	2%	Rice		22%
	20%	FR adult	2,01	12%	Wine grapes	3%	Tomatoes	1%	Rice		20%
	20%	ES child	1,95	7%	Tomatoes	4%	Rice	3%	Olives for oil production		20%
	19%	IT toddler	1,86	10%	Tomatoes	2%	Rice	2%	Lettuces		19%
	18%	FR child 3 15 yr	1,78	6%	Tomatoes	4%	Rice	2%	Wine grapes		18%
	17%	ES adult	1,72	6%	Tomatoes	3%	Lettuces	2%	Wine grapes		17%
	17%	IT adult	1,70	8%	Tomatoes	2%	Lettuces	2%	Florence fennels		17%
	15%	UK vegetarian	1,54	4%	Tomatoes	4%	Wine grapes	3%	Rice		15%
	15%	SE general	1,49	6%	Tomatoes	4%	Rice	2%	Lettuces		15%
	15%	DE women 14-50 yr	1,49	5%	Tomatoes	4%	Wine grapes	2%	Table grapes		15%
	15%	NL child	1,47	5%	Table grapes	4%	Tomatoes	1%	Rice		15%
	14%	UK adult	1,42	6%	Wine grapes	3%	Rice	3%	Tomatoes		14%
	14%	DE general	1,37	5%	Tomatoes	4%	Wine grapes	1%	Table grapes		14%
	13%	UK toddler	1,33	5%	Rice	4%	Tomatoes	1%	Table grapes		13%
	13%	FR toddler 2 3 yr	1,32	5%	Rice	3%	Tomatoes	1%	Wine grapes		13%
	13%	FI 3 yr	1,28	5%	Rice	4%	Tomatoes	1%	Table grapes		13%
	12%	DK child	1,23	4%	Tomatoes	3%	Rice	1%	Rye		12%
	12%	DK adult	1,22	5%	Wine grapes	4%	Tomatoes	0,9%	Table grapes		12%
	11%	NL general	1,14	3%	Wine grapes	3%	Tomatoes	1%	Table grapes		11%
	11%	UK infant	1,11	6%	Rice	3%	Tomatoes	1%	Carrots		11%
	10%	FI 6 yr	1,01	4%	Rice	3%	Tomatoes	0,9%	Table grapes		10%
	9%	PL general	0,94	6%	Tomatoes	2%	Table grapes	0,4%	Celery leaves		9%
	9%	FI adult	0,89	4%	Tomatoes	2%	Wine grapes	1%	Rice		9%
	8%	LT adult	0,77	4%	Tomatoes	2%	Rice	0,3%	Lettuces		8%
	5%	FR infant	0,54	0,9%	Carrots	0,8%	Florence fennels	0,7%	Tomatoes		5%
	4%	IE child	0,40	3%	Rice	0,4%	Tomatoes	0,3%	Table grapes		4%

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

A 3.2.3 IESTI calculations - Raw commodities

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

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

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

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**IESTI new Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---				**IESTI new Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**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)
0,2%	Wheat	0,1 / 0,02	0,29	0,1%	Wheat	0,1 / 0,02	0,17	0,9%	Wheat	0,1 / 0,1	1,4	0,5%	Wheat	0,1 / 0,1	0,84
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)**							

A 3.2.4 IESTI calculations - Processed commodities

Processed commodities

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

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

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)
0,2%	Wheat / milling (flour)	0,1 / 0,02	0,24	0,1%	Wheat / bread/pizza	0,1 / 0,02	0,09
0,1%	Wheat / milling (wholemea	0,1 / 0,02	0,11	0,05%	Wheat / pasta	0,1 / 0,02	0,08
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	0,04%	Wheat / bread	0,1 / 0,02	0,07
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!

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

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,8%	Wheat / milling (flour)	0,1 / 0,1	1,2	0,3%	Wheat / bread/pizza	0,1 / 0,1	0,44
0,3%	Wheat / milling	0,1 / 0,1	0,55	0,2%	Wheat / pasta	0,1 / 0,1	0,38
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	0,2%	Wheat / bread (wholemeal)	0,1 / 0,1	0,35
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!
#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!	#¡NUM!

Expand/collapse list

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

Evaluator’s comment:
IESTI (input: MRL for wheat)

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

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

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

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

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 (children)

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,9%	Wheat	0,1 / 0,1	1,4

IESTI (adults)

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,5%	Wheat	0,1 / 0,1	0,84

IESTI new (children)

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,9%	Wheat	0,1 / 0,1	1,4

IESTI new (adults)

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,5%	Wheat	0,1 / 0,1	0,84

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)

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

IESTI (children)

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,8%	Wheat / milling (flour)	0,1 / 0,1	1,2
0,3%	Wheat / milling (wholemea	0,1 / 0,1	0,55
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

IESTI (adults)

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,3%	Wheat / bread/pizza	0,1 / 0,1	0,44
0,2%	Wheat / pasta	0,1 / 0,1	0,38
0,2%	Wheat / bread	0,1 / 0,1	0,35
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

IESTI new (children)

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,8%	Wheat / milling (flour)	0,1 / 0,1	1,2
0,3%	Wheat / milling	0,1 / 0,1	0,55
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

IESTI new (adults)

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,3%	Wheat / bread/pizza	0,1 / 0,1	0,44
0,2%	Wheat / pasta	0,1 / 0,1	0,38
0,2%	Wheat / bread (wholemeal)	0,1 / 0,1	0,35
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

Expand/collapse list

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

A 3.3 TA – TDMs assessment

A 3.3.1 TMDI calculations

European Food Safety Authority
EFSA PRIMo revision 3.1; 2021/01/06

TA

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.3	ARfD (mg/kg bw):	0.3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : –

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	6%	NL toddler	18.21	1%	Maize/corn	0.8%	Wheat	0.8%	Milk: Cattle		0.8%
	4%	GEMS/Food G06	12.64	1%	Wheat	0.4%	Soyabeans	0.3%	Rice		1%
	4%	GEMS/Food G10	12.26	1%	Soyabeans	0.8%	Wheat	0.3%	Rice		0.8%
	4%	GEMS/Food G08	11.31	0.8%	Wheat	0.7%	Soyabeans	0.3%	Olives for oil production		0.8%
	4%	GEMS/Food G11	11.29	1%	Soyabeans	0.7%	Wheat	0.2%	Potatoes		0.7%
	4%	GEMS/Food G07	10.99	0.9%	Wheat	0.6%	Soyabeans	0.2%	Potatoes		0.9%
	4%	GEMS/Food G15	10.58	0.9%	Wheat	0.6%	Soyabeans	0.2%	Potatoes		0.9%
	3%	DK child	10.10	1%	Rye	0.9%	Wheat	0.2%	Bovine: Muscle/meat		0.9%
	3%	NL child	10.09	0.9%	Wheat	0.3%	Milk: Cattle	0.3%	Oil palm fruits		0.9%
	3%	FR child 3 15 yr	9.01	1.0%	Wheat	0.4%	Oranges	0.3%	Milk: Cattle		1.0%
	3%	DE child	8.96	0.9%	Wheat	0.4%	Oranges	0.3%	Milk: Cattle		0.9%
	3%	RO general	8.01	1%	Wheat	0.2%	Sunflower seeds	0.2%	Potatoes		1%
	3%	ES child	7.74	0.9%	Wheat	0.3%	Olives for oil production	0.2%	Oranges		0.9%
	2%	SE general	7.38	0.7%	Bovine: Muscle/meat	0.7%	Wheat	0.3%	Potatoes		0.7%
	2%	UK infant	7.13	0.5%	Wheat	0.5%	Milk: Cattle	0.2%	Maize/corn		0.5%
	2%	FR toddler 2 3 yr	7.04	0.6%	Wheat	0.4%	Milk: Cattle	0.2%	Bovine: Muscle/meat		0.6%
	2%	IE adult	6.81	0.5%	Wheat	0.2%	Sweet potatoes	0.1%	Potatoes		0.5%
	2%	UK toddler	6.75	0.8%	Wheat	0.3%	Milk: Cattle	0.2%	Potatoes		0.8%
	2%	IT toddler	6.53	1%	Wheat	0.3%	Other cereals	0.1%	Tomatoes		1%
	2%	PT general	6.37	0.8%	Wheat	0.3%	Potatoes	0.2%	Rice		0.8%
	2%	NL general	5.48	0.4%	Wheat	0.2%	Oil palm fruits	0.1%	Potatoes		0.4%
	2%	DE women 14-50 yr	5.01	0.4%	Wheat	0.2%	Oranges	0.2%	Milk: Cattle		0.4%
	2%	DE general	4.99	0.4%	Wheat	0.2%	Oranges	0.2%	Milk: Cattle		0.4%
	2%	ES adult	4.71	0.5%	Wheat	0.1%	Olives for oil production	0.1%	Oranges		0.5%
	1%	IT adult	4.30	0.9%	Wheat	0.1%	Other cereals	0.1%	Tomatoes		0.9%
	1%	FI 3 yr	4.12	0.3%	Potatoes	0.2%	Wheat	0.1%	Rye		0.2%
	1%	FR adult	3.67	0.5%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Oranges		0.5%
	1%	LT adult	3.38	0.2%	Rye	0.2%	Wheat	0.2%	Potatoes		0.2%
	1%	FI 6 yr	3.26	0.2%	Potatoes	0.2%	Wheat	0.1%	Rye		0.2%
	1.0%	UK vegetarian	2.97	0.4%	Wheat	0.1%	Oranges	0.1%	Potatoes		0.4%
	1.0%	FR infant	2.86	0.2%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes		0.2%
	0.9%	UK adult	2.77	0.3%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Potatoes		0.3%
	0.9%	DK adult	2.74	0.2%	Wheat	0.1%	Rye	0.1%	Bovine: Muscle/meat		0.2%
	0.6%	FI adult	1.80	0.1%	Rye	0.1%	Potatoes	0.1%	Wheat		0.1%
	0.5%	IE child	1.45	0.2%	Wheat	0.1%	Rice	0.0%	Milk: Cattle		0.2%
	0.5%	PL general	1.39	0.2%	Potatoes	0.1%	Tomatoes	0.0%	Apples		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of TA 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 3.3.2 IEDI calculations

Not relevant

A 3.3.3 IESTI calculations - Raw commodities

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): —			
IE STI				**IE STI**			
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%	Wheat	0 / 0.62	9.0	2%	Wheat	0 / 0.62	5.2
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IE STI calculation)							

A 3.3.4 IESTI calculations - Processed commodities

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)
3%	Wheat / milling (flour)	0 / 0.62	7.5	0.9%	Wheat / bread/pizza	0 / 0.62	2.7
1%	Wheat / milling (wholemea	0 / 0.62	3.4	0.8%	Wheat / pasta	0 / 0.62	2.4
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	0.7%	Wheat / bread (wholemeal)	0 / 0.62	2.2

A 3.4 TLA – TDMs assessment

A 3.4.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

TLA

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.3	ARfD (mg/kg bw):	0.3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMD/WEDI/EDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
	1%	NL toddler	4.01	0.8%	Milk: Cattle	0.1%	Apples	0.1%	Maize/corn		0.0%
	0.7%	UK infant	2.05	0.5%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat		0.0%
	0.7%	NL child	2.01	0.3%	Milk: Cattle	0.1%	Apples	0.0%	Wheat		0.0%
	0.7%	DE child	1.96	0.3%	Milk: Cattle	0.1%	Apples	0.1%	Oranges		0.0%
	0.6%	FR toddler 2 3 yr	1.82	0.4%	Milk: Cattle	0.0%	Apples	0.0%	Wheat		0.0%
	0.6%	FR child 3 15 yr	1.73	0.3%	Milk: Cattle	0.0%	Oranges	0.0%	Wheat		0.0%
	0.5%	UK toddler	1.39	0.3%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.0%
	0.4%	GEMS/Food G11	1.27	0.1%	Milk: Cattle	0.1%	Soyabeans	0.0%	Potatoes		0.0%
	0.4%	DK child	1.25	0.2%	Milk: Cattle	0.0%	Rye	0.0%	Wheat		0.0%
	0.4%	GEMS/Food G07	1.19	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.0%
	0.4%	GEMS/Food G10	1.19	0.1%	Milk: Cattle	0.1%	Soyabeans	0.0%	Wheat		0.0%
	0.4%	ES child	1.18	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.0%
	0.4%	GEMS/Food G08	1.17	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.0%
	0.4%	GEMS/Food G15	1.16	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.0%
	0.4%	RO general	1.15	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.0%
	0.4%	SE general	1.15	0.2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	Potatoes		0.0%
	0.4%	GEMS/Food G06	1.06	0.1%	Wheat	0.0%	Tomatoes	0.0%	Milk: Cattle		0.1%
	0.4%	DE women 14-50 yr	1.05	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.0%
	0.3%	DE general	1.03	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.0%
	0.3%	FR infant	0.97	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Potatoes		0.0%
	0.3%	NL general	0.89	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.0%
	0.3%	IE adult	0.85	0.1%	Milk: Cattle	0.0%	Sweet potatoes	0.0%	Wheat		0.0%
	0.2%	ES adult	0.67	0.1%	Milk: Cattle	0.0%	Oranges	0.0%	Wheat		0.0%
	0.2%	FR adult	0.61	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.0%
	0.2%	PT general	0.56	0.0%	Potatoes	0.0%	Wine grapes	0.0%	Wheat		0.0%
	0.2%	DK adult	0.54	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Swine: Muscle/meat		0.0%
	0.2%	LT adult	0.49	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.0%
	0.1%	IT toddler	0.43	0.0%	Wheat	0.0%	Tomatoes	0.0%	Other cereals		0.0%
	0.1%	UK vegetarian	0.41	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.0%
	0.1%	UK adult	0.40	0.0%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.0%
	0.1%	FI 3 yr	0.38	0.0%	Potatoes	0.0%	Cucumbers	0.0%	Apples		0.0%
	0.1%	IT adult	0.35	0.0%	Wheat	0.0%	Tomatoes	0.0%	Lettuces		0.0%
	0.1%	FI 6 yr	0.30	0.0%	Potatoes	0.0%	Wheat	0.0%	Cucumbers		0.0%
	0.1%	IE child	0.25	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.0%
	0.1%	PL general	0.23	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		
	0.1%	FI adult	0.19	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		0.0%

A 3.4.2 IEDI calculations

Not relevant.

A 3.4.3 IESTI calculations - Raw commodities

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Wheat	0 / 0.02	0.32

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.06%	Wheat	0 / 0.02	0.18

A 3.4.4 IESTI calculations - Processed commodities

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
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%	Wheat / milling (flour)	0 / 0.02	0.27	0.0%	Wheat / bread/pizza	0 / 0.02	0.10
0.0%	Wheat / milling (wholemeal)-t	0 / 0.02	0.12	0.03%	Wheat / pasta	0 / 0.02	0.08
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	0.03%	Wheat / bread (wholemeal)	0 / 0.02	0.08

A 3.5 TAA – TDMs assessment

A 3.5.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

TAA

LOQs (mg/kg) range from: to:

Toxicological reference values

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

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
1%	NL toddler	14.21	0.6%	Maize/corn	0.3%	Wheat	0.2%	Milk: Cattle		0.3%
0.9%	DK child	9.35	0.4%	Rye	0.3%	Wheat	0.1%	Milk: Cattle		0.3%
0.9%	GEMS/Food G06	9.03	0.6%	Wheat	0.1%	Rice	0.1%	Maize/corn		0.6%
0.7%	IT toddler	6.81	0.5%	Wheat	0.1%	Other cereals	0.0%	Rice		0.5%
0.7%	GEMS/Food G10	6.52	0.3%	Wheat	0.1%	Rice	0.1%	Maize/corn		0.3%
0.6%	DE child	6.35	0.3%	Wheat	0.1%	Milk: Cattle	0.1%	Rye		0.3%
0.6%	GEMS/Food G15	6.32	0.4%	Wheat	0.1%	Barley	0.1%	Maize/corn		0.4%
0.6%	GEMS/Food G08	6.26	0.3%	Wheat	0.1%	Barley	0.0%	Rye		0.3%
0.6%	NL child	6.21	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.3%
0.6%	FR child 3 15 yr	6.21	0.4%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.4%
0.6%	RO general	5.99	0.4%	Wheat	0.1%	Maize/corn	0.0%	Milk: Cattle		0.4%
0.6%	GEMS/Food G07	5.75	0.3%	Wheat	0.0%	Barley	0.0%	Rice		0.3%
0.6%	UK infant	5.64	0.2%	Wheat	0.2%	Milk: Cattle	0.1%	Maize/corn		0.2%
0.5%	GEMS/Food G11	5.29	0.3%	Wheat	0.1%	Barley	0.0%	Soyabeans		0.3%
0.5%	ES child	5.24	0.4%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.4%
0.5%	UK toddler	5.09	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.3%
0.5%	FR toddler 2 3 yr	4.91	0.2%	Wheat	0.1%	Milk: Cattle	0.0%	Rice		0.2%
0.5%	PT general	4.69	0.3%	Wheat	0.1%	Rice	0.0%	Maize/corn		0.3%
0.4%	IT adult	4.15	0.3%	Wheat	0.1%	Other cereals	0.0%	Rice		0.3%
0.4%	SE general	4.12	0.3%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.3%
0.4%	DE general	3.61	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.1%
0.4%	DE women 14-50 yr	3.53	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.2%
0.3%	IE adult	3.43	0.2%	Wheat	0.0%	Buckwheat and other pseudo-cereals	0.0%	Rice		0.2%
0.3%	ES adult	3.10	0.2%	Wheat	0.0%	Barley	0.0%	Milk: Cattle		0.2%
0.3%	NL general	3.02	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Barley		0.2%
0.3%	FI 3 yr	2.73	0.1%	Wheat	0.1%	Rye	0.0%	Oat		0.1%
0.3%	FR adult	2.55	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Rice		0.2%
0.3%	LT adult	2.51	0.1%	Rye	0.1%	Wheat	0.0%	Rice		0.1%
0.2%	UK vegetarian	2.38	0.2%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.2%
0.2%	FI 6 yr	2.13	0.1%	Wheat	0.0%	Rye	0.0%	Rice		0.1%
0.2%	UK adult	2.04	0.1%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.1%
0.2%	DK adult	1.85	0.1%	Wheat	0.0%	Rye	0.0%	Milk: Cattle		0.1%
0.2%	FR infant	1.66	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Sugar beet roots		0.1%
0.1%	IE child	1.38	0.1%	Wheat	0.0%	Rice	0.0%	Milk: Cattle		0.1%
0.1%	FI adult	1.19	0.1%	Rye	0.0%	Wheat	0.0%	Oat		0.0%
0.0%	PL general	0.18	0.0%	Apples	0.0%	Potatoes	0.0%	Table grapes		

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

A 3.5.2 IEDI calculations

Not relevant.

A 3.5.3 IESTI calculations - Raw commodities

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)
1%	Wheat	0 / 0.79	11	0.7%	Wheat	0 / 0.79	6.6
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

A 3.5.4 IESTI calculations - Processed commodities

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
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)
1.0%	Wheat / milling (flour)	0 / 0.79	9.6	0.3%	Wheat / bread/pizza	0 / 0.79	3.5
0.4%	Wheat / milling (wholemeal)-t	0 / 0.79	4.4	0.3%	Wheat / pasta	0 / 0.79	3.0
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	0.3%	Wheat / bread (wholemeal)	0 / 0.79	2.8

A 3.6 1,2,4-triazole – TDMs assessment

A 3.6.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

1,2,4-triazole

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.023	ARfD (mg/kg bw):	0.1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	88%	NL toddler	20.22	78%	Milk: Cattle	2%	Maize/corn	1%	Bovine: Muscle/meat		0.9%
	55%	UK infant	12.62	50%	Milk: Cattle	1%	Bovine: Muscle/meat	0.6%	Wheat		0.6%
	44%	FR toddler 2 3 yr	10.07	38%	Milk: Cattle	1%	Bovine: Muscle/meat	0.7%	Wheat		0.7%
	39%	NL child	9.00	32%	Milk: Cattle	2%	Sugar beet roots	1%	Bovine: Muscle/meat		0.9%
	37%	FR child 3 15 yr	8.46	30%	Milk: Cattle	2%	Bovine: Muscle/meat	1.0%	Wheat		1.0%
	32%	UK toddler	7.32	27%	Milk: Cattle	2%	Bovine: Muscle/meat	0.9%	Wheat		0.9%
	31%	DE child	7.05	26%	Milk: Cattle	0.9%	Wheat	0.9%	Oranges		0.9%
	24%	FR infant	5.46	22%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.3%	Sugar beet roots		0.2%
	24%	SE general	5.44	16%	Milk: Cattle	5%	Bovine: Muscle/meat	0.7%	Wheat		0.7%
	23%	DK child	5.25	16%	Milk: Cattle	2%	Bovine: Muscle/meat	1%	Swine: Muscle/meat		1.0%
	22%	ES child	5.03	16%	Milk: Cattle	2%	Bovine: Muscle/meat	1.0%	Wheat		1.0%
	20%	DE women 14-50 yr	4.65	16%	Milk: Cattle	1.0%	Sugar beet roots	0.5%	Swine: Muscle/meat		0.5%
	20%	DE general	4.63	16%	Milk: Cattle	0.9%	Sugar beet roots	0.6%	Swine: Muscle/meat		0.4%
	19%	RO general	4.43	15%	Milk: Cattle	1%	Wheat	0.7%	Swine: Muscle/meat		1%
	16%	GEMS/Food G11	3.61	10%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.8%	Soyabeans		0.8%
	15%	NL general	3.43	11%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.6%	Sugar beet roots		0.4%
	15%	GEMS/Food G15	3.40	9%	Milk: Cattle	1.0%	Wheat	0.8%	Swine: Muscle/meat		1.0%
	14%	GEMS/Food G07	3.32	8%	Milk: Cattle	1%	Bovine: Muscle/meat	0.9%	Wheat		0.9%
	13%	GEMS/Food G10	2.99	7%	Milk: Cattle	1%	Bovine: Muscle/meat	0.9%	Wheat		0.9%
	13%	GEMS/Food G08	2.97	7%	Milk: Cattle	1%	Swine: Muscle/meat	0.9%	Wheat		0.9%
	10%	ES adult	2.24	6%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.5%	Wheat		0.5%
	10%	IE adult	2.24	6%	Milk: Cattle	0.5%	Wheat	0.5%	Bovine: Muscle/meat		0.5%
	9%	DK adult	2.12	7%	Milk: Cattle	0.6%	Bovine: Muscle/meat	0.5%	Swine: Muscle/meat		0.2%
	9%	GEMS/Food G06	2.10	3%	Milk: Cattle	2%	Wheat	0.4%	Sugar canes		2%
	9%	FR adult	2.01	6%	Milk: Cattle	0.7%	Bovine: Muscle/meat	0.5%	Wheat		0.5%
	7%	LT adult	1.66	5%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.3%	Bovine: Muscle/meat		0.2%
	6%	UK adult	1.37	4%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.4%	Wheat		0.4%
	6%	UK vegetarian	1.31	4%	Milk: Cattle	0.4%	Wheat	0.2%	Oranges		0.4%
	5%	IE child	1.25	5%	Milk: Cattle	0.3%	Wheat	0.1%	Swine: Muscle/meat		0.3%
	2%	IT toddler	0.56	1%	Wheat	0.3%	Other cereals	0.1%	Bananas		1%
	2%	PT general	0.52	0.9%	Wheat	0.2%	Potatoes	0.2%	Rice		0.9%
	2%	FI 3 yr	0.38	0.3%	Bananas	0.3%	Wheat	0.2%	Potatoes		0.3%
	2%	IT adult	0.37	0.9%	Wheat	0.2%	Other cereals	0.1%	Oranges		0.9%
	1%	FI 6 yr	0.29	0.2%	Wheat	0.2%	Potatoes	0.2%	Bananas		0.2%
	0.7%	FI adult	0.17	0.2%	Rye	0.1%	Oranges	0.1%	Wheat		0.1%
	0.5%	PL general	0.13	0.1%	Potatoes	0.1%	Apples	0.1%	Head cabbages		

A 3.6.2 IEDI calculations

Not relevant.

A 3.6.3 IESTI calculations - Raw commodities

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Wheat	0 / 0.05	0.72

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Wheat	0 / 0.05	0.42

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

A 3.6.4 IESTI calculations - Processed commodities

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
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)
0.6%	Wheat / milling (flour)	0 / 0.05	0.60	0.2%	Wheat / bread/pizza	0 / 0.05	0.22
0.3%	Wheat / milling (wholemeal)-t	0 / 0.05	0.28	0.2%	Wheat / pasta	0 / 0.05	0.19
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	0.2%	Wheat / bread (wholemeal)	0 / 0.05	0.17

Appendix 4 Additional information provided by the applicant