REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: GLOB1911F

Product name(s): **CURRANDO/ SUBIGON/ COLLECTOR**

Chemical active substance:

Difenoconazole, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: December 2020

MS Finalisation date: May 2021

Revision date: October 2021

Version history

When	What
December 2020	Initial zRMS version
May 2021	Initial zRMS assessment
October 2021	The update after comments

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

The applicant text was not rewritten by the evaluator. The evaluator comments are on grey background. In yellow are the applicant's dossier updates after submission.

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation GLOB1911F are presented in Table 7.1-1. These GAPs are not the representative GAPs supported in the EU. However, the applicant except his own data applies the EU data out of protection to support the authorisation request. A list of all intended uses within the zone is given in Part B, Section 0.

Overall conclusion

The applicant submitted no new data except 3 field residue studies.
The out of protection EFSA data sufficiently covered the essential areas of the residues assessment – stability, metabolism, crops rotation, processing and livestock burden in the context of this submission. Adequate and acceptable conclusions are included in the respective paragraphs of the report.
According to the available data on succeeding crops the residues above LOQ in rotation are not expected.
In addition, no residues of difenoconazole are expected in honey above the default MRL of 0.05 mg/kg after the use of GLOB1911F according to the intended GAP.
The data available are considered sufficient for risk assessment.
The use in fodder beet can be extrapolated from sugar beets. The relevant MRL is higher than for sugar beet – the extrapolation is permissible.
According to the data available an exceedance of the current MRL of 0,2/0,4 mg/kg in sugar/fodder beet and 0,5 mg/kg in OSR as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of difenoconazole residues are unlikely to present a public health concern.
EFSA Journal 2018;16(7):5376: "A 'worst-case' consumer dietary intake assessment with regard to the TDMs for the complete group of triazole active substances that were assessed in the framework of these confirmatory data has been conducted and it was demonstrated that the risk for the consumers is unlikely. The overall consumer exposure assessment for the TDMs could, however, not be finalised in view of the identified data gaps for additional storage stability data for the TDMs in several crop commodities and missing data to finalise the livestock exposure assessment."
As far as consumer health protection is concerned zRMS agrees with the authorization of the accepted intended uses.

Crop and/ or situation **	Application				Application rate per treatment		PHI (days)
	method kind	growth stage & season	number min max	interval (min)	water L/ha min max	kg as/ha min max	
Potatoes	Tractor mounted sprayer, broadcast, ground directed spraying	40-99	a) 1-4 b) 1-4	10	100-400	0.125 0.500	14
Sugar beet/ fodder beet		31 till 49	a) 1-2 b) 1-2	14	100-400	0.125 0.250	21
Oilseed rape (winter and spring)		19-69	a) 1-2 b) 1-2	14	100-400	0.125 0.250	56

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

Data gaps

No data gaps are identified.

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

1	2	3	4	5	6	7		8				9		10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**		**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**water L/ha min max**	**kg as/ha min max**		
1	Potatoes SOLTU *Solanum tuberosum* Crop code number: 0211000	North-ern	GLOB1911 F	F	*Alternaria* sp. (ALTESP)	SC	500 g/L	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 40-99	a) 1-4 b) 1-4	10	100-400	c) 0.125 d) 0.500	14	
2	Sugar beet/ fodder beet BEAVA *Beta vulgaris* Crop code number: 0900010 (sugar beet roots), 0213010 (beetroots)	North-ern	GLOB1911 F	F	Rust (UROMBE), *Ramularia beticola* (RAMUBE), powdery mildew (ERYSBE), *Cercospora beticola* (CERCBE)	SC	500 g/L	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 31 till 49	a) 1-2 b) 1-2	14	100-400	c) 0.125 d) 0.250	21	

4, 5, 6	Oilseed rape (winter and spring) BRSNW/BRSNS Brassica napus/ Brassica napus spring Crop code number: 0401060	North-ern	GLOB1911F	F	*Phoma lingam* (LEPTMA), *Alternaria brassicae* (ALTEBA), *Sclerotinia sclerotiorum* (SCLESC), *Erysiphe cruciferarum* (ERYSCR) *Pyrenopeziza brassicae* (PYRPBR)	SC	500 g/L	Tractor mounted sprayer, broadcast, ground directed spraying	BBCH 19-69	a) 1-2 b) 1-2	14	100-400	c) 0.125 d) 0.250	56	

* 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

Important Note of applicant: The residue trials and risk assessment for the use in sugar/fodder beet are performed with a worst-case envelope of maximum 3 applications and can therefore be use in support of the intended use of maximum 2 applications in the Central Zone.

7.1.1 Summary of the evaluation

The preparation GLOB1911F is composed of difenoconazole.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
difenoconazole					
ADI	EFSA	2011	0.01	2 yr rats (combined chronic toxicity/oncogenicity)	100
ARfD	EFSA	2011	0.16	developmental, rat	100

7.1.1.1 Summary for Difenoconazole

Table 7.1-3: Summary for Difenoconazole

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Potato	Yes	No (6)	Yes	Yes	Yes	No	No
2	Sugar /fodder beet	Yes	Yes (>8)	Yes	Yes	Yes		No
3	OSR	Yes	Yes (8)	Yes	Yes	Yes		No

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

7.1.1.2 Summary for GLOB1911F

Table 7.1-4: Information on GLOB1911F (KCA 6.8)

Crop	PHI for product code proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for product code proposed by zRMS	zRMS Comments (if different PHI proposed)
		difenoconazole	~~Active substance 2~~	~~Active substance 3~~		
Potato	14 days	Yes	~~Yes/No/NR~~	~~Yes/No/NR~~	-	-
Sugar /fodder beet	21 days					
OSR	56 days					

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

Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops				Overall waiting period proposed by zRMS for GLOB1911F
Crop group	**difenoconazole**	**~~Led by active substance 2~~**	**~~Led by active substance 3~~**	
…	NR	~~NR~~	~~NR~~	NR

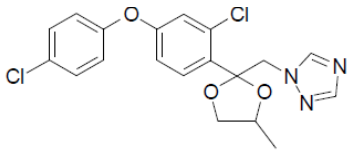
NR: not relevant

Since the maximum annual application rate on the crops under consideration is lower than the application rate tested in the limited rotational crop field trials and very similar to the application rate used in the confined rotational crop studies, it is concluded that significant difenoconazole residues in rotational crops are not expected, provided that the active substance is applied according to the intended GAP.

7.2 Difenoconazole

General data on Difenoconazole are summarized in the table below.

Table 7.2-1: General information on Difenoconazole

Active substance (ISO Common Name)	Difenoconazole
IUPAC	3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chloro-phenyl ether
Chemical structure	
Molecular formula	$C_{19}H_{17}Cl_2N_3O_3$
Molar mass	406.3
Chemical group	Triazole
Mode of action (if available)	Disrupts membrane function - inhibition of demethylation during ergosterol synthesis.
Systemic	Yes
Company (ies)	Syngenta Ltd.
Rapporteur Member State (RMS)	SE
Approval status	Approved 01/01/2009 COMMISSION DIRECTIVE 2008/69/EC - REGULATION (EU) No 2019/1589, No 1100/2011 and No 540/2011
Restriction	Only uses as fungicide may be authorised.
Review Report	SANCO/830/08 – rev. 3 13/12/2013
Current MRL regulation	Reg. (EU) 2019/552 (Applicable from: 25/04/2019)
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Pending
EFSA Journal : Conclusion on the peer review	Yes EFSA Journal 2011;9(1):1967 (EFSA, 2011)
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	None

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

Stability of Difenoconazole residues when stored deep frozen was assessed in several crop and animal matrices during the EU review of Difenoconazole. The studies submitted to address this point at the EU level were actually submitted, accepted and are all out of data protection. The applicant refers to these data for the registration of GLOB1911F. The results of these studies are summarized in the tables below.

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at ≤ - 20°C

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Tomato, wheat (forage)	High water content	24 months	SE, 2006 EFSA, 2011
Lettuce (head), banana	High water content	12 months	SE, 2006 EFSA, 2011
Potato, wheat (grain)	High starch content	24 months	SE, 2006 EFSA, 2011
Cotton (cottonseed oil)	High oil content	24 months	SE, 2006 EFSA, 2011
Soybean (beans)	High oil content	12 months	SE, 2006 EFSA, 2011
Animal Products			
Animal commodities	eggs, milk, beef liver, poultry breast	12 months	SE, 2006 EFSA, 2011
	Milk, liver, kidney, fat and muscle	10 months at -18°C (difenoconazole and difenoconazole alcohol (CGA-205375))	SE, 2006 EFSA, 2011

Conclusion on stability of residues during storage

Storage stability studies of Difenoconazole assessed in this section cover the requested use on sugar beet, potato and oilseed rape belonging to high water, high starch and high oil content commodities for GLOB1911F and cover the maximum storage period for samples taken from residue trials.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Recoveries in the freshly fortified samples acting as procedural recoveries covering the longest storage period of sample extracts were within the acceptable range 70-120%, thus, according to SANCO 825/00 rev.8.1, extract stability of the analyte is sufficiently proven.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data are submitted in the framework of this application. The data evaluated during the EU Review of Difenoconazole are out of protection and are sufficient to describe the behaviour of the formulated product, so no further studies are required.

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								
Root and tuber vegetables	Potatoes	[Phenyl-^{14}C] difenoconazole [Triazole-^{14}C] difenoconazole	foliar treatment, G	123.5 g a.i./ha, 7 days interval	6	After the 1st and prior to the 3rd and the 5th appli., and 11 days PHI	/	SE, 2006 EFSA, 2011
Pulses and oilseeds	Rape seed	[Phenyl-^{14}C] difenoconazole [Triazole-^{14}C] difenoconazole	foliar treatment, F	125 g a.i./ha, 14 days interval	2	After the 1st appli., prior to and after the 2nd appli., and at maturity (39 days after the 2nd)	/	SE, 2006 EFSA, 2011

(a): Outdoor or field use (F), glasshouse application (G) or indoor application (I)

Summary of plant metabolism studies reported in the EU

Metabolism in plant was investigated in four plant groups: fruit crops (tomato, grape), cereals (wheat), tuber/root crops (potato) and on oilseeds/pulses crops (oilseed rape), using ^{14}C-difenoconazole labelled in the phenyl or the triazole ring and foliar applications with a total of 2 to 6 treatments. Samples were collected for analysis at interim intervals and 6 to 40 days after the final application. In addition, metabolism was also considered in cereals following seed application.

The metabolism was seen to be similar in all four crop types. The parent difenoconazole remained the major component of the residues in the majority of the plant parts (mostly >40 % TRR), with the exception of the cereal grains, potato tubers and rape seeds, where it accounted for less than 10 – 15 % of the TRR. In these crops, and for the triazole labelling, TRRs are mainly composed of the triazole derivative metabolites (TDM): triazole alanine (56 % and 79 % TRR in rape seeds and potato tubers) and triazole acetic acid (20 % TRR in cereal grain). In addition, triazole alanine was detected up to 42 % TRR in tomato fruits and 1,2,4-triazole up to 12 % in grape. TDM were also the major components of the residues in cereal grains following seed treatment and the major metabolites in the succeeding crop studies. Metabolites CGA 205374 (ketone), CGA 205375 (alcohol) and CGA 189138 (benzoic acid) were also identified in low proportions (below 5 % TRR). Based on the different structures identified, the following metabolic pathway in plants was proposed. As a first step, the metabolism involves hydrolysis of the dioxolane ring to form the ketone metabolite which is then reduced to the corresponding alcohol. Further oxidation of the difenoconazole-alcohol metabolite results in the cleavage of the alkyl bridge to form the difenoconazole-benzoic acid metabolite and the 1,2,4-triazole which is further metabolised to triazole alanine and triazole acetic

acid. 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.

Conclusion on metabolism in primary crops

As European data are out of protection, the results of the metabolism studies in root and tuber vegetables (potato) and pulses and oilseeds (oilseed rape) can be used by the applicant and are sufficient to support the intended use of GLOB1911F on sugar beet, potato and oilseed rape.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data are submitted in the framework of this application. The data evaluated during the EU Review of Difenoconazole are out of protection and are sufficient to describe the behaviour of the formulated product, so no further studies are required.

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	Mustard	[Phenyl-^{14}C] difenoconazole	Soil treatment, F	32.4 g a.i./ha	30-33 days	At maturity (greens)	/	SE, 2006 EFSA, 2011
	Lettuce	[Phenyl-^{14}C] difenoconazole and [Triazole-^{14}C] difenoconazole	Soil treatment, F	125 g a.i./ha	98, 126, 342, 369 days	At 50% maturity and maturity	/	SE, 2006 EFSA, 2011
Root and tuber vegetables	Turnip	[Phenyl-^{14}C] difenoconazole	Soil treatment, F	32.4 g a.i./ha	30-33 days	At maturity (root and tops)	/	SE, 2006 EFSA, 2011
	Sugar beet	[Phenyl-^{14}C] difenoconazole and [Triazole-^{14}C] difenoconazole	Soil treatment, F	125 g a.i./ha	98, 126, 342, 369 days	At 25% and 50% maturity and at maturity	/	SE, 2006 EFSA, 2011
Cereals	Wheat	[Phenyl-^{14}C] difenoconazole and [Triazole-^{14}C] difenoconazole	Soil treatment, F	125 g a.i./ha	98, 126, 342, 369 days	At emergence, 25% and 50% maturity and at maturity	/	SE, 2006 EFSA, 2011
	Maize	[Phenyl-^{14}C] difenoconazole and	Soil treatment,	125 g a.i./ha	98, 126, 342, 369	At 25% and 50%	/	SE, 2006 EFSA, 2011

		[Triazole-^{14}C] difenoconazole	F		days	maturity and at maturity		
	Wheat	[Phenyl-^{14}C] difenoconazole	Soil treatment, F	32.4 g a.i./ha	30-33 days	At 25% and 50% maturity (tops) and at maturity (straw, grain)	/	SE, 2006 EFSA, 2011

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

Summary of plant metabolism studies reported in the EU

Difenoconazole is proposed to be used on several crops that can be grown in a crop rotation. According to the soil degradation studies evaluated in the framework of the peer review, the DT90 value of difenoconazole is 879 days (EFSA, 2011a). The trigger value of 100 days is exceeded and therefore further studies investigating the nature and magnitude of residues in rotational crops are required.
Metabolism of difenoconazole in rotational crops has been investigated in the framework of the peer review in two studies with [14C-triazole-] and [14C-phenyl-] difenoconazole (Sweden, 2006; EFSA, 2011a). Bare soil was treated with difenoconazole at either 32.4 g/ha (study 1) or 125 g/ha (study 2) and rotational crops belonging to cereal/grasses, leafy and root crop groups were planted/sown 30 days (study 1) or 98, 126, 342 and 369 days (study 2) after the soil treatment. In mature turnip, wheat and mustard from study 1 (performed only with [14C-phenyl] difenoconazole), the total TRR was below 0.01 mg eq/kg and was not further characterized. The TRR in mature crops from the study 2 when treated with [14C-triazole] difenoconazole accounted for up to 0.02 mg eq/kg in lettuce, 0.34 mg eq/kg wheat grain, 0.11 mg eq/kg in straw, 0.005 mg eq/kg sugar beet roots, 0.03 mg eq/kg in sugar beet tops and 0.21 mg eq/kg in maize grain and was mainly composed of the TDMs. The TRR in crops treated with [14C-phenyl-] difenoconazole was too low to be characterized.
The peer review concluded that the metabolic pathway in primary and rotational crops is partially similar. Pending the outcome of the evaluation of confirmatory data (according to Regulation (EC) No 1100/2011) on the formation of TDMs in rotational crops, the same residue definitions as established in primary crops are currently applicable.

Conclusion on metabolism in rotational crops

European data are sufficient to support the intended uses of GLOB1911F on sugar beet, potato and winter oilseed rape.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data are submitted in the framework of this application. The data evaluated during the EU Review of Difenoconazole are out of protection and are sufficient to describe the behaviour of the formulated product, so no further studies are required.

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)	Difenoconazole (95.6%), no unknown degradates	SE, 2006 EFSA, 2011
Baking, boiling, brewing	Difenoconazole (98.1%), unknown	SE, 2006

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
(60 minutes, 100°C, pH 5)	degradates (1.0%)	EFSA, 2011
Sterilisation (20 minutes, 120°C, pH 6)	Difenoconazole (98.6%), unknown degradates (0.9%)	SE, 2006 EFSA, 2011

A study was conducted to simulate the conditions of pasteurisation, sterilisation and baking, brewing and boiling. The fortified buffer solutions were incubated at 90°C for 20 minutes, 100 °C for 60 minutes or 120°C for 20 minutes. The recovery of applied radioactivity was 103.9 to 108.9% for the three processing conditions. The majority of the applied radioactivity consisted of parent Difenoconazole (95.6 to 98.6%). There was less than 5% degradation of Difenoconazole following hydrolysis. One minor degradation product was observed at low levels (mean ≤ 1.0% radioactivity) at pH 5 and 6. No other degradation products were quantifiable. Difenoconazole is therefore considered stable under conditions representative of pasteurisation, baking, brewing and boiling, and sterilisation.

Conclusion on nature of residues in processed commodities

As European data are out of protection, they can be used by the applicant and are sufficient to support the intended use of GLOB1911F on sugar beet, potato and oilseed rape.

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	Cereals (spring wheat) Root and tuber vegetables (potato) Fruits and fruiting vegetables (tomato, grapes) Pulses and oilseeds (oilseed rape)
Rotational crops covered	Leafy vegetables (lettuce, mustard) Root and tuber vegetables (sugarbeet, turnip) Cereals (spring and winter wheat, maize)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Difenoconazole is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Difenoconazole (Reg. (EU) 2019/552)
Plant residue definition for risk assessment	Two separate residue definitions: 1) Difenoconazole 2) Triazole derivative meatbolites (TDM) (provisional, pending the definition of a common and harmonised approach for all the active substances of the triazole chemical class) (EFSA, 2011)
Conversion factor from enforcement to RA	None

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

Available data

The intended crops under consideration and their by-products may be fed to livestock, therefore the potential transfer of residues to products of animal origin was investigated.

No new data are submitted in the framework of this application. The data evaluated during the EU Review of Difenoconazole are out of protection and are sufficient to describe the behaviour of the formulated product, so no further studies are required.

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.

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	^{14}C-Phenyl	1	5 mg/kg feed/d	10	Milk	daily	SE, 2006 EFSA, 2011
						Urine and faeces	daily	
						Tissues	at sacrifice	
		^{14}C-Triazole	1	5 mg/kg feed/d	10	Milk	daily	SE, 2006 EFSA, 2011
						Urine and faeces	daily	
						Tissues	at sacrifice	
	Goat	^{14}C-Phenyl	2	100 mg/kg feed/d	3	Milk	Twice daily	SE, 2006 EFSA, 2011
						Urine and faeces	daily	
						Tissues	at sacrifice	
		^{14}C-Triazole	2	100 mg/kg feed/d	3	Milk	Twice daily	SE, 2006 EFSA, 2011
						Urine and faeces	daily	
						Tissues	at sacrifice	
	Goat	^{14}C-Phenyl	2	100 mg/kg feed/d	4	Milk	Twice daily	SE, 2006 EFSA, 2011
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying	Hens	^{14}C-	2	5 mg/kg	14	Eggs	daily	SE, 2006

poultry		Phenyl		feed/d		Excreta	daily	EFSA, 2011
						Tissues	At sacrifice	
		^{14}C-Triazole	2	5 mg/kg feed/d	14	Eggs	daily	SE, 2006 EFSA, 2011
						Excreta	daily	
						Tissues	At sacrifice	
	Hens	^{14}C-Phenyl	10	68 mg/kg feed/d	3	Eggs	daily	SE, 2006 EFSA, 2011
						Excreta	daily	
						Tissues	At sacrifice	
		^{14}C-Triazole	10	68 mg/kg feed/d	3	Eggs	daily	SE, 2006 EFSA, 2011
						Excreta	daily	
						Tissues	At sacrifice	
	Hens	^{14}C-Triazole	5	121 mg/kg feed/d	4	Eggs	daily	SE, 2006 EFSA, 2011
						Excreta	daily	
						Tissues	At sacrifice	

Summary of plant metabolism studies reported in the EU

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 the metabolic pattern in ruminants does not significantly differ compared to rats, a pig study is not required (Guideline document 7030/VI/95-rev.3, 22/7/1997).

Conclusion on metabolism in livestock

European data are sufficient to support the intended use of GLOB1911F.

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	48 hours in milk for [^{14}C-phenyl]-Difenoconazole 144 hours in milk for [^{14}C-triazole]-Difenoconazole
	168 hours in egg yolk for [^{14}C-phenyl] and [^{14}C-triazole]-Difenoconazole 120 hours in eggs white for [^{14}C-triazole]-Difenoconazole
Animal residue definition for monitoring	Difenoconazole (Reg. (EU) 2019/552)
Animal residue for risk assessment	Two separate residue definitions: 1) Difenoconazole alcohol (CGA205375) expressed as Difenoconazole 2) Triazole derivative metabolites (TDM) (provisional, pending information on metabolism of TDM in animals and pending the definition of a common and harmonised approach for all the active substances of the triazole chemical class) (EFSA, 2011)
Conversion factor	Not concluded
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

This application is for the authorisation of the product GLOB1911F, a suspension concentrate formulation containing 500g/L Difenoconazole.
New bridging studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table 7.2-9a and Table 7.2-9b. The detailed assessment of these studies is presented in Appendix 2.
According to the OECD Guidance 509 (7 September 2009), bridging studies can be used for the purpose of data extrapolation by comparing different formulations. In this case, bridging studies were performed on the intended uses potato, sugar beet and oilseed rape, each consisting of 3 field trials with a side-by-side comparison of the products GLOB1911F and Difenoconazole 250 EC. Difenoconazole 250 EC is already authorised in many Member States for the use on potato, sugar beet and oilseed rape. Dependent on the Member State and crop, this product is authorised under product name 'Difcor 250 EC', 'DIFCOR' or 'Narita'. The OECD Guidance states that "If residues from the new formulation type are comparable to or less than those from the registered formulation, the new formulation may be considered equivalent from a residue perspective with no additional data" and therefore the complete residue data package established with the registered formulation Difenoconazole 250 EC can be used in support of this application. The applied GAP of both formulations in the bridging trials is presented below (Table 7.2-9a).

Table 7.2-9a Bridging trials: Comparison of the applied GAP of GLOB1911F and Difenoconazole 250 EC

Crop	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
GLOB1911F					
Potatoes	1-4	125 g a.s./ha	7d	BBCH 47	14 d
Sugar beet*	1-3	125 g a.s./ha	14 d	BBCH 39	21 d
Oilseed rape	1-2	125 g a.s./ha	14 d	BBCH 65 (1 trial) BBCH 69 (2 trials)	56 d
Difenoconazole 250 EC					
Potatoes	1-4	125 g a.s./ha	7d	BBCH 47	14 d
Sugar beet*	1-3	125 g a.s./ha	14 d	BBCH 39	21 d
Oilseed rape	1-2	125 g a.s./ha	14 d	BBCH 65 (1 trial) BBCH 69 (2 trials)	56 d

*The residue trials with Difenoconazole 250 EC and GLOB1911F on sugar beet were performed at maximum 3 applications and cover the applied use on sugar/fodder beet in theCentral Zone with maximum 2 applications.

Potatoes:

3 bridging trials in potatoes were performed in Northern EU countries with GLOB1911F and Difenoconazole 250 EC (Ertus C., 2020a).
Difenoconazole was applied as formulated product Difenoconazole 250 EC or as formulated product GLOB1911F. The product was applied 4 times with an interval of 7 days, at an application rate of 125 g a.s./ha. The last application was performed 14 (±1) days before harvest (corresponding with BBCH 47).
Samples were taken at normal commercial harvest and 13-15 days after the last application. These trials are summarized in the Table 7.2-9. For both formulations, no residues were found above the LOQ of 0.01 mg/kg. It can be concluded that the residues from the new formulation GLOB1911F are comparable to those from the formulation Difenoconazole 250 EC and therefore no additional data on GLOB1911F are required and the complete residue data set established for Difenoconazole 250 EC can be used in this application.

Additionally, residue trials performed with Difenoconazole 250 EC are also summarised in Table 7.2-9 (Jonchère F., 2011b). This study has already been submitted in Poland (zRMS) to support the authorisation of the registered product Narita and was positively evaluated. For completeness, the summary is given below once again. In total 4 trials (2 trials in Northern Europe (France and Poland) and 2 trials in Southern Europe (France and Spain)) were conducted. Difenoconazole was applied as formulated product Difenoconazole 250 EC six times with an interval of 7 days, to BBCH 47 and at an application rate of 125 g a.s./ha. Samples were taken at normal commercial harvest and 13-15 days after the last application. The residues in potato tubers were all below the LOQ (0.01 mg/kg).
Since the proposed use pattern of GLOB1911F is only maximum 4 applications with an interval of 10 days, the results of these trials are representative for our product GLOB1911F.

No residues were found at harvest and therefore 4 trials in Northern Europe are required to support the cGAP. This requirement has been met when the two NEU trials from study Jonchère F., 2011b are combined with the 2 NEU trials from the bridging study Ertus C., 2020a.

Sugar beet:

In the Northern EU countries, 3 bridging trials in sugar beet were performed in which difenoconazole was applied as the formulated product GLOB1911F and Difenoconazole 250 EC (Ertus C., 2020b). In those, the respective product was applied 3 times with an interval of 13-15 days, at an application rate of 125 g a.s./ha and the last application was performed 21 (±2) days before harvest (BBCH 39).
Samples of leaves with tops and roots were taken at normal commercial harvest and 20-22 days after the last application. These trials are summarized in the Table 7.2-9. The residues in roots and leaves with tops derived from treatment with GLOB1911F were found comparable to the residues found after application with Difenoconazole 250 EC. No additional data on GLOB1911F is required and the complete residue data set established for Difenoconazole 250 EC can be used in this application.

Additionally, residue trials performed with Difenoconazole 250 EC in sugar beet are also summarised in Table 7.2-9 (Ertus C., 2013a). This study has already been submitted in Poland (zRMS) to support the use on sugar beet for the registered product Difcor 250 EC and was positively evaluated. In total, 8 trials in Northern

Europe were conducted of which 4 residue decline trials and 4 residue at harvest trials. Difenoconazole was applied as formulated product Difenoconazole 250 EC 3 times with an interval of 13-15 days, to BBCH 49, at an application rate of 125 g a.s./ha and the last application was performed 21 (±2) days before harvest. In the 4 residue decline trials, sampling was performed just after the last application, then 3, 7 (±1), 14 (±1), and 21 (±2) days (harvest) after last application. In the 4 residue at harvest trials, sampling was performed 21 (±2) days after last application (harvest).

The residue trials conducted with Difenoconazole 250 EC and GLOB1911F on sugar beet were performed at maximum 3 applications. This critical GAP is considered worst-case and can therefore be use in support of the intended GAP on sugar/fodder beet in Central Zone of maximum 2 applications.

Oilseed rape:

The residues of Difenoconazole 250 EC and GLOB1911F in winter oilseed rape were measured in 3 bridging trials in Northern and Southern EU countries (Ertus C., 2020c). Difenoconazole 250 EC or GLOB1911F was applied twice with an interval of 13-15 days and an application rate of 125 g a.s./ha. The last application was performed at BBCH 64-BBCH69.
Samples of seeds were taken at maturity of the crop, 51-59 days after the last application. These trials are summarized in the Table 7.2-9. For both formulations, no residues were found above the LOQ of 0.01 mg/kg. It can be concluded that the residues from the new formulation GLOB1911F are comparable to those from the formulation Difenoconazole 250 EC and therefore no additional data on GLOB1911F is required and the complete residue data set established for Difenoconazole 250 EC can be used in this application.

Additionally, residue trials performed with Difenoconazole 250 EC in sugar beet are also summarised in Table 7.2-9 (Jonchère F., 2011c and Jonchère F., 2011d). These two studies have already been submitted in Poland (zRMS) to support the use on oilseed rape for the registered product Difcor 250 EC and was positively evaluated. 8 trials in Northern EU countries were performed and only 4 trials in Southern EU countries as no residues were expected for the Southern zone trials. Difenoconazole was applied as the formulated product Difenoconazole 250 EC two times with an interval of 13-15 days, to BBCH 72 and at an application rate of 125 g a.s./ha. Samples of seeds were taken at different time point after application in the decline curve trials and at maturity of the crop in the harvest trials, 51-63 days after the last application.

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of Difenoconazole 250 EC and GLOB1911F (Difenoconazole 500 SC) 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
Potatoes	Ertus C., 2020a	N-EU	**Difenoconazole 250 EC** Trials GAP: 4 x 125 g as/ha, PHI 14d, outdoor Residues: 2 x NDR (not detectable)	N/A	N/A	0.01*	0.1	Yes

			GLOB1911F (Difenoconazole 500 SC) Trials GAP: 4 x 125 g as/ha, PHI 14d, outdoor Residues: 2 x NDR (not detectable), 1 x < 0.01 (LOQ)	N/A	N/A	0.01*	0.1	Yes
	Jonchère F., 2011b	N-EU	**Difenoconazole 250 EC** Trials GAP: 6 x 125 g as/ha, PHI 14d, outdoor Residues: 2 x < 0.01 (LOQ)	N/A	N/A	0.01*	0.1	Yes
		S-EU	**Difenoconazole 250 EC** Trials GAP: 6 x 125 g as/ha, PHI 14d, outdoor Residues: 2 x < 0.01 (LOQ)	N/A	N/A	0.01*	0.1	Yes
Sugar beet	Ertus C., 2020b	N-EU	**Difenoconazole 250 EC** Trials GAP: 3 x 125 g as/ha, PHI 21d, outdoor Residues roots: 0.02, **0.10**, **0.09** Residues leaves with tops: 0.46, 0.66, **0.84**	0.09 0.66	0.10 0.84	-	-	-
			GLOB1911F (Difenoconazole 500 SC) Trials GAP: 3 x 125 g as/ha, PHI 21d, outdoor Residues roots: **0.03**, 0.09, 0.07 Residues leaves with tops: **0.51**, **0.92**, 0.58	0.07 0.58	0.09 0.92	-	-	-
	Ertus C., 2013a	N-EU	**Difenoconazole 250 EC** Trials GAP: 3 x 125 g as/ha, PHI 21d, outdoor Residues roots: 0.02, 0.03, 0.03, 0.04, 0.05, 0.07, 0.07, 0.08 Residues leaves with tops: 0.51; 0.69; 2.73; 0.61; 0.12; 1.03; 3.32; 0.27 (used for dietary burden)	0.045 0.65	0.08 3.32	-	-	-
	Overall supporting data	N-EU	Residues roots: 0.02, 3 x 0.03, 0.04, 0.05, 2 x 0.07, 0.08, 0.09, 0.10, Residues leaves with tops: 0.51; 0.69; 2.73; 0.61; 0.12; 1.03; 3.32; 0.27, 0.84, 0.51, 0.92	0.05 0.690	0.10 3.32	0.166	0.2	Yes
Oilseed rape	Ertus C., 2020c	N-EU	**Difenoconazole 250 EC** Trials GAP: 2 x 125 g as/ha, PHI 56d, outdoor Residues seeds: 3 x NDR (not detectable)	N/A	N/A	-	-	-
			GLOB1911F (Difenoconazole 500 SC) Trials GAP: 2 x 125 g as/ha, PHI 56d, outdoor Residues seeds: 3 x NDR (not detectable)	N/A	N/A	-	-	-
		S-EU	**Difenoconazole 250 EC**	N/A	N/A	-	-	-

			Trials GAP: 2 x 125 g as/ha, PHI 56d, outdoor Residues seeds: 2 x NDR (not detectable), 1 x < 0.01 (LOQ)					
			GLOB1911F (Difenoconazole 500 SC) Trials GAP: 2 x 125 g as/ha, PHI 56d, outdoor Residues seeds: 2 x NDR (not detectable), 1 x < 0.01 (LOQ)	N/A	N/A	-	-	-
	Jonchère F., 2011c and Jonchère F., 2011d	N-EU	**Difenoconazole 250 EC** Trials GAP: 2 x 125 g as/ha, PHI 56d, outdoor Residues seeds: 6 x < 0.01 (LOQ), 1 x 0.04, 1 x 0.40	0.01	0.40	-	-	-
		S-EU	**Difenoconazole 250 EC** Trials GAP: 2 x 125 g as/ha, PHI 56d, outdoor Residues seeds: 4 x < 0.01 (LOQ)	N/A	N/A	-	-	-
	Overall supporting data	N-EU	Residues seeds: 9 x < 0.01 (LOQ), 1 x 0.04, 1 x 0.40	0.01	0.40	0.4	0.5	Yes
	Overall supporting data	S-EU	Residues seeds: 7 x < 0.01 (LOQ)	N/A	N/A			

* Indicates that the MRL is set at the limit of analytical quantification.
** Source of EU MRL: Reg. (EU) 2019/552

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on potatoes, sugar beet and oilseed rape are considered acceptable, for outdoor uses.

The data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

The potential dietary burden of animals to Difenoconazole is calculated according to the STMR's and HR's provided by EFSA (EFSA Journal 2017; 15(7):4893) except for the intended uses for which own STMR and HR data is available from the field residue trials performed with the formulated product Difenoconazole 250 EC (reference is made to Table 7.2-9 for the STMR and HR values)

Table 7.2-10: Input values for the dietary burden calculation (considering the uses authorized within the zone and the uses under consideration) (EFSA Journal 2017;15(7):4893).

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sugar beet tops	0.65	STMR (Ertus C., 2013a)	3.32	HR (Ertus C., 2013a)
Potato, culls	0.01*	STMR* (Jonchère F., 2011b)	0.01*	HR* (Jonchère F., 2011b)
Sugar beet, dried pulp	0.81	STMR (Ertus C., 2013a) x PF (0.045 x 18[(a)])	-	
Sugar beet, ensiled pulp	0.14	STMR (Ertus C., 2013a) x PF (0.045 x 3[(a)])	-	
Sugar beet, molasses	1.26	STMR (Ertus C., 2013a) x PF (0.045 x 28[(a)])	-	
Rape seed meal	0.02	STMR (Jonchère F., 2011c and Jonchère F., 2011d) x PF (0.01 x 2[(a)])	-	
Potato process waste	0.01	STMR* (Jonchère F., 2011b) x PF (0.01 x 1[(b)])	-	
Potato dried pulp	0.01	STMR* (Jonchère F., 2011b) x PF (0.01 x 1[(b)])	-	
Rape seed/canola meal	0.01	STMR (Jonchère F., 2011c and Jonchère F., 2011d) x PF (0.01 x 1[(b)])	-	

(a): In the absence of processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in the processed commodities.
(b): Since the residues in the RAC < LOQ a PF of 1 has been used.
* is set at LOQ
EU MRL: Reg. (EU) 2019/552

Two different calculations of dietary burden were performed with the input data of table above: once with sugar beet tops included in the calculations and once without sugar beet tops.

Table 7.2-11: Results of the dietary burden calculation (sugar beet tops included)

New data requirements (Regulation (EU) No 283/2013)

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)	0.183	0.256	4.76	6.67	Dairy cattle	Beet, sugar	tops	Yes
Cattle (dairy only)	0.183	0.256	4.76	6.67	Dairy cattle	Beet, sugar	tops	Yes
Sheep (all diets)	0.189	0.271	4.44	6.38	Lamb	Beet, sugar	tops	Yes
Sheep (ewe only)	0.148	0.213	4.44	6.38	Ram/Ewe	Beet, sugar	tops	Yes
Swine (all diets)	0.058	0.073	2.53	3.18	Swine (breeding)	Beet, sugar	tops	Yes
Poultry (all diets)	0.076	0.097	1.08	1.42	Poultry layer	Beet, sugar	tops	Yes
Poultry (layer only)	0.050	0.097	0.73	1.42	Poultry layer	Beet, sugar	tops	Yes

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

Table 7.2-12: Results of the dietary burden calculation (without sugar beet tops)

New data requirements (Regulation (EU) No 283/2013)

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)	0.183	0.192	4.76	5.00	Dairy cattle	Kale	leaves	Yes
Cattle (dairy only)	0.183	0.192	4.76	5.00	Dairy cattle	Kale	leaves	Yes
Sheep (all diets)	0.189	0.205	4.44	4.83	Lamb	Kale	leaves	Yes
Sheep (ewe only)	0.148	0.161	4.44	4.83	Ram/Ewe	Kale	leaves	Yes
Swine (all diets)	0.058	0.071	2.53	3.07	Swine (breeding)	Kale	leaves	Yes
Poultry (all diets)	0.076	0.083	1.08	1.18	Poultry broiler	Rice	bran/pollard	Yes
Poultry (layer only)	0.044	0.057	0.64	0.84	Poultry layer	Rice	bran/pollard	Yes

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

The calculated dietary burdens for all relevant groups were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation on residues is therefore required in all commodities of ruminant and poultry origin.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application. The data evaluated during the EU Review of Difenoconazole are out of protection and are sufficient to describe the behaviour of the formulated product, so no further studies are required.

Poultry:

During the EU Review of Difenoconazole, two metabolism studies on poultry were performed and are free from data protection and can therefore be used in support of GLOB1911F.

In xxxxx (1989), hens were given 0.55 mg difenoconazole/animal, equivalent to 0.36-0.38 mg/kg bw/d. In xxxxx (1990b), hens were given 7.5 mg difenoconazole/animal, equivalent to 5 mg/kg bw/d. These concentrations are respectively 3.9 and 52 x higher than the estimated feeding rate of 0.097 mg/kg bw/day (see Table 7.2-11) and can therefore be used in support of GLOB1911F.

TRR in these studies were up to 0.137 and 0.248 mg difenoconazole equivalent/kg in egg white in hens dosed with 0.55 and 7.5 mg/animal. In egg yolks and in tissues, the TRR were up to 0.795 and 7.76 mg/kg respectively. Residues of parent difenoconazole were up to 0.001 and 0.236 mg/kg in egg yolk, and in tissues up to 0.207 and 2.80 mg/kg.

Following the realistic exposure level of 0.097 mg/kg bw/day and based on the above studies, it is anticipated that residues of difenoconazole in eggs or any edible tissues will be in compliance with the EU MRLs 0.05* and 0.1 mg/kg respectively.

Pigs:

A pig feeding study is not required since the metabolism pattern in ruminants is not different compared to rats.

Ruminants:

During the EU Review of Difenoconazole, a livestock feeding study was conducted in dairy cows using dose levels of 1, 3 and 10 mg/kg in the diet. Results of this study are presented in table 7.2-13 below.

Following dosing at these levels, residues of difenoconazole were below 5 µg/L in the milk samples taken on all days during the feeding period from all treatment groups. No measurable residues of parent difenoconazole (< 0.01 mg/kg) were found in all tissues samples with the exception of liver, which contained a residue of 0.02 mg/kg following administration of 10 mg/kg.

Mean and (maximum) residues of difenoconazole alcohol (CGA-205375) corresponding to 10 mg/kg in the diet were 0.022 (0.024) mg/kg in muscle, 0.30 (0.35) mg/kg in liver, 0.044 (0.052) in kidney, 0.077 (0.095) mg/kg in fat and 0.007 (0.009) mg/L in milk.

Table 7.2-13: Mean and (Maximum) residues of difenoconazole and CGA 205375 in tissues, blood and milk

Sample	Mean Residues (mg/kg)			
	0 mg/kg (Control)	1 mg/kg (1 X)	3 mg/kg (3 X)	10 mg/kg (10 X)
Difenoconazole				
Muscle - tenderloin	< 0.01	< 0.01 (<0.01)	< 0.01 (<0.01)	< 0.01 (<0.01)
Muscle - round steak	< 0.01	< 0.01 (<0.01)	< 0.01 (<0.01)	< 0.01 (<0.01)
Muscle - diaphragm	< 0.01	< 0.01 (<0.01)	< 0.01 (<0.01)	< 0.01 (<0.01)
Liver	< 0.01	< 0.01 (<0.01)	< 0.01 (<0.01)	0.014 (0.020)
Kidney	< 0.01	< 0.01 (<0.01)	< 0.01 (<0.01)	< 0.01 (<0.01)
Fat - perirenal	< 0.01	< 0.01 (<0.01)	< 0.01 (<0.01)	< 0.01 (<0.01)
Fat - omental	< 0.01	< 0.01 (<0.01)	< 0.01 (<0.01)	< 0.01 (<0.01)
Blood (µg/L)	< 10	< 10 (<10)	< 10 (<10)	< 10 (<10)
Milk (0 to 28 days, µg/L)[a]	< 5	< 5 (<5)	< 5 (<5)	< 5 (<5)
CGA 205375				
Muscle - tenderloin	< 0.01	< 0.01 (<0.01)	0.011 (0.012)	0.022 (0.024)
Muscle - round steak	< 0.01	< 0.01 (<0.01)	0.01 (0.010)	0.016 (0.019)
Muscle - diaphragm	< 0.01	< 0.01 (<0.01)	0.014 (0.022)	(0.021 (0.028)

Liver	< 0.01	0.039 (0.044)	0.12 (0.13)	0.30 (0.35)
Kidney	< 0.01	< 0.01 (<0.01)	0.017 (0.018)	0.044 (0.052)
Fat - perirenal	< 0.01	0.011 (0.013)	0.028 (0.032)	0.067 (0.079)
Fat - omental	< 0.01	0.011 (0.013)	(0.027 (0.033)	0.077 (0.095)
Blood (µg/L)	< 10	< 10 (<10)	< 10 (<10)	16 (19)
Milk (0 to 28 days, µg/L)[a]	< 5	< 5 (<5)	< 5 (<5)	7[b]

[a] Milk samples were taken on Day 2, 5, 8, 12, 15, 19, 22 and 28 during dosing.
[b] A mean level of 7 µg/L was recorded at each interval, with the exception of Day 22 where a level of 6 µg/L was recorded (see Table B.7.8.1-4).

Additionally, in the DAR-addendum (Sweden, 2010) a new livestock feeding study was conducted in dairy cows using dose levels of 1, 5 and 15 mg/kg in the diet was evaluated. Results of this study are presented in table 7.2-14 below.

The tested dose rate of 5 mg/kg from this study can be used in support of the estimated dietary burden of 4.76 mg/kg dry feed for cattle (see Table 7.2-11). Mean and (maximum) residues of difenoconazole and corresponding to this dose of 5 mg/kg in the diet were <0.01 (<0.01) mg/kg in muscle, 0.01 (0.02) mg/kg in liver, < 0.01 (< 0.01) mg/kg in kidney, < 0.01 (< 0.01) mg/kg in fat and <0.005 (<0.005) mg/L in milk. Mean and (maximum) residues of CGA-205375 corresponding to this dose of 5 mg/kg in the diet were 0.01 (0.01) mg/kg in muscle, 0.20 (0.23) mg/kg in liver, 0.04 (0.04) in kidney, 0.04 (0.05) mg/kg in fat and 0.005 (0.007) mg/L in milk

Table 7.2-14: Mean and (Maximum) residues of difenoconazole and CGA 205375 in tissues, blood and milk

Sample	Mean Residues (mg/kg)			
	0 mg/kg (Control)	1 mg/kg (1 X)	5 mg/kg (5 X)	15 mg/kg (15 X)
Difenoconazole				
Muscle - tenderloin	<0.01	<0.01 (<0.01)	<0.01 (<0.01)	<0.01 (<0.01)
Muscle - round steak	<0.01	<0.01 (<0.01)	<0.01 (<0.01)	<0.01 (<0.01)
Muscle - diaphragm	<0.01	<0.01 (<0.01)	<0.01 (<0.01)	<0.01 (<0.01)
Liver	<0.01	<0.01 (<0.01)	0.01 (0.02)	0.03 (0.03)
Kidney	<0.01	<0.01 (<0.01)	<0.01 (<0.01)	<0.01 (<0.01)
Fat - perirenal	<0.01	<0.01 (<0.01)	<0.01 (<0.01)	<0.01 (<0.01)
Fat - omental	<0.01	<0.01 (<0.01)	<0.01 (<0.01)	<0.01 (<0.01)
Blood (µg/L)	<0.01	<0.01 (<0.01)	<0.01 (<0.01)	<0.01 (<0.01)
Milk (0 to 28 days, µg/L)[a]	<0.005	<0.005 (<0.01)	<0.005 (<0.005)	<0.005 (<0.005)
CGA 205375				
Muscle - tenderloin	<0.01	<0.01 (<0.01)	0.01 (0.01)	0.04 (0.04)
Muscle - round steak	<0.01	<0.01 (<0.01)	0.01 (0.01)	0.04 (0.04)
Muscle - diaphragm	<0.01	<0.01 (<0.01)	0.01 (0.01)	0.05 (0.05)
Liver	<0.01	0.06 (0.07)	0.20 (0.23)	0.57 (0.66)
Kidney	<0.01	0.01 (0.01)	0.04 (0.04)	0.11 (0.12)
Fat - perirenal	<0.01	0.01 (0.01)	0.04 (0.05)	0.12 (0.13)
Fat - omental	<0.01	0.01 (0.01)	0.04 (0.04)	0.13 (0.14)
Blood (µg/L)	<0.01	0.01 (0.01)	0.04 (0.04)	0.12 (0.13)
Milk (0 to 28 days, µg/L)[a]	<0.005	<0.005	0.005 (0.007)	0.01 (0.02)

[a] Milk samples were taken on Day 2, 5, 8, 12, 15, 19, 22 and 28 during dosing.

In force MRLs (Reg. (EU) 2019/552) are 0.05 in muscle and fat, 0.2 in liver and kidney and 0.005* mg/kg in milk. Therefore, based on calculation in Table 7.2-11, there is no risk for animal MRL in tissues and body fluids to be exceeded.

~~According to the OECD Animal model the main contributor to lactating ruminants' intake is sugar beet tops. Therefore, new calculation of the dietary burden has been performed without taking into account sugar beet tops in the diet of cattle (see Table 7.2-12). This calculation is justified because nowadays, it is common practice that at harvest sugar beet tops are cut, chopped and spread back onto the field by the harvester for fertilization. It is therefore unlikely they will be fed to livestock.~~

~~This calculation leads to a value of 0.38 mg/kg dry feed for beef and dairy cattle. Residues of difenoconazole alcohol (CGA-205375) corresponding to this dietary burden are <0.01 mg/kg in muscle, 0.039 (0.044) mg/kg in liver, <0.01 in kidney, 0.011 (0.013) mg/kg in fat and <0.005 mg/kg in milk.~~

Conclusion on feeding studies

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals when taking into account sugar beet tops in ruminants diet, and regarding available feeding data, there is a risk for animal MRL to be exceeded. However, nowadays it is common practice that at harvest sugar beet tops are cut, chopped and spread back onto the field by the harvester for fertilization. It is therefore unlikely they will be fed to livestock and no restriction sentence on the label is required.

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

Data/information on processing studies on apple were reviewed during the Annex I inclusion of Difenoconazole and were considered acceptable. No further studies have been performed.

7.2.5.1 Available data for all crops under consideration

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

The 8 residue trials on oilseed rape conducted with Difenoconazole 250 EC in the Northern zone (Jonchère F., 2011c and Jonchère F., 2011d) resulted in Difenoconazole residues in seeds of 6 x < 0.01 (LOQ), 1 x 0.04, 1 x 0.40. The highest residue of 0.40 mg/kg found in one of these trials could be considered as an outlier, seeing the results of the additional 6 trials conducted in the Northern zone with Difenoconazole 250 EC or GLOB1911F (Ertus C., 2020c) in which no residues were detectable (< LOD) in all trials. Considering the overall supporting data and removing this value, resulted STMR and HR are respectively 0.01 and 0.04 mg/kg.

Regard to sugar beet and oilseed rape, no processing factors have been derived for processed commodities of these crops, as indicated the new data requirement (Regulation (EU) No 283/2013): *"if the level of residues is less than 0.1 mg/kg, processing studies shall be carried out if the contribution of the commodity under consideration to the theoretical maximum daily intake (TMDI) is ≥ 10 % of the ADI or if the estimated daily intake is ≥ 10 % of the ARfD for any European consumer group diet".*
Since the residues in sugar beet roots and oilseed rape seeds are less than 0.1 mg/kg and the contribution of these commodities to the theoretical maximum daily intake (TMDI) is less than 10% of the ADI and the estimated daily intake is less than 10% of the ARfD (see Appendix 3), no processing studies are necessary for sugar beet and oilseed rape.

7.2.5.2 Conclusion on processing studies

For the intended uses under consideration, no processing studies are required.

7.2.6 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), study dealing with magnitude of residues in succeeding crops is needed.

No new data are submitted in the framework of this application. The data evaluated during the EU Review of Difenoconazole are out of protection and are sufficient to describe the behaviour of the formulated product, so no further studies are required.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data are submitted in the framework of this application. The data evaluated during the EU Review of Difenoconazole are out of protection and are sufficient to describe the behaviour of the formulated product, so no further studies are required.

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

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
EU data					
/	750 g a.s./ha, Bare soil	Root and tuber vegetables	Carrot, roots	30	SE, 2006 EFSA, 2011
		Leafy vegetables	Spinach	31	SE, 2006 EFSA, 2011

In the rotational crop field studies submitted for the peer review the magnitude of difenoconazole was investigated in two crops- spinach and carrots (Sweden, 2006). Difenoconazole was applied to bare soil at a rate of 750 g/ha one month prior to crop planting and samples were analysed for difenoconazole and triazole alanine. The samples were not analysed for the other TDM compounds. The residues in the samples analysed were below the LOQs.

Conclusion on rotational crops studies

European data are sufficient to support the intended use of GLOB1911F.

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

7.2.7.1 Residue level in pollen and bee products (KCA 6.10.1)

According to Regulation (EU) No. 283/2013 studies to determine the residue level in pollen and bee products are required to determine the residue in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom.

A Guidance Document SANTE/11956/2016 rev. 9 (14 September 2018) *'Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey'* is available and implemented by 1 January 2020.

According to this Guidance further data on crop or field/tunnel trials are required when residue in honey are expected considering the proposed uses and the properties of the active substance.

Following the different steps in this Guidance, residue in honey can be expected after pesticide application under one of the following conditions:

Residues in honey can occur:

- When a substance is applied during the flowering stage (BBCH 60-69) of a crop which is foraged by bees (the so-called melliferous crops which are attractive to bees and from which it is possible to produce honey)
- When a substance with systemic properties is applied prior to the flowering stage (before BBCH 60), including treatment of seeds, of a crop which is foraged by bees .
- from uses on non-target plants (in-field weeds and adjacent plants) when a substance is applied during the flowering period from April to September.
- from succeeding crops after application of a persistent and systemic active substance
- via honeydew collected from plant-sucking insects in forestry (such as *Picea* spp., *Abies* spp, *Pinus* spp. and *Quercus* spp.)

GLOB1911F, containing 500 g/L Difenoconazole, is a fungicide with intended uses on potatoes at BBCH 40-89, on sugar beet at BBCH 40-89 and on oilseed rape at BBCH 69 at the latest. According to SANTE/11956/2016 rev. 9 Appendix II, the intended crops oilseed rape and sugar beet (for seed production) are considered as a melliferous crops, whereas potato is not. GLOB1911F is applied during the flowering stage of the intended crops sugar beet and oilseed rape. Next to the exposure of bees to the crop itself, the exposure of bees to non-target plants (in-field flowering weeds and flowering adjacent plants (off-field flowering weeds)) need to be considered. However, if realistic farming practices (e.g. tillage and herbicide applications) are considered, weeds are not usually prevalent in arable fields. This is also confirmed by a recent publication (Maynard *et al*, 2014), where it was shown that less than 2% of all weeds recorded in arable crops (wheat, oilseed rape, sugar beet, sunflower, potatoes, maize, peas and beans) are at flowering growth stage. For arable crops, it can therefore be considered that the exposure of bees to in-field flowering weeds is not a realistic and relevant scenario as flowering weeds are not present in the field in significant quantities in realistic conditions.

Relating to exposure of bees to the intended melliferous crops sugar beet and oilseed rape itself and the potential to expect residue in honey, the applicant refers to monitoring data. In the minutes of the SCOPAFF meeting (sante.ddg2.g.5(2019)6930972) the Commission refers to the EFSA residue monitoring programs for the years 2014-2017 and which are outlined in EFSA Scientific Reports (EFSA, 2016, 2017c, 2018, 2019). Those reports provide an insight into the official control activities carried out by EU Member States and provide data analysis regarding pesticide residue occurrence in the most important food products consumed including honey. During the SCOPAFF meeting, the Commission gave an overview of these findings and concluded that only a limited number of substances were found regularly in honey and that for most of them the MRLs in honey were not exceeded in any of the samples analysed. In this monitoring results no residue of Difenoconazole was found in honey and therefore it can serve as a weight of evidence that no residues of Difenoconazole are expected in honey after the use of GLOB1911F according to the intended GAP and therefore no further data on crop or field/tunnel trials would be necessary. To confirm these expectations a tunnel residue study was performed.

The applicant submitted a Letter of Access (LOA) to the following study of Syngenta:

Data point	Author	Year	Title
KCA 6.10.1	Gätschenberger H.	2017	Difenoconazole – Residues in honey following exposure of bees to treated winter oilseed rape in Germany during 2017. Study Number: S17-01051 GLP

Study Gätschenberger H. (2017) consists of a tunnel residue study in which 3 trials were conducted. The trials are situated in 3 independent sites in Germany, at more than 15 km apart. Difenoconazole was applied at a single dose rate of 125 g a.i./ha at BBCH 63 on oilseed rape. Oilseed rape is a highly melliferous crop and can be considered as worst case situation in terms of residues in honey and covers the expected residue in honey of sugar beet and off-field weeds. Bees were exposed to the treated crop and levels of Difenoconazole residue in honey were determined. All residues in honey were below the LOQ (0.01 mg/kg).

Although Guidance Document SANTE/11956/2016 rev. 9 requires minimum 4 trials and in this study consists of only 3 trials, the applicant considers this as sufficient since all residues were < LOQ.
Also according to the guidance tunnel tests should be carried out considering the most critical scenario, this is the highest total application rate in one season. The intended GAP consists of four applications on potato with a minimum interval of 10 days, three applications on sugar beet with a minimum interval of 14 days and two applications on oilseed rape with a minimum interval of 14 days. Thus the critical GAP of GLOB1911F is four applications of 125 g a.i./ha on potato and covers the use pattern on sugar beet and oilseed rape. It should be noted that because of the large interval of 10 or 14 days, it is in practice impossible to spray all four applications of GLOB1911F to one and the same flower during its whole flowering period. The maximum dose to which one and the same flower will be exposed to would be very worst-case if all 4 applications would be considered. However, if we would consider this very worst-case scenario, extrapolation of the residue level in honey can be made from the single tested dose rate to the total seasonal dose rate. The expected residue level in honey after four applications of 125 g a.i./ha would be 0.04 mg/kg (4 x LOQ of 0.01 mg/kg). This level is still below the default MRL of 0.05 mg/kg for honey and therefore no further studies are required.

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

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.1).

Chronic exposure calculations for all crops were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo v3.1) (EFSA, 2019). In first place, TMDI calculations were performed by using current EU MRLs (Reg. (EU) 2019/552). Since the ADI was exceeded, refined exposure calculations (IEDI) were made with STMR values derived from the residue trials conducted for the intended crops and STMR values reported in EFSA reasoned opinions (EFSA, 2017a and 2017b). for the remaining commodities of plant and animal origin, the existing MRLs as established in Reg. (EU) 2019/552 were used as input values. The acute consumer exposure assessment was performed only with regard to the intended crops under consideration. The input values for the exposure calculations are summarized in table below.

7.2.8.1 Input values for the consumer risk assessment

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: difenoconazole				
Potato	0.01*	Median residue (Jonchère F., 2011b)	0.01*	Highest residue (Jonchère F., 2011b)
Sugar beet root	0.045	Median residue (Ertus C., 2013a)	~~0.08~~ 0.045	Median residue (Ertus C., 2013a)
Oilseed rape	0.01	Median residue (Jonchère F., 2011c and Jonchère F., 2011d)	~~0.4~~ 0.01	Median residue (Jonchère F., 2011c and Jonchère F., 2011d)
Other flowering brassica	0.01	Median residue (EFSA, 2017b)	Acute risk assessment performed only for the crops under consideration.	
Brussels sprouts	0.07	Median residue (EFSA, 2017b)		
Escaroles/broad leaved endives, spinach, purslane, other spinach and similar leaves	0.33	Median residue (EFSA, 2017b)		
Witloofs/Belgian endives	1.30	Median residue (EFSA, 2017b)		
Rhubarb	0.70	Median residue (EFSA, 2017b)		
Barley	0.02	Median residue (EFSA, 2017a)		
Citrus fruit	0.16	Median residue (EFSA, 2017a)		
Pome fruit	0.16	Median residue (EFSA, 2017a)		
Apricots	0.17	Median residue (EFSA, 2017a)		
Peaches	0.15	Median residue (EFSA, 2017a)		
Tables and wine grapes	0.52	Median residue (EFSA, 2017a)		
Strawberries	0.14	Median residue (EFSA, 2017a)		
Head cabbages	0.02	Median residue (EFSA, 2017a)		
Blackberries, raspberries	0.04	Median residue (EFSA, 2017a)		
Beet leaves/chards	0.52	Median residue		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		(EFSA, 2017a)		
Table olives, olives for oil production	0.47	Median residue (EFSA, 2017a)		
Avocados	0.05	Median residue (EFSA, 2017a)		
Papaya	0.01	Median residue x PF (EFSA, 2017a)		
Beetroot, carrots, horseradish, Jerusalem artichokes, parsnips, parsley roots, radishes, salsify, swedes, turnips	0.08	Median residue (EFSA, 2017a)		
Garlic, onions, shallots	0.01	Median residue (EFSA, 2017a)		
Spring onions	2.80	Median residue (EFSA, 2017a)		
Tomatoes	0.72	Median residue (EFSA, 2017a)		
Peppers	0.17	Median residue (EFSA, 2017a)		
Aubergines	0.18	Median residue (EFSA, 2017a)		
Cucumbers, gherkins, courgettes	0.01	Median residue (EFSA, 2017a)		
Melons, pumpkins, watermelons	0.01	Median residue (EFSA, 2017a)		
Broccoli	0.13	Median residue (EFSA, 2017a)		
Lamb's lettuce	1.45	Median residue (EFSA, 2017a)		
Lettuce, cress, land cress, red mustard, leaves and sprouts of Brassica spp., other lettuce and other salad plants, beet leaves	0.52	Median residue (EFSA, 2017a)		
Rocket, rucola	0.44	Median residue (EFSA, 2017a)		
Chervil, celery leaves, parsley, basil	4.65	Median residue (EFSA, 2017a)		
Chives, sage, rosemary, thyme, bay leaves, tarragon, other herbs	0.52	Median residue (EFSA, 2017a)		
Cardoons, celery	1.22	Median residue (EFSA, 2017a)		
Fennel	1.66	Median residue (EFSA, 2017a)		
Globe artichokes	0.36	Median residue		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
		(EFSA, 2017a)		
Leek	0.13	Median residue (EFSA, 2017a)		
Pulses,(except peas)	0.02	Median residue (EFSA, 2017a)		
Soybeans	0.01	Median residue (EFSA, 2017a)		
rye, wheat	0.02	Median residue (EFSA, 2017a)		
Rice	0.88	Median residue (EFSA, 2017a)		
Spices (roots or rhizome)	0.64	Median residue (EFSA, 2017a)		
Chicory roots	0.20	Median residue (EFSA, 2017a)		
Other commodities	MRL from Reg. (EU) 2019/552			

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-17: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	351 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	98 % (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities: 1% (potatoes) for children and 0.2% (potatoes) for adults Processed commodities: 3% (sugar beets (root)/sugar) for children and 1% (sugar beets (root)/sugar) for adults
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 GLOB1911F do not represent unacceptable acute and chronic risks for the consumer.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

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, 71 pp. https://doi.org/10.2903/j.efsa.2011.1967

EFSA (European Food Safety Authority), 2013. Reasoned opinion on the modification of the existing MRLs for difenoconazole in various crops. EFSA Journal 2013;11(3):3149, 37 pp. https://doi.org/10.2903/j.efsa.2013.3149

EFSA (European Food Safety Authority), 2016. The 2014 European Union Report on Pesticide Residues in Food. EFSA Journal 2016;14(10):461130 doi:10.2903/j.efsa.2016.4611

EFSA (European Food Safety Authority), 2017a. Reasoned Opinion on the modification of the existing maximum residue levels for difenoconazole in various crops. EFSA Journal 2017;15(7):4893, 33 pp. https://doi.org/10.2903/j.efsa.2017.4893

EFSA (European Food Safety Authority), 2017b. Reasoned opinion on the modification of the existing maximum residue levels for difenoconazole in various crops. EFSA Journal 2018;16(1):5143, 30 pp. doi:10.2903/j.efsa.2018.5143

EFSA (European Food Safety Authority), 2017c. The 2015 European Union Report on Pesticide Residues in Food. EFSA Journal 2017;15(4):4791 doi:10.2903/j.efsa.2017.4791

EFSA (European Food Safety Authority), 2018. The 2016 European Union Report on Pesticide Residues in Food. EFSA Journal 2018;16(7):5348 doi: 10.2903/j.efsa.2018.5348

EFSA (European Food Safety Authority), 2019. The 2017 European Union Report on Pesticide Residues in Food. EFSA Journal 2019;17(6):5743 doi: 10.2903/j.efsa.2019.5743

Maynard *et al*, 2014. Hazards of pesticides to bees - 12th International Symposium of the ICP-PR Bee Protection Group, Ghent (Belgium), September 15-17, 2014. 1.8 Weeds in the treated field - a realistic scenario for pollinator risk assessment?

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

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

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

According to the applicant information the studies on grey background were not evaluated again since they have already been submitted in Poland (zRMS) to support the authorisation of the registered products Difcor 250 EC and Narita and were already positively assessed.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCA 6.3-01	Ertus C.	2020a	Determination of Difenoconazole residues in potato following four foliar applications with Difenoconazole 250 EC and GLOB1911F under field conditions in Northern Europe in 2019. Lab: Anadiag SA, France Study Number: R B9108 GLP not published	N	Globachem NV
KCA 6.3-02	Jonchère F.	2011b	Determination of Difenoconazole residues in potato following treatment with Difenoconazole 250 EC under field conditions in Northern and Southern Europe in 2010. Lab: Anadiag SA, France Study Number: R B0126 GLP not published	N	Globachem NV
KCA 6.3-03	Ertus C.	2020b	Determination of Difenoconazole residues in sugar beet following three foliar applications with Difenoconazole 250 EC and GLOB1911F under field conditions in Northern Europe in 2019. Lab: Anadiag SA, France Study Number: R B9106 GLP not published	N	Globachem NV
KCA 6.3-04	Ertus C.	2013a	Determination of Difenoconazole residues in sugar beet following treatment with Difenoconazole 250 EC under field conditions in Northern Europe in 2012. Lab: Anadiag SA, France Study Number: R B2185	N	Globachem NV

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			GLP not published		
KCA 6.3-05	Ertus C.	2020c	Determination of Difenoconazole residues in winter oilseed rape following two foliar applications with Difenoconazole 250 EC and GLOB1911F under field conditions in Northern and Southern Europe in 2019. Lab: Anadiag SA, France Study Number: R B9107 GLP not published	N	Globachem NV
KCA 6.3-06	Jonchère F.	2011c	Determination of Difenoconazole residues in oilseed rape following treatment with Difenoconazole 250 EC under field conditions in Northern Europe in 2010. Lab: Anadiag SA, France Study Number: R B0119 GLP not published	N	Globachem NV
KCA 6.3-07a	Jonchère F.,	2011d	Determination of Difenoconazole residues in oilseed rape following treatment with Difenoconazole 250 EC under field conditions in Northern and Southern Europe in 2011. Lab: Anadiag SA, France Study Number: R B1114 GLP not published	N	Globachem NV
KCA 6.3-07b	Jonchère F.,	2013b	Amendment No. 1 to final Report Number R B1114: Determination of Difenoconazole residues in oilseed rape following treatment with Difenoconazole 250 EC under field conditions in Northern and Southern Europe in 2011. Lab: Anadiag SA, France Study Number: R B1114 GLP not published	N	Globachem NV
KCA 6.10.1	Gätschenberger H.	2017	Difenoconazole – Residues in honey following exposure of bees to treated winter oilseed rape in Germany during 2017.	N	Syngenta*

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			Study Number: S17-01051 GLP		

*Globachem N.V. has a Letter of Access to this study from Syngenta.

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Difenoconazole

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

No new data submitted.

A 2.1.1.1.2 Storage stability of residues in animal products

No new data submitted.

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

No new data submitted.

A 2.1.2.1.2 Nature of residue in rotational crops

No new data submitted.

A 2.1.2.1.3 Nature of residues in processed commodities

No new data submitted.

A 2.1.2.2 Nature of residues in livestock

No new data submitted.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Potato

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, RMS, year)	NA				
cGAP EU (Art. 12, EFSA, year)	NA				
Intended cGAP	1-4	125 g a.s./ha	10 d	BBCH 40-89	14 d

NA: not applicable

A 2.1.3.1.1 Study 1

Comments of zRMS:

The study can be accepted.
However, the basis of the acceptance of this study analytics is the applicant information on the method B0128 validation report (see section 5). At the same time, however, the zRMS must draw the applicant's attention to the fact that the analytical phase of the present study is not described accurately enough within the original study as well as in the report below (below description is in analytics definitely too short). E.g., since the number of recovery replicate assays (n) is essential, the applicant always should provide the analytical procedure with the specific number "n" clearly shown to avoid unnecessary doubts. In addition, it is worth remembering that according to the so-called limited validation set, the suggested minimum number of repetitions performed is 3.
The present fortification procedure described in the study is as follows:

2.2.8 **Fortification procedure**

Fortifications were performed by adding known amounts of the spiking solutions to control specimens just prior to the extraction step (spiking solutions were added to the control specimens, before mixing with the extraction solvent).

During the residue analysis, control samples were fortified, extracted and stored together with field samples until analysis. These fortified extracts were run during the analysis of the other extracts.

Analytical Sample No.	Matrix	Fortification level (mg/kg)	% Recovery	Extraction date
B9108 01 01 AA	Tubers	0.01	93.6%	07/11/2019
B9108 03 01 AA	Tubers	0.10	101.2%	07/11/2019

Summary of fortifications

Matrix	Mean % recovery	Standard deviation %	Relative standard deviation %	Number of spiked samples
Tubers	97.4%	-	-	2

The method validation of this study has been positively evaluated in Part B Section 2 of the Registration Report from 0.7.03.2016 prepared by Eko-Futura Sp. z.o.o; IOR for the extension of authorisation of product Difcor 250 EC for minor uses.
The following conclusion was made:
"*To be fit for the intended purpose, the method was successfully evaluated and met certain validation characteristics: specificity, linearity, repeatability and accuracy. The analytical method fulfils the criteria of SANCO/825/00 rev. 8.1.*
The study has been performed in compliance with Good Laboratory Practice and is acceptable."

Reference:	KCA 6.3-01
Report	Determination of Difenoconazole residues in potato following four foliar applications with Difenoconazole 250 EC and GLOB1911F under field conditions in Northern Europe in 2019, Ertus C., 2020a, R B9108
Guideline(s):	Yes (Regulation (EC) No. 1107/2009, Regulation (EU) No. 283/2013 and 284/2013, 2004/10/EC GLP Directive)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue levels of difenoconazole in potato raw agricultural commodity after four foliar applications of the formulated product(s) DIFENOCONAZOLE 250 EC (250 g difenoconazole/L) and/or GLOB1911F (500 g difenoconazole/L). In total, 3 trials in Northern Europe (France, Hungary and Czech Republic) were conducted. In the trials in France and Hungary, both formulated products were tested in separate plots as in the trial in Czech Republic only the formulated product GLOB1911F was tested. Difenoconazole was applied in the form of the respective formulated product four times with an interval of 6-7 days, to BBCH 47 and at an application rate of 125 g a.s./ha. Samples were taken at normal commercial harvest and 13-15 days after the last application.

Materials and methods

Analytical Method: Method B0128. The principle of the method is based on a manual extraction of the crop with acetone, followed by a clean-up of the crude extract by a liquid/liquid partition. The residues are quantified by LC with MS/MS detection. The LOQ was set at 0.01 mg/kg for potato tubers. The validation of this method was performed under the ANADIAG validation study No. B0128 entitled "Validation of the Analytical Method for the Determination of Difenoconazole Residues in Potato (tubers) and wheat (grain and straw)" (KCP 5.2-01a, Jonchère, F., 2011a , see dRR Section B5) and Amendment No. 1 of this study (KCP 5.2-01b, Jonchère, F., 2013a , see dRR Section B5).

Results and discussions

The residues were below the limit of detection in all control samples. The analytical results obtained are summarised in the table below.

Conclusion

Difenoconazole residues in potato tubers from field trials were not detectable or < LOQ.

Table A 2: Summary of the study 1 trials

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient:	Difenoconazole	Producer of commercial product:	GLOBACHEM NV
Crop/crop group:	Potatoes/Potatoes		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	250 g/L	Other a.s. in formulation:	-
Formulation	EC	(common name and content):	
Product name:	**DIFENOCONAZOLE 250 EC**	Residues calculated as:	mg/kg difenoconazole

Trial No./ Location (including postal code)/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.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)**	**DALA (days)** (d)	**Details on trial** (e)
			g a.s./ ha	**Water (l/ha)**	**g a.s./hl**						
B9108 AN2 Bischwiller, 67240 France Northern Europe 2019	Potato / Adora	1) 15/04/2019 2) 04/06/2019 to 25/06/2019 3) 25/07/2019	120.8 126.3 123.8 127.9	290 303 297 307	41.7 41.7 41.7 41.7	18/06/2019 25/06/2019 1/07/2019 8/07/2019	47	Tuber	NDR	14	Report No: R B9108 Method B0128 (Jonchère, F., 2011a and 2013a) LOQ = 0.01; LOD = 0.003 Mean procedural recovery 97.4 %. Maximum storage time of samples 108 days. Maximum storage time of extracts 6 days.
B9108 HU1 Komarom, H-2921 Hungary Northern Europe 2019	Potato / Red Scarlett	1) 12/04/2019 2) n.r. 3) 19/08/2019*	119.6 132.1 122.1 116.7	287 317 293 280	41.7 41.7 41.7 41.7	17/07/2019 23/07/2019 30/07/2019 6/08/2019	47	Tuber	NDR	13	Report No: R B9108 Method B0128 (Jonchère, F., 2011a and 2013a) LOQ = 0.01; LOD = 0.003 Mean procedural recovery 97.4 %. Maximum storage time of samples 80 days. Maximum storage time of extracts 6 days.

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

(d) DALA: Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
NDR: no detectable residues (residues below the limit of detection (LOD); LOD = 0.003 mg/kg)
n.r.: not recorded
*Date of harvest of the samples. The crop was sown only for experimental purpose.

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active ingredient:	Difenoconazole	Producer of commercial product:	GLOBACHEM NV
Crop/crop group:	Potatoes/Potatoes		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	500 g/L	Other a.s. in formulation:	-
Formulation	SC	(common name and content):	
Product name:	**GLOB1911F (Difenoconazole 500 SC)**	Residues calculated as:	mg/kg difenoconazole

Trial No./ Location (including postal code)/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.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)**	**DALA (days)** (d)	**Details on trial** (e)
			g a.s./ ha	**Water (l/ha)**	**g a.s./hl**						
B9108 AN2 Bischwiller, 67240 France Northern Europe 2019	Potato / Adora	1) 15/04/2019 2) 04/06/2019 to 25/06/2019 3) 25/07/2019	130.4 129.2 120.8 130.4	313 310 290 313	41.7 41.7 41.7 41.7	18/06/2019 25/06/2019 1/07/2019 8/07/2019	47	Tuber	NDR	14	Report No: R B9108 Method B0128 (Jonchère, F., 2011a and 2013a) LOQ = 0.01; LOD = 0.003 Mean procedural recovery 97.4 %. Maximum storage time of samples 108 days. Maximum storage time of extracts 6 days.

Trial No./ Location (including postal code)/ EU zone/ Year (a)	Commodity/ Variety (b)	Date of 1.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)	DALA (days) (d)	Details on trial (e)
B9108 HU1 Komarom, H-2921 Hungary Northern Europe 2019	Potato / Red Scarlett	1) 12/04/2019 2) n.r. 3) 19/08/2019*	125.0 122.1 122.1 119.6	300 293 293 287	41.7 41.7 41.7 41.7	17/07/2019 23/07/2019 30/07/2019 6/08/2019	47	Tuber	NDR	13	Report No: R B9108 Method B0128 (Jonchère, F., 2011a and 2013a) LOQ = 0.01; LOD = 0.003 Mean procedural recovery 97.4 %. Maximum storage time of samples 80 days. Maximum storage time of extracts 6 days.
B9108 CZ1 Rychnov nad Kneznou, 51601 Czech Republic Northern Europe 2019	Potato / Marabel	1) 20/04/2019 2) n.r. 3) 15/09/2019	133.1 135.6 120.6 133.1	213 217 193 213	62.5 62.5 62.5 62.5	9/08/2019 15/08/2019 22/08/2019 28/08/2019	47	Tuber	<LOQ	15	Report No: R B9108 Method B0128 (Jonchère, F., 2011a and 2013a) LOQ = 0.01; LOD = 0.003 Mean procedural recovery 97.4 %. Maximum storage time of samples 56 days. Maximum storage time of extracts 6 days.

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) DALA: Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
NDR: no detectable residues (residues below the limit of detection (LOD); LOD = 0.003 mg/kg)
n.r.: not recorded
< LOQ: residues between LOD and LOQ (LOQ = 0.01 mg/kg)
*Date of harvest of the sample. The crop was sown only for experimental purpose.

A 2.1.3.1.2 Study 2

This study has already been submitted in Poland (zRMS) to support the authorisation of the registered product Narita and was positively evaluated.

Comments of zRMS:	According to the applicant information the study formerly and positively evaluated is treated here as already accepted. For the initial method validation see section 5 (for B0128 see also previous grey box). However, this is the zonal assessment and in the evaluator's opinion for such – not peer-reviewed – but nationally evaluated studies, the full details of the previous assessment with the respectively detailed study description should be provided. Furthermore, the evaluator kindly draws the applicant's attention to the general rule that although this is section 7, not only the field part but also the analytical part should be included in the sufficiently detailed description of the study – since both phases – field and analytical - are integral parts of the study under evaluation. The method of this study has been positively evaluated in Part B Section 2 of the Registration Report from 0.7.03.2016 prepared by Eko-Futura Sp. z.o.o; IOR for the extension of authorisation of product Difcor 250 EC for minor uses. The following conclusion was made: "*To be fit for the intended purpose, the method was successfully evaluated and met certain validation characteristics: specificity, linearity, repeatability and accuracy. The analytical method fulfils the criteria of SANCO/825/00 rev. 8.1.* *The study has been performed in compliance with Good Laboratory Practice and is acceptable."* The study itself has been positively evaluated previously in the application of Narita in PL.

Reference:	KCA 6.3-02
Report	Determination of Difenoconazole residues in potato following treatment with Difenoconazole 250 EC under field conditions in Northern and Southern Europe in 2010, Jonchère F., 2011b, R B0126
Guideline(s):	Yes (Dir 91/414/EEC)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue levels of difenoconazole in potato raw agricultural commodity after six foliar applications of the formulated product DIFENOCONAZOLE 250 EC (250 g difenoconazole/L). 2 trials in Northern Europe (France and Poland) and 2 trials in Southern Europe (France and Spain) were conducted. Difenoconazole was applied as formulated product DIFENOCONAZOLE 250 EC six times with an interval of 7 days, to BBCH 47 and at an application rate of 125 g a.s./ha. Samples were taken at normal commercial harvest and 13-15 days after the last application.

Materials and methods

Analytical Method: Method B0128. The principle of the method is based on a manual or automatic extraction of the crop with acetone, followed by a clean-up of the crude extract by a liquid/liquid partition. The residues are quantified by LC with MS/MS detection. The LOQ was set at 0.01 mg/kg for potato tubers. The validation of this method was performed under the ANADIAG validation study No. B0128 entitled "Validation of the Analytical Method for the Determination of Difenoconazole Residues in Potato (tubers) and wheat (grain and straw)" (KCP 5.2-01a, Jonchère, F., 2011a , see dRR Section B5) and Amendment No. 1

of this study (KCP 5.2-01b, Jonchère, F., 2013a , see dRR Section B5).

Results and discussions
The residues were below the limit of detection in all control samples. The analytical results obtained are summarised in the table below.

Conclusion
Difenoconazole residues in potato tubers from field trials were < LOQ.

Table A 3: Summary of the study 2 trials

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient:	Difenoconazole	Producer of commercial product:	GLOBACHEM NV
Crop/crop group:	Potatoes/Potatoes		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	252.4 g/L	Other a.s. in formulation:	-
Formulation	EC	(common name and content):	
Product name:	**DIFENOCONAZOLE 250 EC**	Residues calculated as:	mg/kg difenoconazole

Trial No./ Location (including postal code)/ EU zone/ Year (a)	**Commodity/ Variety**	**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**						
B0126 BP1 Engenville, 45300 France Northern Europe 2010	Potato/ Franceline	1)04/05/10 2) n.r. 3) 31/07/10	119.2 119.2 125.8 128.3 127.1 128.3	286 286 302 308 305 308	41.7 41.7 41.7 41.7 41.7 41.7	11/06/2010 18/06/2010 25/06/2010 02/07/2010 10/07/2010 17/07/2010	45	Tuber	<LOQ	14	Report No: R B0126 Method B0128 (Jonchère, F., 2011a and 2013a) LOQ = 0.01; LOD = 0.002 Mean procedural recovery 70.8 %. Maximum storage time of samples 81 days. Maximum storage time of extracts 6 days.

Trial No./ Location (including postal code)/ EU zone/ Year (a)	Commodity/ Variety (b)	Date of 1. Sowing or planting 2.Flowering 3. Harvest (c)	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	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Details on trial (e)
B0126 PL1 Gora Swiety Malgo-rzaty, 99-122 Poland Northern Europe 2010	Potato/ Tayfun	1)15/04/10 2) n.r. 3) 21/08/10	122.1 129.2 161.3 130.4 132.1 144.6	293 310 387 313 317 347	41.7 41.7 41.7 41.7 41.7 41.7	02/07/2010 09/07/2010 16/07/2010 23/07/2010 29/07/2010 06/08/2010	47	Tuber	<LOQ	15	Report No: R B0126 Method B0128 (Jonchère, F., 2011a and 2013a) LOQ = 0.01; LOD = 0.002 Mean procedural recovery 70.8 %. Maximum storage time of samples 60 days. Maximum storage time of extracts 6 days.
B0126 TL1 Ondes , 31330 France Southern Europe 2010	Potato/ Agatha	1)14/04/10 2) n.r 3) 29/07/10 to 31/07/10	136.6 132.1 130.4 133.3 136.3 127.9	327 317 313 320 327 307	41.7 41.7 41.7 41.7 41.7 41.7	10/06/2010 17/06/2010 24/06/2010 01/07/2010 08/07/2010 15/07/2010	47	Tuber	<LOQ	14	Report No: R B0126 Method B0128 (Jonchère, F., 2011a and 2013a) LOQ = 0.01; LOD = 0.002 Mean procedural recovery 70.8 %. Maximum storage time of samples 83 days. Maximum storage time of extracts 6 days.
B0126 ES1 Fontanilles, 17257 Spain Southern Europe 2010	Potato/ Kennebec	1)25/03/10 2)01/06/10 to n.r 3) 12/07/10	135.4 122.1 117.9 131.3 126.7 133.3	325 293 283 315 304 320	41.7 41.7 41.7 41.7 41.7 41.7	24/05/2010 01/06/2010 09/06/2010 17/06/2010 23/06/2010 29/06/2010	42/43	Tuber	<LOQ	13	Report No: R B0126 Method B0128 (Jonchère, F., 2011a and 2013a) LOQ = 0.01; LOD = 0.002 Mean procedural recovery 70.8 %. Maximum storage time of samples 100 days. Maximum storage time of extracts 6 days.

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) DALA: Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
< LOQ: residues below LOQ (LOQ = 0.01 mg/kg)
n.r.: not recorded

A 2.1.3.2 Sugar beet

Table A 4: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, RMS, year)	NA				
cGAP EU (Art. 12, EFSA, year)	NA				
Intended cGAP	1-2	125 g a.s./ha	14 d	BBCH 31-49	21 d

NA: Not applicable

A 2.1.3.2.1 Study 1

Comments of zRMS:	The study can be accepted. The method B2196 employed in this study was successfully validated (also according to the applicant information - see section 5) and this is the basis for the acceptance of the analytics of the present study. At the same time, however, the RMS must draw the applicant's attention to the fact that the analytical phase is not described accurately enough. This is applicable to the original study as well as to the study description below. E.g., since the number of recovery replicate assays (n) is essential, the applicant always should provide the analytical procedure with the specific number "n" clearly shown to avoid unnecessary doubts. In addition, it is worth remembering that according to the so-called limited validation set, the suggested minimum number of repetitions performed is 3. The validation of the method has been been positively evaluated in Part B Section 2 of the Registration Report from 0.7.03.2016 prepared by Eko-Futura Sp. z.o.o; IOR for the extension of authorisation of product Difcor 250 EC for minor uses. The following conclusion was made: "*To be fit for the intended purpose, the method was successfully evaluated and met certain validation characteristics: specificity, linearity, repeatability and accuracy. The analytical method fulfils the criteria of SANCO/825/00 rev. 8.1.* *The study has been performed in compliance with Good Laboratory Practice and is acceptable."*

Reference:	KCA 6.3-03
Report	Determination of Difenoconazole residues in sugar beet following three foliar applications with Difenoconazole 250 EC and GLOB1911F under field conditions in Northern Europe in 2019, Ertus C., 2020b, R B9106
Guideline(s):	Yes (Regulation (EC) No. 1107/2009, Regulation (EU) No. 283/2013 and 284/2013, 2004/10/EC GLP Directive)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue levels of difenoconazole in sugar beet raw

agricultural commodity (leaves with tops and roots) after three foliar applications of the formulated products DIFENOCONAZOLE 250 EC (250 g difenoconazole/L) and GLOB1911F (500 g difenoconazole/L). In total, 3 trials in Northern Europe (France, Poland) were conducted where both formulated products were tested in separate plots. Difenoconazole was applied in the form of the respective formulated product three times with an interval of 13-15 days, to BBCH 39 and at an application rate of 125 g a.s./ha. Samples of leaves with tops and roots were taken at normal commercial harvest and 20-22 days after the last application.

Materials and methods
Analytical Method: Method B2196. The principle of the method is based on a manual extraction of the crop with acetone, followed by a clean-up of the crude extract by a liquid/liquid partition. The residues are quantified by LC with MS/MS detection. The LOQ was set at 0.01 mg/kg for leaves with tops and roots. The validation of this method was performed under the ANADIAG validation study No. B2196 entitled "Validation of the Analytical Method for the Determination of Difenoconazole Residues in Apricot, sugar beet (roots and leaves), carrot (roots) and celery (leaves)" (KCP 5.2-02, Faessel V., 2012a, see dRR Section B5).

Results and discussions
The residues were below the limit of detection in all control samples. The analytical results obtained are summarised in the table below.

Conclusion

Difenoconazole residues in sugar beet leaves with tops and roots from field trials were above the LOQ.

Table A 5: Summary of the study 1 trials

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient:	Difenoconazole	Producer of commercial product:	GLOBACHEM NV
Crop/crop group:	Sugar beet/Sugar beet		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	250 g/L	Other a.s. in formulation:	-
Formulation	EC	(common name and content):	
Product name:	**DIFENOCONAZOLE 250 EC**	Residues calculated as:	mg/kg difenoconazole

Trial No./ Location (including postal code)/ EU zone/ Year (a)	**Commodity/ Variety**	**Date of 1.planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treat-ment or no. of treatments and last date** (c)	**Growth stage at last treat-ment or date**	**Portion analyzed**	**Residues (mg/kg)**	**DALA (days)** (d)	**Details on trial** (e)
			g a.s./ ha	**Water (l/ha)**	**g a.s./hl**						
B9106 AN1 Seebach, 67160 France Northern Europe 2019	Sugar Beet / Okapi	1) 01/04/2019 2) n.a. 3) 30/09/2019	123.8 133.3 134.6	297 320 323	41.7 41.7 41.7	31/07/2019 13/08/2019 27/08/2019	39	Roots Leaves with tops	0.02 0.46	21	Report No: R B9106 Method B2196 (Faessel V., 2012a) LOQ = 0.01; LOD = 0.003 (both roots and leaves with tops) Mean procedural recovery 78.4 % (leaves with tops) 92.6 % (roots). Maximum storage time of samples 59 days. Maximum storage time of extracts 5 days.

Trial No./ Location (including postal code)/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.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)	DALA (days) (d)	Details on trial (e)
B9106 ND1 Steenbecque, 59189 France Northern Europe 2019	Sugar Beet / Chloelia	1) 02/04/2019 2) n.a. 3) 10/10/2019	131.3 135.3 129.1	420 433 413	31.3 31.2 31.3	8/08/2019 22/08/2019 5/09/2019	39	Roots Leaves with tops	0.10 0.66	20	Report No: R B9106 Method B2196 (Faessel V., 2012a) LOQ = 0.01; LOD = 0.003 (both roots and leaves with tops) Mean procedural recovery 78.4 % (leaves with tops) 92.6 % (roots). Maximum storage time of samples 51 days. Maximum storage time of extracts 5 days.
B9106 PL1 Gora Swietej Malgo-rzaty, 99122 Poland Northern Europe 2019	Sugar Beet / Gracjana	1) 20/04/2019 2) n.a. 3) 17/10/2019 to 18/10/2019	124.1 129.1 125.9	397 413 403	31.3 31.3 31.2	26/08/2019 9/09/2019 24/09/2019	39	Roots Leaves with tops	0.09 0.84	22	Report No: R B9106 Method B2196 (Faessel V., 2012a) LOQ = 0.01; LOD = 0.003 (both roots and leaves with tops) Mean procedural recovery 78.4 % (leaves with tops) 92.6 % (roots). Maximum storage time of samples 30 days. Maximum storage time of extracts 5 days.

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) DALA: Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
n.a.: not applicable

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient:	Difenoconazole	Producer of commercial product:	GLOBACHEM NV
Crop/crop group:	Sugar beet/Sugar beet		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	500 g/L	Other a.s. in formulation:	-
Formulation	SC	(common name and content):	
Product name:	**GLOB1911F (Difenoconazole 500 SC)**	Residues calculated as:	mg/kg difenoconazole

Trial No./ Location (including postal code)/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.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)**	**DALA (days)** (d)	**Details on trial** (e)
			g a.s./ ha	**Water (l/ha)**	**g a.s./hl**						
B9106 AN1 Seebach, 67160 France Northern Europe 2019	Sugar Beet / Okapi	1) 01/04/2019 2) n.a. 3) 30/09/2019	119.6 136.3 133.3	287 327 320	41.7 41.7 41.7	31/07/2019 13/08/2019 27/08/2019	39	Roots Leaves with tops	0.03 0.51	21	Report No: R B9106 Method B2196 (Faessel V., 2012a) LOQ = 0.01; LOD = 0.003 (both roots and leaves with tops) Mean procedural recovery 78.4 % (leaves with tops) 92.6 % (roots). Maximum storage time of samples 59 days. Maximum storage time of extracts 5 days.

Trial No./ Location (including postal code)/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.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)	DALA (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl						
B9106 ND1 Steenbecque, 59189 France Northern Europe 2019	Sugar Beet / Chloelia	1) 02/04/2019 2) n.a. 3) 10/10/2019	133.4 129.1 127.2	427 413 407	31.2 31.3 31.3	8/08/2019 22/08/2019 5/09/2019	39	Roots Leaves with tops	0.09 0.92	20	Report No: R B9106 Method B2196 (Faessel V., 2012a) LOQ = 0.01; LOD = 0.003 (both roots and leaves with tops) Mean procedural recovery 78.4 % (leaves with tops) 92.6 % (roots). Maximum storage time of samples 51 days. Maximum storage time of extracts 5 days.
B9106 PL1 Gora Swietej Malgorzaty, 99122 Poland Northern Europe 2019	Sugar Beet / Gracjana	1) 20/04/2019 2) n.a. 3) 17/10/2019 to 18/10/2019	122.5 131.3 128.1	392 420 410	31.3 31.3 31.2	26/08/2019 9/09/2019 24/09/2019	39	Roots Leaves with tops	0.07 0.58	22	Report No: R B9106 Method B2196 (Faessel V., 2012a) LOQ = 0.01; LOD = 0.003 (both roots and leaves with tops) Mean procedural recovery 78.4 % (leaves with tops) 92.6 % (roots). Maximum storage time of samples 30 days. Maximum storage time of extracts 5 days.

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) DALA: Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
n.a.: not applicable

A 2.1.3.2.2 Study 2

This study has already been submitted in Poland (zRMS) to support the use on sugar beet for the registered product Difcor 250 EC and was positively evaluated.

Comments of zRMS:	According to the applicant information the study is treated as already accepted. This study has been positively evaluated in Part B Section 4 of the Registration Report from 0.7.03.2016 prepared by Eko-Futura Sp. z.o.o.; IOR for the extension of authorisation of product Difcor 250 EC for minor uses. The following conclusion was made: "*The study was performed according to the current guidelines, GLP requirements and is considered adequate.*" No sufficient study description below.

Reference:	KCA 6.3-04
Report	Determination of Difenoconazole residues in sugar beet following treatment with Difenoconazole 250 EC under field conditions in Northern Europe in 2012, Ertus C., 2013a, R B2185
Guideline(s):	Yes (Regulation (EC) No. 1107/2009)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue levels of difenoconazole in sugar beet raw agricultural commodity (leaves with tops and roots) after three foliar applications of the formulated product DIFENOCONAZOLE 250 EC (250 g difenoconazole/L). In total, 8 trials in Northern Europe were conducted of which 4 residue decline trials and 4 residue at harvest trials. Difenoconazole was applied as formulated product DIFENOCONAZOLE 250 EC three times with an interval of 13-15 days, to BBCH 49, at an application rate of 125 g a.s./ha and the last application was performed 21 (±2) days before harvest. In the 4 residue decline trials, sampling was performed just after the last application, then 3, 7 (±1), 14 (±1), and 21 (±2) days (harvest) after last application. In the 4 residue at harvest trials, sampling was performed 21 (±2) days after last application (harvest).

Materials and methods

Analytical Method: Method B2196. The principle of the method is based on a manual extraction of the crop with acetone, followed by a clean-up of the crude extract by a liquid/liquid partition. The residues are quantified by LC with MS/MS detection. The LOQ was set at 0.01 mg/kg for leaves with tops and roots. The validation of this method was performed under the ANADIAG validation study No. B2196 entitled "Validation of the Analytical Method for the Determination of Difenoconazole Residues in Apricot, sugar beet (roots and leaves), carrot (roots) and celery (leaves)" (KCP 5.2-02, Faessel V., 2012a, see dRR Section B5).

Results and discussions

The residues were below the limit of detection in all control samples. The analytical results obtained are summarised in the table below.

Conclusion

Difenoconazole residues in sugar beet leaves with tops and roots from field trials were above the LOQ.

Table A 6: Summary of the study 2 trials

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient:	Difenoconazole	Producer of commercial product:	GLOBACHEM NV
Crop/crop group:	Sugar beet/Sugar beet		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	250 g/L	Other a.s. in formulation:	-
Formulation	EC	(common name and content):	
Product name:	**DIFENOCONAZOLE 250 EC**	Residues calculated as:	mg/kg difenoconazole

Trial No./ Location (including postal code)/ EU zone/ Year (a)	**Commodity/ Variety**	**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)**	**DALA (days)** (d)	**Details on trial** (e)
			g a.s./ ha	**Water (l/ha)**	**g a.s./hl**						
B2185 AN1 Handschuheim, 67117 France Northern Europe 2012	Sugarbeet /Iceberg	1)24/03/2012 2) n.r. 3)14/09/2012	128.3 120.0 123.3	513 480 493	25.0 25.0 25.0	27/07/2012 09/08/2012 23/08/2012	39-49	Leaves with tops Roots	0.51 0.02	21	Report No: R B2185 Method B2196 (Faessel V., 2012a) LOQ = 0.01; LOD = 0.001 (both roots and leaves with tops) Mean procedural recovery 92.0 % (leaves with tops) 86.1 % (roots). Maximum storage time of samples 141 days. Maximum storage time of extracts 6 days.

Trial No./ Location (including postal code)/ 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)	DALA (days) (d)	Details on trial (e)
B2185 MA1 Herpont, 51460 France Northern Europe 2012	Sugarbeet /Magellan	1)27/03/2012 2) n.r. 3)01/10/2012	121.8 129.3 133.3	487 517 533	25.0 25.0 25.0	05/08/2012 20/08/2012 02/09/2012	39-49	Leaves with tops Roots	0.69 0.05	23	Report No: R B2185 Method B2196 (Faessel V., 2012a) LOQ = 0.01; LOD = 0.001 (both roots and leaves with tops) Mean procedural recovery 92.0 % (leaves with tops) 86.1 % (roots). Maximum storage time of samples 129 days. Maximum storage time of extracts 6 days.
B2185 PL1 Piatek, 99-120, Poland Northern Europe 2012	Sugarbeet / Nevenka	1)22/04/2012 2) n.r. 3)14/10/2012 to 17/10/2012	133.3 115.0 123.3	533 460 493	25.0 25.0 25.0	30/08/2012 14/09/2012 27/09/2012	49	Leaves with tops Roots	2.73 0.04	20	Report No: R B2185 Method B2196 (Faessel V., 2012a) LOQ = 0.01; LOD = 0.001 (both roots and leaves with tops) Mean procedural recovery 92.0 % (leaves with tops) 86.1 % (roots). Maximum storage time of samples 107 days. Maximum storage time of extracts 6 days.
B2185 HA1 Neustadt, Esperks, 31535 Germany Northern Europe 2012	Sugarbeet/ Lukas	1)22/03/2012 2) n.r. 3)17/10/2012	131.8 128.3 125.8	527 513 503	25.0 25.0 25.0	30/08/2012 12/09/2012 27/09/2012	49	Leaves with tops Roots	0.61 0.07	20	Report No: R B2185 Method B2196 (Faessel V., 2012a) LOQ = 0.01; LOD = 0.001 (both roots and leaves with tops) Mean procedural recovery 92.0 % (leaves with tops) 86.1 % (roots). Maximum storage time of samples 107 days. Maximum storage time of extracts 6 days.

Trial No./ Location (including postal code)/ 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)	DALA (days) (d)	Details on trial (e)
B2185 AN2 Seebach, 67160, France Northern Europe 2012	Sugarbeet/ Molière	1)27/03/2012 2) n.r. 3)28/09/2012	131.8 117.5 116.8	527 470 467	25.0 25.0 25.0	31/07/2012 13/08/2012 27/08/2012	39-49	Leaves with tops Roots 	2.90 1.28 0.84 0.63 0.12 0.03 0.05 0.03 0.06 0.03	0 3 8 14 22 0 3 8 14 22	Report No: R B2185 Method B2196 (Faessel V., 2012a) LOQ = 0.01; LOD = 0.001 (both roots and leaves with tops) Mean procedural recovery 92.0 % (leaves with tops) 86.1 % (roots). Maximum storage time of samples 154 days. Maximum storage time of extracts 4 days.
B2185 CZ1 Kostelec Nad Orlici, 51741 Czech Republic Northern Europe 2012	Sugarbeet / Lukata	1)30/03/2012 2) n.r. 3)05/10/2012 to 10/10/2012	124.3 126.5 133.3	497 506 533	25.0 25.0 25.0	18/08/2012 02/09/2012 18/09/2012	39	Leaves with tops Roots 	3.57 0.86 1.29 1.98 1.03 0.03 0.05 0.05 0.06 0.07	0 3 8 14 20 0 3 8 14 20	Report No: R B2185 Method B2196 (Faessel V., 2012a) LOQ = 0.01; LOD = 0.001 (both roots and leaves with tops) Mean procedural recovery 92.0 % (leaves with tops) 86.1 % (roots). Maximum storage time of samples 139 days. Maximum storage time of extracts 3 days.
B2185 PL2 Gora Swietej Malgo- rzaty, 99-122 Poland Northern Europe 2012	Sugarbeet/ Peuniak	1)21/03/2012 2) n.r. 3)06/10/2012	132.3 117.8 123.5	529 471 494	25.0 25.0 25.0	29/08/2012 14/09/2012 27/09/2012	49	Leaves with tops Roots 	4.48 2.79 3.17 3.64 3.32 0.04 0.06 0.03 0.06 0.03	0 3 7 13 20 0 3 7 13 20	Report No: R B2185 Method B2196 (Faessel V., 2012a) LOQ = 0.01; LOD = 0.001 (both roots and leaves with tops) Mean procedural recovery 92.0 % (leaves with tops) 86.1 % (roots). Maximum storage time of samples 125 days. Maximum storage time of extracts 10 days.

Trial No./ Location (including postal code)/ 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)	DALA (days) (d)	Details on trial (e)
B2185 HA2 Harsum, 31177, Germany Northern Europe 2012	Sugarbeet / Belladonna	1)30/03/2012 2) n.r. 3)01/10/2012 to 17/10/2012	125.5 131.8 124.5	502 527 498	25.0 25.0 25.0	03/09/2012 17/09/2012 01/10/2012	49	Leaves with tops Roots 	1.66 0.89 0.41 0.34 <u>0.27</u> 0.06 0.18 0.08 0.12 <u>0.08</u>	0 3 7 14 16 0 3 7 14 16	Report No: R B2185 Method B2196 (Faessel V., 2012a) LOQ = 0.01; LOD = 0.001 (both roots and leaves with tops) Mean procedural recovery 92.0 % (leaves with tops) 86.1 % (roots). Maximum storage time of samples 119 days. Maximum storage time of extracts 7 days.

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) DALA: Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
n.r.: not recorded

A 2.1.3.3 Oilseed rape

Table A 7: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, RMS, year)	NA				
cGAP EU (Art. 12, EFSA, year)	NA				
Intended cGAP	1-2	125 g a.s./ha	14 d	BBCH 69 at the latest	56 d

NA: Not applicable

A 2.1.3.3.1 Study 1

Comments of zRMS:	The study can be accepted. The method A8143 employed in this study was successfully validated - according to the applicant information (see section 5) and this is the basis for the acceptance of the study analytics. At the same time, however, the RMS must draw the applicant's attention to the fact that the analytical phase is not described accurately enough. This is applicable to the original study as well as to the study description below. E.g., since the number of recovery replicate assays (n) is essential, the applicant always should provide the analytical procedure with the specific number "n" clearly shown to avoid unnecessary doubts. In addition, it is worth remembering that according to the so-called limited validation set, the suggested minimum number of repetitions applied is 3. The method validation was was previously positively evaluated in Part B Section 2 of the Registration Report from 18.01.2014 prepared by Eko-Futura Sp. z o.o., IOR for the Step 2 dossier of Difcor 250 EC. The following conclusion was made (cited by translation): "The presented method meets the required criteria to ensure the correct determination of the residue of difenoconazole and its metabolite CGA205375 in seeds of winter rape, apples and pears and in food of animal origin. *The obtained results for individual components meet the requirements of SANCO / 825/00 rev.7 and SANCO / 3029/99 rev.4 on 11 July 2000. The presented test method is suitable for use in accordance with the application table of Difcor 250 EC in selected central zone countries."*

Reference:	KCA 6.3-05
Report	Determination of Difenoconazole residues in winter oilseed rape following two foliar applications with Difenoconazole 250 EC and GLOB1911F under field conditions in Northern and Southern Europe in 2019, Ertus C., 2020c, R B9107
Guideline(s):	Yes (Regulation (EC) No. 1107/2009, Regulation (EU) No. 283/2013 and 284/2013, 2004/10/EC GLP Directive)
Deviations:	No

GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue levels of difenoconazole in winter oilseed rape raw agricultural commodity after two foliar applications of the formulated products DIFENOCONAZOLE 250 EC (250 g difenoconazole/L) and GLOB1911F (500 g difenoconazole/L). In total, 3 trials in Northern Europe (France, Hungary and Poland) and 3 trials in Southern Europe (France, Greece and Italy) were conducted where both formulated products were tested in separate plots. Difenoconazole was applied in the form of the respective formulated product two times with an interval of 13-15 days, to BBCH 69 and at an application rate of 125 g a.s./ha. Samples of seeds were taken at maturity of the crop, 51-59 days after the last application except for the trial B9107 HU1 for which the harvest was done at 66 days after the last application.

Materials and methods

Analytical Method: Method A8143. The principle of the method is based on a manual extraction of the crop with acetone, followed by a clean-up of the crude extract by a liquid/liquid partition. The residues are quantified by LC with MS/MS detection. The LOQ was set at 0.01 mg/kg for oilseed rape seeds. The validation of this method was performed under the ANADIAG validation study No. A8143 entitled "Validation of the Analytical Method for the Determination of Difenoconazole (and its metabolites) Residues in vegetables, fruits, cereals and animal matrices" (KCP 5.2-03a, Perny A., 2008a, see dRR Section B5) and Amendments to this study (KCP 5.2-03b, Perny A., 2008b and KCP 5.2-03c, Perny A. 2013a).

Results and discussions

The residues were below the limit of detection in all control samples. The analytical results obtained are summarised in the table below.

Conclusion

Difenoconazole residues in winter oilseed rape seeds from field trials were not detectable or < LOQ.

Table A 8: Summary of the study 1 trials

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active ingredient:	Difenoconazole	Producer of commercial product:	GLOBACHEM NV
Crop/crop group:	Rape/Oilseed		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	250 g/L	Other a.s. in formulation:	-
Formulation	EC	(common name and content):	
Product name:	**DIFENOCONAZOLE 250 EC**	Residues calculated as:	mg/kg difenoconazole

Trial No./ Location (including postal code)/ EU zone/ Year (a)	**Commodity/ Variety**	**Date of 1.planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treat-ment or no. of treatments and last date** (c)	**Growth stage at last treat-ment or date**	**Portion analyzed**	**Residues (mg/kg)**	**DALA (days)** (d)	**Details on trial** (e)
			g a.s./ ha	**Water (l/ha)**	**g a.s./hl**						
B9107 HU1 Komarom, 2921 Hungary Northern Europe 2019	Winter oilseed rape / GK Lampas	1) 15/09/2018 2) 10/04/2019 to 19/04/2019 3) 28/06/2019	135.0 116.5	270 233	50.0 50.0	8/04/2019 23/04/2019	65	Seeds	NDR	66	Report No: R B9107 Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.003 Mean procedural recovery 79.0 %. Maximum storage time of samples 143 days. Maximum storage time of extracts 2 days.

Trial No./ Location (including postal code)/ EU zone/ Year	Commodity/ Variety	Date of 1.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)	DALA (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl						
	(a)	(b)				(c)				(d)	(e)
B9107 ND1 Steenbecque, 59189 France Northern Europe 2019	Winter oilseed rape / DK Exception	1) 03/09/2018 2) 18/04/2019 to 21/05/2019 3) 23/07/2019	125.0 133.5	250 267	50.0 50.0	7/05/2019 22/05/2019	69	Seeds	NDR	58	Report No: R B9107 Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.003 Mean procedural recovery 79.0 %. Maximum storage time of samples 122 days. Maximum storage time of extracts 2 days.
B9107 PL1 Dmosin, Nadolna, 95-061 Poland Northern Europe 2019	Winter oilseed rape / Sherpa	1) 21/08/2018 2) 20/04/2019 to 22/05/2019 3) 12/07/2019	125.0 129.0	250 258	50.0 50.0	8/05/2019 22/05/2019	69	Seeds	NDR	51	Report No: R B9107 Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.003 Mean procedural recovery 79.0 %. Maximum storage time of samples 129 days. Maximum storage time of extracts 2 days.
B9107 TL1 Larra, 31330 France Southern Europe 2019	Winter oilseed rape / DK Exception	1) 15/09/2018 2) 18/03/2019 to 29/04/2019 3) 27/06/2019 to 28/06/2019	133.5 130.0	267 260	50.0 50.0	16/04/2019 29/04/2019	67	Seeds	< LOQ	59	Report No: R B9107 Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.003 Mean procedural recovery 79.0 %. Maximum storage time of samples 144 days. Maximum storage time of extracts 2 days.
B9107 GR1 Anatoliko, 50200 Greece Southern Europe 2019	Winter oilseed rape / Edimax	1) 27/09/2018 2) 10/04/2019 to 05/05/2019 3) 30/06/2019	128.5 136.5	257 273	50.0 50.0	11/04/2019 24/04/2019	65	Seeds	NDR	59	Report No: R B9107 Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.003 Mean procedural recovery 79.0 %. Maximum storage time of samples 149 days. Maximum storage time of extracts 2 days.

Trial No./ Location (including postal code)/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.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)	DALA (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl						
B9107 IT1 Castagnole Piemonte, 10060 Italy Southern Europe 2019	Winter oilseed rape / Pioneer D 06	1) 08/09/2018 2) 14/04/2019 to 26/04/2019 3) 21/06/2019	120.0 121.5	240 243	50.0 50.0	8/04/2019 22/04/2019	64	Seeds	NDR	59	Report No: R B9107 Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.003 Mean procedural recovery 79.0 %. Maximum storage time of samples 151 days. Maximum storage time of extracts 2 days.

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) DALA: Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
NDR: no detectable residues (residues below the limit of detection (LOD); LOD = 0.003 mg/kg)
< LOQ: residues between LOD and LOQ (LOQ = 0.01 mg/kg)
n.a.: not applicable

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active ingredient:	Difenoconazole	Producer of commercial product:	GLOBACHEM NV
Crop/crop group:	Rape/Oilseed		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	500 g/L	Other a.s. in formulation:	-
Formulation	SC	(common name and content):	
Product name:	**GLOB1911F (Difenoconazole 500 SC)**	Residues calculated as:	mg/kg difenoconazole

Trial No./ Location (including postal code)/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.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)**	**DALA (days)** (d)	**Details on trial** (e)
			g a.s./ ha	**Water (l/ha)**	**g a.s./hl**						
B9107 HU1 Komarom, 2921 Hungary Northern Europe 2019	Winter oilseed rape / GK Lampas	1) 15/09/2018 2) 10/04/2019 to 19/04/2019 3) 28/06/2019	135.0 133.5	270 267	50.0 50.0	8/04/2019 23/04/2019	65	Seeds	NDR	66	Report No: R B9107 Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.003 Mean procedural recovery 79.0 %. Maximum storage time of samples 143 days. Maximum storage time of extracts 2 days.

Trial No./ Location (including postal code)/ EU zone/ Year (a)	Commodity/ Variety (b)	Date of 1.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)	DALA (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl						
B9107 ND1 Steenbecque, 59189 France Northern Europe 2019	Winter oilseed rape / DK Exception	1) 03/09/2018 2) 18/04/2019 to 21/05/2019 3) 23/07/2019	133.5 136.5	267 273	50.1 50.0	7/05/2019 22/05/2019	69	Seeds	NDR	58	Report No: R B9107 Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.003 Mean procedural recovery 79.0 %. Maximum storage time of samples 122 days. Maximum storage time of extracts 2 days.
B9107 PL1 Dmosin, Nadolna, 95-061 Poland Northern Europe 2019	Winter oilseed rape / Sherpa	1) 21/08/2018 2) 20/04/2019 to 22/05/2019 3) 12/07/2019	124.0 126.0	248 252	50.0 50.0	8/05/2019 22/05/2019	69	Seeds	NDR	51	Report No: R B9107 Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.003 Mean procedural recovery 79.0 %. Maximum storage time of samples 129 days. Maximum storage time of extracts 2 days.
B9107 TL1 Larra, 31330 France Southern Europe 2019	Winter oilseed rape / DK Exception	1) 15/09/2018 2) 18/03/2019 to 29/04/2019 3) 27/06/2019 to 28/06/2019	130.0 133.5	260 267	50.0 50.0	16/04/2019 29/04/2019	67	Seeds	< LOQ	59	Report No: R B9107 Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.003 Mean procedural recovery 79.0 %. Maximum storage time of samples 144 days. Maximum storage time of extracts 2 days.
B9107 GR1 Anatoliko, 50200 Greece Southern Europe 2019	Winter oilseed rape / Edimax	1) 27/09/2018 2) 10/04/2019 to 05/05/2019 3) 30/06/2019	130.0 133.5	260 267	50.0 50.0	11/04/2019 24/04/2019	65	Seeds	NDR	59	Report No: R B9107 Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.003 Mean procedural recovery 79.0 %. Maximum storage time of samples 149 days. Maximum storage time of extracts 2 days.

Trial No./ Location (including postal code)/ EU zone/ Year	Commodity/ Variety	Date of 1.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)	DALA (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl						
	(a)	(b)				(c)				(d)	(e)
B9107 IT1 Castagnole Piemonte, 10060 Italy Southern Europe 2019	Winter oilseed rape / Pioneer D 06	1) 08/09/2018 2) 14/04/2019 to 26/04/2019 3) 21/06/2019	118.5 118.5	237 237	50.0 50.0	8/04/2019 22/04/2019	64	Seeds	NDR	59	Report No: R B9107 Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.003 Mean procedural recovery 79.0 %. Maximum storage time of samples 151 days. Maximum storage time of extracts 2 days.

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) DALA: Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
NDR: no detectable residues (residues below the limit of detection (LOD); LOD = 0.003 mg/kg)
< LOQ: residues between LOD and LOQ (LOQ = 0.01 mg/kg)
n.a.: not applicable

A 2.1.3.3.2 Study 2

This study has already been submitted in Poland (zRMS) to support the use on oilseed rape for the registered product Difcor 250 EC and was positively evaluated.

Comments of zRMS:	According to the applicant information the study was formerly recognized as acceptable. This study was previously positively evaluated in Part B Section 4 of the Registration Report from 18.01.2014 prepared by Eko-Futura Sp. z o.o., IOR for the Step 2 dossier of Difcor 250 EC. The following conclusion was made (cited by translation): *"The study was conducted in accordance with EU guidelines, GLP principles and in accordance with the proposed application. The study was approved."* No sufficient study description below.

Reference:	KCA 6.3-06
Report	Determination of Difenoconazole residues in oilseed rape following treatment with Difenoconazole 250 EC under field conditions in Northern Europe in 2010, Jonchère F., 2011c, R B0119
Guideline(s):	Yes (Dir 91/414/EEC)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue levels of difenoconazole in oilseed rape raw agricultural commodity after two foliar applications of the formulated product DIFENOCONAZOLE 250 EC (250 g difenoconazole/L). 4 trials in Northern Europe (France, Poland and Czech Republic) were conducted. Difenoconazole was applied as the formulated product DIFENOCONAZOLE 250 EC two times with an interval of 13-15 days, to BBCH 72 (56 (±8) days before harvest) and at an application rate of 125 g a.s./ha. Samples of seeds were taken at maturity of the crop, 51-63 days after the last application.

Materials and methods

Analytical Method: Method A8143. The principle of the method is based on a manual or automatic extraction of the crop with acetone, followed by a clean-up of the crude extract by a liquid/liquid partition. The residues are quantified by LC with MS/MS detection. The LOQ was set at 0.01 mg/kg for oilseed rape seeds. The validation of this method was performed under the ANADIAG validation study No. A8143 entitled "Validation of the Analytical Method for the Determination of Difenoconazole (and its metabolites) Residues in vegetables, fruits, cereals and animal matrices" (KCP 5.2-03a, Perny A., 2008a, see dRR Section B5) and Amendments to this study (KCP 5.2-03b, Perny A., 2008b and KCP 5.2-03c, Perny A. 2013a).

Results and discussions

The residues were below the limit of detection in all control samples. The analytical results obtained are summarised in the table below.

Conclusion

Difenoconazole residues in oilseed rape seeds from 4 field trials were 0.04, 0.40, <LOQ and NDR.

Table A 9: Summary of the study 2 trials

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Active ingredient:	Difenoconazole	Producer of commercial product:	GLOBACHEM NV
Crop/crop group:	Rape/Oilseed		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	250 g/L	Other a.s. in formulation:	-
Formulation	EC	(common name and content):	
Product name:	**DIFENOCONAZOLE 250 EC**	Residues calculated as:	mg/kg difenoconazole

Trial No./ Location (including postal code)/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.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)**	**DALA (days)** (d)	**Details on trial** (e)
			g a.s./ ha	**Water (l/ha)**	**g a.s./hl**						
B0119 BP1 Attray, 45170 Centre, France Northern Europe 2010	Oilseed rape/ Excel	1)21/08/09 2) 19/04/10 to 10/05/10 3) 15/07/10	122.5 123.5	245 247	50.0 50.0	30/04/2010 14/05/2010	71/73	Seeds	0.04	62	Report No: R B0119 Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.001 Mean procedural recovery 94.0 %. Maximum storage time of samples 96 days. Maximum storage time of extracts 4 days.

Trial No./ Location (including postal code)/ EU zone/ Year	Commodity/ Variety	Date of 1.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)	DALA (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl						
	(a)	(b)				(c)				(d)	(e)
B0119 SO1 Saint Etienne a Arnes, 08130 France Northern Europe 2010	Oilseed rape/ DK Cabernet	1)aug 2009 2) n.r. 3)19/07/10	126.9 126.9	203 203	62.5 62.5	05/05/2010 20/05/2010	72	Seeds	0.40	60	Report No: R B0119 Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.001 Mean procedural recovery 94.0 %. Maximum storage time of samples 88 days. Maximum storage time of extracts 4 days.
B0119 PL1 Olszowka, 62-641 Poland Northern Europe 2010	Oilseed rape/ Monolit	1)28/08/09 2) 01/05/10 to 22/05/10 3)12/07/10	133.5 116.5	267 233	50.0 50.0	08/05/2010 22/05/2010	72	Seeds	<LOQ	51	Report No: R B0119 Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.001 Mean procedural recovery 94.0 %. Maximum storage time of samples 95 days. Maximum storage time of extracts 4 days.
B0119 CZ1 Kostelec Nad Orlici, 51741 Czech Republic Northern Europe 2010	Oilseed rape/ Visby	1)28/08/09 2)03/05/10 to 22/05/10 3)03/08/10	133.5 135.0	267 270	50.0 50.0	15/05/2010 28/05/2010	72	Seeds	NDR	63	Report No: R B0119 Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.001 Mean procedural recovery 94.0 %. Maximum storage time of samples 77 days. Maximum storage time of extracts 4 days.

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) DALA: Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
NDR: no detectable residues (residues below the limit of detection (LOD); LOD = 0.001 mg/kg)
< LOQ: residues between LOD and LOQ (LOQ = 0.01 mg/kg)
n.r.: not recorded

A 2.1.3.3.3 Study 3

This study has already been submitted in Poland (zRMS) to support the use on oilseed rape for the registered product Difcor 250 EC and was positively evaluated.

Comments of zRMS:	According to the applicant information the study was formerly recognized as acceptable. See also section 5 for method validation. Insufficient description below. This study has been positively evaluated in Part B Section 4 of the Registration Report from 0.7.03.2016 prepared by Eko-Futura Sp. z.o.o; IOR for the extension of authorisation of product Difcor 250 EC for minor uses.

Reference:	KCA 6.3-07
Report	Determination of Difenoconazole residues in oilseed rape following treatment with Difenoconazole 250 EC under field conditions in Northern and Southern Europe in 2011, Jonchère F., 2011d, R B1114 + amendment 1
Guideline(s):	Yes (Dir 91/414/EEC)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue levels of difenoconazole in oilseed rape raw agricultural commodity after two foliar applications of the formulated product DIFENOCONAZOLE 250 EC (250 g difenoconazole/L). In total, 4 trials in Northern Europe (France, Germany and Poland) and 4 trials in Southern Europe (France, Italy and Spain). 6 trials were sampled frequently to monitor the decline of residues shortly after the last treatment and at harvest and 2 trials were sampled at harvest. Difenoconazole was applied as formulated product DIFENOCONAZOLE 250 EC two times with an interval of 13-15 days and at an application rate of 125 g a.s./ha. The last application was performed at BBCH 72, (56 (±8) days before harvest for Northern Europe trials, and (56 (±14) days before harvest for Southern Europe trials). In the 4 Northern Europe decline curve trials, sampling was performed just after the last application, then 14 (±1), 28 (±2), 42 (±4) and 56 (±8) days after the last application (at harvest, BBCH 89). For the Southern Europe decline curve trials, the 4th and 5th samplings events were conducted at 35 (±4)
DALA and at 56 (±14) DALA (normal commercial harvest, BBCH 89). In the 2 Southern Europe residue at harvest trials, sampling were conducted at 56 (±14) DALA (normal commercial harvest, BBCH 89).

Materials and methods

Analytical Method: Method A8143. The principle of the method is based on a manual extraction of the crop with acetone, followed by a clean-up of the crude extract by a liquid/liquid partition. The residues are quantified by LC with MS/MS detection. The LOQ was set at 0.01 mg/kg for oilseed rape seeds. The validation of this method for oilseed seeds and pods was performed under the ANADIAG validation study No. A8143 entitled "Validation of the Analytical Method for the Determination of Difenoconazole (and its metabolites) Residues in vegetables, fruits, cereals and animal matrices" (KCP 5.2-03a, Perny A., 2008a, see dRR Section B5) and Amendments to this study (KCP 5.2-03b, Perny A., 2008b and KCP 5.2-03c, Perny A. 2013a). This method was further validated for oilseed rape whole plants and rest of plants in the ANADIAG study No. B1114 (KCP 5.2-04a (submitted as KCA 6.3-07a), Jonchère F., 2011d) and Amendment No. 1 of this study (KCP 5.2-04b (submitted as KCA 6.3-07b, Jonchère F., 2013b) (see dRR Section B5)

Results and discussions

The residues were below the limit of detection in all control samples. The analytical results obtained are summarised in the table below.

Conclusion

In this field trials Difenoconazole residues in oilseed rape whole plants, pods and rest of plants were found above the LOQ expect for seeds where residues were < LOQ or non-detectable.

Table A 10: Summary of the study 3 trials

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient:	Difenoconazole	Producer of commercial product:	GLOBACHEM NV
Crop/crop group:	Rape/Oilseed		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	250 g/L	Other a.s. in formulation:	-
Formulation	EC	(common name and content):	
Product name:	**DIFENOCONAZOLE 250 EC**	Residues calculated as:	mg/kg difenoconazole

Trial No./ Location (including postal code)/ EU zone/ Year (a)	**Commodity/ Variety** (a)	**Date of 1.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 analysed***	**Residues (mg/kg)**	**DALA (days)** (d)	**Details on trial** (e)
			g a.s./ ha	**Water (l/ha)**	**g a.s./hl**						
B1114 AN1 Seebach, 67160 France Northern Europe 2011	Oilseed rape/ NK Festivo	1)03/09/10 2)08/04/11 To 03/05/11 3) 22/06/11	131.5 118.5	263 237	50.0 50.0	19/04/2011 03/05/2011	69-72	Whole plants Whole plants Whole plants Pods Rest of plants Seeds	0.14 0.02 0.02 <LOQ <LOQ NDR	0 14 28 43 43 50	Report No: R B1114 Pods/seeds: Method A8143 (Perny A., 2008a, 2008b and 2013a) Whole plants/rest of plants: Method validated in B1114 (Jonchère F., 2011d and . 2013b) LOQ = 0.01; LOD = 0.001 Mean procedural recovery 78.8 % (seeds/pods), 82.7 % (whole plants/rest of plants). Maximum storage time of samples 121 days. Maximum storage time of extracts 9 days.

Trial No./ Location (including postal code)/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.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 analysed*	Residues (mg/kg)	DALA (days) (d)	Details on trial (e)
B1114 SO1 Saint Hilaire le Petit, 51490 France Northern Europe 2011	Oilseed rape/ DK Esquisit	1)30/08/10 2)11/04/11 to 0905/11 3) 08/07/11	130.0 121.0	260 242	50.0 50.0	09/05/2011 23/05/2011	72	Whole plants Whole plants Whole plants Pods Rest of plants Seeds	0.08 0.02 <LOQ 0.02 <LOQ NDR	0 14 28 38 38 46	Report No: R B1114 Pods/seeds: Method A8143 (Perny A., 2008a, 2008b and 2013a) Whole plants/rest of plants: Method validated in B1114 (Jonchère F., 2011d and 2013b) LOQ = 0.01; LOD = 0.001 Mean procedural recovery 78.8 % (seeds/pods), 82.7 % (whole plants/rest of plants). Maximum storage time of samples 101 days. Maximum storage time of extracts 7 days.
B1114 DE1 Uedem, 47589 Germany Northern Europe 2011	Oilseed rape/ Pioneer PR 46 W 20	1)04/09/10 2) 01/05/11 tp 15/05/11 3) 12/07/11	128.5 126.0	257 252	50.0 50.0	04/05/2011 19/05/2011	72	Whole plants Whole plants Whole plants Pods Rest of plants Seeds	0.16 0.05 0.02 0.01 <LOQ <LOQ	0 13 28 43 43 54	Report No: R B1114 Pods/seeds: Method A8143 (Perny A., 2008a, 2008b and 2013a) Whole plants/rest of plants: Method validated in B1114 (Jonchère F., 2011d and 2013b) LOQ = 0.01; LOD = 0.001 Mean procedural recovery 78.8 % (seeds/pods), 82.7 % (whole plants/rest of plants). Maximum storage time of samples 110 days. Maximum storage time of extracts 6 days.

Trial No./ Location (including postal code)/ EU zone/ Year (a)	Commodity/ Variety (a)	Date of 1.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 analysed*	Residues (mg/kg)	DALA (days) (d)	Details on trial (e)
B1114 PL1 Teresin, 95-061 Poland Northern Europe 2011	Oilseed rape/ Monolit	1)26/08/10 2)06/05/11 to 20/05/11 3)17/07/11	125.0 137.5	250 275	50.0 50.0	16/05/2011 30/05/2011	72	Whole plants Whole plants Whole plants Pods Rest of plants Seeds	0.24 0.03 0.01 0.02 0.01 NDR	0 14 28 39 39 48	Report No: R B1114 Pods/seeds: Method A8143 (Perny A., 2008a, 2008b and 2013a) Whole plants/rest of plants: Method validated in B1114 (Jonchère F., 2011d and 2013b) LOQ = 0.01; LOD = 0.001 Mean procedural recovery 78.8 % (seeds/pods), 82.7 % (whole plants/rest of plants). Maximum storage time of samples 95 days. Maximum storage time of extracts 8 days.
B1114 TL1 Pompigana, 82170 France Southern Europe 2011	Oilseed rape/ Mercure	1)23/09/10 2) 02/04/11 to 27/04/11 3) 28/06/11 to 30/06/11	133.5 129.0	267 258	50.0 50.0	21/04/2011 06/05/2011	72	Whole plants Whole plants Whole plants Pods Rest of plants Seeds	0.22 0.08 0.05 0.04 <LOQ <LOQ	0 14 26 38 38 55	Report No: R B1114 Pods/seeds: Method A8143 (Perny A., 2008a, 2008b and 2013a) Whole plants/rest of plants: Method validated in B1114 (Jonchère F., 2011d and 2013b) LOQ = 0.01; LOD = 0.001 Mean procedural recovery 78.8 % (seeds/pods), 82.7 % (whole plants/rest of plants). Maximum storage time of samples 119 days. Maximum storage time of extracts 8 days.

Trial No./ Location (including postal code)/ EU zone/ Year	Commodity/ Variety	Date of 1.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 analysed*	Residues (mg/kg)	DALA (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl						
	(a)	(b)				(c)				(d)	(e)
B1114 TL2 Castelnau D'Estrefonds, 31620 France Southern Europe 2011	Oilseed rape/ Alarmi	1)27/09/10 2) 02/04/11 to 27/04/11 3) 28/06/11 to 30/06/11	129.0 133.5	258 267	50.0 50.0	21/04/2011 06/05/2011	72	Seeds	<LOQ	55	Report No: R B1114 Pods/seeds: Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.001 Mean procedural recovery 78.8 % (seeds/pods), 82.7 % (whole plants/rest of plants). Maximum storage time of samples 60 days. Maximum storage time of extracts 2 days.
B1114 IT1 Corana, 27050 Italy Southern Europe 2011	Oilseed rape/ Vectra	1)11/09/10 2) 31/03/11 to 20/04/11 3) 14/06/11 to 16/06/11	134.0 133.5	268 267	50.0 50.0	15/04/2011 29/04/2011	72	Seeds	<LOQ	47	Report No: R B1114 Pods/seeds: Method A8143 (Perny A., 2008a, 2008b and 2013a) LOQ = 0.01; LOD = 0.001 Mean procedural recovery 78.8 % (seeds/pods), 82.7 % (whole plants/rest of plants). Maximum storage time of samples 75 days. Maximum storage time of extracts 2 days.
B1114 ES1 Formells de la Selva, 17458 Spain Southern Europe 2011	Oilseed rape/ Artist	1)01/10/10 2) 06/04/11 3) 14/06/11	124.0 127.0	248 254	50.0 50.0	19/04/2011 02/05/2011	72	Whole plants Whole plants Whole plants Pods Rest of plants Seeds	0.26 0.03 0.02 0.01 <LOQ <LOQ	0 14 26 39 39 43	Report No: R B1114 Pods/seeds: Method A8143 (Perny A., 2008a, 2008b and 2013a) whole plants/rest of plants: Method validated in B1114 (Jonchère F., 2011d and 2013b) LOQ = 0.01; LOD = 0.001 Mean procedural recovery 78.8 % (seeds/pods), 82.7 % (whole plants/rest of plants). Maximum storage time of samples 127 days. Maximum storage time of extracts 4 days.

(a) According to CODEX Classification / Guide

(b) Only if relevant
(c) Year must be indicated
(d) DALA: Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
* whole plants: these are whole plants without roots; rest of plants: these are rest of plants without roots
NDR: no detectable residues (residues below the limit of detection (LOD); LOD = 0.001 mg/kg)
< LOQ: residues between LOD and LOQ (LOQ = 0.01 mg/kg)
n.r.: not recorded

A 2.1.4 Magnitude of residues in livestock

No additional studies required.

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

No additional studies required.

A 2.1.6 Magnitude of residues in representative succeeding crops

No additional studies required.

A 2.1.7 Other/Special Studies

Comments of zRMS:	The study has been accepted. Although SANTE/11956/2016 rev. 9 requires a minimum of 4 trials and in this study consists of only 3 trials, the zRMS agrees with the applicant which considers this as sufficient since all residues were < LOQ (0,01). The performed in trials GAP is consistent with the intended GAP thus the study supports the approval in the honey context.

Reference:	KCA 6.10.1
Report	Difenoconazole – Residues in honey following exposure of bees to treated winter oilseed rape in Germany during 2017, Gätschenberger H., 2017, S17-01051
Guideline(s):	Dir 91/414/EEC Implementing Regulations (EU) 283/2013 and 284/2013 EC (1997) Guidance Document 7029/VI/95 rev. 5 SANCO/3029/99 rev. 4 SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary

The objective of the study was to determine the magnitude of residues of difenoconazole in honey following exposure of honeybees to winter oilseed rape plants, treated once with Difenoconazole 250 g/L EC (A7402T, formulation similar to Difcor 250 EC) at a rate of 125 g a.s./ha at BBCH 63. The study was conducted, under confined semi-field conditions. The target of the study was to obtain honey from each of the employed colonies, which is exclusively produced from the nectar of winter OSR plants, confined under gauze tunnels.

The study consisted of two treatment groups; test item treatment group T and a control group C. The actual application rate was 125 g a.s./ha for Difenoconazole 250 g/L EC (A7402T) at BBCH 63. All applications were carried out with a spray volume of 300 L/ha.
Commercial honeybee hives were placed in the tunnel tents on the day of application, either in the evening

or 2 hours after the application. The condition of the hives and the brood development were checked once prior to the set up in the tunnels and once after the sampling S1 of honey.
During the exposure of the bees to the crop in four separate tunnel tents (C, Ta, Tb, Tc) at each trial honey was sampled.

Materials and methods

Test Organism / Test System

Normally developed, healthy and queen-right honeybee colonies were used (one colony per tunnel). All colonies were produced at the same time. The corresponding queens originated from one breeding line in order to guarantee uniform honeybees material in all treatment groups. Each colony contained nine combs. The numbers of honeybees were in the range from 5655 to 12805 per colony. The number of honeybees and cells containing brood and food per colony were estimated according to IMDORF & GERIG, 1999, and IMDORF et al., 1987. The colonies were as homogeneous as possible. Honeybees were free of Nosema or Varroa disease symptoms or other bee diseases. All colonies were obtained from inhouse stock keeping of the test facility Eurofins Agroscience Services EcoChem GmbH /Eurofins Agroscience Services Ecotox GmbH in Niefern-Öschelbronn.
The honeybee colonies were placed in the tunnels at the day of application.
The honeybee queen was caged on one comb to obtain more honey. The comb inside the fixing comb was changed regularly, if necessary.

Test location

The semi-field trials were carried out in Pforzheim, Dusslingen and Stutensee, all situated in the region of Baden-Württemberg, Germany. The trials were performed in fields covered with Winter oilseed rape (*Brassica napus*).
The area covered per tunnel tent was about 200 m². The dimensions of each tunnel (covered plot) were 40 m long, 5 m wide and about 3.5 m high in the centre. There were two crop areas within each tunnel measuring 2.2 m x 38.8 m each (applied crop area: 2 x 85.36 m² = 170.72 m²). The distance between the tunnels was at least 3.0 m in all trials. The tunnel tent frames were covered with light plastic gauze (mesh size: 1.5 x 1.5 mm). Before start of the test, paths were created in each tunnel by removal of the plants and smoothing the ground.
No linen sheets were spread out in the tunnel tents.
No other formulations containing difenoconazole were applied during the actual growing season of the winter oil seed rape until the sampling S1 at each trial side.
A container filled with water was placed into each tunnel as water supply for the bees. The surface of the water was covered with floatable material to prevent the honeybees from drowning.
After the sampling of the honey the honey bee colonies were moved out of the tents and winter oil seed rape was destroyed after dismantling of the tunnel tents.

Recording of meteorological data

During the exposure period inside the tunnel tents meteorological data including rain were provided by weather stations next to the trial site (non GLP data):

- air temperature (daily min/max)
- relative air humidity (daily min/max)
- daily rainfall [mm]

During application, the following climatic data were recorded at the field site (GLP record):

- cloud cover
- air temperature, relative air humidity
- wind speed

Application

The actual application rate was 125 g a.s./ha for Difenoconazole 250 g/L EC (A7402T) at BBCH 63. All applications were carried out with a spray volume of 300 L/ha. The control plots remained untreated.
The test item solution was prepared shortly before the application. The application was carried out with a portable boom sprayer simulating a commercial application.
The following conditions were met for application:

- *Brassica napus* was in full bloom (BBCH 63) at application
- air temperature was below 30 °C
- wind speed inside the tunnel was < 2 m/s
- no rainfall for at least 2 hours after the application
- spray tolerance of 10 % per treatment group was met.

The amount of test item solution actually applied per plot was determined by measuring the initial and the remaining spray solution.

Conditions of the colonies and colony assessment

The condition of the colonies and the development of the honeybees' brood were checked once before start of exposure and once after the sampling of honey.
The following parameters were assessed:

- Hive strength
- Presence of a healthy queen (e.g. presence of eggs)
- Pollen storage area and area with nectar or honey
- Area containing cells with brood stages

At each assessment the comb area covered with honeybees or containing cells with nectar, pollen, eggs, larvae, and capped cells was estimated per comb side. The total number of bees and the number of cells containing the single brood stages, pollen and nectar was calculated for each hive.
Furthermore, colonies were assessed for bee diseases according to standard beekeeping practice. Accordingly, any unusual occurrences (e.g. presence of dead honeybees, dark "bald" bees, "crawlers" or flightless bees, unusual brood patterns or brood age structure) and clear symptoms of disease (e.g. chalk brood, sacbrood, Nosema, American or European foulbrood) or pests (e.g. Varroa sp., Aethina tumida, Tropilaelaps spp.) were recorded.

Sampling of honey

Honey was collected by gently pushing a plastic spoon into the walls of storage cells, allowing the honey to flow onto the spoon. Honey was sampled mature if possible. The water content in honey from unclosed cells was not measured due to the small sample amount in this cases. However, due to the changing weather condition sampling was done although conditions were not met to ensure to get a honey sample at all. Samples were taken from colonies C, Ta, Tb and Tc, at all trials if possible.
Control samples were collected before the treated samples or by different personnel, and different equipment was used. Samples were chilled during transport to the freezer (stored on blue ice) and were subsequently stored deep frozen within 3 h after sampling. Samples were kept deep-frozen (typically at or below -18 °C).

Results and discussions

Samples of honey were analyzed for residues of difenoconazole applied at BBCH 63. Results are given in the table below.

Sample	Difenoconazole (g a.i./ha)	Sample Type	Difenoconazole Residue (mg/kg)
Trial -01			
Treated Plot			
Ta	125	n.a.	n.a.
Tb	125	Honey	< 0.01
Tc	125	Honey	< 0.01
Control Plot			
C	Control	Honey	< 0.01
Trial -02			
Treated Plot			
Ta	125	Honey	< 0.01

Tb	125	Honey	< 0.01
Tc	125	Honey	< 0.01
Control Plot			
C	Control	Honey	< 0.01
Trial -03			
Treated Plot			
Ta	125	Honey	< 0.01
Tb	125	Honey	< 0.01
Tc	125	Honey	< 0.01
Control Plot			
C	Control	Honey	< 0.01

n.a. = no sample available
No correction of results for either control residues or recovery values has been performed.
(LOQ, 0.01 mg/kg)

Conclusion

The residues of difenoconazole in all treated honey samples were below the limit of quantification (LOQ, 0.01 mg/kg).
No residues of difenoconazole at or above the limit of quantitation (LOQ, 0.01 mg/kg) were found in the untreated honey samples.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations (based on current EU MRLs)

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

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)
351%	NL toddler	35.13	86%	Apples	46%	Table grapes	35%	Pears	8%	20%
280%	DE child	28.04	100%	Apples	41%	Table grapes	24%	Oranges	2%	3%
241%	GEMS/Food G06	24.08	72%	Tomatoes	47%	Rice	32%	Table grapes	2%	5%
195%	NL child	19.50	46%	Apples	31%	Table grapes	17%	Sugar beet roots	3%	23%
188%	GEMS/Food G11	18.82	31%	Wine grapes	20%	Celeries	18%	Tomatoes	2%	4%
183%	GEMS/Food G10	18.29	38%	Rice	27%	Tomatoes	13%	Lettuces	2%	4%
183%	GEMS/Food G07	18.26	44%	Wine grapes	22%	Tomatoes	10%	Rice	2%	6%
180%	PT general	17.98	75%	Wine grapes	24%	Rice	18%	Tomatoes	0.4%	5%
177%	GEMS/Food G08	17.72	31%	Wine grapes	23%	Tomatoes	16%	Olives for oil production	2%	6%
176%	IE adult	17.58	38%	Wine grapes	12%	Rhubarbs	9%	Celeries	1%	2%
155%	GEMS/Food G15	15.52	30%	Wine grapes	24%	Tomatoes	10%	Table grapes	2%	5%
155%	RO general	15.51	50%	Wine grapes	39%	Tomatoes	11%	Apples	2%	6%
150%	FR child 3 15 yr	14.96	20%	Oranges	17%	Tomatoes	13%	Apples	3%	9%
135%	FR adult	13.51	70%	Wine grapes	9%	Tomatoes	6%	Apples	1%	2%
130%	DE women 14-50 yr	13.04	25%	Wine grapes	21%	Apples	15%	Tomatoes	1%	10%
129%	FR toddler 2 3 yr	12.89	25%	Apples	18%	Rice	10%	Tomatoes	2%	8%
125%	ES child	12.47	20%	Tomatoes	17%	Lettuces	15%	Olives for oil production	2%	2%
121%	DE general	12.08	25%	Wine grapes	19%	Apples	13%	Tomatoes	1%	10%
115%	SE general	11.50	16%	Lettuces	15%	Tomatoes	12%	Rice	1%	4%
111%	ES adult	11.11	21%	Lettuces	16%	Tomatoes	12%	Wine grapes	0.7%	1%
108%	NL general	10.77	18%	Wine grapes	12%	Apples	8%	Tomatoes	2%	9%
105%	UK toddler	10.53	17%	Rice	14%	Apples	12%	Oranges	2%	10%
103%	IT toddler	10.34	29%	Tomatoes	12%	Lettuces	7%	Apples	0.9%	0.9%
100%	IT adult	10.04	23%	Tomatoes	15%	Lettuces	6%	Apples	0.4%	0.6%
96%	DK child	9.55	19%	Apples	11%	Tomatoes	9%	Rice	1%	2%
89%	UK vegetarian	8.92	24%	Wine grapes	12%	Tomatoes	11%	Rice	0.5%	2%
89%	UK infant	8.90	19%	Rice	13%	Apples	8%	Oranges	3%	6%
86%	FI 3 yr	8.63	17%	Rice	11%	Tomatoes	8%	Apples	0.5%	5%
82%	UK adult	8.18	32%	Wine grapes	11%	Rice	9%	Tomatoes	0.4%	3%
78%	DK adult	7.83	29%	Wine grapes	10%	Tomatoes	8%	Apples	0.5%	1%
68%	FI 6 yr	6.83	13%	Rice	9%	Tomatoes	6%	Strawberries	0.4%	4%
67%	FR infant	6.68	13%	Apples	8%	Spinaches	5%	Beans (with pods)	1%	5%
63%	PL general	6.29	18%	Tomatoes	16%	Apples	10%	Table grapes	0.1%	3%
57%	FI adult	5.70	11%	Tomatoes	9%	Wine grapes	6%	Lettuces	3%	1%
51%	LT adult	5.14	15%	Apples	12%	Tomatoes	6%	Rice	0.6%	3%
23%	IE child	2.34	9%	Rice	3%	Apples	2%	Table grapes	0.3%	0.6%

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 IEDI calculations (based on STMR values)

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 : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	98%	NL toddler	9.75	17%	Apples	8%	Beans (with pods)	8%	Table grapes	8%	3%
	72%	DE child	7.18	20%	Apples	7%	Tomatoes	7%	Table grapes	2%	0.3%
	70%	GEMS/Food G06	6.97	26%	Tomatoes	14%	Rice	5%	Table grapes	2%	0.9%
	53%	IE adult	5.25	7%	Wine grapes	4%	Other leafy brassica	4%	Sweet potatoes	1%	0.2%
	52%	GEMS/Food G10	5.21	11%	Rice	10%	Tomatoes	3%	Chinese cabbages/pe-tsai	2%	0.3%
	51%	NL child	5.07	9%	Apples	5%	Table grapes	4%	Tomatoes	3%	4%
	48%	GEMS/Food G07	4.80	8%	Tomatoes	8%	Wine grapes	3%	Rice	2%	0.4%
	48%	GEMS/Food G11	4.78	7%	Tomatoes	5%	Wine grapes	3%	Celeries	2%	0.4%
	46%	PT general	4.59	13%	Wine grapes	7%	Rice	6%	Tomatoes	0.4%	0.5%
	45%	FR child 3 15 yr	4.54	6%	Tomatoes	5%	Oranges	5%	Beans (with pods)	3%	2%
	45%	GEMS/Food G08	4.48	8%	Tomatoes	5%	Wine grapes	4%	Olives for oil production	2%	0.4%
	41%	FR toddler 2 3 yr	4.15	8%	Beans (with pods)	5%	Rice	5%	Apples	2%	1%
	40%	GEMS/Food G15	4.03	9%	Tomatoes	5%	Wine grapes	3%	Rice	2%	0.4%
	40%	RO general	4.00	14%	Tomatoes	9%	Wine grapes	2%	Apples	2%	1.0%
	36%	ES child	3.64	7%	Tomatoes	4%	Rice	3%	Oranges	2%	0.3%
	36%	SE general	3.62	6%	Tomatoes	4%	Chinese cabbages/pe-tsai	4%	Rice	1%	0.4%
	35%	DE women 14-50 yr	3.51	5%	Tomatoes	4%	Wine grapes	4%	Apples	1%	2%
	32%	DE general	3.21	5%	Tomatoes	4%	Wine grapes	4%	Apples	1%	2%
	32%	FR adult	3.18	12%	Wine grapes	3%	Tomatoes	2%	Beans (with pods)	1%	0.4%
	31%	UK infant	3.12	6%	Peas (without pods)	6%	Rice	3%	Tomatoes	3%	1.0%
	30%	UK toddler	3.04	5%	Rice	4%	Tomatoes	3%	Oranges	2%	2%
	29%	NL general	2.91	3%	Wine grapes	3%	Tomatoes	2%	Beans (with pods)	2%	2%
	29%	ES adult	2.88	6%	Tomatoes	3%	Lettuces	2%	Beans (with pods)	0.7%	0.2%
	28%	IT toddler	2.84	10%	Tomatoes	2%	Rice	2%	Lettuces	0.9%	0.1%
	26%	IT adult	2.64	8%	Tomatoes	2%	Lettuces	2%	Florence fennels	0.4%	0.1%
	24%	DK child	2.40	4%	Tomatoes	4%	Apples	3%	Rice	1%	0.2%
	22%	UK vegetarian	2.23	4%	Tomatoes	4%	Wine grapes	3%	Rice	0.5%	0.4%
	21%	FI 3 yr	2.06	5%	Rice	4%	Tomatoes	2%	Apples	0.5%	0.5%
	20%	UK adult	2.02	6%	Wine grapes	3%	Rice	3%	Tomatoes	0.4%	0.4%
	19%	FR infant	1.90	5%	Beans (with pods)	3%	Apples	0.9%	Carrots	1%	0.8%
	19%	DK adult	1.90	5%	Wine grapes	4%	Tomatoes	2%	Apples	0.5%	0.1%
	17%	PL general	1.66	6%	Tomatoes	3%	Apples	2%	Table grapes	0.1%	0.3%
	16%	FI 6 yr	1.61	4%	Rice	3%	Tomatoes	0.9%	Apples	0.4%	0.4%
	15%	FI adult	1.54	4%	Tomatoes	3%	Coffee beans	2%	Wine grapes	3%	0.1%
	14%	LT adult	1.39	4%	Tomatoes	3%	Apples	2%	Rice	0.6%	0.3%
	7%	IE child	0.71	3%	Rice	0.9%	Beans (without pods)	0.5%	Apples	0.3%	0.1%

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

A 3.3 IESTI calculations - Raw commodities

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

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

Unprocessed commodities

Results for children				**Results for adults**			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1.0%	Potatoes	0.1 / 0.01	1.5	0.2%	Potatoes	0.1 / 0.01	0.30
0.01%	Rapeseeds/canola seeds	0.5 / 0.01	0.01	0.00%	Rapeseeds/canola seeds	0.5 / 0.01	0.01
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

A 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%	Sugar beets (root) / sugar	0.2 / 0.54	5.0	1%	Sugar beets (root) / sugar	0.2 / 0.54	2.0
0.6%	Potatoes / fried	0.1 / 0.01	0.93	0.05%	Potatoes / chips	0.1 / 0.01	0.08
0.4%	Potatoes / dried (flakes)	0.1 / 0.05	0.59	0.04%	Potatoes / dried (flakes)	0.1 / 0.05	0.06
0.0%	Rapeseeds / oils	0.5 / 0.02	0.01	#GETAL!	#GETAL!	#GETAL!	#GETAL!
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Expand/collapse list							

Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Difenoconazole is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix 4 Additional information provided by the applicant