REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: CHR/F/SCORPIO 325 SC

Product name(s): Clapton 325 SC, Scarp 325 SC

Chemical active substances:

Difenoconazole, 125g/L

Azoxystrobin, 200g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: INNVIGO Sp. z o.o.

Submission date: 09/2023, 04/2024, 10/2024, 02/2025, 03/2025, 05/2025

MS Finalisation date: 18/07/2025, October 2025, July 2026

This document describes the acceptable use conditions required for registration according to Art. 34 and Art. 33 of Regulation 1107/2009 of CHR/F/SCORPIO 325 SC containing azoxystrobin and difenoconazole in POLAND.

Scorpion 325 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for registration data of Scorpion 325 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Scorpion 325 SC has expired. Innvigo Sp. z o.o. refers to above mentioned studies within this document.

zRMS comments:
Scorpion 325 SC was authorized in Poland in 2013 (authorization number R-6/2013 wu). The authorization was valid until 31/12/2025. It should be noted that the label for Scorpion 325 SC does not cover use on oilseeds crops and sugar beets which are proposed in the GAP for CHR/F/SCORPIO 325 SC.

Version history

When	What
04/2024	New and additional information provided by the applicant is highlighted in yellow.
10/2024	New and additional information provided by the applicant is highlighted in blue.
02/2025	New and additional information provided by the applicant is highlighted in green.
03/2025	New and additional information provided by the applicant is highlighted in purple.
04/2025	dRR assessed by zRMS
05/2025	New and additional information provided b the applicant is highlighted in deep blue.
07/2025	Additional data provided by the applicant in May 2025 assessed by zRMS. Draft registration report provided by zRMS for commenting
10/2025	Final RR (changes after commenting round in orange)
07/2026	Final RR (changes following comments from the Ministry of Agriculture and Rural Development are marked in violet)

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zRMS comments:
This dRR has been completed by the Applicant.
The text highlighted in grey was provided by the zRMS.
Assessment of additional data provided by the Applicant in May 2025 is highlighted in dark grey.

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Ornamental nursery plants, forest nursery plants, renewals afforestation, plantations of forest trees and energic plants are not designated for dietary use in humans or livestock. Therefore there will be no further consideration.
As the establishment of a MRL for tobacco is not required, there will be no further consideration.

Azoksystrobin
The residue definition for monitoring and risk assessment in plants was defined as azoxystrobin only.
No significant degradation was observed under standard hydrolysis conditions, and the same residue definition than in raw materials were defined for processed commodities.
The residue definition for risk assessment in animal commodities was tentatively set as azoxystrobin, pending information on the toxicological profile of metabolites L1, L4 and L9.
The storage stability of azoxystrobin residues was evaluated under peer review (EFSA Journal 2010; 8(4):1542). The storage stability of azoxystrobin was demonstrated for a period of 24 months at -18°C in all type of plant matrices.
Studies demonstrated storage stability of azoxystrobin in milk, muscle, fat, liver, kidney and eggs for up to 10 months when stored deep frozen.
Storage stability data assessed in the framework of the peer review cover commodities to support in this dossier.

Oilseeds

Comparison of intended GAP and EU GAP (EFSA Journal 2013;11(12):3497):

Crop	Region	Formulation	Application				PHI (days)
			Growth stage, BBCH	Number	Interval (days)	Max rate (g a.s./ha)	
EU GAP (EFSA Journal 2013;11(12):3497)							
Rape seed	NEU	SC	-	2	-	250	21
Mustard seed	NEU	SC	-	2	-	250	21
Sunflower seed	NEU	SC	Until 55	2	-	250	60
Poppy seeds	NEU	SC	Until 49	2	-	250	21
EU GAP (EFSA Journal 2022;20(1):7051)							
Rape seed	NEU	SC	60-67	1-2	10-14	250	70
Intended GAP							
Rape seed	NEU	SC	14~~-29~~ 22 Autumn 31-55 spring	2	~~90/120~~ **150 is proposed**	200	n/a **60 is proposed**
Rape seed	NEU	SC	61-69	1	-	200	n/a **60 is proposed**

Rape seed, mustard seed, sunflower seed, soybean, pumpkin seed (only for seed production), poppy seeds, linseeds hemp/flax (only for seed production),	NEU	SC	14~~-29~~ 22 31-69 **max 55 is accepted for sunflower seeds and soybean**	2 **1 is proposed for** mustard seed, sunflower seed, soybean, poppy seeds, linseeds	~~90/120~~ 150	200	n/a **60 is proposed**

According to the SANTE/2019/12752 Rev.1 residue data for rapeseed can be extrapolated to whole group oilseeds except peanuts for treatments before forming of the edible part and after forming of the edible part to poppy seeds, linseeds and mustard seeds. For oilseeds, a significant part of the edible part is present from full blossom (BBCH 65) onwards.

Taking the above into account, extrapolation to sunflower seeds, pumpkin seeds, hemp and soybean is possible for treatments at max BBCH 55.

The Applicant provided 8 independent residue field trials on oilseed rape conducted in Hungary (n=2), Poland (n=4), North France (n=1) and Germany (n=1). In all trials two applications (first at BBCH 15-22, second at BBCH 69) of CHR/F/SCORPIO 325 SC were applied at the target dose rate of 1.0 L/ha, equivalent to 200 g azoxystrobin and 125 g difenoconazole. The interval between applications was in the range 132 days – 196 days. One treatment was performed in autumn, the other in spring.

All studies were accepted. Specimen extraction and determination of residues of azoxystrobin in oilseed rape were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg. The limit of detection (LOD) of the analytical method was 0.002 mg/kg.

Residues above the stated LOQ of 0.01 mg/kg were found in one study.

Azoxystrobin residue results in seeds considered for further evaluation:

4 x < 0.002 mg/kg; 3 x < 0.01 mg/kg; 0.02 mg/kg (STMR 0.006 mg/kg, **HR 0.02 mg/kg**)

Residue results in whole plant were presented in 5 studies:

0.038 mg/kg; 0.094 mg/kg; 0.14 mg/kg; 0.17 mg/kg; 0.56 mg/kg (STMR 0.14 mg/kg, HR 0.56 mg/kg)

The current EU MRL for azoxystrobin in:

rapeseed is 0.7 mg/kg;
sunflower seed is 0.5 mg/kg;
mustard seed is 0.5 mg/kg;
soybean is 0.5 mg/kg;
poppy seeds is 0.5 mg/kg;
linseeds is 0.4 mg/kg

pumpkin seed is 0.01 mg/kg;
hemp seeds is 0.01 mg/kg.

The data submitted show that no exceedance of the existing MRL will occur for rapeseed, sunflower, mustard seed, poppy seed, and soybean. However, it is not possible to rule out exceeding the MRLs for pumpkin seeds and hemp seeds.

The proposed uses of azoxystrobin in rapeseed, poppy seeds, linseeds, sunflower, mustard seed and soybean are considered acceptable (at max BBCH 55 for sunflower and soybean).

Considering that the intervals between treatments in the studies provided exceed the min. recommended in GAP (Table 7.1-1) of 60/120 days, zRMS suggests limiting the use to one application for mustard seed, soybean, sunflower seeds, poppy seeds and linseeds.

The proposed uses of azoxystrobin in pumpkin seeds and hemp seeds are not considered acceptable.

At the commenting stage, the Applicant indicated that:
- *Pumpkin (for seed production only),*
- *Hemp (technical material and seed production only),*
- *Flax (technical material and seed production only)*

Considering that all those crops are not eaten by consumer or/and are not feed to animals no further residue studies are required to support those uses in accordance to SANTE/2019/12752.
Taking into account the above, that it concerns only the production of seeds not intended for consumption or/and are not feed to animals, the uses proposed for pumpkin seed and hemp/flax seeds were accepted. An appropriate restriction has been introduced in the label.

Considering that the residue results for rapeseed in the assessment refer to DALA in the range of 45-70 (62, 54, 58, 57, 54, 45, 70, 63), it is proposed to set PHI equal to 60 days for all oilseeds.

Sugar beet

Comparison of intended GAP and EU GAP:

Crop	Region	Formulation	Application				PHI (days)
			Growth stage, BBCH	Number	Interval (days)	Max rate (g a.s./ha)	
EU GAP (EFSA Journal 2013;11(12):3497)							
Sugar beet	NEU	SC	-	2	14-28	250	35
Chicory roots	NEU	SC	-	2		250	14
Celeriac	NEU	SC	-	2	12	250	14
Celeriac	NEU	SC	-	3	-	200	14
Horseradish	NEU	SC	-	4	-	250	10
Beetroot	NEU	SC	-	2	-	250	14
Swedes	NEU	SC	-	2	14-21	250	14
Turnips	NEU	SC	-	2	14-21	250	14
Intended GAP							
Sugar beet	NEU	SC	39-49	1	-	200	n/a **35 is proposed**
Turnip, Chicory roots, beetroot, rutabaga, horseradish, celeriac	NEU	SC	39-49	1	-	200	n/a **35 is proposed**

According to the SANTE/2019/12752 Rev.1 residue data for sugar beets can be extrapolated to beetroots, celeriac, horseradish, swedes/rutabaga and chicory roots for treatments before and after forming of the edible part.
The Applicant provided 8 independent residue field trials on sugar beet conducted in Hungary (n=2), Poland (n=3), North France (n=1) and Denmark (n=1). In all trials one application (at BBCH 49) of CHR/F/SCORPIO 325 SC were applied at the target dose rate of 1.3 L/ha, equivalent to 260 g azoxystrobin and 163 g difenoconazole.
All studies were accepted. Specimen extraction and determination of residues of azoxystrobin in sugar beet root were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg. The limit of detection (LOD) of the analytical method was 0.001 mg/kg.

No residues of azoxystrobin above the LOQ of 0.01 mg/kg were found in the roots.
Azoxystrobin residue results in roots considered for further evaluation:
1 x < 0.001 mg/kg; 7 x < 0.01 mg/kg; (STMR 0.01 mg/kg, HR 0.01 mg/kg)
Residue results in leaves with tops:
0.054 mg/kg; 0.012 mg/kg; 0.043mg/kg; 0.082 mg/kg; 0.34 mg/kg; 0.51 mg/kg; 0.087 mg/kg; 0.049 mg/kg; (STMR 0.068 mg/kg, HR 0.51 mg/kg)
The current EU MRL for azoxystrobin in:
sugar beet is 5 mg/kg;
beetroots (root), celeriac, horseradish, swedes/rutabaga and chicory roots is 1 mg/kg.
The data submitted show that no exceedance of the existing MRLs will occur.
Considering that the residue results for sugar beet roots in the assessment refer to DALA 35 ±1, it is proposed to set PHI equal to 35 days.

According to EFSA Journal 2013;11(12):3497: "During the peer review under Directive 91/414/EEC, the magnitude of azoxystrobin residues in livestock was investigated in feeding studies with lactating cows and laying hens (United Kingdom, 2009a). Four groups of lactating cows, each consisting of three animals, were dosed for 30 consecutive days with azoxystrobin at levels of 5, 25, 75 and 250 mg/kg in the diet (equivalent to 0.18, 0.91, 2.73 and 9.09 mg/kg bw). Three groups of laying hens, each consisting of twelve animals were dosed for 28 consecutive days with azoxystrobin at levels of 6, 18, and 60 mg/kg in the diet (equivalent to 0.39, 1.2 and 3.9 mg/kg bw). The samples were analyzed for parent azoxystrobin. Results of both livestock feeding studies are summarized in Table 3-8. In milk and eggs, a plateau level was never reached and no residues at or above 0.01 mg/kg was found in any of the samples.
The storage stability of azoxystrobin residues in animal products was evaluated under the peer review of Directive 91/414/EEC (United Kingdom, 2009a). Studies demonstrated storage stability of azoxystrobin in milk, muscle, fat, liver and kidney, eggs for up to 10 months when stored deep frozen. According to the RMS, all samples reported in the PROFile were stored in compliance with the above reported storage conditions."
The established MRLs for azoxystrobin in animal products are sufficient.

According to the Commission Reg. (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. The contribution of sugar beet roots to the TMDI is 21 %, processing studies are required. However, it should be noted that the results of azoxystrobin residue studies following GAP compliant CHR/F/SCORPIO 325 SC application indicate no residues in roots above the limit of quantification.
Additional processing studies are not required as they are not expected to affect the outcome of the risk assessment.

Residues in rotational crops have been sufficiently investigated taking into account the cGAP uses being considered for CHR/F/SCORPIO 325 SC. It is very unlikely that residues will present in rotational crops.

For oilseed rape application new magnitude of residues in honey were provided. The Applicant provided 4 adequate studies performed for the SC formulation. All of them are covered by stability studies. The studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage. All studies showed no azoxystrobin residues above LOQ in honey. For honey, the max. storage interval from sampling until extraction was 102 days for difenoconazole and azoxystrobin, and 98 for the triazole metabolites.
The data submitted show that no exceedance of the MRL (0.05 mg/kg for honey according to Reg. (EU) 2024/2633.

zRMS performed a chronic dietary risk assessment using revision 3.1 of the EFSA PRIMo and all applicable MRLs (Reg. (EU) 2024/2633) as input values. Considering the toxicological profile of the active substance, a short-term dietary risk assessment was not required.
The proposed uses of azoxystrobin in the formulation CHR/F/SCORPIO 325 SC do not represent

unacceptable acute and chronic risks for consumers.
It is noted that the uncertainty in the consumer risk assessment related to the calculated consumer exposure to livestock metabolites L1, L4, L9 and K1 (conjugate of L1) highlighted in the framework of the MRL review of the confirmatory data is still valid (EFSA, 2020).

Difenoconazole
The metabolism of difenoconazole in plants is sufficiently addressed to support the uses proposed in the GAP for CHR/F/SCORPIO 325 SC.
Plant residue definition for monitoring: difenoconazole, Reg. (EU) 2024/2612
Plant residue definition for risk assessment according to the EFSA Journal 2024;22:e8987:
RD-RA1: difenoconazole (sum of isomers);
RD-RA2: TA and TLA, since these compounds share the same toxicity;
RD-RA3: TAA;
RD-RA4: 1,2,4-triazole.
The previously derived provisional residue definitions (1. difenoconazole, 2. TDMs; EFSA, 2011a) have been replaced by the abovementioned residue definitions derived during the peer review of the pesticide risk assessment of the TDMs (EFSA, 2018d). EFSA highlights that the residue definitions might be reconsidered in the framework of the on-going peer review for renewal. In the framework of the assessment of confirmatory data (Spain, 2023; EFSA, 2024a,c), an uncertainty factor (UF) of 1.3 was derived from field residue trials submitted on this purpose, to reflect the tendency of a preferential degradation of trans isomers and a shift to the cis isomers of difenoconazole. This UF is applicable to all plant commodities.
Animal residue definition for monitoring: difenoconazole, Reg. (EU) 2024/2612
Animal residue definition for risk assessment according to the EFSA Journal 2024;22:e8987:
RD-RA1: Difenoconazole-alcohol (CGA205375), expressed as difenoconazole;
RD-RA2: TA and TLA;
RD-RA3: TAA;
RD-RA4: 1,2,4-T.
The previously derived provisional residue definitions (1. Difenoconazole, 2. TDMs; EFSA, 2011a) have been replaced by the abovementioned residue definitions derived during the peer review of the pesticide risk assessment of the TDMs (EFSA, 2018d). EFSA highlights that the residue definitions might be reconsidered in the framework of the on-going peer review for renewal. In the framework of the assessment of confirmatory data (EFSA, 2024a,c), an indicative uncertainty factor (UF) of 2 was derived following the EFSA guidance document on stereoisomers, to reflect the possible shift in the isomers ratio of difenoconazole-alcohol(CGA205375). This worst-case UF is applicable to all livestock commodities.

The storage stability of difenoconazole was investigated in the framework of the peer review (EFSA, 2011a) in high water content, high oil content and dry matrices and in the framework of a previous MRL application (EFSA, 2017) in high water content, high oil content, high acid content and dry commodities.
These available studies demonstrated storage stability for difenoconazole for 12–24 months when stored at −18°C, in the four main plant matrix groups.
Storage stability data on the triazole derivative metabolites (TDMs) are part of the peer review of the TDMs confirmatory data (EFSA Journal 2018;16(7):5736) and are out of data protection.
The Applicant provided storage stability studies for triazole metabolites in oilseed rape (seed, plant and straw) and for difenoconazole and triazole metabolites in honey.
The study is deemed sufficient for assessing the stability of triazole metabolites (1,2,4-T, TA, TAA, TLA) in honey upon storage at ≤ -18 °C for 15 months (459 days).
The study is deemed sufficient for assessing the stability of difenoconazole in honey upon storage at ≤ -18 °C for 104 days.
The study is deemed sufficient for assessing the stability of triazole metabolites (1,2,4-T, TA, TAA, TLA) in in oilseed rape (seed, plant and straw) for 300 days.
In the studies provided by the Applicant, rapeseed samples were stored for analysis for max. of 9 months, and sugar beet samples for max. of 6 months.
Sufficient stability has been demonstrated to support the residue data presented in the submission.

Oilseeds
Comparison of intended GAP and EU GAP (EFSA Journal. 2024;22:e8987):

Crop	Region	Formulation	Application				PHI (days)
			Growth stage, BBCH	Number	Interval (days)	Max rate (g a.s./ha)	
EU GAP EFSA Journal. 2024;22:e8987							
Rape seed	NEU	EC	14-69	1-2	14	130	n.a,
Mustard seed	NEU	EC	-69	2	-	125	n.a.
Sunflower seed	NEU	SC	30-55	2	21	125	n.a.
Poppy seeds	NEU	SC	31-69	1	-	125	n.a.
Soya bean	NEU	SC	31-69	1	-	125	n.a.
Intended GAP							
Rape seed	NEU	SC	14 - 22 31-55	2	~~90/120~~ **150 is proposed**	125	n/a **60 is proposed**
Rape seed	NEU	SC	61-69	1	-	125	n/a **60 is proposed**
Rape seed, mustard seed, sunflower seed, soybean, pumpkin seed, poppy seeds, hemp/flax	NEU	SC	14-22 31-69 **max 55 is accepted for sunflower seeds and soybean**	2 **1 is proposed for mustard seed, sunflower seed, soybean, pumpkin seed, poppy seeds, hemp/flax,**	~~90/120~~ **150 is proposed**	125	n/a **60 is proposed**

The Applicant provided 8 independent residue field trials on oilseed rape conducted in Hungary (n=2), Poland (n=4), North France (n=1) and Germany (n=1). In all trials two applications (first at BBCH 15-22, second at BBCH 69) of CHR/F/SCORPIO 325 SC were applied at the target dose rate of 1.0 L/ha, equivalent to 200 g azoxystrobin and 125 g difenoconazole. The interval between applications was in the range 132 days – 196 days. One treatment was performed in autumn, the other in spring.
All studies were accepted. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in oilseed rape (seed) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.004 mg/kg for each compound.
Specimen extraction and determination of residues of difenoconazole in oilseed rape (seed) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound.
According to the SANTE/2019/12752 Rev.1 residue data for rapeseed can be extrapolated to whole group oilseeds except peanuts for treatments before forming of the edible part and after forming of the edible

part to poppy seeds, linseeds and mustard seeds. For oilseeds, a significant part of the edible part is present from full blossom (BBCH 65) onwards.
Taking the above into account, extrapolation to sunflower seeds, pumpkin seeds, hemp and soybean is possible for treatments at max BBCH 55.

Difenoconazole residue results in seeds considered for further evaluation:
3 x < 0.002 mg/kg; 5 x < 0.01 mg/kg (STMR 0.01 mg/kg, HR 0.01 mg/kg)
The current EU MRL (Reg. (EU) 2024/2612) for difenoconazole in:
rapeseed is 0.5 mg/kg;
sunflower seed is 0.05 mg/kg;
mustard seed is 0.2 mg/kg;
linseeds is 0.2 mg/kg
soybean is 0.1 mg/kg;
poppy seeds is 0.05 mg/kg;
pumpkin seed is 0.05 mg/kg;
hemp seeds is 0.05 mg/kg.
The data submitted show that no exceedance of the existing MRL will occur for rapeseed, sunflower, mustard seed, linseeds, soybean, pumpkin seeds, poppy seeds and hemp seeds.
The proposed uses of difenoconazole in rapeseed, poppy seeds, sunflower, mustard seed, soybean pumpkin seeds and hemp seeds are considered acceptable (at max BBCH 55 for sunflower seeds, pumpkin seeds, hemp and soybean).
Considering that the intervals between treatments in the studies provided exceed the min. recommended in GAP (Table 7.1-1) of 60/120 days, zRMS suggests limiting the use to one application for mustard seed, soybean, sunflower seed, poppy seeds and linseeds.
Considering that the residue results for rapeseed in the assessment refer to DALA in the range of 45-70 (62, 54, 58, 57, 54, 45, 70, 63), it is proposed to set PHI equal to 60 days for all oilseeds.

TDMs
No MRLs are set for TDMs.
residue results in seeds considered for further evaluation:
TAA – 6x <0.004, 0.043, 0.058 (STMR 0.004 mg/kg, HR 0.058 mg/kg)
TA - 0.054, 4.84, 0.24, 0.47, 6.72, 0.2, 0.53, 0.17 (STMR 0.355 mg/kg, HR 6.72 mg/kg)
TLA – 5x <0.004, 0.25, 0.23, 0.078 (STMR 0.004 mg/kg, HR 0.25 mg/kg)
1,2,4-T – 8x <0.004 (STMR 0.004 mg/kg, HR 0.004 mg/kg)

residue results in whole plant were presented in 5 studies:
TAA - 3x <0.004, 1x <0.01, 0.049 (STMR 0.004 mg/kg, HR 0.049 mg/kg)
TA - 1x <0.004, 0.064, 0.67, 0.052, 0.13 (STMR 0.064 mg/kg, HR 0.67 mg/kg)
TLA - 4x <0.004, 0.11 (STMR 0.004 mg/kg, HR 0.11 mg/kg)
1,2,4-T - 5x <0.004 (STMR 0.004 mg/kg, HR 0.004 mg/kg)

It should be noted that significant residue levels were found in a few untreated control samples of residue trials on primary and rotational crops suggesting the use of triazole pesticide active substances in previous seasons. Despite these uncertainties these trials were considered with the purpose of performing a‘worst case’ consumer dietary intake calculation.

Sugar beet

Comparison of intended GAP and EU GAP (EFSA Journal. 2024;22:e8987):

Crop	Region	Formulation	Application				PHI (days)
			Growth stage, BBCH	Number	Interval (days)	Max rate (g a.s./ha)	
EU GAP (EFSA Journal. 2024;22:e8987)							
Sugar beet	NEU	EC	-	1-3	-	125	14
Chicory	NEU	SC	40-49	1-2	14	125	14

roots							
Celeriac	NEU	EC	-	1-4	14	125	14
Horseradish	NEU	EC	19-39	1-3	14	130	14
Beetroot	NEU	EC	20-89	1-3	14	125	14
Swedes	NEU	EC	19-39	1-3	14	130	14
Turnips	NEU	EC	19-39	1-3	14	130	14
Intended GAP							
Sugar beet	NEU	SC	39-49	1	-	125	n/a **35 is proposed**
Turnip, Chicory roots, beetroot, rutabaga, horseradish, celeriac	NEU	SC	39-49	1	-	125	n/a **35 is proposed**

According to the SANTE/2019/12752 Rev.1 residue data for sugar beets can be extrapolated to beetroots, celeriac, horseradish, swedes/rutabaga and chicory roots for treatments before and after forming of the edible part.
The Applicant provided 8 independent residue field trials on sugar beet conducted in Hungary (n=2), Poland (n=3), North France (n=1) and Denmark (n=1). In all trials one application (at BBCH 49) of CHR/F/SCORPIO 325 SC were applied at the target dose rate of 1.3 L/ha, equivalent to 260 g azoxystrobin and 163 g difenoconazole.
Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in sugar beet (leaves, roots) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound.
Specimen extraction and determination of residues of difenoconazole in sugar beet (leaves, roots) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.001 mg/kg for each compound.

Difenoconazole
residue results in roots considered for further evaluation:
1 x < 0.001, 3 x < 0.01, 0.019, 2 x 0.013, 0.012 (STMR 0.011 mg/kg, **HR 0.019** mg/kg)
Residue results in leaves with tops:
1 x < 0.010, 0.071, 0.064, 0.12, 0.18, 0.38, 0.1, 0.087 (STMR 0.094 mg/kg, HR 0.12 mg/kg)
The current EU MRL for difenoconazole (Reg. (EU) 2024/2612) in:
sugar beet is 0.2 mg/kg;
beetroots (root) is 0.4 mg/kg;
celeriac is 2.0 mg/kg;
horseradish is 0.4 mg/kg;
swedes/rutabaga is 0.4 mg/kg;
chicory roots is 0.6 mg/kg.
The data submitted show that no exceedance of the existing MRLs will occur.
Considering that the residue results for sugar beet roots in the assessment refer to DALA 35 ±1, it is proposed to set PHI equal to 35 days.

TDMs
No MRLs are set for TDMs.
residue results in roots considered for further evaluation:

TAA – 8x <0.002 (STMR 0.002 mg/kg, HR 0.002 mg/kg)
TA - 5x <0.01, 0.028, 0.011, 0.016 (STMR 0.01 mg/kg, HR 0.028 mg/kg)
TLA – 7x <0.002, 1x <0.01 (STMR 0.002 mg/kg, HR 0.01 mg/kg)
1,2,4-T – 8x <0.002 (STMR 0.002 mg/kg, HR 0.002 mg/kg)

residue results in leaves with tops were presented in 5 studies:
TAA - 8x <0.01 (STMR 0.01 mg/kg, HR 0.01 mg/kg)
TA - 1x <0.01, 0.029, 0.025, 2x 0.016, 0.011, 0.027, 0.015 (STMR 0.016 mg/kg, HR 0.029 mg/kg)
TLA - 1x <0.01, 0.083, 2x 0.012, 0.011, 0.04, 0.013, 0.023 (STMR 0.013 mg/kg, HR 0.083 mg/kg)
1,2,4-T - 8x <0.002 (STMR 0.002 mg/kg, HR 0.002 mg/kg)

It should be noted that significant residue levels were found in a few untreated control samples of residue trials on primary and rotational crops suggesting the use of triazole pesticide active substances in previous seasons. Despite these uncertainties these trials were considered with the purpose of performing a'worst case' consumer dietary intake calculation.

The requested uses do not substantially modify the theoretical maximum daily intake of difenoconazole and TDMs for animals as calculated in EFSA 2024 and EFSA 2018 respectively, and therefore outcome of EFSA, is still considered valid.

zRMS does not agree with the Applicant that the residue results in the plant matrices are below 0.01 mg/kg (see Table 7.3-9). Any studies on the magnitude of residues in processed commodities are not considered to be required for parent difenoconazole, TAA and 1,2,4-T as residues of these compounds are below 0.1 mg/kg in sugar beet root and rapeseed at commercial harvest after application of CHR/F/SCORPIO 325 SC according to the proposed GAP. However, the residue levels of TA and TLA in rapeseed were above 0.1 mg/kg. Therefore studies on industrial processing and/or household preparation for TA and TLA are required.
Studies on industrial processing and/or household preparation for TA and TLA in rapeseed are required – data gap.
zRMS position after evaluating additional data provided by the Applicant in July 2025:
Magnitude of residues in processed commodities are part of the peer review of the TDMs confirmatory data (EFSA Journal 2018; 16(7):5736) and are out of data protection.
According to EFSA Journal 2018; 16(7):5736: "The hydrolysis studies show that all four TDM are stable on processing. As a consequence the relevant residues in processed commodities are the TDM and no breakdown products need be considered. No processing factors have been applied to the consumer risk assessments. However, the processing factors determined do need to be considered for the dietary burden of livestock."

Data/information on difenoconazole residues in succeeding crops were reviewed at EU level and were considered to be acceptable, cover the proposed use.
Field rotation crops studies, analysing for the TDMs are required – data gap.
zRMS position after evaluating additional data provided by the Applicant in July 2025:
zRMS took into account the additional data provided by the Applicant. Consequently, field rotation crops studies, analysing for the TDMs, on crops that can be rotated and the plateau following multiple years of consecutive applications, are in principle still required (data gap). Nevertheless, considering the large margin of safety of the risk assessment performed with the TDMs resulting from the authorised uses of difenoconazole assessed in this dossier, this data gap is not expected to be of concern for the authorised uses of difenoconazole, but might be relevant for the comprehensive assessment of all triazole fungicides.
The position of zRMS is the same as that given in the EFSA Journal. 2024;22:e8987.

The currently established MRL for difenoconazole in honey is 0.05 mg/kg. The use of the CHR/F/SCORPIO 325 SC in accordance with the proposed GAP does not pose a risk of exceeding the currently established MRL in honey.
However, the study provided by the applicant is not accepted for TDMs due to the lack of necessary, complete validation data – data gap.

zRMS position after evaluating additional data provided by the Applicant in July 2025:
zRMS took into account the additional data provided by the Applicant. Method for triazole metabolites was validated and summary of results presented in the report number S21-05866: Prothioconazole – Residues of Triazole Metabolites in Honey Samples. The study was already evaluated and accepted in CHR/F/PROTAZO 375 SC final dossier.

The exposure to difenoconazole and TDMs after use of CHR/F/SCORPIO 325 SC is not expected to present a consumer risk. No further refinement of the assessment is required.

~~**Considering the lack of data on TDMs in field rotational studies, validation data for TDMs in honey and studies on industrial processing and/or household preparation for TA and TLA in rapeseed zRMS disagrees with the authorization of the intended uses.**~~

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation CHR/F/SCORPIO 325 SC are presented in Table 7.11. They have been selected from the individual GAPs in the zone for winter oilseed rape and sugar beet. A list of all intended uses within the zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL for azoxystrobin and difenoconazole as laid down in Reg. (EU) 396/2005 is not expected with exception of pumpkin seeds and hemp seeds – possible exceedance of azoxystrobin MRLs.
The chronic and the short-term intakes of azoxystrobin and difenoconazole residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, Poland, zRMS agrees with the authorization of the intended uses with exception of pumpkin seeds and hemp seeds.
Considering that the residue results for rapeseed in the assessment refer to DALA in the range of 45-70 (62, 54, 58, 57, 54, 45, 70, 63), it is proposed to set PHI equal to 60 days for all oilseeds.
Considering that the residue results for sugar beet roots in the assessment refer to DALA 35 ±1, it is proposed to set PHI equal to 35 days.
Considering that the intervals between treatments in the studies provided exceed the min. recommended in GAP (Table 7.1-1) of 60/120 days, zRMS suggests limiting the use to one application for mustard seed, soybean, sunflower seed, poppy seed and linseeds.
The proposed uses are considered acceptable at max BBCH 55 for sunflower seeds, and soybean.

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

Data gaps

Noticed data gaps are: None

- ~~Studies on industrial processing and/or household preparation for TA and TLA in rapeseed~~
- ~~Field rotation crops studies, analysing for the TDMs~~

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)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
1	Winter oilseed rape (BRSNW) (0401060)	N	CHR/F/SCORPIO 325 SC	F	*Phoma lingam, Alternaria brassicae, Verticillium longisporum*	SC	325	Spray, medium sprayer	Autumn, spring BBCH ~~14-29~~ – 14-22 BBCH 31-55	a)1 b)2	min. ~~90/120~~ 150	a) 0.9-1.0 l/ha b) 1.8-2.0 l/ha	200-400	a) 0.2925-0.325 kg a.s./ha (AZX 0.18-0.2 kg a.s./ha + DIF 0.1125-0.125 kg a.s/ha) b) 0.585-0.65 kg a.s./ha (AZX 0.36-0.4 kg a.s./ha + DIF 0.225-0.25 kg a.s/ha)	~~n/a~~ 60	
2	Winter oilseed rape (BRSNW) (0401060)	N	CHR/F/SCORPIO 325 SC	F	*Sclerotinia sclerotiorum, ~~Botryotina fuckeliana,~~ Botrytis cinerea Alternaria brassicae Verticillium longisporum*	SC	325	Spray, medium sprayer	Spring BBCH 61-69	a)1 b)1	n/a	a) 0.9-1.0 l/ha b) 0.9-1.0 l/ha	200-400	a) 0.2925-0.325 kg a.s./ha (AZX 0.18-0.2 kg a.s./ha + DIF 0.1125-0.125 kg a.s/ha) b) 0.2925-0.325 kg a.s./ha (AZX 0.18-0.2 kg a.s./ha + DIF 0.1125-0.125 kg a.s/ha)	~~n/a~~ 60	
3	Sugar beet (BEAVX) (0900010)	N	CHR/F/SCORPIO 325 SC	F	*Cercospora beticola, Ramularia beticola, Erysiphe betae.*	SC	325	Spray, medium sprayer	Spring BBCH 39-49	a)1 b)1	n/a	a) 0.8-1.0 l/ha b) 0.8-1.0 l/ha	200-400	a) 0.26-0.325 kg a.s./ha (AZX 0.16-0.2 kg a.s./ha + DIF 0.1-0.125 kg a.s/ha)	~~n/a~~ 35	

														b) 0.26-0.325 kg a.s./ha (AZX 0.16-0.2 kg a.s./ha + DIF 0.1-0.125 kg a.s/ha)		
4	Spring oilseed rape (BRSNS) (0401060), Mustard (3MUSC) (~~0401000~~ 0401080), *Papaver somniferum* (PAPSO) (~~0401000~~) 0401030) Soybean (GLXMA) (0401070), Sunflower (HELAN) (0401050), Pumpkin (CUUPE) (seed production only) (0401080 0401100), Hemp/Flax (technical and seed production) (LIUUT) (0401000 0401140)	N	CHR/F/SCORPIO 325 SC	F	*Sclerotinia sclerotiorum, Alternaria brassicace, Leptosphaeria maculans, Alternaria brassicicola, Botrytis cinerea, Fusarium sp., Fusarium oxysporum, Septoria glycines, Cercospora sojina, Alternaria helianthin, Diaporthe helianthin, Golovinomyces cichoracearum, Alternaria alternata, Golovinomyces orontii, Melampsora lini, Septoria cannabis,*	SC	325	Spray, medium sprayer	Autumn, spring BBCH ~~14-29~~ 14-22 or BBCH 31-69 **For sunflower and soybean allowed for treatments at max BBCH 55**	a)1 b)2 **Only for oilseed rape 2 applications are accepted; For the rest only 1 is accepted**	min.~~90/120~~ 150	a) 0.9-1.0 l/ha b) 1.8-2.0 l/ha	200-400	a) 0.2925-0.325 kg a.s./ha (AZX 0.18-0.2 kg a.s./ha + DIF 0.1125-0.125 kg a.s/ha) b) 0.585-0.65 kg a.s./ha (AZX 0.36-0.4 kg a.s./ha + DIF 0.225-0.25 kg a.s/ha)	~~n/a~~ 60	**Only for oilseed rape 2 appl. are accepted, for the rest 1 appl. is accepted** **Pumpkin. Hemp , Flax - not intended for consumption or/and are not feed to animals**
5	Turnip (BRSNA) (roots only) (0213110), Cichorium intybus (CICIN) (roots only) (0900030), Beetroot	N	CHR/F/SCORPIO 325 SC	F	*Alternaria sp, Erysiphe heraclei, Sclerotinia sclerotiorum, Septoria apiicola, Botrytis cinerea, Erysiphe betae, Cercospora beticola Uromyces beticola, Alternaria brassicicola, Erysiphe cruciferarum, Turnip mosaic virus,*	SC	325	Spray, medium sprayer	Spring BBCH 39-49	a)1 b)1	n/a	a) 0.8-1.0 l/ha b) 0.8-1.0 l/ha	200-400	a) 0.26-0.325 kg a.s./ha (AZX 0.16-0.2 kg a.s./ha + DIF 0.1-0.125 kg a.s/ha) b) 0.26-0.325 kg a.s./ha (AZX 0.16-0.2 kg a.s./ha + DIF 0.1-0.125 kg a.s/ha)	35	

	(BEAVD) (0213010), Rutabaga (BRSNA), ~~(0213110~~ 0213100) Horseradish (ARWLA) (0213040) Celeriac (APUGR) (0213030)				*Albugo candida, Leptosphaeria maculans, Botryotinia fuckeliana, Alternaria radicina*											
6	Ornamental nursery plants, forest nursery plants, renewals, afforestation and plantations of forest trees	N	CHR/F/SCORPIO 325 SC	F	*Podosphaeras p., Gymnosporangium sp., leaf spot, Lophodermium seditiosum, Diplocarpon rosae, Colletotrichum gloeosporioides, diseases caused by soil pathogens*	SC	325	Spray, medium sprayer	Spring the first symptoms of infection	a)1 b)2	14	a) 1.0 l/ha b) 2.0 l/ha	300-1200	a) 0.325 kg a.s./ha (AZX 0.2 kg a.s./ha + DIF 0.125 kg a.s/ha) b) 0.65 kg a.s./ha (AZX 0.4 kg a.s./ha + DIF 0.25 kg a.s/ha)		
7	Energetic plants, Salix viminalis (SAXVI), Wicker (1SAXG)	N	CHR/F/SCORPIO 325 SC	F	*Podosphaeras p., Gymnosporangium sp., leaf spot, Lophodermium seditiosum, Diplocarpon rosae, Colletotrichum gloeosporioides, diseases caused by soil pathogens*	SC	325	Spray, medium sprayer	Spring the first symptoms of infection	a)1 b)2	14	a) 0.8 l/ha b) 1.6 l/ha	300-1200	a) 0.260 kg a.s./ha (AZX 0.16 kg a.s./ha + DIF 0.100 kg a.s/ha) b) 0.52 kg a.s./ha (AZX 0.32 kg a.s./ha + DIF 0.200 kg a.s/ha)		
8	Tobacco (NIOTA)	N	CHR/F/SCORPIO 325 SC	F	*Alternaria spp., Golovinomyces cichoracearum*	SC	325	Spray, medium sprayer	Spring the first symptoms of infection	a)1 b)2	14	a) 1.0 l/ha b) 2.0 l/ha	300-1200	a) 0.325 kg a.s./ha (AZX 0.2 kg a.s./ha + DIF 0.125 kg a.s/ha) b) 0.65 kg a.s./ha (AZX 0.4 kg a.s./ha + DIF 0.25 kg a.s/ha)		

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

Explanation for Column 11 “Conclusion”

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

7.1.2 Summary of the evaluation

The preparation CHR/F/SCORPIO 325 SC is composed of azoxystrobin and difenoconazole.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Difenoconazole					
ADI	EFSA	2011	0.01	2-yr rat	100
ARfD	EFSA	2011	0.16	Developmental, rat	100
Azoxystrobin					
ADI	EFSA	2010	0.2	2-year rat	100
ARfD	Not required.				
Triazole alanine (TA)					
ADI	EFSA Journal 2018; 16(7):5376	2018	0.3 mg/kg bw/day	Rabbit developmental study	100
ARfD		2018	0.3 mg/kg bw	Rabbit developmental study	100
Triazole lactic acid (TLA)					
ADI	EFSA Journal 2018; 16(7):5376	2018	0.3 mg/kg bw/day	Bridging from TA	
ARfD		2018	0.3 mg/kg bw	Bridging from TA	
Triazole acetic acid (TAA)					
ADI	EFSA Journal 2018; 16(7):5376	2018	1 mg/kg bw/day	Rat 2 generation and Rabbit developmental studies	100
ARfD		2018	1 mg/kg bw	Rat 2 generation and Rabbit developmental studies	100
1, 2, 4-triazole (1,2,4-T)					
ADI	EFSA Journal 2018; 16(7):5376	2018	0.023 mg/kg bw/day	Rat 12-month study	300
ARfD		2018	0.1 mg/kg bw	Rabbit developmental study	300

7.1.2.1 Summary for azoxystrobin

Table 7.1.3: Summary for azoxystrobin

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	Winter oilseed rape (BRSNW) (0401060)	Yes	Yes	N/A	Yes	Yes	No	No
2	Winter oilseed rape (BRSNW) (0401060)	Yes	Yes	N/A	Yes	Yes		No
3	Sugar beet (BEAVX) (0900010)	Yes	Yes	N/A	Yes	Yes		No
6	Spring oilseed rape (BRSNS) (0401060), Mustard (3MUSC) (0401000), *Papaver somniferum* (PAPSO) (0401000) Soybean (GLXMA) (0401070), Sunflower (HELAN) (0401050), ~~Pumpkin (CUUPE) (seed production only) (0401080), Hemp~~/Flax ~~(technical and seed production) (LIUUT) (0401000)~~	Yes	Yes	N/A	Yes	Yes		No

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
7	Turnip (BRSNA) (roots only) (0213110), Cichorium intybus (CICIN) (roots only) (0900030), Beetroot (BEAVD) (0213010), Rutabaga (BRSNA), (0213110) Horseradish (ARWLA) (0213040) Celeriac (APUGR) (0213030)	Yes	Yes	N/A	Yes	Yes		No
8	Ornamental nursery plants, forest nursery plants, renewals, afforestation and plantations of forest trees	~~Yes~~ Not required	~~Yes~~ Not required	~~N/A~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required		~~No~~ Not required
9	Energetic plants, Salix viminalis (SAXVI), Wicker (1SAXG)	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required		~~Yes~~ Not required
10	Tobacco (NIOTA)	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required		~~Yes~~ Not required

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

7.1.2.2 Summary for difenoconazole

Table 7.1.4: Summary for difenoconazole

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Winter oilseed rape (BRSNW) (0401060)	Yes	Yes	N/A	Yes	Yes	No	No
2	Winter oilseed rape (BRSNW) (0401060)	Yes	Yes	N/A	Yes	Yes		No
3	Sugar beet (BEAVX) (0900010)	Yes	Yes	N/A	Yes	Yes		No
6	Spring oilseed rape (BRSNS) (0401060), Mustard (3MUSC) (0401000), *Papaver somniferum* (PAPSO) (0401000) Soybean (GLXMA) (0401070), Sunflower (HELAN) (0401050), Pumpkin (CUUPE) (seed production only) (0401080), Hemp/Flax (technical and seed production) (LIUUT) (0401000)	Yes	Yes	N/A	Yes	Yes		No

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
7	Turnip (BRSNA) (roots only) (0213110), Cichorium intybus (CICIN) (roots only) (0900030), Beetroot (BEAVD) (0213010), Rutabaga (BRSNA), (0213110) Horseradish (ARWLA) (0213040) Celeriac (APUGR) (0213030)	Yes	Yes	N/A	Yes	Yes		No
8	Ornamental nursery plants, forest nursery plants, renewals, afforestation and plantations of forest trees	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required		~~Yes~~ ~~Yes~~ Not required
9	Energetic plants, Salix viminalis (SAXVI), Wicker (1SAXG)	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required		~~Yes~~ Not required
10	Tobacco (NIOTA)	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required		~~Yes~~ Not required

7.1.2.3 Summary for CHR/F/SCORPIO 325 SC

Table 7.1-5: Information on CHR//F/SCORPIO 325 SC (KCA 6.8)

Crop	PHI for CHR/F/SCORPIO 325 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for CHR/F/SCORPIO 325 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		azoxystrobin	difenoconazole		
Winter oilseed rape (BRSNW) (0401060)	N/A	Yes	Yes	60	Considering that the residue results for rapeseed in the assessment refer to DALA in the range of 45-70 (62, 54, 58, 57, 54, 45, 70, 63), it is proposed to set PHI equal to 60 days for all oilseeds.
Winter oilseed rape (BRSNW) (0401060)	N/A	Yes	Yes	60	
Sugar beet (BEAVX) (0900010)	N/A	Yes	Yes	35	Considering that the residue results for sugar beet roots in the assessment refer to DALA 35 ±1, it is proposed to set PHI equal to 35 days.
Spring oilseed rape (BRSNS) (0401060), Mustard (3MUSC) (0401000), *Papaver somniferum* (PAPSO) (0401000) Soybean (GLXMA) (0401070), Sunflower (HELAN) (0401050), Pumpkin (CUUPE) (seed production only) (0401080), Hemp/Flax (technical and seed production)	N/A	Yes	Yes	60	The proposed uses of difenoconazole in rapeseed, poppy seeds, sunflower, mustard seed, soybean pumpkin seeds and hemp seeds are considered acceptable (at max BBCH 55 for sunflower seeds, pumpkin seeds, hemp and soybean). Considering that the residue results for rapeseed in the assessment refer to DALA in the range of 45-70 (62, 54, 58, 57, 54, 45, 70, 63), it is proposed to set PHI equal to 60 days for all oilseeds.

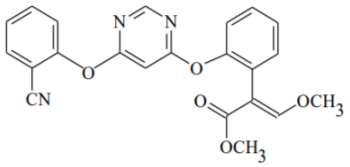
Crop	PHI for CHR/F/SCORPIO 325 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for CHR/F/SCORPIO 325 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		azoxystrobin	difenoconazole		
(LIUUT) (0401000)					
Turnip (BRSNA) (roots only) (0213110), Cichorium intybus (CICIN) (roots only) (0900030), Beetroot (BEAVD) (0213010), Rutabaga (BRSNA), (0213110) Horseradish (ARWLA) (0213040) Celeriac (APUGR) (0213030)	N/A	Yes	Yes	35	Considering that the residue results for sugar beet roots in the assessment refer to DALA 35 ±1, it is proposed to set PHI equal to 35 days.
Ornamental nursery plants, forest nursery plants, renewals, afforestation and plantations of forest trees	N/A	Yes	Yes		
Energetic plants, Salix viminalis (SAXVI), Wicker (1SAXG)	N/A	Yes	Yes		
Tobacco (NIOTA)	N/A	Yes	Yes		

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

7.2 Azoxystrobin

General data on azoxystrobin are summarized in the table below.

Table 7.2-1: General information on Azoxystrobin

Active substance (ISO Common Name)	azoxystrobin
IUPAC	methyl (E)-2-{2[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate
Chemical structure	
Molecular formula	$C_{22}H_{17}N_3O_5$
Molar mass	403.4
Chemical group	aryloxypyrimidine
Mode of action (if available)	inhibit mitochondrial respiration by blocking electron transpor
Systemic	Yes
Company (ies)	Syngenta
Rapporteur Member State (RMS)	AT
Approval status	Approve Date of approval 01.01.2012, Reg. (EU) 703/2011 Expiration of approval 31/05/2027
Restriction	SANCO/11027/2011 Rev 3 20 March 2015~~2~~ COMMISSION IMPLEMENTING REGULATION (EU) No 703/2011 of 20 July 2011 Only uses as fungicide may be authorised.
Review Report	SANCO/11027/2011 Rev 3 20 March 2015
Current MRL regulation	Reg. (EU) ~~2021/1807~~ 2024/2633
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	~~EFSA Journal 2010; 8(4):1542~~ Yes
EFSA Journal : Conclusion on the peer review	EFSA Journal 2010; 8(4):1542
EFSA Journal: conclusion on article 12	EFSA Journal ~~2010; 8(4):1542~~ 2013;11(12):3497
Current MRL applications on intended uses	None

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

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat	High starch content	24 month	Burke, S.R., 1995a EFSA 2013
Oilseed rape	High oil content	24 month	Burke, S.R., 1997
Honey	Honey	104 days	S. Mahlow, 2023, Report no S22-08436, see dRR Part B5

Conclusion on stability of residues during storage

The storage stability evaluated during Annex I inclusion covers plant matrices for use CHR/F/SCORPIO 325 SC according to the label.

zRMS comments:
The Applicant provided data only for high oil and starch content matrices but the potential degradation of residues during storage of the residue trials samples was assessed in the framework of the peer review (EFSA Journal 2010; 8(4):1542) also for commodities with high water content (banana, peach, tomato, cucumber, lettuce, carrot) and high acid content (grape, apple, orange). The storage stability of azoxystrobin was demonstrated for a period of 24 months at -18°C in all type of plant matrices.
The storage stability of azoxystrobin residues in animal products was also evaluated under peer review. Studies demonstrated storage stability of azoxystrobin in milk, muscle, fat, liver, kidney and eggs for up to 10 months when stored deep frozen.
zRMS comments:
The Applicant provided storage stability studies for azoxystrobin in honey (S. Mahlow, 2023, Report no S22-08436, see dRR Part B5)

Storage Period	Procedural Recoveries		Storage Samples			
	Single Values (%)	Mean (%) [a] in brackets: rel. std. deviation (%)	Percentage of analyte found relative to the nominal fortification level (%)		Percentage recovered corrected for the (mean) procedural recovery of the individual date of extraction [a]	Percentage recovered relative to the mean percentage recovered at Day 0 [a]
			Single Values [b]	Mean [a] in brackets: rel. std. deviation (%)		
Analyte: Difenoconazole Test System: Honey Nominal Fortification Level: 0.10 mg/kg (10xLOQ)						
0 days	-	-	94, 95	94	-	-
1 month (54 days)	70, 70	70	74, 74	74	105	78
3 months (104 days)	90, 94	92	93, 104	98	107	104
Analyte: Azoxystrobin Test System: Honey Nominal Fortification Level: 0.10 mg/kg (10xLOQ)						
0 days	-	-	94, 83	88	-	-
1 month (54 days)	75, 78	76	75, 80	77	102	87
3 months (104 days)	98, 90	94	92, 86	89	95	100
[a] calculated from unrounded values; [b] not corrected for procedural recoveries						

The study is deemed sufficient for asssessing the stability of azoxystrobin in honey upon storage at ≤ -18 °C for 104 days.
Data assessed in the framework of the peer review cover commodities to support in this dossier.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Conclusion on stability of residues in sample extracts

Analysis time were less than 24 hours between extraction and analysis or it was shown that study extracts are stable.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

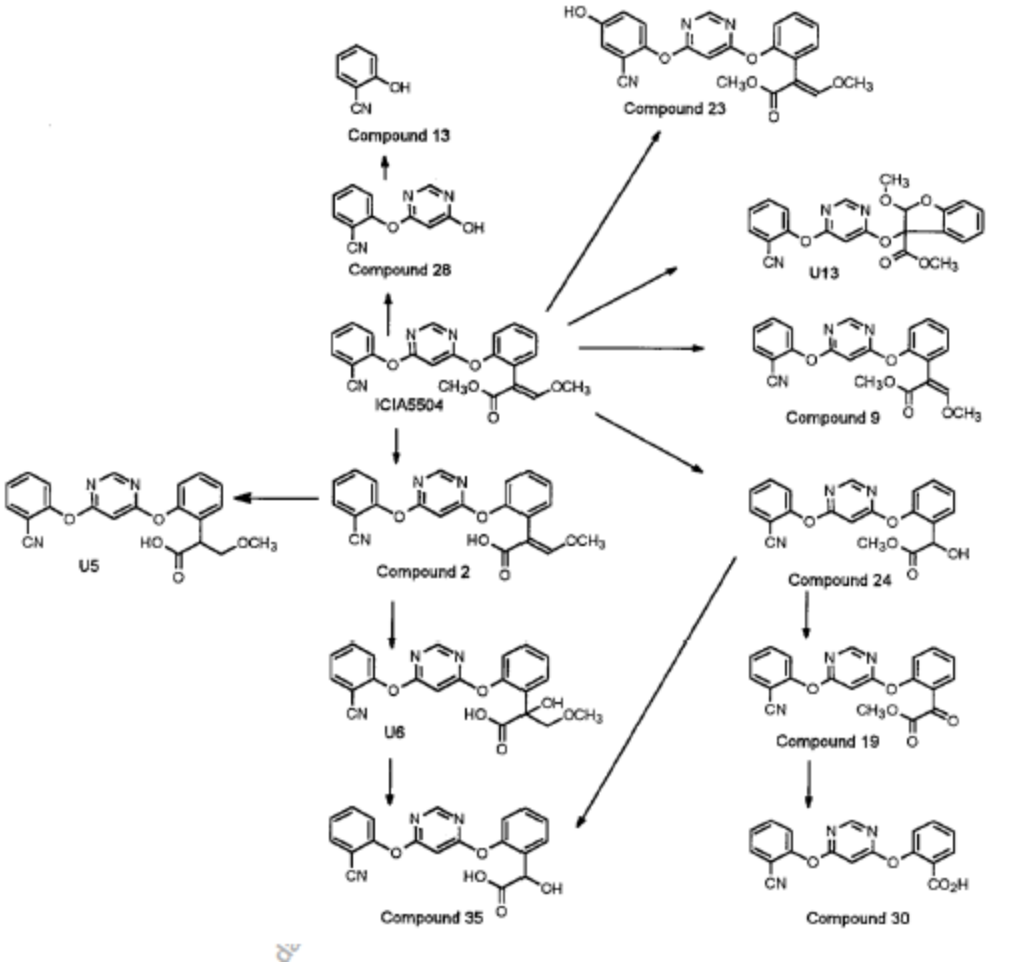
Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (~~kg~~ g a.s./ha)	No	Sampling (DAT)	Remarks	

EU data								
Pulses and oilseeds	Peanut	14C-pyrimidinyl 14C-cyanophenyl 14C-phenylacrylate	foliar treatment, F	850 g as/ha 850+ 300	~~2~~ 3	10 days	-	Webb, J. et al, 1995
Cereals	Wheat	14C-pyrimidinyl 14 C-cyanophenyl 14 C-phenylacrylate	foliar treatment, F	500 g as/ha	2	13 and 62 days	Applications at BBCH 30-31 and BBCH 59-61	Wilkinson, M. J. et al., 1994 Allin, R. et al., 1995
Fruit crops (grapes)	Grapes	14C-pyrimidinyl 14C-cyanophenyl 14C-phenylacrylate	foliar treatment, F	0.25, 1.0, 1.0 and 0.25 kg as/ha	4	21 days	-	Earl, V. L. et al., 1994

Summary of plant metabolism studies reported in the EU

1. Cleavage of the ether linkage between the phenylacrylate ring and the pyrimidinyl ring gives metabolite M 28 [R401553], and the cleavage of the ether linkage between the cyanophenyl ring and the pyrimidinyl ring to give M 13.
2. Complex photochemical rearrangement leads to M U13.
3. The Z-isomer M 09 [R230310] of azoxystrobin is formed by photochemical isomerisation.
4. Oxidative cleavage of the acryllic bond leads to M 24 and M 19, and further oxidation will give M 30.
5. M 02 [R234886] can be formed from azoxystrobin by hydrolysis of the ester group or oxidative o-dealkylation. Hydration of the acryllic bond in M 02 [R234886] gives metabolite M U6.
6. Reduction of the acryllic bond of M 02 [R234886] gives M U5.
7. Azoxystrobin and its metabolites can be incorporated naturally in the form of simple sugars, for example glucose. This is indicative of the mineralisation of azoxystrobin in soil to give carbon dioxide, which is subsequently assimilated and converted to simple sugars via photochemical reactions.
8. N-glucosylation of M 28 *[R401553]* forms M 42 *[R405287]*.

Figure B.7.1.1.4-1 Proposed metabolism of azoxystrobin in plants



Conclusion on metabolism in primary crops

The metabolism in primary crops presented during Annex I inclusion, covers use of CHR/F/SCORPIO 325 SC on winter oilseed rape and sugar beet. No new studies were necessary.

zRMS comments:
The metabolism pattern was similar in all plant groups, parent azoxystrobin being the major compound, accounting for 17-43 % TRR in cereal grain and straw, 35-65 % TRR in grapes, and 14-48 % TRR in peanut hulls and hay. Azoxystrobin was not detected in peanut nuts, where radioactivity was found to be mainly incorporated in fatty acids (up to 49 % TRR), but no individual metabolite was present in peanut kernels at a level greater than 1 %. In the other crops, the major metabolites identified were M2817, resulting from the cleavage of the ester link between the phenylacrylate and pyrimidyl ring, and metabolite M0918 (Z-isomer of azoxystrobin), both mostly below 10 % TRR. Other metabolites were identified but they were all present in very small amounts (EFSA Journal 2010; 8(4):1542).
Based on these studies the residue for monitoring and risk assessment was defined as azoxystrobin only.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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 vegetable	lettuce	14C-pyrimidinyl	F	2.21 kg as/ha	30, 200 and 365 days	30, 200 and 365 days	-	Goldsby, G., et al., 1995
		14C-cyanophenyl		2.2 kg as/ha	30, 200 and 365 days	30, 200 and 365 days		Miller, M. M. and Wilson, W., 1995
		14C-phenylacrylate		2.2 kg as/ha	30, 200 and 365 days	30, 200 and 365 days		Tambling, D.R. et al., 1995
Root and tuber vegetables	Radish	14C-pyrimidinyl	F	2.21 kg as/ha	30, 200 and 365 days	30, 200 and 365 days	-	Goldsby, G., et al., 1995
		14C-cyanophenyl		2.2 kg as/ha	30, 200 and 365 days	30, 200 and 365 days		Miller, M. M. and Wilson, W., 1995
		14C-phenylacrylate		2.2 kg as/ha	30, 200 and 365 days	30, 200 and 365 days		Tambling, D.R. et al., 1995
Cereals	wheat	14C-pyrimidinyl	F	2.21 kg as/ha	30, 200 and 365 days	30, 200 and 365 days	-	Goldsby, G., et al., 1995
		14C-cyanophenyl		2.2 kg as/ha	30, 200 and 365 days	30, 200 and 365 days		Miller, M. M. and Wilson, W., 1995
		14C-phenylacrylate		2.2 kg as/ha	30, 200 and 365 days	30, 200 and 365 days		Tambling, D.R. et al., 1995

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

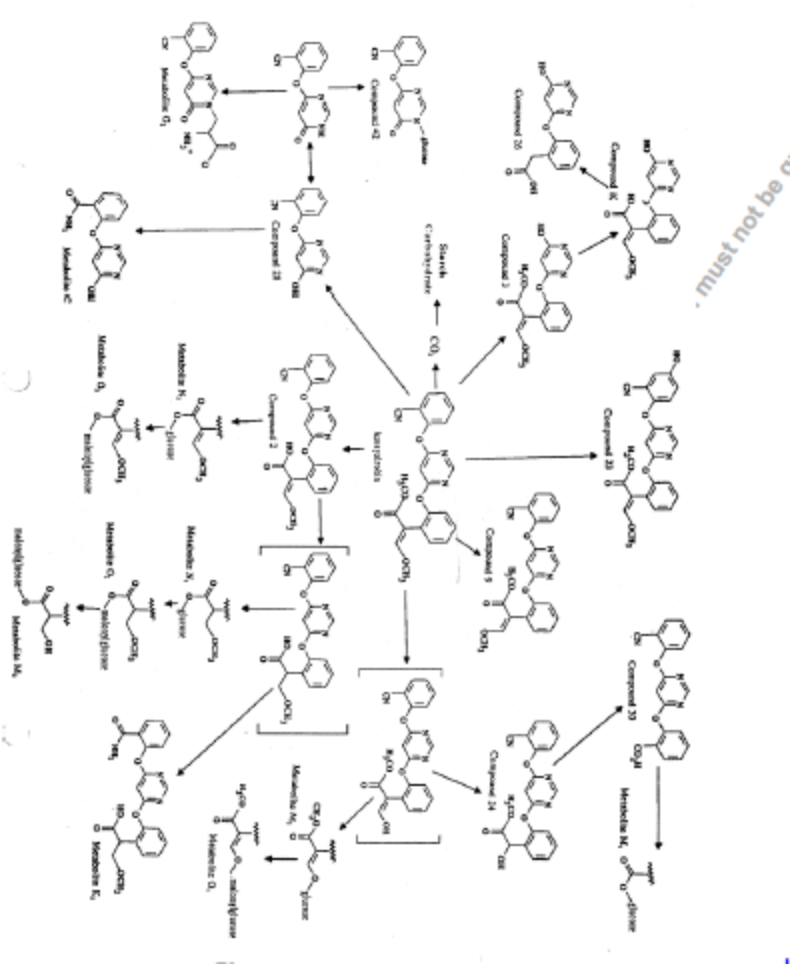
Summary of plant metabolism studies reported in the EU

Based on the three studies available the identification and the behaviour of breakdown and reaction products and of metabolites in rotational crops were cleared up. The metabolism of azoxystrobin in succeeding crops is almost similar for all the analysed crops and also similar to that observed in the primary crops. The metabolism of azoxystrobin in rotational crops is more extensive with more metabolites being formed than in the primary crops but the metabolites in succeeding crops are produced in low concentrations.

Many metabolites produced in rotated crops are glucose or amino acid conjugates of the corresponding primary crop free metabolites. As in the primary crops, azoxystrobin is found in amounts well above 10% of the total radioactive residue. Metabolites M 42 *[R405287]*, M N2, M O2 and M O3, which are major metabolites in succeeding crops, are found in the primary crops in greatly reduced concentrations in both free and conjugated forms. M 09 [R230310] the corresponding Z-isomer to azoxystrobin is not detected in most rotated crops and if detected, it is present in low concentrations (<2.0%). In general, ^{14}C-azoxystrobin was metabolised in succeeding crops by four major routes:

1. Hydrolysis of the ester to give the free acid (M 02 *[R234886]*) followed by conjugation to glucose (N2) and malonylglucose (O3).
2. Reduction of the double bond on the acid (M 02 *[R234886]*) followed by conjugation to glucose (N1) and malonylglucose (O2 and M2).
3. Cleavage of the ether linkage to give two ring compounds followed by further conjugation to glucose.
4. Mineralisation to ^{14}C-CO_2 and subsequent incorporation into natural products.

Figure B.7.1.2-1 Proposed metabolism of azoxystrobin in rotational crops



Conclusion on metabolism in rotational crops

The metabolism in rotational crops covers use of CHR/F/SCORPIO 325 SC according to the label.

zRMS comments:
According to the EFSA Journal 2013;11(12):3497: The TRR in soil declined on average from 0.74–1.0 mg/kg at treatment to 0.79, 0.67 and 0.24 mg/kg at 30, 200, and 365 days after treatment, respectively. The metabolism of azoxystrobin in rotational crops was complex with a large number of conjugated metabolites formed. The residues declined significantly at longer plant back intervals. Radioactive residues in the 365-day crops were generally in concentrations below 0.01 mg/kg. As in the primary crops, parent azoxystrobin represented the major residue detected in all rotational crops (up to 17–44% TRR); with very low residue levels in the tested crops (< 0.01–0.08 mg/kg at 30 days and < 0.01–0.01 mg/kg at 200 days). In wheat forage and wheat straw at 30 days, TRRs were 0.15–0.34 and 1.4–1.9 mg/kg, respectively, which declined significantly at the longer plant back intervals of 200 days (0.02–0.05 and 0.06– 0.12 mg/kg, respectively) and 365 days (< 0.01 mg/kg). Azoxystrobin residues in wheat grain were < 0.01 mg/kg even in wheat planted 30 days after the treatment. Compounds G219, M4220, N121, N222, O223 and O324, which are the principal metabolites in rotated crops, are glucose conjugates and were also found in the primary crops in both free and conjugated forms. These metabolites are not more toxicologically significant than parent (United Kingdom, 2009a).
It was concluded that the metabolism of azoxystrobin in succeeding crops is almost similar for all the analysed crops and also similar to that observed in the primary crops. The relevant residue in rotational crops should be defined as parent azoxystrobin.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No significant residues, i.e. >0.1 mg/kg, were found and therefore processing studies are not required. No new studies are necessary for CHR/F/SCORPIO 325 SC, since all residues are expected to be below 0.1 mg/kg.

No new data submitted in the framework of this application.

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

Conclusion on nature of residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	~~Yes~~ Parent	EFSA 2010
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	~~Yes~~ Parent	EFSA 2010
Sterilisation (20 minutes, 120°C, pH 6)	~~Yes~~ Parent	EFSA 2010

Conclusion on nature of residues in processed commodities

The residue pattern in processed commodities is similar to residue pattern in raw commodities

zRMS comments:
No significant degradation was observed under standard hydrolysis conditions, and the same residue definition than in raw materials were defined for processed commodities (EFSA Journal 2010; 8(4):1542).

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	Pulses and oilseeds (Peanut) Cereals (Wheat) Fruit crops (grapes)
Rotational crops covered	Cereals (wheat) Leafy vegetables (lettuce) Root vegetables (radish)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Azoxystrobin (no significant degradation observed under standard hydrolysis conditions)
Residue pattern in processed commodities similar to	Yes

pattern in raw commodities?	
Plant residue definition for monitoring	Azoxystrobin (Reg. (EU) 2024/2633)
Plant residue definition for risk assessment	Azoxystrobin (EFSA Journal 2010; 8(4):1542, EFSA Journal 2020;18(8):6231)
Conversion factor from enforcement to RA	None

~~* If residue pattern in processed commodities is not similar to that in raw commodities~~
~~** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).~~
~~*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.~~

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

Available data

No new data submitted in the framework of this application.

Table 7.2-7: 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	14C-pyrimidinyl 14C-cyanophenyl 14C-phenylacrylate	2	23.2-32.7 25 (^{14}C-cyanophenyl)	7	Milk	twice daily	Mayes S. et al., 1995 Webb J. et al., 1996
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	14C-pyrimidinyl 14C-cyanophenyl 14C-phenylacrylate	6	~~15~~ 11 12.5	10	Eggs	twice daily	Bramley, Y. M., Turner, J. 1996
						Excreta	Regular intervals	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

Azoxystrobin is rapidly excreted and extensively metabolised by hens, with 92 to 98% of the total radioactivity excreted within 23 hours after the final dose. The highest TRRs were in the egg yolk (0.144 mg/kg, [14C-pyrimidinyl]-azoxystrobin) and liver (up to 0.11 mg/kg, [14C-phenylacrylate]-azoxystrobin). The recovery data indicate transfer of azoxystrobin and its metabolites into tissues and eggs is low. Azoxystrobin and R401553 were identified in egg yolk at levels of <0.001-0.006 mg/kg azoxystrobin (parent) equivalents. In all tissues (for all labels):
* all components present at levels between 0.01 and 0.05 mg/kg were characterised
* no components were present at levels >0.05 mg/kg and no further work was therefore required to identify them.
Even at the exaggerated dose rate used (8N), the transfer of residue into tissues and egg was very small. Expected transfer of the residue into tissues under normal use patterns will be significantly lower than 0.01 mg/kg.

Figure B.7.2.2-2 Proposed Biotransformation Pathway of Azoxystrobin in the Hen

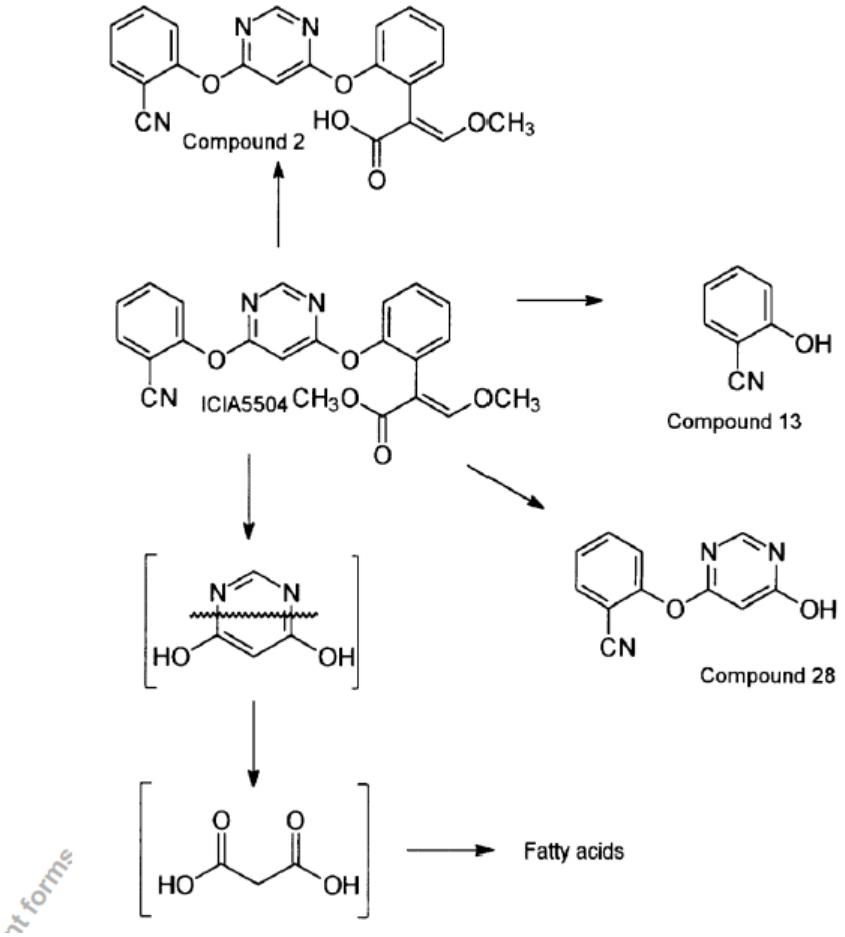
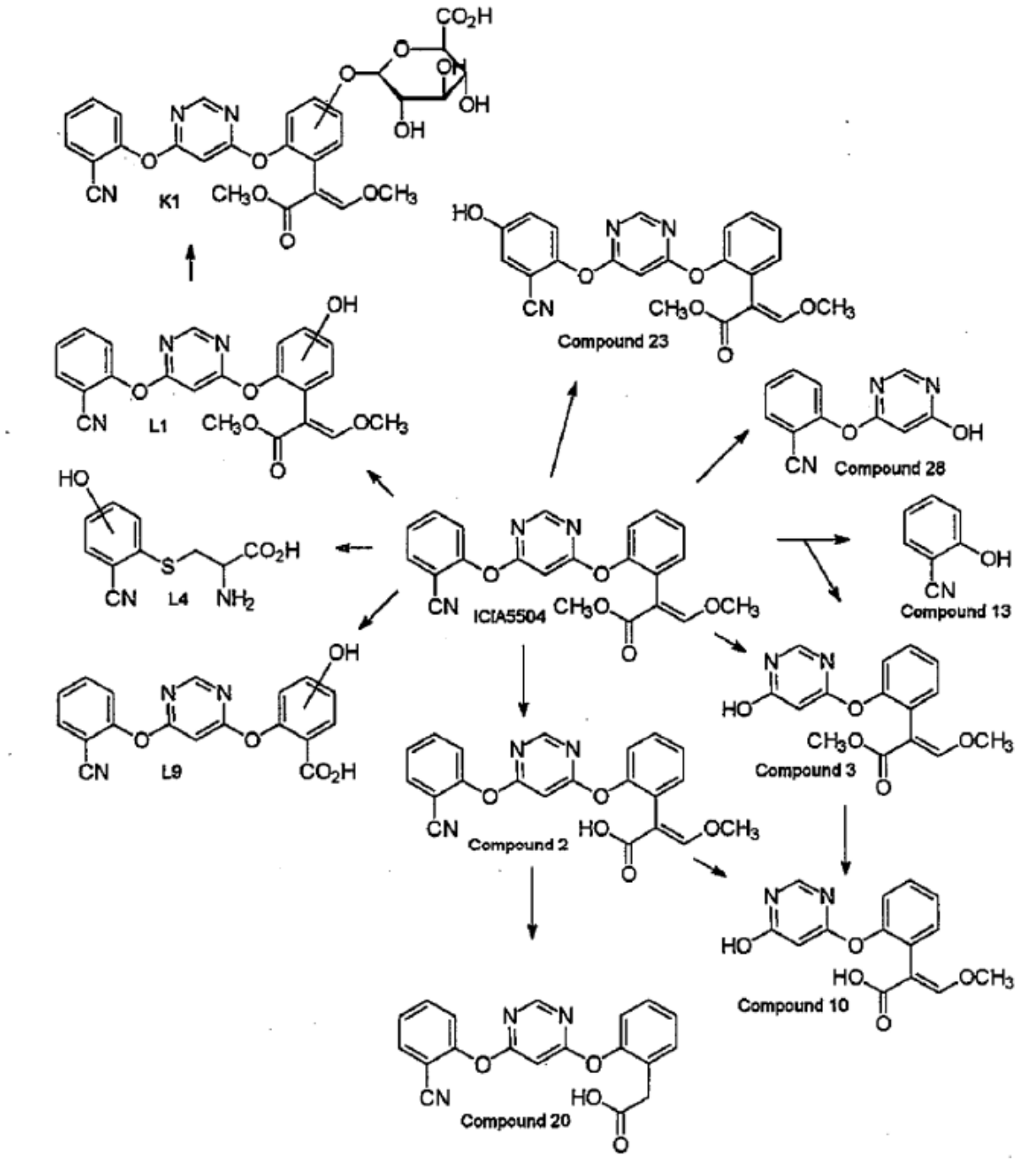


Figure B.7.2.1-2 Proposed Biotransformation Pathway of Azoxystrobin in the Goat



Conclusion on metabolism in livestock

Available metabolism studies demonstrated the residues of azoxystrobin are not expected in significant amount since they are very polar and extensively excreted. The metabolic patterns identified in lactating goats and laying hens is consistent with the rat metabolism and a specific metabolism study in pigs is not considered necessary.

zRMS comments:
According to the EFSA Journal 2010; 8(4):1542: Azoxystrobin was rapidly excreted in the metabolism studies performed on goats (2N dose) and poultry (8N dose). The transfer in tissues was limited, the TRRs in muscle, fat, milk and egg white being <0.02 mg/kg. Thus, characterisation of

residues was only performed in goat liver and kidney, and in poultry liver and egg yolk, where the TRRs were in the range of 0.05 to 1.19 mg/kg. In these matrices, the metabolism was shown to be very extensive, more than 20 compounds being identified/characterised, each accounting mostly for less than 5% of the TRR. Some metabolites (M28, M20, L4...) were however observed in higher proportions in some matrices, depending on the 14C-label. The parent compound was less than 2% of the TRR, except in egg yolk (12% TRR for the cyanophenyl label). None of these compounds were considered as a sufficient marker for the residue in animal matrices, and the residue for monitoring and risk assessment was then defined by default as azoxystrobin only. However, the definition for risk assessment has to be considered provisional, pending additional information on the toxicological relevance of metabolites L1, L4 and L9. Considering the calculated animal burdens and the results of the feeding studies, no MRLs were proposed for poultry products and a global MRL of 0.01* mg/kg was set for the other products of animal origin.
According to the EFSA Journal 2020;18(8):6231: The RMS proposed to confirm the residue definition for risk assessment in animal commodities which was tentatively set as azoxystrobin, pending information on the toxicological profile of metabolites L1, L4 and L9.
Azoxystrobin residues are not expected above LOQ in animals, so data previously evaluated at EU level are considered enough to support the uses purposed in this dossier.

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	Milk: not relevant, low residues in milk 0.004-0.01 mg eq/L
	Eggs: 6-8 days
Animal residue definition for monitoring	Azoxystrobin, ~~EFSA Journal 2020;18(8):6231,~~ Reg. (EU) ~~2021/1807~~ 2024/2633
Animal residue definition for risk assessment	Azoxystrobin (tentative, EFSA, 2010, 2013) [genotoxicity of metabolites L1, L4 and L9 can be ruled out but general toxicity of these metabolites was not addressed], EFSA Journal 2020;18(8):6231
Conversion factor	-
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No, Log Po/w < 3

~~* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)~~
~~** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.~~
~~*** If metabolism in rat and ruminant are not similar~~

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

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of CHR/F/SCORPIO 325 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
Oilseed rape (seeds) → mustard seeds, poppy seeds, soybean, sunflower, pumpkin seeds, hemp seeds	New trials K. Wańczyk 22SGS48-01, K.Wańczyk 22SGS49-01, K.Wańczyk 22SGS51-01, K.Wańczyk 22SGS52-01, K.Wańczyk 22SGS53-01, K.Wańczyk 22SGS54-01, K.Wańczyk 22SGS55-01 K.Wańczyk 23SGS47	N-EU	GAP: 2x 200 g/ha azoxystrobin, 2x125 g/ha difenoconazole BBCH 18-69, outdoor, PHI: 45-70 E: <0.010, <0.002, <0.002, <0.010, <0.010, 0.020, <0.002, <0.002 RA: <0.010, <0.002, <0.002, <0.010, <0.010, 0.020, <0.002, <0.002	~~0.010~~ 0.006	0.020	0.04	0.7 for rapeseeds 0.5 for mustard seeds, poppy seeds, soybean, sunflower, 0.4 for linseeds **0.01 for pumpkin seeds, hemp seeds**	Yes for rapeseeds, mustard seeds, poppy seeds, soybean, sunflower **No for pumpkin seeds, hemp seeds**

Oilseed rape (whole plant roots)	New trials K. Wańczyk 22SGS52-01, K. Wańczyk 22SGS53-01, K. Wańczyk 22SGS54-01, K. Wańczyk 22SGS55-01 K.Wańczyk 23SGS47	N-EU	GAP: 2x 200 g/ha azoxystrobin, 2x125 g/ha difenoconazole, BBCH 22-69, outdoor, PHI: 28 E: 0.17, 0.14, 0.56, 0.038, 0.094 RA: 0.17, 0.14, 0.56, 0.038, 0.094	~~0.155~~ 0.140	0.560	-	-	N/A
Sugar beet (roots)→ beetroots, celeriac, horseradish, swedes/rutabaga and chicory roots	New trials T.Peda 23SGS01-01, T.Peda 23SGS02-01, T.Peda 23SGS04-01, T.Peda 23SGS05-01, T.Peda 23SGS06-01, T.Peda 23SGS07-01, T.Peda 23SGS08-01, T.Peda 23SGS46-01,	N-EU	GAP: 2x 200 g/ha azoxystrobin, 2x125 g/ha difenoconazole, BBCH 49, outdoor, PHI: 34-36 E: <0.010, ~~<0.002,~~ <0.001, <0.010, <0.010, <0.010, <0.010, <0.010, <0.010 RA: <0.010, ~~<0.002,~~ <0.001, <0.010, <0.010, <0.010, <0.010, <0.010, <0.010	0.010	0.010	~~0.03~~ 0.01	5 for sugar beet 1 for beetroots, celeriac, horseradish, swedes/rutabaga and chicory roots	Yes

Sugar beet (leaves with tops)	New trials T.Peda 23SGS01-01, T.Peda 23SGS02-01, T.Peda 23SGS04-01, T.Peda 23SGS05-01, T.Peda 23SGS06-01, T.Peda 23SGS07-01, T.Peda 23SGS08-01, T.Peda 23SGS46-01,		GAP: 2x 200 g/ha azoxystrobin, 2x125 g/ha difenoconazole, BBCH 49, outdoor, PHI: 34-36 E: 0.054, 0.012, 0.043, 0.082*, 0.34*, 0.51*, 0.087*, 0.049* RA: 0.054, 0.012, 0.043, 0.082*, 0.34*, 0.51*, 0.087*, 0.049*	0.068	0.510	-	-	N/A
Honey	S.Mahlow C. Ezeobi-Chris S22-08279	2023	GAP: 2x 200 g/ha azoxystrobin, 2x125 g/ha difenoconazole, 14-64 BBCH, outdoor, PHI: 6-18, E: <0.01, <0.01, <0.01, <0.01 RA: <0.01, <0.01, <0.01, <0.01	0.010	0.010	0.03	0.05	Yes

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

LOD= 0.002 mg/kg, LOQ= 0.010 mg/kg azoxystrobin - rapeseed; LOD= 0.001 mg/kg, LOQ= 0.010 mg/kg azoxystrobin - sugar beet

7.2.3.2 Conclusion on the magnitude of residues in plants

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

zRMS comments:
zRMS does not agree with the Applicant's above conclusion that all proposed uses can be accepted based on the study results presented.

Oilseeds

Comparison of intended GAP and EU GAP (EFSA Journal 2013;11(12):3497):

Crop	Region	Formulation	Application				PHI (days)
			Growth stage, BBCH	Number	Interval (days)	Max rate (g a.s./ha)	
EU GAP (EFSA Journal 2013;11(12):3497)							
Rape seed	NEU	SC	-	2	-	250	21
Mustard seed	NEU	SC	-	2	-	250	21
Sunflower seed	NEU	SC	Until 55	2	-	250	60
Poppy seeds	NEU	SC	Until 49	2	-	250	21
EU GAP (EFSA Journal 2022;20(1):7051)							
Rape seed	NEU	SC	60-67	1-2	10-14	250	70
Intended GAP							
Rape seed	NEU	SC	14~~-29~~ 22 Autumn 31-55 spring	2	~~90/120~~ **150 is proposed**	200	n/a **60 is proposed**
Rape seed	NEU	SC	61-69	1	-	200	n/a **60 is proposed**
Rape seed, mustard seed, sunflower seed, soybean, ~~pumpkin seed,~~ poppy seeds, linseeds ~~hemp/flax~~	NEU	SC	14~~-29~~ 22 31-69 **max 55 is accepted for sunflower seeds and soybean**	~~2~~ **1 is proposed**	~~90/120~~	200	n/a **60 is proposed**

According to the SANTE/2019/12752 Rev.1 residue data for rapeseed can be extrapolated to whole group oilseeds except peanuts for treatments before forming of the edible part and after forming of the edible part to poppy seeds, linseeds and mustard seeds. For oilseeds, a significant part of the edible part is present from full blossom (BBCH 65) onwards.
Taking the above into account, extrapolation to sunflower seeds, pumpkin seeds, hemp and soybean is possible for treatments at max BBCH 55.
The Applicant provided 8 independent residue field trials on oilseed rape conducted in Hungary (n=2), Poland (n=4), North France (n=1) and Germany (n=1). In all trials two applications (first at BBCH 15-22, second at BBCH 69) of CHR/F/SCORPIO 325 SC were applied at the target dose rate of 1.0 L/ha,

equivalent to 200 g azoxystrobin and 125 g difenoconazole. The interval between applications was in the range 132 days – 196 days. One treatment was performed in autumn, the other in spring.
All studies were accepted. Specimen extraction and determination of residues of azoxystrobin in oilseed rape were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg. The limit of detection (LOD) of the analytical method was 0.002 mg/kg.
Residues above the stated LOQ of 0.01 mg/kg were found in one study.
Azoxystrobin residue results in seeds considered for further evaluation:
4 x < 0.002 mg/kg; 3 x < 0.01 mg/kg; 0.02 mg/kg (STMR 0.006 mg/kg, **HR 0.02 mg/kg**)
Residue results in whole plant were presented in 5 studies:
0.038 mg/kg; 0.094 mg/kg; 0.14 mg/kg; 0.17 mg/kg; 0.56 mg/kg (STMR 0.14 mg/kg, HR 0.56 mg/kg)
The current EU MRL for azoxystrobin in:
rapeseed is 0.7 mg/kg;
sunflower seed is 0.5 mg/kg;
mustard seed is 0.5 mg/kg;
soybean is 0.5 mg/kg;
poppy seeds is 0.5 mg/kg;
linseeds is 0.4 mg/kg
pumpkin seed is 0.01 mg/kg;
hemp seeds is 0.01 mg/kg.
The data submitted show that no exceedance of the existing MRL will occur for rapeseed, sunflower, mustard seed, linseeds, poppy seeds and soybean. However, it is not possible to rule out exceeding the MRLs for pumpkin seeds and hemp seeds.
Considering that the intervals between treatments in the studies provided exceed the min. recommended in GAP (Table 7.1-1) of 60/120 days, zRMS suggests limiting the use to one application for mustard seed, soybean, sunflower seed, and poppy seed.
The proposed uses of azoxystrobin in rapeseed, poppy seeds, sunflower, mustard seed, and soybean are considered acceptable (at max BBCH 55 for sunflower and soybean).

The proposed uses of azoxystrobin in pumpkin seeds and hemp seeds are not considered acceptable.
Taking into account that it concerns only the production of seeds not intended for consumption or/and are not feed to animals, the uses proposed for pumpkin seed and hemp/flax seeds were accepted. An appropriate restriction has been introduced in the label.

Considering that the residue results for rapeseed in the assessment refer to DALA in the range of 45-70 (62, 54, 58, 57, 54, 45, 70, 63), it is proposed to set PHI equal to 60 days for all oilseeds.

Sugar beet

Comparison of intended GAP and EU GAP:

Crop	Region	Formulation	Application				PHI (days)
			Growth stage, BBCH	Number	Interval (days)	Max rate (g a.s./ha)	
EU GAP (EFSA Journal 2013;11(12):3497)							
Sugar beet	NEU	SC	-	2	14-28	250	35
Chicory roots	NEU	SC	-	2		250	14
Celeriac	NEU	SC	-	2	12	250	14
Celeriac	NEU	SC	-	3	-	200	14
Horseradish	NEU	SC	-	4	-	250	10
Beetroot	NEU	SC	-	2	-	250	14
Swedes	NEU	SC	-	2	14-21	250	14
Turnips	NEU	SC	-	2	14-21	250	14

Intended GAP							
Sugar beet	NEU	SC	39-49	1	-	200	n/a **35 is proposed**
Turnip, Chicory roots, beetroot, rutabaga, horseradish, celeriac	NEU	SC	39-49	1	-	200	n/a **35 is proposed**

According to the SANTE/2019/12752 Rev.1 residue data for sugar beets can be extrapolated to beetroots, celeriac, horseradish, swedes/rutabaga and chicory roots for treatments before and after forming of the edible part.
The Applicant provided 8 independent residue field trials on sugar beet conducted in Hungary (n=2), Poland (n=3), North France (n=1) and Denmark (n=1). In all trials one application (at BBCH 49) of CHR/F/SCORPIO 325 SC were applied at the target dose rate of 1.3 L/ha, equivalent to 260 g azoxystrobin and 163 g difenoconazole.
All studies were accepted. Specimen extraction and determination of residues of azoxystrobin in sugar beet root were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg. The limit of detection (LOD) of the analytical method was 0.001 mg/kg.
No residues of azoxystrobin above the LOQ of 0.01 mg/kg were found in the roots.
Azoxystrobin residue results in roots considered for further evaluation:
1 x < 0.001 mg/kg; 7 x < 0.01 mg/kg; (STMR 0.01 mg/kg, HR 0.01 mg/kg)
Residue results in leaves with tops:
0.054 mg/kg; 0.012 mg/kg; 0.043mg/kg; 0.082 mg/kg; 0.34 mg/kg; 0.51 mg/kg; 0.087 mg/kg; 0.049 mg/kg; (STMR 0.068 mg/kg, HR 0.51 mg/kg)
The current EU MRL for azoxystrobin in:
sugar beet is 5 mg/kg;
beetroots (root), celeriac, horseradish, swedes/rutabaga and chicory roots is 1 mg/kg.
The data submitted show that no exceedance of the existing MRLs will occur.
Considering that the residue results for sugar beet roots in the assessment refer to DALA 35 ±1, it is proposed to set PHI equal to 35 days.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Data/information on livestock feeding studies were reviewed during the Annex I inclusion process and was considered to be acceptable and no further data have been generated.

~~Azoxystrobin residue feeding study in cows - Azoxystrobin residues have been shown to be up to 0.43 mg/kg in cereal grain and up to 3.5 mg/kg in kale; this corresponds to a dietary exposure level of 1.6 mg/kg diet (DM). It is therefore demonstrated that the level of azoxystrobin reaching human diets from ingestion of eggs and poultry meat will not exceed the LOQ of the method.~~

~~The maximum intakes of azoxystrobin, calculated using HRs are: 12.43mg/kg diet for beef cattle, 10.39 mg/kg diet for dairy cattle and 4.15 mg/kg diet for pig (all values are DM).~~
~~In the residue transfer study, cows were fed azoxystrobin at rates of 5 (0.4N), 25 (2N) and 250 (20 N) mg/kg diet for 30 consecutive days (N rates calculated on basis of intakes calculated for beef cattle:~~

~~12.43 mg/kg diet (DM) which represents worst case). Residues of azoxystrobin in the milk were very low from all the dose levels, ranging from 0.003 to 0.009 mg/kg. No residues of azoxystrobin above the limit of quantification (0.01 mg/kg) were found in the meat , kidney or fat of cows fed at 5 25 mg azoxystrobin/kg diet. Residues of azoxystrobin in the liver were <0.01 mg/kg from the 5 mg/kg dose level and 0.01 mg/kg from the 25 mg/kg dose level.~~
~~The level of azoxystrobin reaching human diets from ingestion of milk and meat will not exceed the LOQ of the method.~~

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	10.24/12.37 mg/kg DM (dairy/beef cattle)	1.36 mg/kg DM	3.84 mg/kg DM
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues	No	No	No
	Feeding studies: (Feeding rate up to 45N in poultry study and up to 24N in the cattle study) Residue levels in matrices : max (mg/kg)		
Muscle	<0.01 (20N dose)	<0.01 mg/kg (45N dose)	Not addressed
Liver	0.01 (2N dose)	<0.01 mg/kg (45N dose)	Not addressed
Kidney	0.01 (6N dose)	<0.01 mg/kg (45N dose)	Not addressed
Fat	0.02 mg/kg (6N dose)	<0.01 mg/kg (45N dose)	Not addressed
Milk	0.004 mg/kg (2N dose)		
Eggs		<0.01 mg/kg (45N dose)	

Table 7.2-10: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Azoxystrobin				
Beet, mangel	0.07	See point 7.2.9	0.51	See point 7.2.9
Beet sugar, tops	0.07	See point 7.2.9	0.51	See point 7.2.9
Rape, forage	0.014	See point 7.2.9	0.56	See point 7.2.9

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Turnip, tops (leaves)	0.07	See point 7.2.9	0.51	See point 7.2.9
Swede, roots	0.01	See point 7.2.9	0.01	See point 7.2.9
Turnip, roots	0.01	See point 7.2.9	0.01	See point 7.2.9
Soybean, seed	0.01	See point 7.2.9	-	-
Beet, sugar, dried pulp	0.18	See point 7.2.9	-	-
Beet, sugar, ensiled pulp	0.03	See point 7.2.9	-	-
Beet, sugar, molasses	0.28	See point 7.2.9	-	-
Canola (rape seed), meal	0.02	See point 7.2.9	-	-
Rape, meal	0.02	See point 7.2.9	-	-
Soybean, meal	0.01	See point 7.2.9	-	-
Soybean, hulls	0.08	See point 7.2.9	-	-
Wheat gluten, milled byproduts	0.02	See point 7.2.9	-	-

Table 7.2-11: Overview of the dietary burden calculation

Animal burden calculation — **AZOXYSTROBIN**

According to: "OECD Guidance Document, Series on testing and assessment No 64 and Series on pesticides No 32" and "OECD Guidance Document on Residues in livestock, Series on Pesticides No 73"

Maximum Intake	Cattle						Sheep					
	Beef (500 kg / 12 kg)			Dairy (650 kg / 25 kg)			Ram/Ewe (75 kg / 2.5 kg)			Lamb (40 kg / 1.7 kg)		
(mg/kg bw/d)	0.027	mg/kg bw/d	%	0.037	mg/kg bw/d	%	0.028	mg/kg bw/d	%	0.036	mg/kg bw/d	%
Contributor 1	Beet, mangel	fodder	30	Beet, mangel	fodder	25	Rape	forage	40	Rape	forage	40
Contributor 2	Beet, sugar	ensiled pulp	25	Beet, sugar	ensiled pulp	40	Beet, sugar	dried pulp	40	Beet, sugar	dried pulp	40
Contributor 3	Swede	roots	40	Swede	roots	20	Swede	roots	20	Swede	roots	20
Contributor 4	Soybean	seed	5	Soybean	seed	10			0			0
Median intake	0.0054	mg/kg bw/d		0.0082	mg/kg bw/d		0.0078	mg/kg bw/d		0.0123	mg/kg bw/d	

Maximum Intake	Swine					
	Breeding (260 kg / 6 kg)			Finishing (100 kg / 3 kg)		
(mg/kg bw/d)	0.014	mg/kg bw/d	%	0.002	mg/kg bw/d	%
Contributor 1	Beet, mangel	fodder	15	Beet, sugar	dried pulp	20
Contributor 2	Beet, sugar	dried pulp	20	Swede	roots	40
Contributor 3	Swede	roots	40	Soybean	seed	20
Contributor 4	Soybean	seed	10			
Median intake	0.004	mg/kg bw/d		0.002	mg/kg bw/d	

Intakes >0.004 mg/kg bw/d are highlighted

Maximum Intake	Poultry								
	Broiler (1.7 kg / 0.12 kg)			Layer (1.9 kg / 0.13 kg)			Turkey (7 kg / 0.5 kg)		
(mg/kg bw/d)	0.001	mg/kg bw/d	%	0.014	mg/kg bw/d	%	0.001	mg/kg bw/d	%
Contributor 1	Swede	roots	10	Rape	forage	10	Swede	roots	10
Contributor 2	Soybean	hulls	5	Swede	roots	10	Canola	meal	20
Contributor 3	Soybean	seed	20	Soybean	hulls	5	Soybean	seed	15
Contributor 4				Soybean	seed	15			
Median intake	0.001	mg/kg bw		0.004	mg/kg bw		0.001	mg/kg bw	

Intakes expressed on the dry mater basis (mg/kg DM)

mg/kg DM	Cattle		Sheep		Swine	
	Beef	Dairy	Ram/Ewe	Lamb	Breeding	Finishing
Maximum	1.11	0.95	0.8	0.85	0.59	0.08
Median	0.23	0.21	0.23	0.29	0.17	0.08

	Poultry		
	Broiler	Layer	Turkey
Maximum	0.02	0.20	0.02
Median	0.02	0.06	0.02

Intake >0.1 mg/kg DM in red characters

zRMS comments:
The calculation of the dietary burden was conducted considering the uses evaluated by EFSA, (EFSA Journal 2022;20(1):705).

Relevant groups (sub-groups)	Dietary burden expressed in				Most critical subgroup[a]	Most critical commodity[b]	Trigger exceeded (Y/N)	Previous assessment (EFSA, 2020)
	mg/kg bw per day		mg/kg DM					mg/kg DM
	Median	Maximum	Median	Maximum				Maximum
Cattle (all)	0.46	0.59	11.97	15.35	Dairy cattle	Citrus, dried pulp	Y	15.35
Cattle (dairy only)	0.46	0.59	11.97	15.35	Dairy cattle	Citrus, dried pulp	Y	15.35
Sheep (all)	0.10	0.23	2.85	5.79	Lamb	Rye, straw	Y	5.79
Sheep (ewe only)	0.10	0.19	2.85	5.79	Ram/Ewe	Rye, straw	Y	5.79
Swine (all)	0.20	0.25	8.76	10.60	Swine (breeding)	Citrus, dried pulp	Y	10.60
Poultry (all)	0.05	0.10	0.66	1.42	Poultry layer	Wheat, straw	Y	1.42
Poultry (layer only)	0.05	0.10	0.66	1.42	Poultry layer	Wheat, straw	Y	1.42
Fish	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

bw: body weight; DM: dry matter; n.a.: not applicable.
(a): When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup 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 respective trigger values are exceeded indicating the requirement of livestock feeding studies for all species.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

According to DAR, Azoxystrobin – Volume 3 B.7, May 2009 and EFSA Journal 2010; 8(4): 1542 new livestock feeding studies are performed during Annex I inclusion and renewal. No new livestock studies feeding studies are necessary.

Azoxystrobin residue feeding study in cows– Azoxystrobin residues have been shown to be up to 0.43 mg/kg in cereal grain and up to 3.5 mg/kg in kale; this corresponds to a dietary exposure level of 1.6 mg/kg diet (DM). It is therefore demonstrated that the level of azoxystrobin reaching human diets from ingestion of eggs and poultry meat will not exceed the LOQ of the method.

The maximum intakes of azoxystrobin, calculated using HRs are: 12.43mg/kg diet for beef cattle, 10.39 mg/kg diet for dairy cattle and 4.15 mg/kg diet for pig (all values are DM).
In the residue transfer study, cows were fed azoxystrobin at rates of 5 (0.4N), 25 (2N) and 250 (20 N) mg/kg diet for 30 consecutive days (N rates calculated on basis of intakes calculated for beef cattle: 12.43 mg/kg diet (DM) which represents worst case). Residues of azoxystrobin in the milk were very low from all the dose levels, ranging from 0.003 to 0.009 mg/kg. No residues of azoxystrobin above the limit of quantification (0.01 mg/kg) were found in the meat , kidney or fat of cows fed at 5-25 mg azoxystrobin/kg diet. Residues of azoxystrobin in the liver were <0.01 mg/kg from the 5 mg/kg dose level and 0.01 mg/kg from the 25 mg/kg dose level.
The level of azoxystrobin reaching human diets from ingestion of milk and meat will not exceed the LOQ of the method.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	**Poultry:**	**Pig:**
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	10.24/12.37 mg/kg DM (dairy/beef cattle)	1.36 mg/kg DM	3.84 mg/kg DM
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues	No	No	No
	Feeding studies: (Feeding rate up to 45N in poultry study and up to 24N in the cattle study) Residue levels in matrices : max (mg/kg)		
Muscle	<0.01 (20N dose)	<0.01 mg/kg (45N dose)	Not addressed
Liver	0.01 (2N dose)	<0.01 mg/kg (45N dose)	Not addressed
Kidney	0.01 (6N dose)	<0.01 mg/kg (45N dose)	Not addressed
Fat	0.02 mg/kg (6N dose)	<0.01 mg/kg (45N dose)	Not addressed
Milk	0.004 mg/kg (2N dose)		
Eggs		<0.01 mg/kg (45N dose)	

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

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	Calculated MRL (mg/kg)	CF for RA[d]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) [C]	No	Residues at the closest feeding		Estimated value at 1N					
					Mean (mg/kg)	Max. (mg/kg)	Mean[a] (mg/kg)	Max.[b] (mg/kg)				
EU data (EFSA Journal 2020;18(8):6231)												
Cattle (all) Muscle	0.0045	0.026	0.91	1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
Cattle (all) Fat	0.0045	0.026	0.91	2	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
Cattle (all) Liver	0.0045	0.026	0.91	3	0.01	0.01	<0.01	<0.01	<0.01	<0.01	0.01* [f]	1
Cattle (dairy only) [d] Milk	0.0075	0.036	0.91	4	<0.01	n.a.	<0.01	<0.01	<0.01	<0.01	0.01*[f]	1
Sheep (all) [e] Muscle	0.0068	0.028	0.18	5	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
Sheep (all) [e] Fat	0.0068	0.028	0.18	6	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
Sheep (all) [e] Liver	0.0068	0.028	0.18	7	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*[f]	1
Sheep (all) [e] Kidney	0.0068	0.028	0.18	8	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*[f]	1
Sheep (ewe only) Milk	0.0115	0.035	0.18	9	<0.01	n.a.	<0.01	<0.01	<0.01	<0.01	0.01*	1
Swine (all) [e] Muscle	0.003	0.013	0.18	10	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1

Swine (all) [e] Fat	0.003	0.013	0.18	11	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
Swine (all) [e] Liver	0.003	0.013	0.18	12	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*[f]	1
Swine (all) [e] Kidney	0.003	0.013	0.18	13	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*[f]	1
Poultry (all) Muscle	0.004	0.013	0.39	14	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
Poultry (all) Fat	0.004	0.013	0.39	15	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
Poultry (all) Liver	0.004	0.013	0.39	16	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1
Poultry (layer only) Eggs	0.004	0.013	0.39	17	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01*	1

n.a.: not applicable.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): Median residues recalculated at the 1N rate for the median dietary burden.
(b): Highest residues recalculated at the 1N rate for the maximum dietary burden.
(c): Closest feeding level and N dose rate related to the maximum dietary burden.
(d): For milk, mean was derived from samplings performed from day 1 to day 30 (daily mean of four cows)
e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study onruminants were relied upon to derive the MRL and risk assessment values in sheep and swine,
(f): Noting that the general toxicity of metabolites L1, L4 and L9 (found in liver and kidney) was not addressed.

Conclusion on feeding studies

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

zRMS comments:
According to EFSA Journal 2013;11(12):3497: "During the peer review under Directive 91/414/EEC, the magnitude of azoxystrobin residues in livestock was investigated in feeding studies with lactating cows and laying hens (United Kingdom, 2009a). Four groups of lactating cows, each consisting of three animals, were dosed for 30 consecutive days with azoxystrobin at levels of 5, 25, 75 and 250 mg/kg in the diet (equivalent to 0.18, 0.91, 2.73 and 9.09 mg/kg bw). Three groups of laying hens, each consisting of twelve animals were dosed for 28 consecutive days with azoxystrobin at levels of 6, 18, and 60 mg/kg in the diet (equivalent to 0.39, 1.2 and 3.9 mg/kg bw). The samples were analyzed for parent azoxystrobin. Results of both livestock feeding studies are summarized in Table 3-8. In milk and eggs, a plateau level was never reached and no residues at or above 0.01 mg/kg was found in any of the samples.
The storage stability of azoxystrobin residues in animal products was evaluated under the peer review of Directive 91/414/EEC (United Kingdom, 2009a). Studies demonstrated storage stability of azoxystrobin in milk, muscle, fat, liver and kidney, eggs for up to 10 months when stored deep frozen. According to the RMS, all samples reported in the PROFile were stored in compliance with the above reported storage conditions."

The established MRLs for azoxystrobin in animal products are sufficient.

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 were reviewed during the Annex I inclusion of Azoxystrobin were considered acceptable. No further studies have been performed.~~
~~Under conditions designed to mimic pasteurisation, baking, brewing, boiling and sterilization there was no significant hydrolysis of azoxystrobin following incubation at different pH values and temperatures. Azoxystrobin in stable under conditions representative of pasteuristaion, baking, brewing, boiling and sterilisation and no additional metabolites are formed in processed commodities as compared to raw agricultural commodities. The definition of the residue in processed commodities as compared to raw agricultural commodities. The definition of the residue in processed crop commodities is azoxystrobin only.~~
~~Effects on residue levels have been investigated in studies on three crops, beans, barley and wheat – Three mass balance studies were conducted for the cooking and canning of beans. For barley two processes were investigated:~~
~~Malting and brewing; one balance and three follow-up studies~~
~~Production of pot barley; two balance and two follow-up studies~~
~~For wheat two sequentional processes were investigated:~~
~~Milling: one balance and three follow-up, followed by~~
~~Baking: one balance and three follow-up~~

Studies on Industrial Processing and/or Household Preparation are not relevant, because residues in magnitude of the residues in the plant matrices are below 0.1 mg/kg.

zRMS comments:
According to the Commission Reg. (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. The contribution of sugar beet roots to the TMDI is

21 %, processing studies are required. However, it should be noted that the results of azoxystrobin residue studies following GAP compliant CHR/F/SCORPIO 325 SC application indicate no residues in roots above the limit of quantification. In addition, according to EFSA Journal 2013;11(12):3497: "The effect of processing on the nature of azoxystrobin was investigated in the framework of the peer review. Studies were conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). From these studies, it was concluded that processing by pasteurization, baking/brewing/boiling and sterilization is not expected to have a significant impact on the composition of residues in matrices of plant origin (United Kingdom, 2009a). The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops.
Studies investigating the magnitude of residues in processed commodities of grapes, wheat, barley and fresh beans with pods were reported in the framework of the peer review (United Kingdom, 2009a). After azoxystrobin was included in Annex I to Directive 91/414/EEC, studies investigating the magnitude of residues in processed commodities of oranges, strawberries, bananas, tomatoes, fresh beans without pods, rice and hops were evaluated by EFSA or EMSs. An overview of all available processing studies is available in Table 3-3. Robust processing factors for enforcement and risk assessment were derived for peeled bananas, white wine, must, grape juice, grape pomace (wet and dry), brewing malt, beer, barley pot, barley bran, whole-meal and white flour, bread, wheat bran, fresh beans with pods cooked and canned. The processing factors reported for the other processed commodities should be considered as indicative as a minimum of 3 processing studies is normally required.
Nevertheless, further processing studies are not required for the time being as they are not expected to affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed in the future."

Table 3-3: Overview of the available processing studies

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Enforcement residue definition: azoxystrobin				
Processing factors recommended (sufficiently supported by data)				
Bananas, peeled	6	0.04	1.00	PROFile
Wine grapes, must	6	0.51	1.00	United Kingdom, 2009a
Wine grapes, white wine	6	0.52	1.00	
Wine grapes, juice	4	0.34	1.00	
Wine grapes, dry pomace	4	4.79	1.00	
Wine grapes, wet pomace	4	3.16	1.00	
Barley, brewing malt	4	0.19	1.00	Processing factor for malt, beer and pot are actually lower than the value reported as residues were below the LOQ (worst case assumption) (United Kingdom, 2009a)
Barley, beer	4	0.23	1.00	
Barley, pot/pearl	4	0.25	1.00	
Barley, bran	4	3.25	1.00	

Processed commodity	Number of studies	Median PF [a]	Median CF [b]	Comments
Wheat/rye, whole-meal flour	4	0.68	1.00	United Kingdom, 2009a
Wheat/rye, whole-meal bread	4	0.51	1.00	
Wheat/rye, white flour	4	0.45	1.00	
Wheat/rye, bran	4	1.67	1.00	
Beans (fresh, with pods), cooked	3	0.29	1.00	Processing factor for cooked beans is lower than 0.29 as residues were below the LOQ (worst case assumption). DAR (United Kingdom, 2009a)
Beans (fresh, with pods), canned	3	0.42	1.00	
Hops, beer	3	0.00	1.00	Additional PF: spent hops: 0,053; wort: 0,005; spent yeast: 0,016 (PROFile).
Indicative processing factors (limited dataset)				
Oranges, juice	1	0.08	1.00	PROFile
Oranges, dry pomace	1	0.42	1.00	
Strawberries, jam	2	0.36	1.00	PROFile
Strawberries, canned	2	0.90	1.00	PROFile
Tomatoes, peeled and canned	2	0.12	1.00	Canned/peeled tomatoes: no residues in processed product (PROFile).
Tomatoes, paste	2	0.99	1.00	
Tomatoes, ketchup	2	0.48	1.00	
Tomatoes, juice	2	0.32	1.00	
Beans (fresh, without pods), cooked	2	0.05	1.00	PROFile
Beans (fresh, without pods), canned	2	0.30	1.00	
Wheat/rye, white bread	2	0.57	1.00	United Kingdom, 2009a
Rice, polished	1	0.09	1.00	PROFile
Rice, bran	1	1.18	1.00	

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

Additional processing studies are not required as they are not expected to affect the outcome of the risk assessment.

7.2.5.1 Available data for all crops under consideration

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

~~**Table 7.2-13: Overview of the available processing studies**~~

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Bean processing studies were evaluated to support uses on cauliflower, broccoli, kale (leafy brassicas) and Brussels sprouts.

Crop / processed crop	Number of studies	Transfer factor	% Transference*
Beans with pods → tips	3	1.6	
Beans with pods → trimmed beans	3	0.41	
Beans with pods → blanched beans	3	<0.3	
Beans with pods → canned beans	3	0.42	
Beans with pods → cooked beans	3	<0.29	
Barley grain → cleaned grain	1	0.8	
Barley grain → malt	4	<0.19	
Barley grain → malt sprouts	1	0.4	
Barley grain → spent grain	3	0.61	
Barley grain → flocs	1	0.6	
Barley grain → wort	2	<0.35	
Barley grain → spent yeast	3	0.31	
Barley grain → young beer	2	<0.35	
Barley grain → beer	4	<0.23	
Barley grain → abrasion dust	4	3.25	
Barley grain → pot barley	4	<0.25	
Wheat → cleaned grain	2	0.42	
Wheat → offal/screenings	2	12.4	
Wheat → bran	4	1.67	
Wheat → flour type 550	4	0.45	
Wheat → wholemeal flour	4	0.68	

7.2.5.2 Conclusion on processing studies

N/A

zRMS comments:
Additional processing studies are not required as they are not expected to affect the outcome of the risk assessment.

7.2.6 Magnitude of residues in representative succeeding crops

~~Crops under evaluation are not expected to be grown in rotation. Further investigation of residues in rotational crops is therefore not required.~~

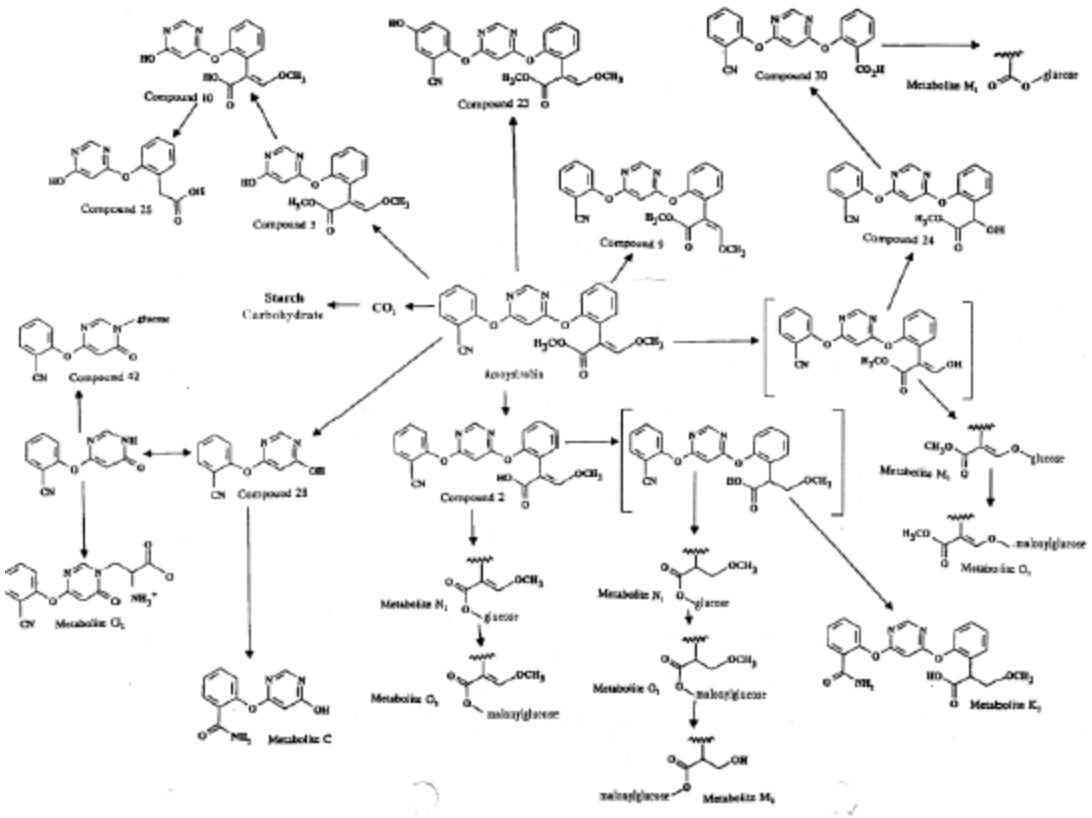
Crops under evaluation are expected to be grown in rotation. Further investigation of residues in rotational crops is therefore required.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.
Data/information on residues in succeeding crops were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated. Three separate studies were carried out using 14C-labelled azoxystrobin in either the cyanophenyl-,pyrimidinyl- or phenylacrylate ring to study the metabolism of azoxystrobin in succeeding crops. The rotational crops studies were radish , lettuce and wheat. Based on three studies available the identification and the beahaviour of breakdown and reaction products and of metabolites in rotational crops were cleared up. The metabolism of azoxystrobin in succeeding crops is almost similar for all the analysed crops and also similar to that observed in the primary crops.

Proposed metabolism of azoxystrobin in rotational crops:



The three field rotational crop studies conducted in the USA and summarised in Evans , P 2009 were all conducted at exaggerated rates (compared with the proposed use pattern of azoxystrobin in cereals and brassicae in the EU).
The RMS concludes that the field rotational crop studies provide sufficient evidence to demonstrate that relevant residues (with reference to SANCO 7254) are not present and none of the already established MRLs will be exceed as a result of the cultivation of rotational crops.

Table 7.2-14: Summary of available studies in field rotational crops

Residues of azoxystrobin from field rotational crops

Crop Type	Crop (part)	Trial	Highest Residue Found (mg/kg)*	Application Rate (g/ha)*	Field-rate residue** (mg/kg)
Leafy vegetable	Mustard Greens	04-IL-95-521	<0.01	896	<0.01
		01-NC-95-522	<0.01	896	<0.01
		05-MS-95-526	<0.01	1792	<0.01
		01-NC-95-527	<0.01	1792	<0.01
	Leaf Lettuce	E5-FR-002-01	<0.01	2240	<0.01
		W2-FR-004/01/005-01	0.02	2240	<0.01
Root vegetable	Radish Tops	04-IL-95-521	<0.01	896	<0.01
	Turnip Tops	01-NC-95-522	<0.01	896	<0.01
		05-MS-95-526	<0.01	1792	<0.01
		01-NC-95-527	<0.01	1792	<0.01
	Beet Tops	E5-FR-002-01	<0.01	2240	<0.01
		W2-FR-004/01/005-01	0.02	2240	<0.01
Root vegetable	Radish Roots	04-IL-95-521	<0.01	896	<0.01
	Turnip Roots	01-NC-95-522	<0.01	896	<0.01
		05-MS-95-526	<0.01	1792	<0.01
		01-NC-95-527	<0.01	1792	<0.01
	Beet Roots	E5-FR-002-01	<0.01	2240	<0.01
		W2-FR-004/01/005-01	0.02	2240	<0.01

Residues of azoxystrobin from field rotational crops

Crop Type	Crop (part)	Trial	Highest Residue Found (mg/kg)*	Application Rate (g/ha)**	Field-rate residue** (mg/kg)
Cereal	Wheat Forage	04-IL-95-521	<0.01	896	<0.01
		01-NC-95-522	0.02	896	0.01
		05-MS-95-526	0.02	1792	<0.01
		01-NC-95-527	0.02	1792	<0.01
		E5-FR-001-01	0.04	2240	<0.01
		W2-FR-004/01/005-01	0.21	2240	0.05
Cereal	Wheat Hay	04-IL-95-521	<0.01	896	<0.01
		01-NC-95-522	<0.01	896	<0.01
		05-MS-95-526	0.01	1792	<0.01
		01-NC-95-527	<0.01	1792	<0.01
		E5-FR-001-01	0.03	2240	<0.01
		W2-FR-004/01/005-01	0.12	2240	0.03
Cereal	Wheat Straw	04-IL-95-521	<0.01	896	<0.01
		01-NC-95-522	<0.01	896	<0.01
		05-MS-95-526	0.04	1792	0.01
		01-NC-95-527	0.01	1792	<0.01
		E5-FR-001-01	0.09	2240	0.02
		W2-FR-004/01/005-01	0.19	2240	0.04
Cereal	Wheat Grain	04-IL-95-521	<0.01	896	<0.01
		01-NC-95-522	<0.01	896	<0.01
		05-MS-95-526	<0.01	1792	<0.01
		01-NC-95-527	<0.01	1792	<0.01
		E5-FR-001-01	<0.01	2240	<0.01
		W2-FR-004/01/005-01	<0.01	2240	<0.01

Conclusion on rotational crops studies

No risk mitigation measures are necessary.

zRMS comments:
Rotational crop studies were evaluated at EU level. According to the EFSA Journal 2013;11(12):3497: "the confined rotational crop study, several rotational crop field trials were evaluated in the framework of the peer review (United Kingdom, 2009a, 2009b). Azoxystrobin was applied on wheat, cucumber or lettuce at 2 x 0.896 kg a.s./ha, 7-8 x 0.224 kg a.s./ha and 6 x 0.373 kg a.s./ha respectively. After harvest of these crops, rotational crops (mustard, lettuce, radish, turnip, beetroot and wheat) were sown at one, two or three different plant-back intervals (29 to 60 days following application of the active substance) and magnitude of residues was investigated in the different commodities thereof. Considering that all trials were overdosed, a correction factor was applied to the highest residue found in each commodity. At harvest, azoxystrobin residues were expected to be below the LOQ (0.01 mg/kg) in all mature plant parts

except in wheat forage and wheat straw. The highest residues were expected to be 0.05 mg/kg and 0.04 mg/kg, respectively. However, although these residues might increase the dietary burden intake of livestock, no impact on the residue level in products of animal origin is awaited (see also section 3.2.3). These studies are considered sufficient by EFSA to demonstrate that residues in rotational crops have no impact on the MRLs in plants and livestock products, provided that azoxystrobin is applied in compliance with the GAPs reported in Appendix A."

Residues in rotational crops have been sufficiently investigated taking into account the cGAP uses being considered for CHR/F/SCORPIO 325 SC. It is very unlikely that residues will present in rotational crops.

7.2.7 Other / special studies (KCA 6.10, 6.10.1)

The residue in honey are expected after pesticide application. (the zonal uses application from GAP table – on winter oilseed rape is during the flowering stage of a crop which is forage by bees.

The new study was conducted as four field trials in Germany (2 trials), Southern France (1 trial) and Spain (1 trial) in 2022/2023.

There were two applications, both at a nominal rate of 1000 mL formulated product/ha in 300 L water/ha (equivalent to 125 g difenoconazole/ha and 200 g azoxystrobin/ha).

Table 3: Summary of residues of Azoxystrobin, Difenoconazole and Metabolites of Difenoconazole (1,2,4 triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA)) Residues in Honey Samples

Sampling code	Trial No.	Sample timing	Treatment	Sample	Residues					
					Azoxy-strobin	Difeno-conazole	1,2,4-T	TA	TAA	TLA
					[mg/kg]					
S1	-01	04 May 2023	C	A1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
			T	A1	<0.01	<0.01	<0.01	0.02	<0.01	<0.01
S1	-02	24 Apr 2023	C	A1	<0.01	<0.01	<0.01	0.01	<0.01	<0.01
			T	A1	<0.01	<0.01	<0.01	0.01	<0.01	<0.01
S1	-04	04 May 2023	C	A1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
			T	A1	<0.01	0.014	<0.01	0.01	<0.01	<0.01
S1	-05	13 Apr 2023	C	A1	<0.01	<0.01	<0.01	0.03	<0.01	<0.01
			T	A1	<0.01	0.012	<0.01	0.04	<0.01	<0.01

C: control sample; T: treated sample,
LOQ = Limit of quantification (0.01 mg/kg), LOD = Limit of detection (0.003 mg/kg)

No residues of Azoxystrobin, Difenoconazole, 1,2,4 triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) at or above 30 % of the LOQ were detected in any of the untreated honey samples. Residues of triazole alanine (TA) were detected in untreated honey samples of trial -02 with 0.01 mg/kg and of trial -05 at 0.03 mg/kg. No residues of Azoxystrobin, 1,2,4 triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) at or above 30 % of the LOQ were detected in any of the treated honey samples.
The results are below the MRL value – 0.05 mg/kg.

zRMS comments:

For oilseed rape application new magnitude of residues in honey were provided.
The Applicant provided 4 adequate studies performed for the SC formulation. All of them are covered by stability studies. The studies were performed in accordance with the proposed GAP in terms of the number of applications, application rate and growth stage.
All studies showed no azoxystrobin residues above LOQ in honey.
For honey, the max. storage interval from sampling until extraction was 102 days for difenoconazole and azoxystrobin, and 98 for the triazole metabolites.
The data submitted show that no exceedance of the MRL (0.05 mg/kg for honey according to Reg. (EU) 2024/2633.

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

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

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-15: 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 Azoxystrobin				
Winter oilseed rape	1	Reg. (EU) 2024/2633	1	Reg. (EU) 2024/2633
Celeriacs, Horseradish, swedes	1.0	Reg. (EU) 2024/2633	1.0	Reg. (EU) 2024/2633
Pumpkin	1.0	Reg. (EU) 2024/2633	1.0	Reg. (EU) 2024/2633
Poppy seed, sunflower seed, soybeans, mustard seed	0.5	Reg. (EU) 2024/2633	0.5	Reg. (EU) 2024/2633
Rapeseed seeds	0.7	Reg. (EU) 2024/2633	0.7	Reg. (EU) 2024/2633
Hemp seed	0.01	Reg. (EU) 2024/2633	0.01	Reg. (EU) 2024/2633
Sugar beet roots	5.0	Reg. (EU) 2024/2633	5.0	Reg. (EU) 2024/2633
Chicory roots	0.09	Reg. (EU) 2024/2633	0.09	Reg. (EU) 2024/2633
Honey	0.05	Reg. (EU) 2024/2633	0.05	Reg. (EU) 2024/2633
Swine: Muscle/meat	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Swine: Fat tissue	0.050	Reg. (EU) 2024/2633	0.050	Reg. (EU) 2024/2633
Swine: Liver	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633
Swine: Kidney	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633
Swine: Edible offals (other than liver and kidney)	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633
Swine: Other products	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Bovine: Muscle/meat	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Bovine: Fat tissue	0.050	Reg. (EU) 2024/2633	0.050	Reg. (EU) 2024/2633
Bovine: Liver	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633
Bovine: Kidney	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633
Bovine: Edible offals (other than liver and kidney)	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633
Bovine: Other products	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Sheep: Muscle/meat	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Sheep: Fat tissue	0.050	Reg. (EU) 2024/2633	0.050	Reg. (EU) 2024/2633
Sheep: Liver	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633
Sheep: Kidney	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633
Sheep: Edible offals (other than liver and kidney)	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633
Sheep: other products	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Goat: Muscle/meat	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Goat: Fat tissue	0.050	Reg. (EU) 2024/2633	0.050	Reg. (EU) 2024/2633
Goat: Liver	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Goat: Kidney	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633
Goat: Edible offals (other tha liver and kindey)	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633
Goat: other products	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Equine: Muscle/meat	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Equine: Fat tissue	0.050	Reg. (EU) 2024/2633	0.050	Reg. (EU) 2024/2633
Equine: Liver	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633
Equine: Kidney	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633
Equine: Edible offals (other than liver and kidney)	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633
Equine: Other products	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Poultry: Muscle/meat	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Poultry: Fat tissue	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Poultry: Liver	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Poultry: Kidney	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Poultry: Edible offals (other than liver and kideny)	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Poultry: Other products	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Other farmed animals: Muscle/meat	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Other farmed animals: Fat tissue	0.050	Reg. (EU) 2024/2633	0.050	Reg. (EU) 2024/2633
Other farmed animals: Liver	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633
Other farmed animals: Kidney	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633
Other farmed animals: Edible offals (other than liver and kidney)	0.070	Reg. (EU) 2024/2633	0.070	Reg. (EU) 2024/2633

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Other farmed animals: Other products	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Milk: Cattle	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Milk: Sheep	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Milk: Goat	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Milk: Horse	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Milk: Others	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Eggs: Chicken	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Eggs: Duck	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Eggs: Goose	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Eggs: Quail	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633
Eggs: Others	0.010	Reg. (EU) 2024/2633	0.010	Reg. (EU) 2024/2633

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-16: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	21 % for sugar beet roots (based on NL child)
IEDI (% ADI) according to EFSA PRIMo	0.3% for milk: cattle(based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo	Not necessary

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

The proposed uses of azoxystrobin in the formulation CHR/F/SCORPIO 325 SC do not represent unacceptable risk for the consumer.

zRMS comments:
zRMS performed a chronic dietary risk assessment using revision 3.1 of the EFSA PRIMo and all applicable MRLs (Reg. (EU) 2024/2633) as input values.
Considering the toxicological profile of the active substance, a short-term dietary risk assessment was not

required.

TMDI (% ADI) according to EFSA PRIMo	82 % (based on NL child)
IEDI (% ADI) according to EFSA PRIMo	Not necessary
IESTI (% ARfD) according to EFSA PRIMo	Not necessary

EFSA PRIMo revision 3.1; 2021/01/06

Azoxystrobin

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day): 0,2 ARfD (mg/kg bw): nn

Source of ADI: Source of ARfD:

Year of evaluation: Year of evaluation:

Input values

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
82%	NL toddler	164,42	17%	Oranges	15%	Potatoes	13%	Sugar beet roots		
69%	DE child	137,73	30%	Oranges	9%	Potatoes	3%	Mandarins		
68%	NL child	135,17	21%	Sugar beet roots	12%	Potatoes	11%	Oranges		
56%	FR child 3 15 yr	112,53	26%	Oranges	9%	Sugar beet roots	5%	Potatoes		
49%	GEMS/Food G06	98,99	7%	Oranges	7%	Potatoes	5%	Tomatoes		
48%	UK toddler	95,87	15%	Oranges	12%	Potatoes	8%	Sugar beet roots		
47%	IE adult	93,60	8%	Potatoes	8%	Oranges	5%	Grapefruits		
46%	GEMS/Food G07	91,17	13%	Potatoes	10%	Oranges	2%	Wine grapes		
44%	GEMS/Food G10	88,63	10%	Potatoes	8%	Oranges	3%	Rice		
44%	FR toddler 2 3 yr	88,04	11%	Oranges	7%	Sugar beet roots	7%	Potatoes		
44%	GEMS/Food G11	87,09	14%	Potatoes	5%	Oranges	3%	Lemons		
43%	DE women 14-50 yr	86,85	14%	Oranges	11%	Sugar beet roots	4%	Potatoes		
42%	SE general	84,96	15%	Potatoes	6%	Oranges	3%	Mandarins		
41%	GEMS/Food G08	81,64	14%	Potatoes	3%	Oranges	3%	Onions		
40%	DE general	79,25	12%	Oranges	11%	Sugar beet roots	4%	Potatoes		
39%	GEMS/Food G15	78,01	12%	Potatoes	5%	Oranges	3%	Onions		
39%	PT general	77,09	19%	Potatoes	5%	Oranges	4%	Wine grapes		
38%	RO general	76,13	13%	Potatoes	4%	Onions	4%	Head cabbages		
36%	NL general	72,22	9%	Potatoes	8%	Oranges	7%	Sugar beet roots		
36%	ES child	72,21	16%	Oranges	6%	Potatoes	2%	Lettuces		
36%	UK infant	71,27	11%	Potatoes	10%	Oranges	4%	Sugar beet roots		
33%	FI 3 yr	66,89	17%	Potatoes	3%	Mandarins	2%	Onions		
27%	FI 6 yr	53,74	14%	Potatoes	2%	Mandarins	1%	Onions		
26%	ES adult	51,21	10%	Oranges	3%	Potatoes	3%	Lettuces		
23%	FR infant	46,40	7%	Potatoes	3%	Sugar beet roots	2%	Spinaches		
23%	UK vegetarian	46,20	6%	Oranges	5%	Potatoes	1%	Sugar beet roots		
23%	DK child	45,03	9%	Potatoes	1%	Rye	1%	Oranges		
21%	IT toddler	42,92	4%	Oranges	3%	Potatoes	2%	Tomatoes		
21%	FR adult	42,41	4%	Oranges	3%	Wine grapes	3%	Potatoes		
20%	PL general	39,50	12%	Potatoes	2%	Onions	1%	Tomatoes		
19%	IT adult	38,02	3%	Oranges	2%	Potatoes	2%	Lettuces		
19%	UK adult	37,99	5%	Potatoes	4%	Oranges	2%	Wine grapes		
16%	LT adult	32,50	11%	Potatoes	1,0%	Head cabbages	0,9%	Tomatoes		
14%	FI adult	28,97	4%	Potatoes	3%	Oranges	1%	Mandarins		
13%	DK adult	26,95	4%	Potatoes	1%	Wine grapes	1%	Oranges		
6%	IE child	11,31	2%	Potatoes	0,7%	Rice	0,6%	Oranges		

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

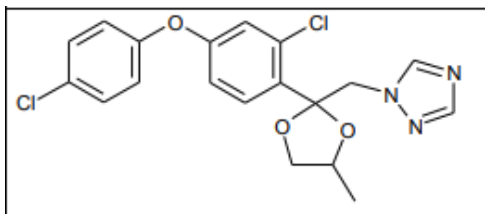
The proposed uses of azoxystrobin in the formulation CHR/F/SCORPIO 325 SC do not represent unacceptable acute and chronic risks for consumers.
It is noted that the uncertainty in the consumer risk assessment related to the calculated consumer exposure to livestock metabolites L1, L4, L9 and K1 (conjugate of L1) highlighted in the framework of the MRL review of the confirmatory data is still valid (EFSA, 2020).

7.3 Difenoconazole

General data on difenoconazole are summarized in the table below

Table 7.3-1: General information on difenoconazole

Active substance (ISO Common Name)	difenoconazole
IUPAC	3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether

Chemical structure	
Molecular formula	$C_{19}H_{17}Cl_2N_3O_3$
Molar mass	406.3
Chemical group	Conazole fungicide
Mode of action (if available)	a sterol demethylation inhibitor which prevents the development of the fungus by inhibiting cell membrane ergosterol biosynthesis
Systemic	Yes
Company (ies)	Syngenta
Rapporteur Member State (RMS)	The original was Sweden, for ongoing renewal ES
Approval status	Date of approval 01.01.2009, Reg. (EU) 540/2011 COMMISSION IMPLEMENTING REGULATION (EU) 2021/1449
Restriction	Reg. (EU) 540/2011 Only uses as fungicide may be authorised.
Review Report	SANCO/830/08 – rev. 3 18 March 2020
Current MRL regulation	Reg. (EU) 2024/2633
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	~~EFSA Journal 2023;21(8):8207~~ Yes
EFSA Journal : Conclusion on the peer review	EFSA Journal 2011;9(1):1967
EFSA Journal: conclusion on article 12	~~EFSA Journal 2011;9(1):1967~~ EFSA Journal. 2024;22:e8987
Current MRL applications on intended uses	None

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

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

~~No new data submitted in the framework of this application~~

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Potato	High water content	24 month	EFSA Journal 2011;9(1):1967
Tomato	High water content	24 month	EFSA Journal 2011;9(1):1967
Cotton	High oil content	24 month	EFSA Journal 2011;9(1):1967
Wheat (straw, forage, grain)	High starch content High water content Different matrices	24 month	EFSA Journal 2011;9(1):1967
Lettuce (head)	High water content	12 month	EFSA Journal 2011;9(1):1967
Soybean	High oil content	12 month	EFSA Journal 2011;9(1):1967
Banana	High water content	12 month	EFSA Journal 2011;9(1):1967
Oilseed rape seed (stability storage of the triazole metabolites 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid)	High oil content	303 d	S. Niewelt-Stasiak, 2022
Oilseed rape plant (stability storage of the triazole metabolites 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid)	High oil content	301 d	S. Niewelt-Stasiak, 2022
Oilseed rape straw (stability storage of the triazole metabolites 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid)	High oil content	300 d	S. Niewelt-Stasiak, 2022
Animal products			
Eggs, milk, poultry breast and beef liver	Animal matrices	12 months	EFSA Journal 2011;9(1):1967
Honey (stability storage of the triazole metabolites 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid)	Honey	15 months	S. Mahlow, 2023, Report no S21-05867, see dRR Part B5
Honey (stability of difenoconazole)	Honey	104 days	S. Mahlow, 2023, Report no S22-08436, see dRR Part B5

Conclusion on stability of residues during storage

The storage stability evaluated during Annex I inclusion covers plant matrices for use CHR/F/SCORPIO 325 SC according to the label.

zRMS comments:
The Applicant provided storage stability studies for triazole metabolites in oilseed rape (seed, plant and straw) and for difenoconazole and triazole metabolites in honey.
Honey
S. Mahlow, 2023, Report no S21-05867, see dRR Part B5

Storage Period	Concurrent Recoveries		Storage Samples			
	Single Values (%)	Mean (%) [a] in brackets: rel. std. deviation (%)	Percentage of analyte found relative to the nominal fortification level (%)		Percentage recovered corrected for the (mean) concurrent recovery of the individual date of extraction [a]	Percentage recovered relative to the mean percentage recovered at Day 0 [a]
			Single Values (%) [b]	Mean [a] in brackets: rel. std. deviation (%)		
Analyte: 1,2,4-Triazole		Matrix Type: Honey		Nominal Fortification Level: 0.1 mg/kg (10x LOQ)		
0 days	-	-	82, 92, 90	88 (5.8)	-	-
3 months (96 days)	109, 97	103	118, 120	119	116	135
15 months (459 days)	89, 88	89	91, 92	92	103	104
Analyte: Triazole alanine		Matrix Type: Honey		Nominal Fortification Level: 0.1 mg/kg (10x LOQ)		
0 days	-	-	88, 85, 85	86 (2.1)	-	-
3 months (96 days)	80, 84	82	112, 102	107	130	125
15 months (459 days)	97, 92	94	100, 100	100	106	117
Analyte: Triazole acetic acid		Matrix Type: Honey		Nominal Fortification Level: 0.1 mg/kg (10x LOQ)		
0 days	-	-	93, 93, 90	92 (1.4)	-	-
3 months (96 days)	84, 83	83	101, 92	96	116	105
15 months (459 days)	95, 87	91	102, 89	96	105	104
Analyte: Triazole lactic acid		Matrix Type: Honey		Nominal Fortification Level: 0.1 mg/kg (10x LOQ)		
0 days	-	-	82, 78, 80	80 (2.3)	-	-
3 months (96 days)	94, 91	92	120, 118	119	129	148
15 months (459 days)	90, 83	86	83, 92	87	101	109

[a] calculated from unrounded values; [b] not corrected for concurrent recoveries

The study is deemed sufficient for asssessing the stability of triazole metabolites (1,2,4-T, TA, TAA, TLA) in honey upon storage at ≤ -18 °C for 15 months (459 days).

S. Mahlow, 2023, Report no S22-08436, see dRR Part B5

Storage Period	Procedural Recoveries		Storage Samples			
	Single Values (%)	Mean (%) [a] in brackets: rel. std. deviation (%)	Percentage of analyte found relative to the nominal fortification level (%)		Percentage recovered corrected for the (mean) procedural recovery of the individual date of extraction [a]	Percentage recovered relative to the mean percentage recovered at Day 0 [a]
			Single Values [b]	Mean [a] in brackets: rel. std. deviation (%)		
Analyte: Difenoconazole Test System: Honey Nominal Fortification Level: 0.10 mg/kg (10xLOQ)						
0 days	-	-	94, 95	94	-	-
1 month (54 days)	70, 70	70	74, 74	74	105	78
3 months (104 days)	90, 94	92	93, 104	98	107	104
Analyte: Azoxystrobin Test System: Honey Nominal Fortification Level: 0.10 mg/kg (10xLOQ)						
0 days	-	-	94, 83	88	-	-
1 month (54 days)	75, 78	76	75, 80	77	102	87
3 months (104 days)	98, 90	94	92, 86	89	95	100
[a] calculated from unrounded values; [b] not corrected for procedural recoveries						

The study is deemed sufficient for asssessing the stability of difenoconazole in honey upon storage at ≤ -18 °C for 104 days.

The storage stability of difenoconazole was investigated in the framework of the peer review (EFSA, 2011a) in high water content, high oil content and dry matrices and in the framework of a previous MRL application (EFSA, 2017) in high wate rcontent, high oil content, high acid content and dry commodities. These available studies demonstrated storage stability for difenoconazole for 12–24 months when stored at −18°C, in the four main plant matrix groups.
Storage stability data on the triazole derivative metabolites (TDMs) are part of the peer review of the TDMs confirmatory data (EFSA Journal 2018;16(7):5736) and are out of data protection.

Plant products(category)	Commodity	Storage stability (Months)			
		1,2,4-Triazole	TA	TAA	TLA
High water content	apples, tomatoes, mustardleaves, wheat forage,radishes tops/roots, turnipsroots, sugar beet roots,cabbages, lettuces	6	53	53	48 (lettuce only)
High oil content	Rapeseeds, soya beans	12 (soya beano nly; not stable in rape seed)	26 (soya bean only; not stable in rape seed)	53	48

In the studies provided by the Applicant, rapeseed samples were stored for analysis for max. of 9 months, and sugar beet samples for max. of 6 months.
Sufficient stability has been demonstrated to support the residue data presented in the submission.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Conclusion on stability of residues in sample extracts

Analysis time were less than 24 hours between extraction and analysis or it was shown that study extracts are stable.

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

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruiting vegetables	Tomato	14C-phenyl 14C-triazole	foliar treatment, F	247 g as/ha	3	63 days post planting (after 1st application) 77 days post planting (prior 2nd application) 91 days post planting (prior 3rd application) PHI 40 days	-	Madrid S.O. and Huber M.K., 1987b
Fruitsing vegetables	Tomato	14C-phenyl 14C-triazole	G	123.5 g as/ha	6	55 days post planting (after 1st applicatio	-	Madrid S.O. and Huber M.K., 1987a

						n) 68 days post planting (prior 3rd application) 82 days post planting (prior 5th application) PHI 7-16 days		
Fruitsing vegetables	Tomato	14C-triazole	G	123 g as/ha	6	after 1st application prior to the 3rd, 5th, 6th application PHI 34 days	-	Velagaleti, 1990a
Fruitsing vegetables	Tomato	14C-phenyl	G	123 g as/ha	6	after 1st application prior to the 3rd, 5th, 6th application PHI 34 days	-	Schweiter, 1990a
Fruitsing vegetables	Grapes	14C-phenyl 14C-triazole	F	247 g as/ha	5	35 days after 2nd application, 7days after 3rd application PHI 20d	-	Capps, 1992
Pulses and oilseeds	Oilseed rape	14C-phenyl	foliar treatment, F	125 g as/ha	2	After 1st application, prior and immediately after 2nd application, 39 days after 2nd application	-	Neuman, 1993a
Pulses and oilseeds	Oilseed rape	14C-triazole	foliar treatment, F	125 g as/ha	2	After 1st applicatio	-	Neuman, 1993b

						n, prior and immediately after 2nd application, 39 days after 2nd application		
Cereals	Spring Wheat	14C-phenyl 14C-triazole	foliar treatment, F	247 g as/ha	4	Post 1st application 58 days post planting (8days after 2nd application) 94days post planting (PHI 29)	-	Hubbard, 1991a
Root vegetables	Potato	14C-phenyl	G	123.5 g as/ha	6	After 1st application, prior to 3rd application Prior 5th application PHI11	-	Schweiter, 1990b
Root vegetables	Potato	14C-triazole	G	123 g as/ha	6	after 1st application prior to the 3rd, 5th, 6th application PHI 11 days	-	Velagaleti, 1990a

Summary of plant metabolism studies reported in the EU

The plant metabolism of difenoconazole was carried out in four crops, representing four crop groupings – cereals (wheat), root vegetables (potato), pulses/oilseeds (oilseed rape) and fruits (grape and tomato). The application methods were seed and foliar treatment for wheat and foliar treatment for potato, grape, tomato and oilseed rape. The representative uses for difenoconazole in the Southern and Northern Europe are on cereals (seed treatment), pome fruit (foliar treatment) and carrots (foliar treatment).
Two studies in wheat were conducted under two different conditions, i.e. greenhouse and in field plots. However, no difference was observed in the results. The studies were performed using two radiolabelled forms of difenoconazole. [Phenyl-14C] or [triazole-14C] difenoconazole were applied once as a seed treatment. The application rate in both studies was four times higher than the proposed critical GAP of 6 g

a.i./100 kg seed. At maturity, low levels of TRR were found in [phenyl14C] difenoconazole treated grain and straw (0.003 to 0.004 and 0.013 to 0.016 mg/kg, respectively). This radioactivity was not analysed further. Residues in mature grain and straw from the triazole-14C labelled difenoconazole treated seed were 0.024 to 0.183 and 0.011 to 0.069 mg/kg, respectively. The majority of the radioactivity in straw and grain was aqueous soluble (72 to 90% of the TRR, respectively) and was tentatively identified as 1,2,4-triazole (CGA-71019), triazole acetic acid (CGA-142856) or triazole alanine (CGA-131013). The results demonstrate a preferential translocation of triazole related residues to the grains.
In one study in wheat, conducted indoors under greenhouse condition, following four foliar applications of phenyl 14C or triazole-14C labelled difenoconazole, the distribution of the radioactivity between organic and aqueous soluble fractions was similar in mature straw but not in grain. The TRR in the phenyl-14C labelled difenoconazole treated grain was presented as an unextracted residue (81.5% of the TRR, 0.064 mg/kg) while in the corresponding [triazole-14C] difenoconazole labelled treated grain, 69.5% of the TRR (1.05 mg/kg) was present as aqueous soluble radioactivity. This radioactivity consisted of 1,2,4-triazole (CGA- 17019, 10% of the TRR, 0.14 mg/kg) and triazole acetic acid (CGA-142856, 20% of the TRR, 0.28 mg/kg) while in the phenyl-14C labelled difenoconazole treated grain, the presence of conjugates accounted for ca 35% of the TRR with CGA-189138 or CGA-189138 metabolites.
In two studies in potato (representing root vegetables), at maturity, following six applications of [phenyl-14C] and [triazole-14C] difenoconazole each at a rate of 123.5 g a.i./ha, the TRR in the potato tubers was 0.012 and 0.087 mg/kg, respectively. Mature tubers from plants treated with [phenyl-14C] difenoconazole contained parent difenoconazole (8.7%) together with the metabolites CGA-205375 (3.0%) and CGA-205374 (3.1%). An additional 15.4% of the TRR was released by cellulase treatment as sugar conjugated CGA-205375. The corresponding [triazole-14C] difenoconazole treated mature tubers contained predominantly the metabolite triazole alanine, CGA-131013 (78.9% of the TRR, 0.068 mg/kg), demonstrating preferential translocation of triazole related residues to the tubers. The application rate in both studies was in accordance with the proposed GAP for carrots in Southern and Northern Europe (125 g a.i./ha). However, the pre-harvest intervals were shorter (11 days) than the minimum PHI recommended in both European regions (14 days) and the interval between applications was 7 days, which was shorter than the minimum of 14 days.
In a study in grapes, at maturity, 20 days after the fifth of five applications of either [phenyl-14C] or [triazole-14C] difenoconazole at 247 g a.i./ha, which is 3 to 4 times higher than the proposed critical GAP for pome fruit in Southern and Northern Europe, the TRR in fruit was 0.047 to 0.127 and 0.115 mg/kg, respectively. The PHI was longer than the minimum recommended in Southern (14 days) and shorter than the minimum recommended in Northern Europe (28 days). In the fruit, parent compound was the largest component of the residue (up to 43.5% of the TRR, 0.055 mg/kg). The metabolites CGA-205374 and CGA-205375 were detected in fruit samples at levels between 1.7 to 3.8% and 3.5 to 6.4% of the TRR, respectively. Small amounts of the metabolites CGA-71019 (3.6% of the TRR) and CGA-189138 (4% of the TRR) were also detected, leading to residues less than 0.01 mg/kg. Unidentified metabolites were observed in fruit samples, but none individually exceeded 10% of the TRR. The unextracted radioactivity accounted for up to 36% of the TRR in fruit. A small proportion of these residues were identified as sugar conjugates of either parent compound or the metabolites CGA-205374, CGA 205375, CGA-186138 (phenyl-14C only) and CGA-71019 (triazole-14C only).
In four studies in tomato, using 3 to 6 foliar applications of [phenyl-14C] and [triazole-14C] difenoconazole at a rates of 123 to 247 g a.i./ha, the TRR in mature fruit was 0.037 to 0.170 mg/kg and 122 to 0.267 mg/kg, respectively. Parent difenoconazole was the major residue in fruit accounted for up to 66.3% of the TRR. The major metabolite was CGA-131013 (up to 42.4% of the TRR). The alcohol and ketone metabolites CGA-205375 and CGA-205374 were also identified but at lower levels (<2% of the TRR). The foliar application rates used in the tomato studies were higher than the proposed critical GAP for pome fruit in Southern and Northern Europe (75 and 56.2 g a.i./ha, respectively). The intervals between applications were 7 or 14 days, which were shorter or longer than the minimum of 10 days and the PHI in three of the four available studies were longer (34 or 40 days) than the minimum recommended in Southern and Northern Europe (14 and 28 days, respectively).

In two studies in oilseed rape, [phenyl-14C] and [triazole-14C] difenoconazole were applied on two occasions as a foliar spray at 125 g a.i./ha. The TRR in mature straw and pods contained TRR levels between 3.148 and 4.841mg/kg, whilst TRR levels in the seed were 0.151 and 2.262 mg/kg, respectively.

Parent compound accounted for 4.1 to 17.3% of the TRR in each commodity. The metabolites CGA-205375 and CGA- 189138 were detected in the [phenyl-14C] treated seed at levels of 7.9 to 0.3% of the TRR, respectively. The metabolites CGA-205375, CGA-131013 and CGA-142856 were detected in the [triazole-14C] treated seed at levels of 0.6, 56.4 and 2.8% of the TRR, respectively. Up to 28.3% of the TRR was present as polar compounds that were multi-component.

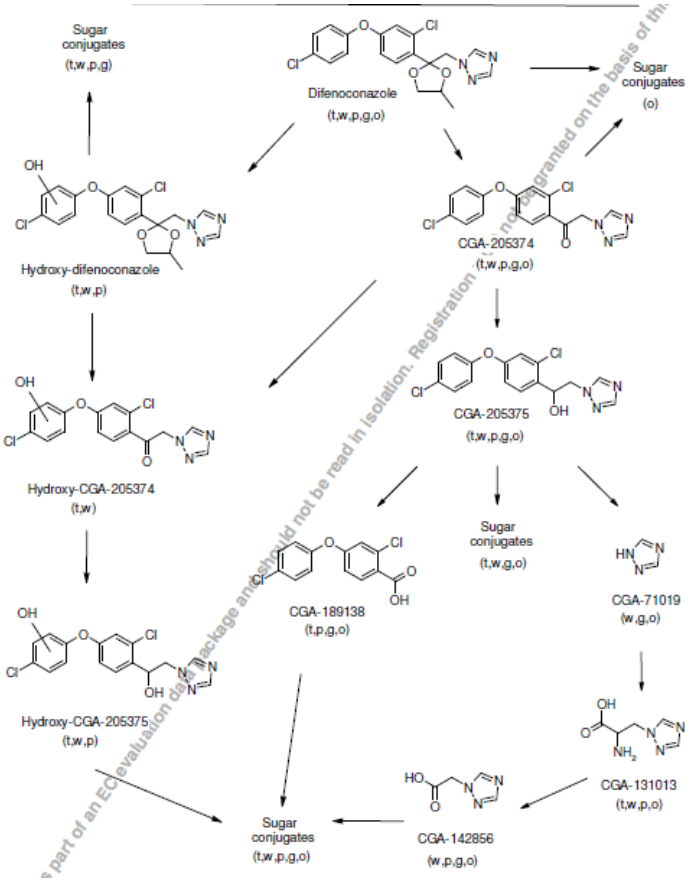
The primary metabolic process in all four crop types involved:

-hydrolysis of the dioxolane ring to form the ketone CGA-205374, which is then reduced to the corresponding alcohol CGA-205375.

-oxidation of CGA-205375 occurred resulting in cleavage of the alkyl bridge to form CGA- 189138 and CGA-71019.

-hydroxylation of parent compound and the metabolites CGA-205374 and CGA-205375. Sugar conjugation of parent compound and hydroxylated metabolites, and conjugation of 1,2,4-triazole was observed as a secondary metabolism process. Conjugation of 1,2,4-triazole resulted in the formation of triazole alanine (CGA-131013), which was further degraded to triazole acetic acid (CGA-142856).

The proposed metabolism of difenoconazole in plants is shown below:



Conclusion on metabolism in primary crops

The metabolism in primary crops presented during Annex I inclusion, covers use of CHR/F/SCORPIO 325 SC on winter oilseed rape and sugar beet. No new studies were necessary.

zRMS comments:

The metabolism in primary crops was evaluated at EU level. According to the EFSA Journal 2024;22:e8987: “The metabolic pathway of difenoconazole was similar in fruits, root and tuber vegetables, pulses and oilseeds and cereals. Parent difenoconazole was the major component of the residues in the majority of plant parts, except in cereal grains, potato tubers and rapeseeds where the

TDMs (TA, TAA and 1,2,4-T) were identified as main metabolites with the triazole label (EFSA, 2011a). A data gap on the investigation of the preferential metabolism/degradation of the four stereoisomers of difenoconazole in plants was identified in the framework of the peer review (EFSA, 2011a). Additional data were provided and assessed as confirmatory data (Spain, 2023; EFSA, 2023b, 2024a, 2024c). It was concluded that there is no shift observed in the ratio of enantiomers within the pairs of stereoisomers but a tendency of a preferential degradation of trans isomers and a shift to the cis isomers of difenoconazole." The metabolism of difenoconazole in plants is sufficiently addressed to support the uses proposed in the GAP for CHR/F/SCORPIO 325 SC.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetable	lettuce	14C-phenyl	F	125 g as/ha	98, 126, 342, 369 days	126 and 151 days after application	-	Walser, 1994a
		14C-triazole		125 g as/ha	98, 126, 342, 369 days	126 and 151 days after application		Walser, 1994b
Root and tuber vegetables	Sugar beet	14C-phenyl	F	125 g as/ha	98, 126, 342, 369 days	427, 473 and 488 days after application	-	Walser, 1994a
		14C-triazole		125 g as/ha	98, 126, 342, 369 days	427, 473 and 488 days after application		Walser, 1994b
Cereals	wheat	14C-phenyl	F	125 g as/ha	98, 126, 342, 369 days	167, 342 and 369 days after application	-	Walser, 1994a

		14C-triazole		125 g as/ha	98, 126, 342, 369 days	167, 342 and 369 days after application		Walser, 1994b
Cereals	Maize	14C-phenyl	F	125 g as/ha	98, 126, 342, 369 days	398, 427 and 488 days after application	-	Walser, 1994a
		14C-triazole		125 g as/ha	98, 126, 342, 369 days	398, 427 and 488 days after application		Walser, 1994b

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

Summary of plant metabolism studies reported in the EU

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

Conclusion on metabolism in rotational crops

The metabolism in rotational crops covers use of CHR/F/SCORPIO 325 SC according to the label.

zRMS comments:
The metabolism in rotational crops was evaluated at EU level. According to the EFSA Journal 2024;22:e8987: “The maximum field DT90 reported in the soil degradation studies evaluated in the framework of the peer review is 879 days (EFSA, 2011a), which triggers the need for studies investigating the nature and magnitude of residues in rotational crops. Metabolite CGA205375 (difenoconazole-alcohol) also shows high persistence in soil, with a maximum laboratory DT90 of 504 days. For what concerns metabolite 1,2,4-T, although studies reported in the framework of the peer review for difenoconazole concluded to a field DT50 of 28 days, available studies assessed under the peer review for ipconazole reported a field DT90 of 718 days (EFSA, 2013b). Two confined rotational crop studies with radiolabelled difenoconazole were available and assessed during the peer review (EFSA, 2011a; Sweden, 2006). A third study was submitted in the framework of a previous MRL application but was not peer reviewed (EFSA, 2021; Netherlands, 2020).
In the first study, difenoconazole radiolabelled in the phenyl or triazole ring was applied onto bare soil at a rate of 125g as/ha (0.1N rate compared to the most critical authorised GAP on root crops). Root crops (sugar beet), leafy crops(lettuces) and cereals (wheat and maize) were planted at nominal plant back interval (PBI) of 98, 126, 342 and 369 days after soil treatment (DAT). With the phenyl label, TRR were very low (< 0.01 mg/kg) and were not further characterised. With the triazole label, in mature crops, highest residue levels were found in cereal grains (up to 0.34 mg eq./kg, at 418 days after application) consisting mainly of TA (44%–66% TRR) and TAA (26% TRR). These residues occurred by selective transport of TDMs from the soil to the grain. TDMs were also major in lettuce head and sugar beet tops with TA accounting for 31% and25% TRR, respectively, and metabolite CGA205369 (triazole lactic acid; TLA) representing 43% and 54% TRR, respectively. The metabolites which were identified in the soil degradation/dissipation studies (CGA205375 and 1,2,4-T) could not be identified in the rotational crop

studies (EFSA, 2011a).
In the second study, [14 C-phenyl-] difenoconazole was applied onto bare soil at a rate of 32.4 g a.s./ha. Crops representative of cereals (wheat), leafy crops (mustard leaves) and root crops (turnip) were planted at nominal PBI of 30–33 DAT. Residue were not characterised because of very low levels measured in mature crops (< 0.01 mg/kg). However, this study complements the first one, as it covers the crop failure and shows that the uptake from the soil is limited.
In the third study, [14 C-phenyl-] difenoconazole was applied onto bare soil at a rate of 516 g a.s./ha (0.46N the most cGAP assessed in this review). Crops representative of cereals (wheat and sorghum), leafy crops (lettuce) and root crops (radishes) were planted at PBI of 30, 60, 120 and 270 DAT. Low residue levels were found in rotational crops and tend to decrease with longer PBI. Parent difenoconazole was major in lettuce (42%–82% TRR; 0.005–0.026 mg eq./kg) and radishes (28%–72%TRR; 0.008–0.06 mg eq./kg). In wheat straw, parent difenoconazole was a minor residue, while metabolite CGA205375 was major (up to 40% TRR; up to 0.021 mg eq./kg). Characterisation of residues was not possible in cereal grains as residue levels were too low. This new study suggested little uptake of difenoconazole and soil metabolites by cereal grains, leafy and root crops from the treated soil (EFSA, 2021).
The EU pesticides peer review concluded that the metabolism of difenoconazole is similar in primary and rotational crops (EFSA, 2011a). In the present review, it is concluded that although the studies were underdosed compared to the most critical GAPs currently authorised, considering that the identification and characterisation of residues were sufficiently addressed, the metabolism and distribution of difenoconazole in rotational crops are adequately elucidated and the conclusions from the peer review are still valid."
A specific definition for rotational crops is not deemed necessary.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

A high temperature hydrolysis study was conducted to determine whether difenoconazole hydrolyses and to identify any major degradates formed, under conditions representing the extremes of pH and temperature that could occur during involved in pasteurisation, baking, brewing, boiling and sterilisation. (Muir G.T, 2003)

The mean total applied radiocactivity recorvered after incubation and neutralization was 103.9 to 108.9% fot 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 5 pH and 6, and no other degradation products were quantifiable.

Radioactivity recovery following incubation under different processing conditions:

Simulated process	Incubation			Radioactivity recovery (% of applied)[a]		
	pH	Time (minutes)	Temperature (°C)	Total	Difenoconazole	Unknown degradates
Pasteurisation	4	20	90	103.9	95.6	0.0
Baking/Brewing/Boiling	5	60	100	108.9	98.1	1.0
Sterilisation	6	20	120	104.9	98.6	0.9

[a] after incubation and neutralisation. Mean of two samples.

There was no significant hydrolysis of difenoconazole following incubation at different pH values and temperatures. Difenoconazole is therefore considered stable under conditions representative of pasteurisation, baking, brewing and boiling and sterilisation.

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

Conditions (Duration, Temperature, pH)	Identified compound(s)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	~~Yes~~ Parrent (>96% TRR)	EFSA 2011
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	~~Yes~~ Parrent (>96% TRR)	EFSA 2011
Sterilisation (20 minutes, 120°C, pH 6)	~~Yes~~ Parrent (>96% TRR)	EFSA 2011

Conclusion on nature of residues in processed commodities

The residue pattern in processed commodities is similar to residue pattern in raw commodities.

zRMS comments:
The metabolism in processed commodities was evaluated at EU level. According to the EFSA Journal 2024;22:e8987: "Studies investigating the nature of residues in processed commodities were assessed in the framework of the peer review(EFSA, 2011a; Sweden, 2006). Studies were conducted with radiolabeled difenoconazole on the triazole ring of the molecule simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking(60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6). With more than 96% TRR consisting of parent difenoconazole, it is concluded that difenoconazole is stable to hydrolysis under standard conditions of pasteurisation, baking/brewing/boiling and sterilisation (EFSA, 2011a).
Regarding TDMs, standard hydrolysis studies are available and were assessed by EFSA as confirmatory data submitted for the risk assessment of the TDMs (EFSA, 2018d). These studies showed that TA, TAA, TLA and 1,2,4-T remain stable under the standard hydrolysis conditions simulating processing of pasteurisation, baking, brewing and boiling and sterilisation. Thus, it can be concluded that the nature of residues in processed commodities resulting from the authorised uses of difenoconazole is sufficiently addressed."

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

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

Endpoints	
Plant groups covered	Foliar treatment: Cereals(spring wheat) Root vegetables(potato) Fruits(tomato, grapes) Pulses/oilseeds(oilseed rape) Seed treatment: Cereals(spring wheat)
Rotational crops covered	Leafy vegetables (lettuce, ~~spinach~~ mustard leaves), root vegetables (carrot, sugarbeet, turnip), cereals (spring and winter wheat, maize), ~~oilseeds (mustard)~~
Metabolism in rotational crops similar to metabolism in primary crops?	Yes. No residues of parent difenoconazole were found. Residues mainly composed of TDM metabolites: triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA).
Processed commodities	Difenoconazole stable under standard hydrolysis conditions representative of pasteurisation/baking/sterilisation (more

	than 96% TRR consisted of parent difenoconazole).
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Difenoconazole, Reg. (EU) 2024/2612
Plant residue definition for risk assessment	~~Triazole derivative metabolites (TDM) (provisional, pending the definition of a common and harmonised approach for all the active substances of the triazole chemical class)~~ According to the EFSA Journal 2024;22:e8987: RD-RA1: Difenoconazole (sum of isomers); RD-RA2: TA and TLA, since these compounds share the same toxicity; RD-RA3: TAA; RD-RA4: 1,2,4-triazole. The previously derived provisional residue definitions (1. difenoconazole, 2. TDMs; EFSA, 2011a) have been replaced by the abovementioned residue definitions derived during the peer review of the pesticide risk assessment of the TDMs (EFSA, 2018d). EFSA highlights that the residue definitions might be reconsidered in the framework of the on-going peer review for renewal. In the framework of the assessment of confirmatory data (Spain, 2023; EFSA, 2024a,c), an uncertainty factor (UF) of 1.3 was derived from field residue trials submitted on this purpose, to reflect the tendency of a preferential degradation of trans isomers and a shift to the cis isomers of difenoconazole. This UF is applicable to all plant commodities
Conversion factor from enforcement to RA	None

* If residue pattern in processed commodities is not similar to that in raw commodities
** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).
*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

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

Available data

No new data submitted in the framework of this application.

Table 7.3-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg feed/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	14C-phenyl 14C-triazole	2	5	10	Milk	daily	Madrid, 1988
						Urine and faeces	daily	
						Blood	1,2,4,6,8,9,10	
						Tissues	at sacrifice	

Lactating ruminants	Goat	14C-phenyl 14C-triazole	4	100	3	Urine and faeces	daily	Maynard, 1990a
						Milk	Twice a day	
						Blood	Prior the sacrifice	
						Tissues	at sacrifice	
Lactating ruminants	Goat	14C-phenyl	2	100	4	Urine and faeces	daily	Ray, 1996
						Milk	Twice a day	
						Blood	Prior the sacrifice	
						Tissues	at sacrifice	
Laying poultry	Hens	14C-phenyl 14C-triazole	4	5	14	Eggs	daily	Madrid, 1989
						Blood	Prior the sacrifice	
						Tissues	at sacrifice	
Laying poultry	Hens	14C-phenyl 14C-triazole	20	68	3	Eggs and excreta	daily	Maynard, 1990b
						Blood	Prior the sacrifice	
						Tissues	at sacrifice	
Laying poultry	Hens	14C-triazole	5	121	4	Eggs and excreta	daily	Ray, 2004
						Blood	Prior the sacrifice	
						Tissues	at sacrifice	

Summary of animal metabolism studies reported in the EU

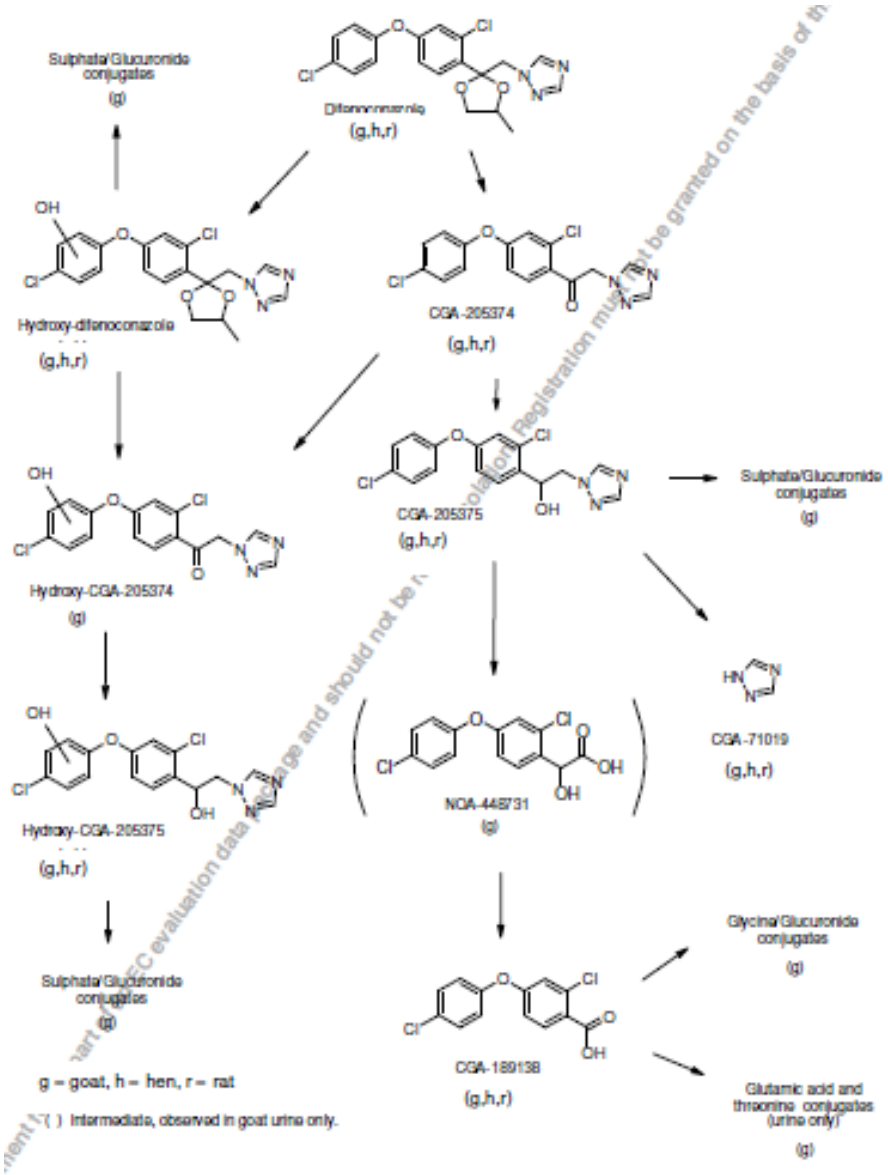
Metabolism studies of difenoconazole were carried out in lactating goats and laying hens. The metabolism studies were performed using two radiolabelled forms of difenoconazole, [phenyl-14C] and [triazole-14C] difenoconazole.

Capsules containing the test substance were administered orally to lactating goats and laying hens with concentrations corresponding to doses of 5 to 100 ppm in feed to the lactating goats and 5, 68 and 121 ppm in feed to the laying hens. Difenoconazole was rapidly metabolised, with the majority of the administered radioactivity excreted in the urine and faeces (up to 96.8% in hen and up to >88% in goat). Maximum residue levels were present in the liver and kidney, at 9.790 and 2.731mg/kg, respectively, in lactating goats and up to 4.660 and 2.247 mg/kg, respectively, in laying hens. Higher tissue residues (up to 20.409 mg/kg in liver) were observed in the hen following an extremely high dose of difenoconazole (121 mg/kg for 4 days) and sampling immediately after the final dose.

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

Plateau level of residues in milk was reached after ca 2 and 6 days for the [phenyl-14C] and [triazole-14C] difenoconazole treated goats, respectively, with residues in the [triazole-14C] group being 2 – 3

times higher than the [phenyl-14C] group (see Figure B.7.2.1-2 and B.7.2.1-3). Plateau level of residues in egg whites and egg yolks was reached slowly, i.e. after ca 5 and 7 days, respectively (see Figure B.7.2.4-1 and B.7.2.4-2). The TRR in the [triazole-14C] egg whites were 10 – 15 times lower than the [phenyl-14C] egg whites while the TRR in egg yolks was very similar for the two labels.
CGA-205375 was the major metabolite in the goats and hens, occurring at levels up to 7.127 mg/kg (72.8% TRR) in liver, 1.180 mg/kg (43.2% TRR) in kidney, 0.949 mg/kg (91.7% TRR) in fat, 0.423 mg/kg (91.4% TRR) in muscle and up to 0.130 mg/kg (34.4% TRR) in milk, egg white and egg yolk. 1,2,4-triazole CGA-71019 was transported preferentially to eggs and milk, occurring at levels of 0.182 mg/kg (67.7% TRR) and 0.043 mg/kg (32.3% TRR) in egg white and yolk, respectively and levels up to 0.022 mg/kg (5.8% TRR) in milk. Ring hydroxylated difenoconazole, CGA-205374 and CGA-205375 were observed in the goats at levels up to 0.235 mg/kg (3.9% TRR) in liver and 0.021 mg/kg (15.2% TRR) in milk. Ring hydroxylated difenoconazole and CGA-205375 were observed in the hen at levels up to 0.457 mg/kg (9.8% TRR) in the liver.
Glucuronide and sulphate conjugates of difenoconazole and CGA-205375 and a glycine conjugate of CGA-189138 were also major metabolites in the goats. The highest residues of these individual metabolites in the tissues and milk were 0.734 mg/kg (7.5% TRR) in liver (CGA-205375 glucuronide conjugate), 0.114 mg/kg (35.8% TRR) in milk (CGA-189138 glycine conjugate), 0.273 mg/kg (10.0% TRR) in kidney (CGA-205375 sulphate conjugate), 0.176 mg/kg (1.8% TRR) in liver (OH-CGA-205375 sulphate conjugate), 0.157 mg/kg (1.5% TRR) in liver (OH difenoconazole glucuronide conjugate) and 0.009 mg/kg (2.9% TRR) in milk (OH-difenoconazole sulphate conjugate).
The primary metabolic processes in each animal involves:
- hydrolysis of the dioxolane ring to form the ketone CGA-205374, with subsequent reduction of CGA-205374 to give the corresponding alcohol CGA-205375 as a major metabolite.
- Oxidation of CGA-205374 resulted in cleavage of the alkyl bridge, leading to the formation of the acid CGA-186138 and 1,2,4-triazole CGA-71019.
A second pathway involves hydroxylation of difenoconazole to form the hydroxylated CGA-205374 and CGA 205375. Sulphate ester, glycine and glucuronide conjugation were observed as secondary metabolism processes in the lactating goats. Hydroxy acetic acid difenoconazole and amino acid (glutamic acid/threonine) conjugates of CGA-189138 were also observed as urine specific metabolites.
The proposed metabolism of difenoconazole in lactating goat, laying hen and rat is shown below:



Conclusion on metabolism in livestock

Available metabolism studies demonstrated the residues of difenoconazole are not expected in significant amount since they are very polar and extensively excreted. The metabolic patterns identified in lactating goats and laying hens is consistent with the rat metabolism and a specific metabolism study in pigs is not considered necessary.

zRMS comments:
The metabolism in rotational crops was evaluated at EU level. According to the EFSA Journal 2024;22:e8987: “It was concluded that the metabolism of difenoconazole in livestock is adequately elucidated, and that metabolite CGA205375 was the most relevant component of the residues in all matrices of ruminants and poultry. The peer review concluded that the metabolism of difenoconazole in ruminants was comparable with the metabolism in rats and a metabolism study on pigs was not required.

Therefore, the residue definition for enforcement is proposed as difenoconazole-alcohol (CGA205375), expressed as difenoconazole (EFSA, 2011a). Parent difenoconazole and metabolite CGA205375 are considered fat soluble.
In the framework of the peer review of the pesticide risk assessment of the TDMs (EFSA, 2018d), the livestock metabolism studies available for several triazole fungicides and for TA were reassessed in view of deriving common risk assessment residue definitions for animal commodities which would cover all triazole fungicides assessed. The compilation of the studies conducted on lactating ruminants and laying hens, with the triazole active substances showed that, apart from parent compound, 1,2,4-T was a major component of the total residues in all animal matrices. From the studies performed with TA, it was concluded that TA was the main residue in all poultry matrices and in ruminant tissues, while 1,2,4-T was predominant in milk. TLA and TAA were detected at very low levels in all matrices. No studies are available to elucidate the potential transfer of TAA, TLA and 1,2,4-T present in feed items to animal matrices. Nevertheless, the available data were found to be sufficient to agree on common residue definitions (EFSA, 2018d).
For risk assessment, considering the conclusions from the peer review for difenoconazole (EFSA, 2011a) and the conclusions set in the framework of the TDMs confirmatory data (EFSA, 2018d), four separate residue definitions are proposed as follows:
• RD-RA1: difenoconazole-alcohol (CGA205375), expressed as difenoconazole;
• RD-RA2: TA and TLA, since they share the same toxicity;
• RD-RA3: TAA;
• RD-RA4: 1,2,4-T.
These residue definitions for enforcement and risk assessment previously agreed are still found appropriate for the current review. However, these residue definitions might be reconsidered in the framework of the ongoing peer review for renewal.
As for plants, a data gap was set during the peer review to address the possible preferential stereoisomeric behavior of difenoconazole in livestock and no further data were submitted in this regard. Metabolite CGA205375 (difenoconazole-alcohol) which is the only relevant compound for the risk assessment in animal commodities has still one chiral centre and might occur as R- or S-isomer. Therefore, in the absence of toxicological data on the individual isomers, following the EFSA guidance document on stereoisomers (EFSA, 2019b), an indicative worst-case UF of 2 is proposed in this review to be applied to accommodate for the possible shift in the isomer ratio (EFSA, 2024c). Until further information on the relative toxicity of the individual isomers or on the preferential metabolism in livestock has become available, this UF is applied to all livestock commodities for the risk assessment calculations according to RD-RA1."

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

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

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	48 hours in milk[14C-phenyl]-difenoconazole 144 hours in milk[14C-triazole]-difenoconazole
	168 hours in egg yolk[14C-phenyl] and [14C-triazole]120 hours in eggs white[14C-triazole]-difenoconazole
Animal residue definition for monitoring	~~Difenoconazole alcohol (CGA-205375) expressed as difenoconazole~~ Difenoconazole, Reg. (EU) 2024/2612

Animal residue definition for risk assessment	~~Two separate residue definitions:1) Difenoconazole alcohol (CGA-205375) expressed as difenoconazole2) Triazole derivative metabolites (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)~~ According to the EFSA Journal 2024;22:e8987: RD-RA1: Difenoconazole-alcohol (CGA205375), expressed as difenoconazole; RD-RA2: TA and TLA; RD-RA3: TAA; RD-RA4: 1,2,4-T. The previously derived provisional residue definitions (1. Difenoconazole, 2. TDMs; EFSA, 2011a) have been replaced by the abovementioned residue definitions derived during the peer review of the pesticide risk assessment of the TDMs (EFSA, 2018d). EFSA highlights that the residue definitions might be reconsidered in the framework of the on-going peer review for renewal. In the framework of the assessment of confirmatory data (EFSA, 2024a,c), an indicative uncertainty factor (UF) of 2 was derived following the EFSA guidance document on stereoisomers, to reflect the possible shift in the isomers ratio of difenoconazole-alcohol(CGA205375). This worst-case UF is applicable to all livestock commodities.
Conversion factor	-
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes Log POW difenoconazole = 4.36 (> 3) Log POW CGA205375 = 3.81 (> 3)

~~* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)~~
~~** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.~~
~~*** If metabolism in rat and ruminant are not similar~~

7.3.3 Magnitude of residues in plants (KCA 6.3)

Summary of European data and new data supporting the intended uses

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

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of CHR/F/SCORPIO 325 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
Oilseed (seeds)	New trials K. Wańczyk 22SGS48-01, K.Wańczyk 22SGS49-01, K.Wańczyk 22SGS51-01, K.Wańczyk 22SGS52-01, K.Wańczyk 22SGS53-01, K.Wańczyk 22SGS54-01,	N-EU	GAP: 2x 200 g/ha azoxystrobin, 2x125 g/ha difenoconazole, BBCH 18-69, outdoor, PHI: 45-70 **Difenoconazole** E: <0.010, <0.010, <0.002, <0.010, <0.010, <0.010, <0.002, <0.002 RA: <0.010, <0.010, <0.002, <0.010, <0.010, <0.010, <0.002, <0.002	0.010	0.010	~~0.03~~ 0.01	0.5 for rapeseeds 0.2 for mustard seeds and linseeds 0.05* for poppy and sunflower seeds, 0.1 for soybean, 0.05* for pumpkin and hemp seeds	Yes

	K.Wańczyk 22SGS55-01, K.Wańczyk 23SGS47-01		**Triazole-acetic Acid TAA** E: <0.004, 0.043, <0.004, <0.004, 0.058, <0.004, <0.004, <0.004 RA: <0.004, 0.043, <0.004, <0.004, 0.058, <0.004, <0.004, <0.004 **Triazole-alanine TA** E: 0.054, ~~3.58~~ 4.84, 0.24, 0.47, 6.72*, 0.20, 0.53~~, 0.12~~ 0.17 RA: 0.054, ~~3.58~~ 4.84, 0.24, 0.47, 6.72*, 0.20, 0.53~~, 0.12~~ 0.17 **Triazole-lactic Acid TLA** E: <0.004~~, 0.16~~ 0.25, <0.004, <0.004, 0.23, <0.004, 0.078, <0.004 RA: <0.004, ~~0.16~~ 0.25, <0.004, <0.004, 0,23, <0.004, 0.078, <0.004 **1.2.4-triazole 1.2.4-T** E: <0.004, <0.004, <0.004, <0.004, <0.004, <0.004, <0.004, <0.004 RA: <0.004, <0.004, <0.004, <0.004, <0.004, <0.010, <0.004, <0.004	0.004 ~~0.47~~ 0.355 0.004 0.004	0.058 6.720 ~~0.230~~ 0.25 0.004	0.1 ~~15~~ 12.057 0.5 ~~0.015~~ 0.004	- - - -	- - - -

Oilseed rape (whole plant roots)	New trials K. Wańczyk 22SGS52-01, K. Wańczyk 22SGS53-01, K. Wańczyk 22SGS54-01, K. Wańczyk 22SGS55-01 K.Wańczyk 23SGS47-01	N-EU	GAP: 2x 200 g/ha azoxystrobin, 2x125 g/ha difenoconazole, BBCH 22 and BBCH 69, outdoor, PHI: 28 **Difenoconazole** E: 0.12, 0.16, 0.36*, 0.093, 0.063 RA: 0.12, 0.16, 0.36, 0.093, 0.063 **Triazole-acetic Acid TAA** E: <0.004, 0.049, <0.010, <0.004, <0.004 RA: <0.004, 0.049, <0.010, <0.004, <0.004 **Triazole-alanine TA** E: 0.064, 0.67, 0.052, 0.13, <0.004 RA: 0.064, 0.67, 0.052, 0.13, <0.004 **Triazole-lactic Acid TLA** E: <0.004, 0.11, <0.004, <0.004, <0.004 RA: <0.004, 0.11, <0.004, <0.004, <0.004 **1.2.4-triazole 1.2.4-T** E: <0.004, <0.004, <0.004, <0.004, <0.004 RA: <0.004, <0.004, <0.004, <0.004, <0.004	~~0.140~~ 0.120 ~~0.007~~ 0.004 ~~0.097~~ 0.064 0.004 0.004	0.360 0.049 0.670 0.110 0.004	0.7 0.1 1.5 ~~0.3~~ ~~0.2~~ 0.3 ~~0.015~~ 0.01	-	-

Sugar beet roots	New trials T.Peda 23SGS01-01, T.Peda 23SGS02-01, T.Peda 23SGS04-01, T.Peda 23SGS05-01, T.Peda 23SGS06-01, T.Peda 23SGS07-01, T.Peda 23SGS08-01, T.Peda 23SGS46-01,		GAP: 2x 200 g/ha azoxystrobin, 2x125 g/ha difenoconazole, BBCH 49, PHI 34-36 **Difenoconazole** E: 0.019, <0.001, <0.010, 0.013, <0.010, 0.012, <0.010, 0.013 RA: 0.019, <0.001, <0.010, 0.013, <0.010, 0.012, <0.010, 0.013 **Triazole-acetic Acid TAA** E: <0.002, <0.002, <0.002, <0.002, <0.002, <0.002, <0.002, <0.002 RA: <0.002, <0.002, <0.002, <0.002, <0.002, <0.002, <0.002, <0.002 **Triazole-alanine TA** E: 0.028, 0.011, <0.010, <0.010, <0.010, <0.010, ~~0.011~~ 0.016, <0.010 RA: 0.028, 0.011, <0.010, <0.010, <0.010, <0.010, ~~0.011~~ 0.016, <0.010 **Triazole-lactic Acid TLA** E: <0.010, <0.002, <0.002, <0.002, <0.002, <0.002, <0.002, <0.002 RA: <0.010, <0.002, <0.002, <0.002, <0.002, <0.002, <0.002, <0.002 **1.2.4-triazole 1.2.4-T** E: <0.002, <0.002, <0.002, <0.002, <0.002, <0.002, <0.002, <0.002 RA: <0.002, <0.002, <0.002, <0.002, <0.002, <0.002, <0.002, <0.002	0.011 0.002 0.010 0.002 0.002	0.019 0.002 0.028 0.010 0.002	0.04 0.01 0.04 ~~0.015~~ 0.01 0.01	0.2 for sugar beet roots 0.4 for beetroots, 2.0 for celeriac, 0.4 for horseradish and swedes 0.6 for chicory roots - - - -	Yes - - - - -

Sugar beet leaves	New trials T.Peda 23SGS01-01, T.Peda 23SGS02-01, T.Peda 23SGS04-01, T.Peda 23SGS05-01, T.Peda 23SGS06-01, T.Peda 23SGS07-01, T.Peda 23SGS08-01, T.Peda 23SGS46-01,		GAP: 2x 200 g/ha azoxystrobin, 2x125 g/ha difenoconazole, BBCH 49, PHI: 34-36 **Difenoconazole** E: 0.071, <0.010, 0.064, 0.12*, 0.18*, 0.38*, 0.10*, 0.087* RA: 0.071, <0.010, 0.064, 0.12*, 0.18*, 0.38*, 0.10*, 0.087*	0.094	0.380	0.6	-	-
			Triazole-acetic Acid TAA E: <0.010, <0.010, <0.010, <0.010, <0.010, <0.010, <0.010, <0.010 RA: <0.010, <0.010, <0.010, <0.010, <0.010, <0.010, <0.010, <0.010	0.010	0.010	~~0.03~~ 0.01	-	-
			Triazole-alanine TA E: 0.029, 0.025, <0.010, 0.016, 0.016, 0.011, 0.027, 0.015 RA: 0.029, 0.025, <0.010, 0.016, 0.016, 0.011, 0.027, 0.015	0.016	0.029	0.06	-	-
			Triazole-lactic Acid TLA E: 0.083, 0.012, 0.012, 0.011, 0.040, 0.013, 0.023, <0.010 RA: 0.083, 0.012, 0.012, 0.011, 0.040, 0.013, 0.023, <0.010	0.013	0.083	0.15	-	-
			1.2.4-triazole 1.2.4-T E: <0.002, <0.010, <0.002, <0.002, <0.002, <0.002, <0.002, <0.002 RA: <0.002, <0.010, <0.002, <0.002, <0.002, <0.002, <0.002, <0.002	0.002	0.010	~~0.015~~ 0.01	-	-

Honey	S.Mahlow, C. Ezeobi-Chris	2023	GAP: 2x 200 g/ha azoxystrobin, 2x125 g/ha difenoconazole, 14-64 BBCH, outdoor, PHI: 6-18, **Difenoconazole** E: <0.01.<0.01, 0.014, 0.012 RA: <0.01.<0.01, 0.014, 0.012	0.011	0.014	0.04	-	-
			Triazole-acetic Acid TAA E: <0.01, <0.01, <0.01, <0.01 RA: <0.01, <0.01, <0.01, <0.01	0.010	0.010	0.03	-	-
			Triazole-alanine TA E: 0.02, 0.01, 0.01, 0.04 RA: 0.02, 0.01, 0.01, 0.04	0.015	0.040	0.08	-	-
			Triazole-lactic Acid TLA E: <0.01, <0.01, <0.01, <0.01 RA: <0.01, <0.01, <0.01, <0.01	0.010	0.010	0.03	-	-
			1.2.4-triazole 1.2.4-T E: <0.01, <0.01, <0.01, <0.01 RA: <0.01, <0.01, <0.01, <0.01	0.010	0.010	0.03	-	-

* Source of EU MRL: Reg. (EU) 2023/129
* diluted sample
LOD= 0.002 mg/kg, LOQ= 0.010 mg/kg triazole metabolites
LOD= 0.001 mg/kg, LOQ= 0.010 mg/kg difenoconazole, azoxystrobin

7.3.3.1 Conclusion on the magnitude of residues in plants

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

Oilseeds

Comparison of intended GAP and EU GAP (EFSA Journal. 2024;22:e8987):

Crop	Region	Formulation	Application				PHI (days)
			Growth stage, BBCH	Number	Interval (days)	Max rate (g a.s./ha)	
EU GAP EFSA Journal. 2024;22:e8987							
Rape seed	NEU	EC	14-69	1-2	14	130	n.a,
Mustard seed	NEU	EC	-69	2	-	125	n.a.
Sunflower seed	NEU	SC	30-55	2	21	125	n.a.
Poppy seeds	NEU	SC	31-69	1	-	125	n.a.
Soya bean	NEU	SC	31-69	1	-	125	n.a.
Intended GAP							
Rape seed	NEU	SC	14~~-29~~ 22 31-55	2	~~90/120~~ **150 is proposed**	125	n/a **60 is proposed**
Rape seed	NEU	SC	61-69	1	-	125	n/a **60 is proposed**
Rape seed, mustard seed, sunflower seed, soybean, pumpkin seed, poppy seeds, hemp/flax	NEU	SC	14~~-29~~ 22 31-69 **max 55 is accepted for sunflower seeds and soybean**	2 **1 is proposed for mustard seed, sunflower seed, soybean, pumpkin seed, poppy seeds, hemp/flax**	~~90/120~~ **150 is proposed**	125	n/a **60 is proposed**

According to the SANTE/2019/12752 Rev.1 residue data for rapeseed can be extrapolated to whole group oilseeds except peanuts for treatments before forming of the edible part and after forming of the edible part to poppy seeds, linseeds and mustard seeds. For oilseeds, a significant part of the edible part is present from full blossom (BBCH 65) onwards.
Taking the above into account, extrapolation to sunflower seeds, pumpkin seeds, hemp and soybean is possible for treatments at max BBCH 55.
The Applicant provided 8 independent residue field trials on oilseed rape conducted in Hungary (n=2), Poland (n=4), North France (n=1) and Germany (n=1). In all trials two applications (first at BBCH 15-22, second at BBCH 69) of CHR/F/SCORPIO 325 SC were applied at the target dose rate of 1.0 L/ha, equivalent to 200 g azoxystrobin and 125 g difenoconazole. The interval between applications was in the

range 132 days – 196 days. One treatment was performed in autumn, the other in spring.
All studies were accepted. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in oilseed rape (seed) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.004 mg/kg for each compound.
Specimen extraction and determination of residues of difenoconazole in oilseed rape (seed) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound.

Difenoconazole
residue results in seeds considered for further evaluation:
3 x < 0.002 mg/kg; 5 x < 0.01 mg/kg (STMR 0.01 mg/kg, HR 0.01 mg/kg)
The current EU MRL (Reg. (EU) 2024/2612) for difenoconazole in:
rapeseed is 0.5 mg/kg;
sunflower seed is 0.05 mg/kg;
mustard seed is 0.2 mg/kg;
linseeds is 0.2 mg/kg
soybean is 0.1 mg/kg;
poppy seeds is 0.05 mg/kg;
pumpkin seed is 0.05 mg/kg;
hemp seeds is 0.05 mg/kg.
The data submitted show that no exceedance of the existing MRL will occur for rapeseed, sunflower, mustard seed, linseeds, soybean, pumpkin seeds and hemp seeds.
The proposed uses of difenoconazole in rapeseed, poppy seeds, sunflower, mustard seed, soybean pumpkin seeds and hemp seeds are considered acceptable (at max BBCH 55 for sunflower seeds, pumpkin seeds, hemp and soybean). Considering that the intervals between treatments in the studies provided exceed the min. recommended in GAP (Table 7.1-1) of 60/120 days, zRMS suggests limiting the use to one application for mustard seed, soybean, sunflower seed and flax.
Considering that the residue results for rapeseed in the assessment refer to DALA in the range of 45-70 (62, 54, 58, 57, 54, 45, 70, 63), it is proposed to set PHI equal to 60 days for all oilseeds.

TDMs
No MRLs are set for TDMs.
residue results in seeds considered for further evaluation:
TAA – 6x <0.004, 0.043, 0.058 (STMR 0.004 mg/kg, HR 0.058 mg/kg)
TA - 0.054, 4.84, 0.24, 0.47, 6.72, 0.2, 0.53, 0.17 (STMR 0.355 mg/kg, HR 6.72 mg/kg)
TLA – 5x <0.004, 0.25, 0.23, 0.078 (STMR 0.004 mg/kg, HR 0.25 mg/kg)
1,2,4-T – 8x <0.004 (STMR 0.004 mg/kg, HR 0.004 mg/kg)

residue results in whole plant were presented in 5 studies:
TAA - 3x <0.004, 1x <0.01, 0.049 (STMR 0.004 mg/kg, HR 0.049 mg/kg)
TA - 1x <0.004, 0.064, 0.67, 0.052, 0.13 (STMR 0.064 mg/kg, HR 0.67 mg/kg)
TLA - 4x <0.004, 0.11 (STMR 0.004 mg/kg, HR 0.11 mg/kg)
1,2,4-T - 5x <0.004 (STMR 0.004 mg/kg, HR 0.004 mg/kg)

It should be noted that significant residue levels were found in a few untreated control samples of residue trials on primary and rotational crops suggesting the use of triazole pesticide active substances in previous seasons. Despite these uncertainties these trials were considered with the purpose of performing a‘worst case’ consumer dietary intake calculation.

<u>Sugar beet</u>

Comparison of intended GAP and EU GAP (EFSA Journal. 2024;22:e8987):

Crop	Region	Formulation	Application				PHI (days)
			Growth stage, BBCH	Number	Interval (days)	Max rate (g a.s./ha)	
EU GAP (EFSA Journal. 2024;22:e8987)							
Sugar beet	NEU	EC	-	1-3	-	125	14
Chicory roots	NEU	SC	40-49	1-2	14	125	14
Celeriac	NEU	EC	-	1-4	14	125	14
Horseradish	NEU	EC	19-39	1-3	14	130	14
Beetroot	NEU	EC	20-89	1-3	14	125	14
Swedes	NEU	EC	19-39	1-3	14	130	14
Turnips	NEU	EC	19-39	1-3	14	130	14
Intended GAP							
Sugar beet	NEU	SC	39-49	1	-	125	n/a **35 is proposed**
Turnip, Chicory roots, beetroot, rutabaga, horseradish, celeriac	NEU	SC	39-49	1	-	125	n/a **35 is proposed**

According to the SANTE/2019/12752 Rev.1 residue data for sugar beets can be extrapolated to beetroots, celeriac, horseradish, swedes/rutabaga and chicory roots for treatments before and after forming of the edible part.
The Applicant provided 8 independent residue field trials on sugar beet conducted in Hungary (n=2), Poland (n=3), North France (n=1) and Denmark (n=1). In all trials one application (at BBCH 49) of CHR/F/SCORPIO 325 SC were applied at the target dose rate of 1.3 L/ha, equivalent to 260 g azoxystrobin and 163 g difenoconazole.
Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in sugar beet (leaves, roots) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound.
Specimen extraction and determination of residues of difenoconazole in sugar beet (leaves, roots) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.001 mg/kg for each compound.
Difenoconazole
residue results in roots considered for further evaluation:
1 x < 0.001, 3 x < 0.01, 0.019, 2 x 0.013, 0.012 (STMR 0.011 mg/kg, **HR 0.019** mg/kg)
Residue results in leaves with tops:
1 x < 0.010, 0.071, 0.064, 0.12, 0.18, 0.38, 0.1, 0.087 (STMR 0.094 mg/kg, HR 0.12 mg/kg)
The current EU MRL for difenoconazole (Reg. (EU) 2024/2612) in:
sugar beet is 0.2 mg/kg;
beetroots (root) is 0.4 mg/kg;
celeriac is 2.0 mg/kg;
horseradish is 0.4 mg/kg;
swedes/rutabaga is 0.4 mg/kg;
chicory roots is 0.6 mg/kg.

The data submitted show that no exceedance of the existing MRLs will occur.
Considering that the residue results for sugar beet roots in the assessment refer to DALA 35 ±1, it is proposed to set PHI equal to 35 days.

TDMs
No MRLs are set for TDMs.
residue results in roots considered for further evaluation:
TAA – 8x <0.002 (STMR 0.002 mg/kg, HR 0.002 mg/kg)
TA - 5x <0.01, 0.028, 0.011, 0.016 (STMR 0.01 mg/kg, HR 0.028 mg/kg)
TLA – 7x <0.002, 1x <0.01 (STMR 0.002 mg/kg, HR 0.01 mg/kg)
1,2,4-T – 8x <0.002 (STMR 0.002 mg/kg, HR 0.002 mg/kg)

residue results in leaves with tops were presented in 5 studies:
TAA - 8x <0.01 (STMR 0.01 mg/kg, HR 0.01 mg/kg)
TA - 1x <0.01, 0.029, 0.025, 2x 0.016, 0.011, 0.027, 0.015 (STMR 0.016 mg/kg, HR 0.029 mg/kg)
TLA - 1x <0.01, 0.083, 2x 0.012, 0.011, 0.04, 0.013, 0.023 (STMR 0.013 mg/kg, HR 0.083 mg/kg)
1,2,4-T - 8x <0.002 (STMR 0.002 mg/kg, HR 0.002 mg/kg)

It should be noted that significant residue levels were found in a few untreated control samples of residue trials on primary and rotational crops suggesting the use of triazole pesticide active substances in previous seasons. Despite these uncertainties these trials were considered with the purpose of performing a‘worst case’ consumer dietary intake calculation.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

Data/information on livestock feeding studies were reviewed during the Annex I inclusion process and was considered to be acceptable and no further data have been generated. Studies were presented in DAR (2006) difenoconazole Vol.3 –B7 residue data and Final Addendum to DAR 2010. ~~and described below.~~

Table 7.3-10 Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Difenoconazole				
Beet, mangel	0.09	See point 7.2.3.9	0.38	See point 7.2.3.9
Beet sugar, tops	0.09	See point 7.2.3.9	0.38	See point 7.2.3.9
Rape, forage	0.01	See point 7.2.3.9	0.01	See point 7.2.3.9

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Turnip, tops (leaves)	0.09	See point 7.2.3.9	0.38	See point 7.2.3.9
Swede, roots	0.01	See point 7.2.3.9	0.02	See point 7.2.3.9
Turnip, roots	0.01	See point 7.2.3.9	0.02	See point 7.2.3.9
Soybean, seed	0.01	See point 7.2.3.9	-	-
Beet, sugar, dried pulp	0.20	See point 7.2.3.9	-	-
Beet, sugar, ensiled pulp	0.03	See point 7.2.3.9	-	-
Beet, sugar, molasses	0.31	See point 7.2.3.9	-	-
Canola (rape seed), meal	0.02	See point 7.2.3.9	-	-
Rape, meal	0.02	See point 7.2.3.9	-	-
Soybean, meal	0.01	See point 7.2.3.9	-	-
Soybean, hulls	0.13	See point 7.2.3.9	-	-
Sunflower, meal	0.02	See point 7.2.3.9	-	-
TAA				
Beet, mangel	0.01	See point 7.2.3.9	0.01	See point 7.2.3.9
Beet sugar, tops	0.01	See point 7.2.3.9	0.01	See point 7.2.3.9
Rape, forage	0.004	See point 7.2.3.9	0.05	See point 7.2.3.9
Turnip, tops (leaves)	0.01	See point 7.2.3.9	0.01	See point 7.2.3.9
Swede, roots	0.002	See point 7.2.3.9	0.002	See point 7.2.3.9
Turnip, roots	0.002	See point 7.2.3.9	0.002	See point 7.2.3.9
Soybean, seed	0.004	See point 7.2.3.9	-	-

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Beet, sugar, dried pulp	0.18	See point 7.2.3.9	-	-
Beet, sugar, ensiled pulp	0.03	See point 7.2.3.9	-	-
Beet, sugar, molasses	0.28	See point 7.2.3.9	-	-
Canola (rape seed), meal	0.01	See point 7.2.3.9	-	-
Rape, meal	0.01	See point 7.2.3.9	-	-
Soybean, meal	0.01	See point 7.2.3.9	-	-
Soybean, hulls	0.05	See point 7.2.3.9	-	-
Sunflower, meal	0.01	See point 7.2.3.9	-	-
TA				
Beet, mangel	0.02	See point 7.2.3.9	0.03	See point 7.2.3.9
Beet sugar, tops	0.02	See point 7.2.3.9	0.03	See point 7.2.3.9
Rape, forage	0.06	See point 7.2.3.9	0.67	See point 7.2.3.9
Turnip, tops (leaves)	0.02	See point 7.2.3.9	0.03	See point 7.2.3.9
Soybean, seed	0.36	See point 7.2.3.9	-	-
Swede, roots	0.01	See point 7.2.3.9	0.03	See point 7.2.3.9
Turnip, roots	0.01	See point 7.2.3.9	0.03	See point 7.2.3.9
Beet, sugar, dried pulp	0.18	See point 7.2.3.9	-	-
Beet, sugar, ensiled pulp	0.03	See point 7.2.3.9	-	-
Beet, sugar, molasses	0.28	See point 7.2.3.9	-	-
Canola (rape seed), meal	1.42	See point 7.2.3.9	-	-

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Rape, meal	1.42	See point 7.2.3.9	-	-
Soybean, meal	0.46	See point 7.2.3.9	-	-
Soybean, hulls	4.62	See point 7.2.3.9	-	-
Sunflower, meal	0.71	See point 7.2.3.9	-	-
TLA				
Beet, mangel	0.01	See point 7.2.3.9	0.08	See point 7.2.3.9
Beet sugar, tops	0.01	See point 7.2.3.9	0.08	See point 7.2.3.9
Rape, forage	0.004	See point 7.2.3.9	0.01	See point 7.2.3.9
Turnip, tops (leaves)	0.01	See point 7.2.3.9	0.08	See point 7.2.3.9
Soybean, seed	0.004	See point 7.2.3.9	-	-
Swede, roots	0.002	See point 7.2.3.9	0.01	See point 7.2.3.9
Turnip, roots	0.002	See point 7.2.3.9	0.01	See point 7.2.3.9
Beet, sugar, dried pulp	0.04	See point 7.2.3.9	-	-
Beet, sugar, ensiled pulp	0.01	See point 7.2.3.9	-	-
Beet, sugar, molasses	0.06	See point 7.2.3.9	-	-
Canola (rape seed), meal	0.02	See point 7.2.3.9	-	-
Rape, meal	0.02	See point 7.2.3.9	-	-
Soybean, meal	0.01	See point 7.2.3.9	-	-
Soybean, hulls	0.05	See point 7.2.3.9	-	-
Sunflower, meal	0.01	See point 7.2.3.9	-	-

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
1,2,4-T				
Beet, mangel	0.002	See point 7.2.3.9	0.02	See point 7.2.3.9
Beet sugar, tops	0.002	See point 7.2.3.9	0.02	See point 7.2.3.9
Rape, forage	0.004	See point 7.2.3.9	0.004	See point 7.2.3.9
Turnip, tops (leaves)	0.002	See point 7.2.3.9	0.02	See point 7.2.3.9
Soybean, seed	0.004	See point 7.2.3.9	-	-
Swede, roots	0.002	See point 7.2.3.9	0.002	See point 7.2.3.9
Turnip, roots	0.002	See point 7.2.3.9	0.002	See point 7.2.3.9
Beet, sugar, dried pulp	0.04	See point 7.2.3.9	-	-
Beet, sugar, ensiled pulp	0.01	See point 7.2.3.9	-	-
Beet, sugar, molasses	0.06	See point 7.2.3.9	-	-
Canola (rape seed), meal	0.02	See point 7.2.3.9	-	-
Rape, meal	0.02	See point 7.2.3.9	-	-
Soybean, meal	0.01	See point 7.2.3.9	-	-
Soybean, hulls	0.05	See point 7.2.3.9	-	-
Sunflower, meal	0.01	See point 7.2.3.9	-	-

~~Tribolet R. (2000)~~
~~Residue of difenoconazole (CGA 169374) and its metabolite CGA 205375 in milk, blood and tissues (muscle, fat, liver, kidney) of dairy cattle resulting from feeding of difenoconazole at three dose levels. The transfer of residues of difenoconazole from cattle into tissues and milk has been investigated. Residue data was supported by fortified procedural recovery.~~
~~There was no significant degradation of difenoconazole or CGA 205375 in milk, blood or tissues stored at< 20°C for periods equivalent to the maximum period of storage of the samples in the study.~~
~~Residues of difenoconazole were below 5 µg/L in the milk samples taken on all days during the feeding~~

~~period from all treatment groups. Residues of difenoconazole were less than 0.01 mg/kg in all tissues samples, with the exception of liver, which contained a residue of 0.01 mg/kg following dosing at the highest rate (10 mg/kg (10X). Residues of difenoconazole in blood were less than 10 µg/L.~~
~~Residues of CGA 205375 were below 5 µg/L in the milk samples taken on all days during the feeding period following difenoconazole 1 mg/kg (1X) and 3 mg/kg (3X). Following 10 mg/kg (10X), the mean residue of CGA 205375 was 7 µg/L. Residues of CGA 205375 in milk reached a plateau after two days of dosing and concentrations were maintained until the end of the study.~~
~~Following 3 and 10 mg/kg, maximum residues of CGA 205375 in muscle were 0.022 mg/kg and 0.028 mg/kg, respectively. In liver, residues of CGA 205375 were 0.04, 0.13 and 0.35 mg/kg following doses of 1, 3 and 10 mg/kg, respectively. In kidney, residues of CGA 205375 were <0.01, 0.02 and 0.05 mg/kg following doses of 1, 3 and 10 mg/kg, respectively. In fat, residues of CGA 205375 were 0.01, 0.03 and 0.09 mg/kg following doses of 1, 3 and 10 mg/kg, respectively. In blood, residues of CGA 205375 were <10, <10 and 19 µg/L following doses of 1, 3 and 10 mg/kg, respectively.~~
~~Residues of difenoconazole and CGA 205375 did not accumulate in milk, fat, liver, kidney or muscle following doses of 1 to 10 mg difenoconazole/kg in the diet. Residues of difenoconazole and CGA 205375 in the liver were 0.01 mg/kg and 0.04 mg/kg following administration of 10 mg/kg diet and of 1 mg/kg diet, respectively (i.e., 43 and 4.3 times higher than the realistic estimated feeding rate of 0.23 mg difenoconazole/kg diet). Hence, following the use of difenoconazole according to the proposed GAP, residues of difenoconazole in liver are not expected to exceed 0.01 mg/kg.~~
~~Ryan J. (2006).~~
~~Difenoconazole (CGA169374): Magnitude of the residue in meat and milk resulting from the feeding at three levels to dairy cattle.~~
~~Residues of difenoconazole were below 0.005 mg/kg in the milk samples taken on all days during the feeding period from all treatment groups. Residues of difenoconazole were less than 0.01 mg/kg in all tissues samples, with the exception of liver, which contained a residue of 0.01 mg/kg and 0.03 mg/kg following dosing at the rate of 5 mg/kg (5X) and 15 mg/kg (15X), respectively.~~

	Ruminant:	**Poultry:**	**Pig:**
	Conditions of requirement of feeding studies		
Expected intakes* by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes 0.23/0.65 mg/kg DM Dairy/Beef cattle	No	No
Potential for accumulation (yes/no):	n/a	n/a	n/a
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	n/a	n/a	n/a
	Feeding study[a] (residues of **difenoconazole-alcohol** (CGA 205375) for the feeding rate 10 mg/kg DM corresponding to a 43N and 15N dose rate for dairy and beef cattle) Residue levels in matrices : **mean (Max) mg/kg CGA 205375**		
Muscle	0.022 (0.024)	--	--
Liver	0.303 (0.350)	--	--
Kidney	0.044 (0.052)	--	--
Fat	0.077 (0.095)	--	--
Milk	0.008 (0.009)		
Eggs		--	

[a]: Parent also analysed for in the feeding study. At the highest feeding rate (10 mg/kg DM), all values below LOQs (0.005 mg/kg milk, 0.01 mg/kg other matrices), except in liver (HR 0.02 mg/kg).

Table 7.3-11a Overview of the dietary burden calculations for Difenoconazole

Animal burden calculation — **DIFENOCONAZOLE**

According to: "OECD Guidance Document, Series on testing and assessment No 64 and Series on pesticides No 32" and "OECD Guidance Document on Residues in livestock, Series on Pesticides No 73"

Maximum Intake	Cattle						Sheep					
	Beef (500 kg / 12 kg)			Dairy (650 kg / 25 kg)			Ram/Ewe (75 kg / 2.5 kg)			Lamb (40 kg / 1.7 kg)		
(mg/kg bw/d)	0.021	mg/kg bw/d	%	0.029	mg/kg bw/d	%	0.018	mg/kg bw/d	%	0.022	mg/kg bw/d	%
Contributor 1	Beet, mangel	fodder	30	Beet, mangel	fodder	25	Turnip	tops (leaves	30	Turnip	tops (leaves	30
Contributor 2	Beet, sugar	ensiled pulp	25	Beet, sugar	ensiled pulp	40	Beet, sugar	dried pulp	40	Beet, sugar	dried pulp	40
Contributor 3	Swede	roots	40	Swede	roots	20	Swede	roots	30	Swede	roots	30
Contributor 4	Soybean	seed	5	Soybean	seed	10			0			0
Median intake	0.0069	mg/kg bw/d		0.0103	mg/kg bw/d		0.0052	mg/kg bw/d		0.0092	mg/kg bw/d	

Maximum Intake	Swine					
	Breeding (260 kg / 6 kg)			Finishing (100 kg / 3 kg)		
(mg/kg bw/d)	0.012	mg/kg bw/d	%	0.004	mg/kg bw/d	%
Contributor 1	Beet, mangel	fodder	15	Beet, sugar	dried pulp	20
Contributor 2	Beet, sugar	dried pulp	20	Swede	roots	40
Contributor 3	Swede	roots	40	Soybean	seed	20
Contributor 4	Soybean	seed	10			
Median intake	0.004	mg/kg bw/d		0.003	mg/kg bw/d	

Intakes >0.004 mg/kg bw/d are highlighted

Maximum Intake	Poultry								
	Broiler (1.7 kg / 0.12 kg)			Layer (1.9 kg / 0.13 kg)			Turkey (7 kg / 0.5 kg)		
(mg/kg bw/d)	0.002	mg/kg bw/d	%	0.008	mg/kg bw/d	%	0.002	mg/kg bw/d	%
Contributor 1	Swede	roots	10	Beet, sugar	tops	5	Swede	roots	10
Contributor 2	Soybean	hulls	5	Swede	roots	10	Soybean	meal	45
Contributor 3	Soybean	seed	20	Soybean	hulls	5	Soybean	seed	15
Contributor 4				Soybean	seed	15			
Median intake	0.001	mg/kg bw		0.003	mg/kg bw		0.001	mg/kg bw	

Intakes expressed on the dry mater basis (mg/kg DM)

mg/kg DM	Cattle		Sheep		Swine	
	Beef	Dairy	Ram/Ewe	Lamb	Breeding	Finishing
Maximum	0.89	0.76	0.5	0.53	0.50	0.12
Median	0.29	0.27	0.16	0.22	0.18	0.09

	Poultry		
	Broiler	Layer	Turkey
Maximum	0.03	0.11	0.03
Median	0.02	0.04	0.02

Intake >0.1 mg/kg DM in red characters

Table 7.3-11b Overview of the dietary burden calculations for TAA

Animal burden calculation — **TAA**

According to: "OECD Guidance Document, Series on testing and assessment No 64 and Series on pesticides No 32" and "OECD Guidance Document on Residues in livestock, Series on Pesticides No 73"

Maximum Intake	Cattle						Sheep					
	Beef (500 kg / 12 kg)			Dairy (650 kg / 25 kg)			Ram/Ewe (75 kg / 2.5 kg)			Lamb (40 kg / 1.7 kg)		
(mg/kg bw/d)	0.0019	mg/kg bw/d	%	0.0039	mg/kg bw/d	%	0.0050	mg/kg bw/d	%	0.0064	mg/kg bw/d	%
Contributor 1	Beet, sugar	ensiled pulp	25	Beet, sugar	ensiled pulp	40	Beet, sugar	dried pulp	40	Beet, sugar	dried pulp	40
Contributor 2	Beet, mangel	fodder	30	Beet, mangel	fodder	25	Rape	forage	40	Rape	forage	40
Contributor 3	Swede	roots	40	Swede	roots	20	Swede	roots	20	Swede	roots	20
Contributor 4	Soybean	seed	5	Soybean	seed	10			0			0
Median intake	0.0019	mg/kg bw/d		0.0039	mg/kg bw/d		0.0009	mg/kg bw/d		0.0042	mg/kg bw/d	

Maximum Intake	Swine					
	Breeding (260 kg / 6 kg)			Finishing (100 kg / 3 kg)		
(mg/kg bw/d)	0.002	mg/kg bw/d	%	0.001	mg/kg bw/d	%
Contributor 1	Beet, sugar	dried pulp	20	Beet, sugar	dried pulp	20
Contributor 2	Rape	forage	20	Swede	roots	40
Contributor 3	Swede	roots	40	Soybean	seed	20
Contributor 4	Soybean	seed	10			
Median intake	0.001	mg/kg bw/d		0.001	mg/kg bw/d	

Intakes >0.004 mg/kg bw/d are highlighted

Maximum Intake	Poultry								
	Broiler (1.7 kg / 0.12 kg)			Layer (1.9 kg / 0.13 kg)			Turkey (7 kg / 0.5 kg)		
(mg/kg bw/d)	0.000	mg/kg bw/d	%	0.001	mg/kg bw/d	%	0.000	mg/kg bw/d	%
Contributor 1	Soybean	hulls	5	Rape	forage	10	Swede	roots	10
Contributor 2	Swede	roots	10	Soybean	hulls	5	Soybean	meal	45
Contributor 3	Soybean	seed	20	Swede	roots	10	Soybean	seed	15
Contributor 4				Soybean	seed	15			
Median intake	0.000	mg/kg bw		0.001	mg/kg bw		0.000	mg/kg bw	

Intakes expressed on the dry mater basis (mg/kg DM)

mg/kg DM	Cattle		Sheep		Swine	
	Beef	Dairy	Ram/Ewe	Lamb	Breeding	Finishing
Maximum	0.0782	**0.10**	**0.15**	**0.15**	0.08	0.05
Median	0.0782	0.10	0.03	0.10	0.06	0.05

	Poultry		
	Broiler	Layer	Turkey
Maximum	0.01	0.02	0.01
Median	0.01	0.01	0.01

Intake >0.1 mg/kg DM
in red characters

Table 7.3-11c Overview of the dietary burden calculations for TA

Animal burden calculation — **TA**

According to: "OECD Guidance Document, Series on testing and assessment No 64 and Series on pesticides No 32" and "OECD Guidance Document on Residues in livestock, Series on Pesticides No 73"

Maximum Intake	Cattle						Sheep					
	Beef (500 kg / 12 kg)			Dairy (650 kg / 25 kg)			Ram/Ewe (75 kg / 2.5 kg)			Lamb (40 kg / 1.7 kg)		
(mg/kg bw/d)	0.0213	mg/kg bw/d	%	0.0185	mg/kg bw/d	%	0.0681	mg/kg bw/d	%	0.0873	mg/kg bw/d	%
Contributor 1	Soybean	hulls	10	Rape	forage	10	Soybean	hulls	20	Soybean	hulls	20
Contributor 2	Rape	forage	10	Canola	meal	10	Rape	forage	40	Rape	forage	40
Contributor 3	Soybean	seed	10	Soybean	seed	10	Soybean	seed	10	Soybean	seed	20
Contributor 4	Swede	roots	40	Swede	roots	20	Swede	roots	30	Swede	roots	20
Median intake	0.0150	mg/kg bw/d		0.0095	mg/kg bw/d		0.0394	mg/kg bw/d		0.0515	mg/kg bw/d	

Maximum Intake	Swine					
	Breeding (260 kg / 6 kg)			Finishing (100 kg / 3 kg)		
(mg/kg bw/d)	0.026	mg/kg bw/d	%	0.021	mg/kg bw/d	%
Contributor 1	Soybean	hulls	10	Soybean	hulls	10
Contributor 2	Rape	forage	20	Soybean	seed	20
Contributor 3	Soybean	seed	10	Swede	roots	40
Contributor 4	Swede	roots	40			
Median intake	0.015	mg/kg bw/d		0.019	mg/kg bw/d	

Intakes >0.004 mg/kg bw/d are highlighted

Maximum Intake	Poultry								
	Broiler (1.7 kg / 0.12 kg)			Layer (1.9 kg / 0.13 kg)			Turkey (7 kg / 0.5 kg)		
(mg/kg bw/d)	0.028	mg/kg bw/d	%	0.039	mg/kg bw/d	%	0.029	mg/kg bw/d	%
Contributor 1	Canola	meal	18	Soybean	hulls	5	Canola	meal	20
Contributor 2	Soybean	seed	20	Rape	forage	10	Soybean	seed	15
Contributor 3	Swede	roots	10	Soybean	seed	15	Swede	roots	10
Contributor 4				Swede	roots	10			
Median intake	0.027	mg/kg bw		0.024	mg/kg bw		0.028	mg/kg bw	

Intakes expressed on the dry mater basis (mg/kg DM)

mg/kg DM	Cattle		Sheep		Swine	
	Beef	Dairy	Ram/Ewe	Lamb	Breeding	Finishing
Maximum	0.8880	0.48	2.04	2.05	1.11	0.70
Median	0.6247	0.25	1.18	1.21	0.64	0.63

	Poultry		
	Broiler	Layer	Turkey
Maximum	0.40	0.57	0.41
Median	0.38	0.35	0.39

Intake >0.1 mg/kg DM in red characters

Table 7.3-11d Overview of the dietary burden calculations for TLA

Animal burden calculation — **TLA**

According to: "OECD Guidance Document, Series on testing and assessment No 64 and Series on pesticides No 32" and "OECD Guidance Document on Residues in livestock, Series on Pesticides No 73"

Maximum Intake	Cattle						Sheep					
	Beef	500 kg 12 kg		Dairy	650 kg 25 kg		Ram/Ewe	75 kg 2.5 kg		Lamb	40 kg 1.7 kg	
(mg/kg bw/d)	0.0052	mg/kg bw/d	%	0.0067	mg/kg bw/d	%	0.0043	mg/kg bw/d	%	0.0055	mg/kg bw/d	%
Contributor 1	Beet, mangel	fodder	30	Beet, mangel	fodder	25	Turnip	tops (leaves	30	Turnip	tops (leaves	30
Contributor 2	Swede	roots	40	Swede	roots	20	Swede	roots	30	Swede	roots	30
Contributor 3	Beet, sugar	ensiled pulp	25	Beet, sugar	ensiled pulp	40	Beet, sugar	dried pulp	40	Beet, sugar	dried pulp	40
Contributor 4	Soybean	seed	5	Soybean	seed	10			0			0
Median intake	0.0011	mg/kg bw/d		0.0016	mg/kg bw/d		0.0010	mg/kg bw/d		0.0015	mg/kg bw/d	

Intakes >0.004 mg/kg bw/d are highlighted

Maximum Intake	Swine					
	Breeding	260 kg 6 kg		Finishing	100 kg 3 kg	
(mg/kg bw/d)	0.003	mg/kg bw/d	%	0.001	mg/kg bw/d	%
Contributor 1	Beet, mangel	fodder	15	Swede	roots	40
Contributor 2	Swede	roots	40	Beet, sugar	dried pulp	20
Contributor 3	Beet, sugar	dried pulp	20	Soybean	seed	20
Contributor 4	Soybean	seed	10			
Median intake	0.001	mg/kg bw/d		0.001	mg/kg bw/d	

Maximum Intake	Poultry								
	Broiler	1.7 kg 0.12 kg		Layer	1.9 kg 0.13 kg		Turkey	7 kg 0.5 kg	
(mg/kg bw/d)	0.001	mg/kg bw/d	%	0.002	mg/kg bw/d	%	0.001	mg/kg bw/d	%
Contributor 1	Swede	roots	10	Beet, sugar	tops	5	Swede	roots	10
Contributor 2	Canola	meal	18	Swede	roots	10	Canola	meal	20
Contributor 3	Soybean	seed	20	Soybean	hulls	5	Soybean	seed	15
Contributor 4				Soybean	seed	15			
Median intake	0.000	mg/kg bw		0.001	mg/kg bw		0.000	mg/kg bw	

Intakes expressed on the dry mater basis (mg/kg DM)

mg/kg DM	Cattle		Sheep		Swine	
	Beef	Dairy	Ram/Ewe	Lamb	Breeding	Finishing
Maximum	0.2162	0.17	0.13	0.13	0.13	0.05
Median	0.0442	0.04	0.03	0.04	0.03	0.02

	Poultry		
	Broiler	Layer	Turkey
Maximum	0.01	0.03	0.01
Median	0.01	0.01	0.01

Intake >0.1 mg/kg DM in red characters

Table 7.3-11e Overview of the dietary burden calculations for 1,2,4-T

Animal burden calculation — **1,2,4-T**

According to: "OECD Guidance Document, Series on testing and assessment No 64 and Series on pesticides No 32" and "OECD Guidance Document on Residues in livestock, Series on Pesticides No 73"

Maximum Intake	Cattle						Sheep					
	Beef (500 kg / 12 kg)			Dairy (650 kg / 25 kg)			Ram/Ewe (75 kg / 2.5 kg)			Lamb (40 kg / 1.7 kg)		
(mg/kg bw/d)	0.0009	mg/kg bw/d	%	0.0014	mg/kg bw/d	%	0.0011	mg/kg bw/d	%	0.0014	mg/kg bw/d	%
Contributor 1	Beet, mangel	fodder	30	Beet, mangel	fodder	25	Beet, sugar	dried pulp	40	Beet, sugar	dried pulp	40
Contributor 2	Beet, sugar	ensiled pulp	25	Beet, sugar	ensiled pulp	40	Turnip	tops (leaves	30	Turnip	tops (leaves	30
Contributor 3	Swede	roots	40	Swede	roots	20	Swede	roots	30	Swede	roots	30
Contributor 4	Soybean	seed	5	Soybean	seed	10			0			0
Median intake	0.0005	mg/kg bw/d		0.0009	mg/kg bw/d		0.0008	mg/kg bw/d		0.0011	mg/kg bw/d	

Maximum Intake	Swine					
	Breeding (260 kg / 6 kg)			Finishing (100 kg / 3 kg)		
(mg/kg bw/d)	0.001	mg/kg bw/d	%	0.001	mg/kg bw/d	%
Contributor 1	Beet, mangel	fodder	15	Beet, sugar	dried pulp	20
Contributor 2	Beet, sugar	dried pulp	20	Swede	roots	40
Contributor 3	Swede	roots	40	Soybean	seed	20
Contributor 4	Soybean	seed	10			
Median intake	0.000	mg/kg bw/d		0.001	mg/kg bw/d	

Intakes >0.004 mg/kg bw/d are highlighted

Maximum Intake	Poultry								
	Broiler (1.7 kg / 0.12 kg)			Layer (1.9 kg / 0.13 kg)			Turkey (7 kg / 0.5 kg)		
(mg/kg bw/d)	0.000	mg/kg bw/d	%	0.001	mg/kg bw/d	%	0.000	mg/kg bw/d	%
Contributor 1	Swede	roots	10	Soybean	hulls	5	Swede	roots	10
Contributor 2	Canola	meal	18	Beet, sugar	tops	5	Canola	meal	20
Contributor 3	Soybean	seed	20	Swede	roots	10	Soybean	seed	15
Contributor 4				Soybean	seed	15			
Median intake	0.000	mg/kg bw		0.000	mg/kg bw		0.000	mg/kg bw	

Intakes expressed on the dry mater basis (mg/kg DM)

mg/kg DM	Cattle		Sheep		Swine	
	Beef	Dairy	Ram/Ewe	Lamb	Breeding	Finishing
Maximum	0.0382	0.04	0.03	0.03	0.03	0.02
Median	0.0222	0.02	0.02	0.03	0.02	0.02

	Poultry		
	Broiler	Layer	Turkey
Maximum	0.01	0.01	0.01
Median	0.01	0.01	0.01

Intake >0.1 mg/kg DM in red characters

zRMS comments:
In the zRMS opinion dietary burden calculations should consider all uses evaluated in the most recent EFSA/EU assessment, not only the uses under consideration.
In the calculations below default processing factor was applied for these commodities for which residues are expected to be below the LOQ. Concentration of residues in these commodities is not expected.

Difenoconazole
The dietary burden calculations were performed during MRL review, EFSA Journal. 2024;22:e8987. It cover the uses proposed in this dossier. The STMS and HR values indicated below, as input values are higher than those derived from the studies provided by the Applicant.
Input values for the dietary burden calculation EFSA Journal. 2024;22:e8987

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Difenoconazole				
Alfalfa forage (green)	0.01	STMR	0.01	HR

Alfalfa hay (fodder)	0.01	STMR	0.01	HR
Alfalfa meal	0.01	STMR	0.01	HR
Alfalfa silage	0.01	STMR	0.01	HR
Barley straw	0.31	STMR	0.71	HR
Bean vines (fodder green)	0.01	STMR	0.01	HR
Beet, mangel fodder	0.84	STMR	3.32	HR
Beet, sugar tops	0.65	STMR	3.32	HR
Cabbage, heads leaves	0.02	STMR	0.19	HR
Clover forage	0.01	STMR	0.01	HR
Clover hay	0.01	STMR	0.01	HR
Clover silage	0.01	STMR	0.01	HR
Kale leaves (forage)	0.83	STMR	3.07	HR
Oat straw	0.02	STMR	0.05	HR
Pea vines (green)	0.01	STMR	0.01	HR
Pea hay (hay or fodder)	0.01	STMR	0.01	HR
Pea silage	0.01	STMR	0.01	HR
Rice straw	1.9	STMR	2.6	HR
Rye straw	0.67	STMR	4.56	HR
Triticale straw	0.67	STMR	4.56	HR
Vetch forage	0.01	STMR	0.01	HR
Vetch hay	0.01	STMR	0.01	HR
Wheat straw	0.67	STMR	4.56	HR
Carrot culls	0.08	STMR	0.3	HR
Cassava/tapioca roots	0.01	STMR	0.01	HR
Potato culls	0.01	STMR	0.07	HR
Swede roots	0.08	STMR	0.3	HR
Turnip roots	0.08	STMR	0.3	HR
Barley grain	0.03	STMR	0.03	STMR
Bean seed (dry)	0.02	STMR	0.02	STMR
Cotton undelinted seed	0.01	STMR	0.01	STMR
Cowpea seed	0.02	STMR	0.02	STMR
Lupin seed	0.02	STMR	0.02	STMR
Oat grain	0.02	STMR	0.02	STMR
Pea (Field pea) seed (dry)	0.02	STMR	0.02	STMR
Rye grain	0.01	STMR	0.01	STMR
Soybean seed	0.02	STMR	0.02	STMR
Triticale grain	0.01	STMR	0.01	STMR
Wheat grain	0.01	STMR	0.01	STMR
Apple pomace, wet	0.36	STMR x PF (3.2)	0.36	STMR x PF (3.2)
Beet, sugar dried pulp	0.81	STMR x default PF (18)	0.81	STMR x default PF (18)
Beet, sugar ensiled pulp	0.14	STMR x default PF (3)	0.14	STMR x default PF (3)
Beet, sugar molasses	1.26	STMR x default PF (28)	1.26	STMR x default PF (28)
Brewer's grain dried	0.10	STMR x default PF (3.3)	0.10	STMR x default PF (3.3)
Canola (Rape seed) meal	0.04	STMR x default PF (2)	0.04	STMR x default PF (2)
Cotton meal	0.01	STMR	0.01	STMR
Distiller's grain dried	0.03	STMR x default PF (3.3)	0.03	STMR x default PF (3.3)
Flaxseed/Linseed meal	0.04	STMR x default PF (2)	0.04	STMR x default PF (2)
Lupin seed meal	0.02	STMR x default PF (1.1)	0.02	STMR x default PF (1.1)

Potato process waste	0.2	STMR x default PF (20)	0.2	STMR x default PF (20)
Potato dried pulp	0.38	STMR x default PF (38)	0.38	STMR x default PF (38)
Rape meal	0.04	STMR x default PF (2)	0.04	STMR x default PF (2)
Rice bran/pollard	8.75	STMR x default PF (10)	8.75	STMR x default PF (10)
Safflower meal	0.02	STMR x default PF (2)	0.02	STMR x default PF (2)
Soybean meal	0.03	STMR x default PF (1.3)	0.03	STMR x default PF (1.3)
Soybean hulls	0.26	STMR x default PF (13)	0.26	STMR x default PF (13)
Sunflower meal	0.02	STMR x default PF (2)	0.02	STMR x default PF (2)
Wheat gluten meal	0.02	STMR x default PF (1.8)	0.02	STMR x default PF (1.8)
Wheat milled by-pdts	0.07	STMR x default PF (7)	0.07	STMR x default PF (7)

Results of the dietary burden calculation (Difenoconazole)

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					0.10
	Median	Maximum	Median	Maximum				mg/kg DM
Cattle (all diets)	0.135	0.311	3.52	8.34	Dairy cattle	Beet, mangel	fodder	Yes
Cattle (dairy only)	0.135	0.311	3.52	8.09	Dairy cattle	Beet, mangel	fodder	Yes
Sheep (all diets)	0.158	0.285	3.73	6.71	Lamb	Beet, sugar	tops	Yes
Sheep (ewe only)	0.124	0.224	3.73	6.71	Ram/Ewe	Beet, sugar	tops	Yes
Swine (all diets)	0.049	0.127	2.14	5.50	Swine (breeding)	Beet, mangel	fodder	Yes
Poultry (all diets)	0.076	0.105	1.08	1.54	Poultry layer	Beet, sugar	tops	Yes
Poultry (layer only)	0.05	0.105	0.73	1.54	Poultry layer	Beet, sugar	tops	Yes

The calculated dietary burdens for cattle, ram/ewe, lamb, pig and poultry were found to exceed the trigger value of 0.1 mg/kg. Further investigation of residues is therefore required.

TDMs

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: 1,2,4-T				
Barley straw	0.01	STMR, EFSA 2024	0.01	HR, EFSA 2024
Beet, mangel fodder	0.01	STMR, EFSA 2024	0.01	HR, EFSA 2024
Beet, sugar tops	0.002	STMR, from present dossier	0.01	HR, from present dossier
Oat straw	0.01	STMR, EFSA 2024	0.01	HR, EFSA 2024
Rye straw	0.01	STMR, EFSA 2024	0.02	HR, EFSA 2024
Rape forage	0.004	STMR, from present dossier	0.004	HR, from present dossier
Triticale straw	0,01	STMR, EFSA 2024	0.02	HR, EFSA 2024
Turnip tops	0.002	STMR, from present dossier	0.002	HR, from present dossier
Wheat straw	0.01	STMR, EFSA 2024	0.02	HR, EFSA 2024
Potato culls	0.01	STMR, EFSA 2024	0.01	HR, EFSA 2024

Swede roots	0.002	STMR, from present dossier	0.002	HR, from present dossier
Turnip roots	0.002	STMR, from present dossier	0.002	HR, from present dossier
Barley grain	0.01	STMR, EFSA 2024	0.01	STMR, EFSA 2024
Oat grain	0.01	STMR, EFSA 2024	0.01	STMR, EFSA 2024
Rye grain	0.01	STMR, EFSA 2024	0.01	STMR, EFSA 2024
Soybean seed	0.004	STMR, from present dossier	0.004	STMR, from present dossier
Triticale grain	0.01	STMR, EFSA 2024	0.01	STMR, EFSA 2024
Wheat grain	0.01	STMR, EFSA 2024	0.01	STMR, EFSA 2024
Apple pomace, wet	0.01	STMR x PF (5) , EFSA 2024	0.01	STMR x PF (5) , EFSA 2024
Beet, sugar dried pulp	0.002	STMR x default PF (18), from present dossier	0.002	STMR x default PF (18), from present dossier
Beet, sugar ensiled pulp	0.002	STMR x default PF (3), from present dossier	0.002	STMR x default PF (3), from present dossier
Beet, sugar molasses	0.002	STMR x default PF (28)	0.002	STMR x default PF (28), from present dossier
Brewer's grain dried	0.03	STMR x default PF (3.3) , EFSA 2024	0.03	STMR x default PF (3.3) , EFSA 2024
Canola (Rape seed) meal	0.004	STMR x default PF (2), from present dossier	0.004	STMR x default PF (2), from present dossier
Distiller's grain dried	0.01	STMR x default PF (3.3) , EFSA 2024	0.01	STMR x default PF (3.3) , EFSA 2024
Potato process waste	0.2	STMR x default PF (20) , EFSA 2024	0.2	STMR x default PF (20) , EFSA 2024
Potato dried pulp	0.01	STMR x default PF (38) , EFSA 2024	0.01	STMR x default PF (38) , EFSA 2024
Safflower meal	0.01	STMR x default PF (2) , EFSA 2024	0.01	STMR x default PF (2) , EFSA 2024
Rape meal	0.002	STMR x default PF (2), from present dossier	0.002	STMR x default PF (2), from present dossier
Soybean meal	0.004	STMR x default PF (1.3), from present dossier	0.004	STMR x default PF (1.3), from present dossier
Soybean hulls	0.004	STMR x default PF (13), from present dossier	0.004	STMR x default PF (13) , from present dossier
Sunflower meal	0.01	STMR x default PF (2) , EFSA 2024	0.02	STMR x default PF (2) , EFSA 2024
Wheat gluten meal	0.01	STMR x default PF (1.8) , EFSA 2024	0.02	STMR x default PF (1.8) , EFSA 2024
Wheat milled by-pdts	0.01	STMR x default PF (7) , EFSA 2024	0.01	STMR x default PF (7) , EFSA 2024

Results of the dietary burden calculation (1,2,4-T)

Relevant groups	**Dietary burden expressed in**				**Most critical diet**	**Most critical commodity**		Trigger exceeded (Yes/No)	EFSA Journal. 2024;22:e8987
	mg/kg bw per day		mg/kg DM					0.004 mg/kg bw	Max burden mg/kg DM
	Median	Maximum	Median	Maximum					
Cattle (all diets)	0.002	0.002	0.07	0.07	Dairy cattle	Potato	process waste	No	0.07
Cattle (dairy only)	0.002	0.002	0.06	0.06	Dairy cattle	Potato	process waste	No	0.06
Sheep (all diets)	0.002	0.003	0.05	0.06	Lamb	Wheat	milled bypdts	No	0.06
Sheep (ewe	0.002	0.002	0.05	0.06	Ram/Ewe	Potato	process	No	0.06

only)							waste		
Swine (all diets)	0.002	0.002	0.07	0.07	Swine (finishing)	Wheat	milled bypdts	No	0.07
Poultry (all diets)	0.002	0.002	0.03	0.03	Turkey	Wheat	milled bypdts	No	0.03
Poultry (layer only)	0.002	0.002	0.03	0.03	Poultry layer	Wheat	milled bypdts	No	0.03

The crops under consideration in these assessment did not change the maximum animal intakes estimated for 1,2,4-T in the EFSA Journal. 2024;22:e8987 for all animal species.

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: TAA				
Barley straw	0.05	STMR, EFSA 2024	0.15	HR, EFSA 2024
Beet, mangel fodder	0.01	STMR, EFSA 2024	0.01	HR, EFSA 2024
Beet, sugar tops	0.01	STMR, from present dossier	0.01	HR, from present dossier
Oat straw	0.05	STMR, EFSA 2024	0.15	HR, EFSA 2024
Rape forage	0.004	STMR, from present dossier	0.049	HR, from present dossier
Rye straw	0.05	STMR, EFSA 2024	0.41	HR, EFSA 2024
Wheat straw	0.05	STMR, EFSA 2024	0.41	HR, EFSA 2024
Potato culls	0.01	STMR, EFSA 2024	0.01	HR, EFSA 2024
Swede roots	0.002	STMR, from present dossier	0.002	HR, from present dossier
Turnip roots	0.002	STMR, from present dossier	0.002	HR, from present dossier
Barley grain	0.07	STMR, EFSA 2024	0.07	STMR, EFSA 2024
Oat grain	0.07	STMR, EFSA 2024	0.07	STMR, EFSA 2024
Rye grain	0.05	STMR, EFSA 2024	0.05	STMR, EFSA 2024
Soybean seed	0.004	STMR, from present dossier	0.004	STMR, from present dossier
Triticale grain	0.05	STMR, EFSA 2024	0.05	STMR, EFSA 2024
Wheat grain	0.05	STMR, EFSA 2024	0.05	STMR, EFSA 2024
Apple pomace, wet	0.01	STMR x PF (5) , EFSA 2024	0.01	STMR x PF (5) , EFSA 2024
Beet, sugar dried pulp	0.002	STMR x default PF (18), from present dossier	0.002	STMR x default PF (18), from present dossier
Beet, sugar ensiled pulp	0.002	STMR x default PF (3), from present dossier	0.002	STMR x default PF (3), from present dossier
Beet, sugar molasses	0.002	STMR x default PF (28)	0.002	STMR x default PF (28), from present dossier
Brewer's grain dried	0.23	STMR x default PF (3.3) , EFSA 2024	0.23	STMR x default PF (3.3) , EFSA 2024
Distiller's grain dried	0.17	STMR x default PF (3.3) , EFSA 2024	0.17	STMR x default PF (3.3) , EFSA 2024
Potato process waste	0.01	STMR x default PF (20) , EFSA 2024	0,01	STMR x default PF (20) , EFSA 2024
Potato dried pulp	0,01	STMR x default PF (38) , EFSA 2024	0,01	STMR x default PF (38) , EFSA 2024
Safflower meal	0.22	STMR x default PF (2) , EFSA 2024	0.22	STMR x default PF (2) , EFSA 2024
Rape meal	0.01	STMR x default PF (2), from present dossier	0.01	STMR x default PF (2), from present dossier
Soybean meal	0.01	STMR x default PF (1.3),	0.01	STMR x default PF (1.3),

		from present dossier		from present dossier
Soybean hulls	0.052	STMR x default PF (13), from present dossier	0.052	STMR x default PF (13), from present dossier
Sunflower meal	0.22	STMR x default PF (2), EFSA 2024	0.02	STMR x default PF (2), EFSA 2024
Wheat gluten meal	0.09	STMR x default PF (1.8), EFSA 2024	0.09	STMR x default PF (1.8), EFSA 2024
Wheat milled by-pdts	0.35	STMR x default PF (7), EFSA 2024	0.35	STMR x default PF (7), EFSA 2024

Results of the dietary burden calculation (TAA)

Relevant groups	**Dietary burden expressed in**				**Most critical diet**	**Most critical commodity**		Trigger exceeded (Yes/No)	Previous assessment
	mg/kg bw per day		mg/kg DM					0.004	Max burden
	Median	Maximum	Median	Maximum				mg/kg bw	mg/kg DM
Cattle (all diets)	0.006	0.010	0.18	0.25	Dairy cattle	Rye	straw	Yes	0.25
Cattle (dairy only)	0.006	0.010	0.17	0.25	Dairy cattle	Rye	straw	Yes	0.25
Sheep (all diets)	0.010	0.017	0.24	0.39	Lamb	Rye	straw	Yes	0.39
Sheep (ewe only)	0.007	0.012	0.20	0.36	Ram/Ewe	Rye	straw	Yes	0.36
Swine (all diets)	0.007	0.007	0.24	0.26	Swine (finishing)	Wheat	milled bypdts	Yes	0.26
Poultry (all diets)	0.010	0.012	0.14	0.18	Poultry layer	Wheat	straw	Yes	0.18
Poultry (layer only)	0.010	0.012	0.14	0.18	Poultry layer	Wheat	straw	Yes	0.18

The crops under consideration in these assessment did not change the maximum animal intakes estimated for TAA in the EFSA Journal. 2024;22:e8987 for all animal species.

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: TA+TLA				
Barley straw	0.11	STMR, EFSA 2024	0.75	HR, EFSA 2024
Beet, mangel fodder	0.1	STMR, EFSA 2024	0.12	HR, EFSA 2024
Beet, sugar tops	0.029	STMR, from present dossier	0.112	HR, from present dossier
Oat straw	0.11	STMR, EFSA 2024	0.75	HR, EFSA 2024
Rape forage	0.068	STMR, from present dossier	0.78	HR, from present dossier
Rye straw	0.04	STMR, EFSA 2024	0.33	HR, EFSA 2024
Triticale straw	0.04	STMR, EFSA 2024	0.33	STMR, EFSA 2024
Wheat straw	0.04	STMR, EFSA 2024	0.33	HR, EFSA 2024
Turnip tops	0.029	STMR, from present dossier	0.112	HR, from present dossier
Potato culls	0.04	STMR, EFSA 2024	0.15	HR, EFSA 2024
Swede roots	0.012	STMR, from present dossier	0.038	HR, from present dossier
Turnip roots	0.012	STMR, from present dossier	0.038	HR, from present dossier
Barley grain	0.14	STMR, EFSA 2024	0.14	STMR, EFSA 2024

Oat grain	0.1	STMR, EFSA 2024	0.1	STMR, EFSA 2024
Rye grain	0.14	STMR, EFSA 2024	0.14	STMR, EFSA 2024
Soybean seed	0.359	STMR, from present dossier	0.359	STMR, from present dossier
Triticale grain	0.14	STMR, EFSA 2024	0.14	STMR, EFSA 2024
Wheat grain	0.14	STMR, EFSA 2024	0.14	STMR, EFSA 2024
Apple pomace, wet	0.01	STMR x PF (5) , EFSA 2024	0.01	STMR x PF (5) , EFSA 2024
Beet, sugar dried pulp	0.216	STMR x default PF (18), from present dossier	0.216	STMR x default PF (18), from present dossier
Beet, sugar ensiled pulp	0.036	STMR x default PF (3), from present dossier	0.036	STMR x default PF (3), from present dossier
Beet, sugar molasses	0.336	STMR x default PF (28)	0.336	STMR x default PF (28), from present dossier
Brewer's grain dried	0,33	STMR x default PF (3.3) , EFSA 2024	0,33	STMR x default PF (3.3) , EFSA 2024
Distiller's grain dried	0.23	STMR x default PF (3.3) , EFSA 2024	0.23	STMR x default PF (3.3) , EFSA 2024
Potato process waste	0.01	STMR x default PF (20) , EFSA 2024	0,01	STMR x default PF (20) , EFSA 2024
Potato dried pulp	1.52	STMR x default PF (38) , EFSA 2024	1.52	STMR x default PF (38) , EFSA 2024
Safflower meal	0.16	STMR x default PF (2) , EFSA 2024	0.16	STMR x default PF (2) , EFSA 2024
Sunflower meal	0.718	STMR x default PF (2), from present dossier	0.718	STMR x default PF (2), from present dossier
Rape meal	0.718	STMR x default PF (2), from present dossier	0.718	STMR x default PF (2), from present dossier
Soybean meal	0.467	STMR x default PF (1.3), from present dossier	0.467	STMR x default PF (1.3), from present dossier
Soybean hulls	4.667	STMR x default PF (13), from present dossier	4.667	STMR x default PF (13) , from present dossier
Sunflower meal	0.718	STMR x default PF (2) , EFSA 2024	0.718	STMR x default PF (2) , EFSA 2024
Wheat gluten meal	0.13	STMR x default PF (1.8) , EFSA 2024	0.13	STMR x default PF (1.8) , EFSA 2024
Wheat milled by-pdts	0.49	STMR x default PF (7) , EFSA 2024	0.49	STMR x default PF (7) , EFSA 2024

Results of the dietary burden calculation (TA+TLA)

Relevant groups	**Dietary burden expressed in**				**Most critical diet (a)**	**Most critical commodity (b)**		Trigger exceeded (Yes/No)	Previous assessment
	mg/kg bw per day		mg/kg DM					0.004	Max burden
	Median	Maximum	Median	Maximum				mg/kg bw	mg/kg DM
Cattle (all diets)	0.020	0.027	0.82	1.06	Dairy cattle	Rape	forage	Yes	0.67
Cattle (dairy only)	0.017	0.027	0.44	0.70	Dairy cattle	Rape	forage	Yes	0.65
Sheep (all diets)	0.053	0.098	1.25	2.34	Lamb	Soybean	hulls	Yes	1.14
Sheep (ewe only)	0.041	0.078	1.23	2.34	Ram/Ewe	Soybean	hulls	Yes	1.14
Swine (all diets)	0.021	0.034	0.76	1.45	Swine (finishing)	Soybean	hulls	Yes	0.75
Poultry (all diets)	0.031	0.046	0.45	0.68	Poultry broiler	Soybean	hulls	Yes	0.5

Poultry (layer only)	0.026	0.046	0.39	0.68	Poultry layer	Soybean	hulls	Yes	0.47

The crops under consideration in these assessment change the maximum animal intakes estimated for TA and TLA in the EFSA Journal. 2024;22:e8987 for all relevant group of livestock but not change the maximum animal intakes estimated for TA and TLA in the EFSA Journal 2018;16(7):5376 (Peer review of the pesticide risk assessment of the triazole derivative metabolites).
Results of the dietary burden calculation for TA in the EFSA Journal 2018;16(7):5376 (UK, 2018).

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)	0,376	0,405	12,97	13,63	Dairy cattle	Potato	process waste	Yes
Cattle (dairy only)	0,376	0,405	9,77	10,52	Dairy cattle	Potato	process waste	Yes
Sheep (all diets)	0,425	0,454	12,76	13,63	Ram/Ewe	Potato	process waste	Yes
Sheep (ewe only)	0,425	0,454	12,76	13,63	Ram/Ewe	Potato	process waste	Yes
Swine (all diets)	0,163	0,178	7,08	7,71	Swine (breeding)	Potato	process waste	Yes
Poultry (all diets)	0,158	0,165	2,24	2,34	Poultry broiler	Potato	dried pulp	Yes
Poultry (layer only)	0,130	0,149	1,91	2,18	Poultry layer	Potato	dried pulp	Yes

Livestock dietary intake calculations for TDMs have been performed during EU peer review of the pesticide risk assessment for the triazole derivative metabolites (UK, 2018 and EFSA Journal 2018;16(7):5376): "The livestock dietary burden calculation has been performed respectively for each TDM compound and triggered livestock feeding studies for 1,2,4-T, TA, TAA and TLA, see chapter B.7.4 of the addendum (United Kingdom, 2015, 2018b)."

Comparison of input values for dietary burden calculation from confirmatory data assessment (UK, 2018) with values derived from studies provided in this dossier:

Crop	**Source of data**	**HR /STMR-P**	**Residue (mg/kg)**			
			T	**TA**	**TAA**	**TLA**
		Residues input values for the max. dietary burden calculation (bold in brackets: HR/STMRs derived from new residue studies)				
Forages						
Beet, mangel fodder	HR of beet leaves or root	HR	0.12 **(0.01)**	0.239 **(0.029)**	0.05 **(0.01)**	0.14 **(0.083)**
Beet tops	Sugar beet leaves	HR	0.12 **(0.01)**	0.218 **(0.0029)**	0.02 **(0.01)**	0.14 **(0.083)**
Rape forage	Oilseed rape plant	HR	0.023 **(0.004)**	0.913 **(0.67)**	0.034 **(0.049)**	0.04 **(0.11)**
Turnip leaves	Sugar beet leaves data	HR	0.12 **(0.01)**	0.218 **(0.0029)**	0.02 **(0.01)**	0.14 **(0.083)**
Root and tubers						
Swede	Root vegetable	HR	0.06 **(0.002)**	0.239 **(0.01)**	0.05 **(0.002)**	0.13 **(0.002)**
Turnip	Root vegetable	HR	0.06 **(0.002)**	0.239 **(0.01)**	0.05 **(0.002)**	0.13 **(0.002)**

Crop	Source of data	HR /STMR-P	Residue (mg/kg)			
			T	TA	TAA	TLA
		Residues input values for the max. dietary burden calculation (bold in brackets: HR/STMRs derived from new residue studies)				
By products						
Beet sugar dried pulp	Sugar beet root data	STMR* default PF (18)	0.9 **(0.002)**	3.3 **(0.18)**	0.9 **(0.002)**	0.38 **(0.036)**
Beet, sugar, ensiled pulp	Sugar beet root data	STMR* default PF (3)	0.15 **(0.002)**	0.55 **(0.03)**	0.15 **(0.002)**	0.06 **(0.006)**
Beet, sugar molasses	Sugar beet root data	STMR* default PF (28)	1.4 **(0.002)**	5.1 **(0.28)**	1.4 **(0.002)**	0.59 **(0.056)**
Rape meal	Oilseed rape data	STMR* PF	0.1 **(0.004)** (STMR * default PF (2))	1.45 **(0.497)** (STMR*1.4)	0.24 **(0.008)** (STMR*2)	0.13 **(0.008)** (STMR*2)
Safflower meal	Oilseed rape data	STMR* PF	0.1 **(0.004)** (STMR * default PF (2))	1.45 **(0.497)** (STMR*1.4)	0.24 **(0.008)** (STMR*2)	0.13 **(0.008)** (STMR*2)
Soybean meal	Oilseed rape data	STMR* PF	0.1 **(0.004)** (STMR * default PF (2))	1.45 **(0.497)** (STMR*1.4)	0.24 **(0.008)** (STMR*2)	0.13 **(0.008)** (STMR*2)
Soybean hulls	Oilseed rape data	STMR* default PF (13)	0.65 **(0.004)**	13.5 **(4.615)**	1.56 **(0.052)**	0.85 **(0.052)**
Sugarcane molasses	Sugar plant data	STMR* default PF (32)	1.6 **(0.002)**	5.89 **(0.32)**	1.6 **(0.002)**	0.67 **(0.064)**
Sunflower meal	Oilseed rape data	STMR* PF	0.1 **(0.004)** (STMR * default PF (2))	1.45 **(0.497)** (STMR*1.4)	0.24 **(0.008)** (STMR*2)	0.13 **(0.008)** (STMR*2)

Results of the dietary burden calculation for TAA including all data assessed by UK, 2018 and data from studies provided by the applicant, if they were higher than previously assessed by UK, 2018.

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)	Previous assessment (UK 2018)
	mg/kg bw per day		mg/kg DM					0.004	Max burden
	Median	Maximum	Median	Maximum				mg/kg bw	mg/kg DM
Cattle (all diets)	0.118	0.140	3.87	4.29	Dairy cattle	Potato	process waste	Yes	4.29
Cattle (dairy only)	0.118	0.140	3.06	3.63	Dairy cattle	Potato	process waste	Yes	3.63
Sheep (all diets)	0.153	0.170	3.80	4.37	Lamb	Wheat	milled bypdts	Yes	4.37

Sheep (ewe only)	0.127	0.146	3.80	4.37	Ram/Ewe	Potato	process waste	Yes	4.37
Swine (all diets)	0.108	0.109	3.60	3.76	Swine (finishing)	Wheat	milled bypdts	Yes	3.76
Poultry (all diets)	0.138	0.140	1.98	2.05	Poultry broiler	Wheat	milled bypdts	Yes	2.05
Poultry (layer only)	0.135	0.140	1.98	2.05	Poultry layer	Wheat	milled bypdts	Yes	2.05

Slightly higher residue results for TAA in oilseed rape plant (rape forage) did not change the maximum animal intakes estimated for TAA by UK 2018 for all animal species.

Results of the dietary burden calculation for TLA including all data assessed by UK, 2018 and data from studies provided by the applicant, if they were higher than previously assessed by UK, 2018.

Relevant groups	**Dietary burden expressed in**				**Most critical diet (a)**	**Most critical commodity (b)**		Trigger exceeded (Yes/No)	Previous assessment (UK 2018)
	mg/kg bw per day		mg/kg DM					0.004	Max burden
	Median	Maximum	Median	Maximum				mg/kg bw	mg/kg bw
Cattle (all diets)	0.078	0.177	2.22	4.61	Dairy cattle	Grass	forage (fresh)	Yes	4.61
Cattle (dairy only)	0.078	0.177	2.03	4.61	Dairy cattle	Grass	forage (fresh)	Yes	4.61
Sheep (all diets)	0.079	0.187	2.36	5.61	Ram/Ewe	Grass	forage (fresh)	Yes	5.61
Sheep (ewe only)	0.079	0.187	2.36	5.61	Ram/Ewe	Grass	forage (fresh)	Yes	5.61
Swine (all diets)	0.026	0.055	1.11	2.37	Swine (breeding)	Grass	forage (fresh)	Yes	2.37
Poultry (all diets)	0.021	0.052	0.31	0.77	Poultry layer	Clover	hay	Yes	0.77
Poultry (layer only)	0.021	0.052	0.31	0.77	Poultry layer	Clover	hay	Yes	0.77

Slightly higher residue results for TLA in oilseed rape plant (rape forage) did not change the maximum animal intakes estimated for TLA by UK, 2018 for all animal species.

The above intake calculations for the maximum dietary burden of livestock demonstrate that residues of T, TA, TAA and TLA are significant in the diets of livestock (above the trigger of 0.1 mg/kg applied on a DM basis (UK, 2018) and 0.004 mg/kg bw/d (Regulation (EU) No 283/2013).

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

According to DAR, Difenoconazole – Volume 3 B.7 (AS), May 2006 Updated December 2006 and EFSA Journal 2011;9(1):1967 new livestock feeding studies are performed during Annex I inclusion and renewal. No new livestock studies feeding studies are necessary.

Tribolet R. (2000)
Residue of difenoconazole (CGA 169374) and its metabolite CGA 205375 in milk, blood and tissues (muscle, fat, liver, kidney) of dairy cattle resulting from feeding of difenoconazole at three dose levels. The transfer of residues of difenoconazole from cattle into tissues and milk has been investigated. Residue data was supported by fortified procedural recovery.
There was no significant degradation of difenoconazole or CGA 205375 in milk, blood or tissues stored at<-20°C for periods equivalent to the maximum period of storage of the samples in the study.

Residues of difenoconazole were below 5 µg/L in the milk samples taken on all days during the feeding period from all treatment groups. Residues of difenoconazole were less than 0.01 mg/kg in all tissues samples, with the exception of liver, which contained a residue of 0.01 mg/kg following dosing at the highest rate (10 mg/kg (10X). Residues of difenoconazole in blood were less than 10 µg/L.
Residues of CGA 205375 were below 5 µg/L in the milk samples taken on all days during the feeding period following difenoconazole 1 mg/kg (1X) and 3 mg/kg (3X). Following 10 mg/kg (10X), the mean residue of CGA 205375 was 7 µg/L. Residues of CGA 205375 in milk reached a plateau after two days of dosing and concentrations were maintained until the end of the study.
Following 3 and 10 mg/kg, maximum residues of CGA 205375 in muscle were 0.022 mg/kg and 0.028 mg/kg, respectively. In liver, residues of CGA 205375 were 0.04, 0.13 and 0.35 mg/kg following doses of 1, 3 and 10 mg/kg, respectively. In kidney, residues of CGA 205375 were <0.01, 0.02 and 0.05 mg/kg following doses of 1, 3 and 10 mg/kg, respectively. In fat, residues of CGA 205375 were 0.01, 0.03 and 0.09 mg/kg following doses of 1, 3 and 10 mg/kg, respectively. In blood, residues of CGA 205375 were <10, <10 and 19 µg/L following doses of 1, 3 and 10 mg/kg, respectively.
Residues of difenoconazole and CGA-205375 did not accumulate in milk, fat, liver, kidney or muscle following doses of 1 to 10 mg difenoconazole/kg in the diet. Residues of difenoconazole and CGA-205375 in the liver were 0.01 mg/kg and 0.04 mg/kg following administration of 10 mg/kg diet and of 1 mg/kg diet, respectively (i.e., 43 and 4.3 times higher than the realistic estimated feeding rate of 0.23 mg difenoconazole/kg diet). Hence, following the use of difenoconazole according to the proposed GAP, residues of difenoconazole in liver are not expected to exceed 0.01 mg/kg.
Ryan J. (2006).
Difenoconazole (CGA169374): Magnitude of the residue in meat and milk resulting from the feeding at three levels to dairy cattle.
Residues of difenoconazole were below 0.005 mg/kg in the milk samples taken on all days during the feeding period from all treatment groups. Residues of difenoconazole were less than 0.01 mg/kg in all tissues samples, with the exception of liver, which contained a residue of 0.01 mg/kg and 0.03 mg/kg following dosing at the rate of 5 mg/kg (5X) and 15 mg/kg (15X), respectively.

	Ruminant:	**Poultry:**	**Pig:**
	Conditions of requirement of feeding studies		
Expected intakes* by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes 0.23/0.65 mg/kg DM Dairy/Beef cattle	No	No
Potential for accumulation (yes/no):	n/a	n/a	n/a
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	n/a	n/a	n/a
	Feeding study[a] (residues of **difenoconazole-alcohol** (CGA 205375) for the feeding rate 10 mg/kg DM corresponding to a 43N and 15N dose rate for dairy and beef cattle) Residue levels in matrices : **mean (Max) mg/kg CGA 205375**		
Muscle	0.022 (0.024)	--	--
Liver	0.303 (0.350)	--	--
Kidney	0.044 (0.052)	--	--
Fat	0.077 (0.095)	--	--
Milk	0.008 (0.009)		
Eggs		--	

[a]: Parent also analysed for in the feeding study. At the highest feeding rate (10 mg/kg DM), all values below LOQs (0.005 mg/kg milk, 0.01 mg/kg other matrices), except in liver (HR 0.02 mg/kg).

Table 7.3-12: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Calculated MRL [f] (mg/kg)	Current MRL	CF for RA
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level[c] (mg/kg bw/d)	No	Residues at the closest feeding level		Estimated value at 1N				
					Mean (mg/kg)	Max. (mg/kg)	Mean[a] (mg/kg)	Max.[b] (mg/kg)			
Difenoconazole											
Cattle (all) Muscle	0.0069	0.021	0.036	1	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	0.05	1
Cattle (all) Fat	0.0069	0.021	0.036	2	0.011	0.013	< 0.01	< 0.01	< 0.01	0.05	1
Cattle (all) Liver	0.0069	0.021	0.036	3	0.07	0.07	0.02	0.07	0.08	0.2	1
Cattle (all) Kidney	0.0069	0.021	0.036	4	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	0.2	1
Cattle (dairy only) Milk [d]	0.0103	0.029	0.036	5	< 0.005	< 0.005	< 0.005	< 0.005	< 0.005	0.005	1
Swine (all) [e] Muscle	0.004	0.012	0.036	6	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	0.05	1
Swine (all) [e] Fat	0.004	0.012	0.036	7	0.011	0.013	< 0.01	< 0.01	< 0.01	0.05	1
Swine (all) [e] Liver	0.004	0.012	0.036	8	0.07	0.07	0.01	0.02	0.03	0.2	1
Swine (all) [e] Kidney	0.004	0.012	0.036	9	0.01	0.01	< 0.01	< 0.01	< 0.01	0.2	1
Poultry (all) [f] Muscle	0.003	0.008	0.019	10	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	0.01	1

Poultry (all) [f] Fat	0.003	0.008	0.019	11	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	0.01	1
Poultry (all) [f] Liver	0.003	0.008	0.019	12	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	0.01	1
Poultry (layer only) Eggs	0.003	0.008	0.019	13	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	0.01	1

(a): The mean residue level for milk and the mean residue levels for tissues were recalculated at the 1N rate for the mediandietary burden.
(b): The mean residue level in milk and the highest residue levels in tissues were recalculated at the 1N rate for the maximumdietary burden.
(c): Closest feeding level and N dose rate related to the maximum dietary burden.
(d): Highest residue level from day 1 to day 29 or day 30 (daily mean of 3 cows).
(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study onruminants were relied upon to derive the MRL and risk assessment values in sheep and swine (EFSA, 2010).
(f): Although these MRL proposals suggest that MRLs for difenoconazole residues in fat tissues, liver and milk would need to beraised, EFSA is of the opinion that the modification of the existing MRLs in products of animal origin at this stage is notrequired as long as metabolite CGA205375 is not included in the residue definition for enforcement, according to theRegulation (EC) No 396/200

For illustrative purpose applicant present below calculations performed for Difenoconazole on EU level (*EFSA Journal.* 2024;22:e8987) to show that risk for animals from applying CHR/F/SCORPIO is negligible:

Animal commodity	Residues at the closest feeding level (mg/kg)		Estimated value at 1N		MRL proposal (mg/kg)
	Mean	Highest	$STMR_{Mo}$[a] (mg/kg)	HR_{Mo}[b] (mg/kg)	
Cattle (all) – Closest feeding level (0.182 mg/kg bw; 0.6N rate)[c]					
Muscle	0.01	0.01	0.01	0.02	**0.03** (tentative)[g]
Fat	0.04	0.04	0.03	0.08	**0.08** (tentative)[g]
Liver	0.20	0.23	0.16	0.39	**0.40** (tentative)[g]
Kidney	0.04	0.04	0.03	0.07	**0.07** (tentative)[g]
Cattle (dairy only) – Closest feeding level (0.182 mg/kg bw; 0.6N rate)[c]					
Milk[d]	0.01	0.01	0.01	0.01	**0.01*** (tentative)[g]
Sheep (all)[e] – Closest feeding level (0.182 mg/kg bw; 0.6N rate)[c]					
Muscle	0.01	0.01	0.01	0.02	**0.03** (tentative)[g]
Fat	0.04	0.04	0.04	0.07	**0.07** (tentative)[g]
Liver	0.20	0.23	0.18	0.36	**0.40** (tentative)[g]
Kidney	0.04	0.04	0.03	0.06	**0.07** (tentative)[g]
Sheep (ewe only)[f] – Closest feeding level (0.182 mg/kg bw; 0.8N rate)[c]					
Milk[d]	0.01	0.01	0.01	0.01	**0.01*** (tentative)[g]
Swine (all)[e] – Closest feeding level (0.182 mg/kg bw; 1.4N rate)[c]					
Muscle	0.01	0.01	0.01	0.01	**0.02** (tentative)[g]
Fat	0.04	0.04	0.02	0.04	**0.04** (tentative)[g]
Liver	0.20	0.23	0.07	0.17	**0.20** (tentative)[g]
Kidney	0.04	0.04	0.01	0.03	**0.03** (tentative)[g]
Poultry (all) – Closest feeding level (0.063 mg/kg bw; 0.6N rate)[c]					
Muscle	0.01	0.01	0.01	0.01	**0.01*** (tentative)[g]
Fat	0.01	0.01	0.01	0.01	**0.01*** (tentative)[g]
Liver	0.01	0.01	0.01	0.01	**0.01*** (tentative)[g]
Poultry (layer only) – Closest feeding level (0.063 mg/kg bw; 0.6N rate)[c]					
Eggs[f]	0.01	0.01	0.01	0.02	**0.03** (tentative)[g]

Abbreviation: bw, body weight.
*Indicates that the MRL is proposed at the limit of quantification.
[a]Median residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.
[b]Highest residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.
[c]Closest feeding level and N dose rate related to the maximum dietary burden.
[d]For milk, mean was derived from samplings performed from day 5 to day 28 (daily mean of 3 cows).
[e]Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.
[f]For eggs, mean and highest residues were derived from samplings performed from day 9 to day 28 (daily mean or daily highest of 5 laying hens).
[g]All MRLs derived are tentative, considering the residue data missing for the TDMs for a major part of the feed crops under assessment.

MRL values proposed based on applicant calculations are lower than ones proposed by EFSA on EU level, therefore it can be assumed that the product is safe for fed animals.

For TA, TLA and TAA, the dietary burdens calculated were found to exceed the trigger value of 0.1 mg/kg DM for all groups of livestock. As a study performed with TLA is not available, risk assessment values for TA and TLA in livestock commodities were derived from livestock feeding studies performed with TA only and analysed for the magnitude of TA, TAA, 1,2,4-T and TLA residues (*EFSA Journal 2018;16(7):5376*).
It is observed that, in the available residue data on the main contributor to the livestock exposure, TLA levels were much lower than TA levels and most of the time below the LOQ. Therefore, the contribution of TLA to the overall dietary burden to the sum of TA and TLA is expected to be negligible in view of the current data.
For 1,2,4-T, since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues in commodities of animal origin is unnecessary for this metabolite.
Regarding TDMs, poultry and ruminants feeding studies were both performed with TA and TAA and assessed in the framework of the peer review for TDMs (*EFSA Journal 2018;16(7):5376*). In all four studies, samples of tissues, eggs and milk were analysed for the magnitude of TA, TLA, TAA and 1,2,4-T.
In the studies performed with TA, results showed that in poultry and ruminants, TA was the main residue found in all matrices. In poultry, residues of TAA and TLA were always below LOQ, while in ruminants, TAA was observed at lower levels in kidney and TLA in fat. A slight metabolisation of TA to 1,2,4-T was observed in eggs, liver and muscle of poultry and was significant in milk (*EFSA Journal 2018;16(7):5376*).
The study conducted with TAA on poultry demonstrated no significant residue transfer from the animal diet to eggs and tissues. TAA was detected only at the highest dose level in eggs, fat and liver, while TA was quantified at all dosing levels only in liver. In ruminants, TAA was detected only at the highest dose level in whole milk and in all tissues, while TA was identified in liver, muscle and kidney at all dosing levels. Metabolites 1,2,4-T and TLA were always below the LOQ (0.01 mg/kg) (*EFSA Journal 2018;16(7):5376*).
The feeding studies carried out with TA were used to derive risk assessment values for TA and TLA in livestock commodities. Significant residues are expected in all commodities, except in eggs and milk, where risk assessment values were set at the LOQ. Concerning TAA, no residues are expected in any livestock commodity and the risk assessment values were set at the LOQ, except in sheep liver. Finally, livestock is not expected to be exposed to significant levels of 1,2,4-T when directly fed with it. Although this metabolite can be present in animal matrices as a result of feeding with parent difenoconazole, considering the dosing levels of the feeding studies performed with the parent and the calculated dietary burden for 1,2,4-T, it is concluded that residues of 1,2,4-T will remain below the LOQ.

Feeding studies performed with triazole alanine (TA) are available from the confirmatory data for TDMs (*EFSA Journal 2018;16(7):5376)*.

Table 7.3-13: Summary of the residue data from livestock feeding studies: triazole alanine (TA).

Animal commodity	Residues at the closet feeding level (mg/kg)		Estimated value at 1N level		MRL proposal (mg/kg)
	Mean	Highest	$STMR_{Mo}$ (mg/kg)	HR_{Mo} (mg/kg)	
Cattle (all diets)					
Closest feeding level[a]:	0.06	mg/kg bw	2.8	N Beef cattle (highest diet)	
Muscle	0.04	0.05	0.01	0.02	**0.02**
Fat	0.02	0.02	0.00	0.01	**0.008**
Liver	0.10	0.15	0.03	0.05	**0.06**
Kidney	0.04	0.04	0.01	0.01	**0.015**
Cattle (dairy only)					
Closest feeding level[a]:	0.06	mg/kg bw	3.2	N Dairy cattle	
Milk[b]	0.01	0.01	0.00	0.00	**0.003**
Sheep (all diets)					
Closest feeding level[a]:	0.11	mg/kg bw	1.3	N Lamb (highest diet)	
Muscle	0.09	0.10	0.05	0.10	**0.1**
Fat	0.04	0.07	0.02	0.06	**0.07**
Liver	0.20	0.21	0.16	0.26	**0.3**
Kidney	0.11	0.13	0.04	0.10	**0.1**
Sheep (dairy only)					
Closest feeding level[a]:	0.11	mg/kg bw	1.6	N Ewe	
Milk[b]	0.01	0.01	0.01	0.01	**0.01**
Swine					
Closest feeding level[a]:	0.06	mg/kg bw	2.3	N Breeding (highest diet)	
Muscle	0.04	0.05	0.01	0.02	**0.03**
Fat	0.02	0.02	0.01	0.01	**0.009**
Liver	0.10	0.15	0.03	0.06	**0.07**
Kidney	0.04	0.04	0.01	0.02	**0.02**
Poultry (all diets)					
Closest feeding level[a]:	0.02	mg/kg bw	0.5	N Layer (highest diet)	
Muscle	0.02	0.02	0.02	0.03	**0.04**
Fat	0.02	0.02	0.03	0.05	**0.05**
Liver	0.06	0.06	0.08	0.12	**0.15**
Poultry (layer only)					
Closest feeding level[a]:	0.02	mg/kg bw	0.5	N Layer	
Eggs[c]	0.01	0.01	0.01	0.02	**0.03**

(a): Closest feeding level and N dose rate related to the maximum dietary burden.
(b): Highest residue level from day D1 to day D2 (daily mean of X cows).
(c): Highest residue level from day D1 to day D2 (daily mean of Y laying hens).

Table 7.3-14: Summary of the residue data from livestock feeding studies: triazole lactic acid (TLA).

Animal commodity	Residues at the closet feeding level (mg/kg)		Estimated value at 1N level		MRL proposal (mg/kg)
	Mean	Highest	$STMR_{Mo}$ (mg/kg)	HR_{Mo} (mg/kg)	
Cattle (all diets)					
Closest feeding level[a]:	0.06	mg/kg bw	2.8 N Beef cattle (highest diet)		
Muscle	0.01	0.01	0.002	0.004	**0.004**
Fat	0.02	0.02	0.004	0.01	**0.008**
Liver	0.01	0.01	0.002	0.004	**0.004**
Kidney	0.01	0.01	0.002	0.004	**0.004**
Cattle (dairy only)					
Closest feeding level[a]:	0.06	mg/kg bw	3.2 N Dairy cattle		
Milk[b]	0.01	0.01	0.002	0.003	**0.003**
Sheep (all diets)					
Closest feeding level[a]:	0.11	mg/kg bw	1.3 N Lamb (highest diet)		
Muscle	0.01	0.01	0.01	0.01	**0.01**
Fat	0.03	0.03	0.02	0.03	**0.03**
Liver	0.01	0.01	0.01	0.01	**0.01**
Kidney	0.01	0.01	0.01	0.01	**0.01**
Sheep (dairy only)					
Closest feeding level[a]:	0.11	mg/kg bw	1.6 N Ewe		
Milk[b]	0.01	0.01	0.01	0.01	**0.01**
Swine					
Closest feeding level[a]:	0.06	mg/kg bw	2.3 N Breeding (highest diet)		
Muscle	0.01	0.01	0.003	0.004	**0.005**
Fat	0.02	0.02	0.01	0.01	**0.009**
Liver	0.01	0.01	0.003	0.004	**0.005**
Kidney	0.01	0.01	0.003	0.004	**0.005**
Poultry (all diets)					
Closest feeding level[a]:	0.02	mg/kg bw	0.5 N Layer (highest diet)		
Muscle	0.02	0.02	0.02	0.03	**0.04**
Fat	0.02	0.02	0.03	0.05	**0.05**
Liver	0.06	0.06	0.08	0.12	**0.15**
Poultry (layer only)					
Closest feeding level[a]:	0.02	mg/kg bw	0.5 N Layer		
Eggs[c]	0.01	0.01	0.01	0.02	**0.03**

(a): Closest feeding level and N dose rate related to the maximum dietary burden.
(b): Highest residue level from day D1 to day D2 (daily mean of X cows).
(c): Highest residue level from day D1 to day D2 (daily mean of Y laying hens).

Feeding studies performed with triazole acetic acid (TAA) are available from the confirmatory data for TDMs (*EFSA Journal 2018;16(7):5376)*

Table 7.3-15: Summary of the residue data from livestock feeding studies: Triazole Acetic Acid (TAA).

Animal commodity	Residues at the closet feeding level (mg/kg)		Estimated value at 1N level		MRL proposal (mg/kg)
	Mean	Highest	$STMR_{Mo}$ (mg/kg)	HR_{Mo} (mg/kg)	
Cattle (all diets)					
Closest feeding level[a]:	0.06	mg/kg bw	2.8	N Beef cattle (highest diet)	
Muscle	0.01	0.01	0.002	0.004	**0.004**
Fat	0.01	0.02	0.003	0.01	**0.008**
Liver	0.01	0.01	0.002	0.004	**0.004**
Kidney	0.01	0.01	0.002	0.004	**0.004**
Cattle (dairy only)					
Closest feeding level[a]:	0.06	mg/kg bw	3.2	N Dairy cattle	
Milk[b]	0.01	0.01	0.002	0.003	**0.003**
Sheep (all diets)					
Closest feeding level[a]:	0.11	mg/kg bw	1.3	N Lamb (highest diet)	
Muscle	0.01	0.01	0.01	0.01	**0.01**
Fat	0.01	0.01	0.01	0.01	**0.015**
Liver	0.01	0.01	0.01	0.01	**0.01**
Kidney	0.01	0.02	0.01	0.02	**0.02**
Sheep (dairy only)					
Closest feeding level[a]:	0.11	mg/kg bw	1.6	N Ewe	
Milk[b]	0.01	0.01	0.01	0.01	**0.01**
Swine					
Closest feeding level[a]:	0.06	mg/kg bw	2.3	N Breeding (highest diet)	
Muscle	0.01	0.01	0.003	0.004	**0.005**
Fat	0.01	0.02	0.00	0.01	**0.009**
Liver	0.01	0.01	0.003	0.004	**0.005**
Kidney	0.01	0.01	0.003	0.004	**0.005**
Poultry (all diets)					
Closest feeding level[a]:	0.02	mg/kg bw	0.5	N Layer (highest diet)	
Muscle	0.01	0.01	0.01	0.01	**0.01**
Fat	0.01	0.01	0.01	0.01	**0.01**
Liver	0.01	0.01	0.01	0.01	**0.01**
Poultry (layer only)					
Closest feeding level[a]:	0.02	mg/kg bw	0.5	N Layer	
Eggs[c]			0.01	0.01	**0.01**

(a): Closest feeding level and N dose rate related to the maximum dietary burden.
(b): Highest residue level from day D1 to day D2 (daily mean of X cows).
(c): Highest residue level from day D1 to day D2 (daily mean of Y laying hens).

Conclusion on feeding studies

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

zRMS comments:
No new studies were submitted in the framework of this application.
According to the EFSA Journal. 2024;22:e8987: “In the framework of the initial peer review, feeding studies performed with ruminants and laying hens were assessed(Sweden, 2006, 2010).In a study on dairy

cows, difenoconazole was administered daily for 29–30 consecutive days, at different dosing levels of 1, 5 and 15 mg/kg DM in the feed (equivalent to 0.036, 0.182 and 0.545 mg/kg bw per day). Samples were analysed for difenoconazole, CGA205375 and 1,2,4-T. Difenoconazole was not detected in any animal tissues or milk, even at the highest dose level (except in liver, at a maximum of 0.03 mg/kg). At the highest dose levels (5 and 15 mg/kg DM), residues of CGA205375 were found up to 0.02 mg/kg in milk, 0.05 mg/kg in muscle, 0.12 mg/kg in kidney, 0.14 mg/kg in fat tissue and 0.66 mg/kg in liver. Residues of 1,2,4-T were always below the LOQ in fat, and in other tissues and milk at the lowest dose level. A maximum of 0.05 mg/kg was reached at the highest dose level in milk and kidney.

A feeding study performed on laying hens was also provided during the peer review for approval (Sweden, 2010), but it was considered as not required at that time. In the study, difenoconazole was administered to hens at dose levels of 0.3, 1, 3 and 10 mg/kg DM (converted to 0.019, 0.063; 0.189 and 0.63 mg/kg bw per day) and eggs and tissue samples were analysed for difenoconazole, CGA205375 and 1,2,4-T. Results showed that no residues of difenoconazole above LOQ were detected in any matrices even at exaggerated dose levels. Residues of CGA205375 were not detected in any of the tissue samples but were detected at low levels in eggs (up to 0.17 mg/kg at the highest dose level). Residues of 1,2,4-T were observed at the highest dose levels, accounting for up to 0.014 mg/kg in the skin with attached fat, up to 0.02 mg/kg in liver and 0.023mg/kg in muscle. In eggs, residues of 1,2,4-T ranged from a maximum of 0.008 mg/kg at 1 mg/kg DM level, to 0.069 mg/kg at the highest dose level (Sweden, 2010). Based on the two above-mentioned studies, MRL and risk assessment values were derived for all commodities of ruminants, pigs and poultry, in compliance with the latest recommendations on this matter (FAO, 2016). Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. It is noted that significant levels of CGA205375 are only expected in eggs and tissues of ruminant, while for milk and tissues of poultry, MRLs are proposed at the LOQ. In both studies, the storage period of the samples was covered by the conditions for which storage stability was demonstrated; thus, decline of residues during storage of the trial samples is not expected. Considering the data missing for the TDMs for a major part of the feed crops under assessment, all MRLs proposed for animal commodities are tentative.

Regarding TDMs, poultry and ruminants feeding studies were both performed with TA and TAA and assessed in the framework of the peer review for TDMs (EFSA, 2018d). In all four studies, samples of tissues, eggs and milk were analysed for the magnitude of TA, TLA, TAA and 1,2,4-T. In the studies performed with TA, results showed that in poultry and ruminants, TA was the main residue found in all matrices. In poultry, residues of TAA and TLA were always below LOQ, while in ruminants, TAA was observed at lower levels in kidney and TLA in fat. A slight metabolisation of TA to 1,2,4-T was observed in eggs, liver and muscle of poultry and was significant in milk (EFSA, 2018d).

The study conducted with TAA on poultry demonstrated no significant residue transfer from the animal diet to eggs and tissues. TAA was detected only at the highest dose level in eggs, fat and liver, while TA was quantified at all dosing levels only in liver. In ruminants, TAA was detected only at the highest dose level in whole milk and in all tissues, while TA was identified in liver, muscle and kidney at all dosing levels. Metabolites 1,2,4-T and TLA were always below the LOQ (0.01mg/kg) (EFSA, 2018d).The feeding studies carried out with TA were used to derive risk assessment values for RD-RA2 (TA and TLA) in livestock commodities. Significant residues are expected in all commodities, except in eggs and milk, where risk assessment values were set at the LOQ. Concerning TAA (RD-RA3), no residues are expected in any livestock commodity and the risk assessment values were set at the LOQ, except in sheep liver. Finally, livestock is not expected to be exposed to significant levels of 1,2,4-T when directly fed with it. Although this metabolite can be present in animal matrices as a result of feeding with parent difenoconazole, considering the dosing levels of the feeding studies performed with the parent and the calculated dietary burden for 1,2,4-T, it is concluded that residues of 1,2,4-T will remain below the LOQ."

The requested uses do not substantially modify the theoretical maximum daily intake of difenoconazole and TDMs for animals as calculated in EFSA 2024 and EFSA 2018 respectively, and therefore outcome of EFSA, is still considered valid.

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

~~Studies on Industrial Processing and/or Household Preparation are not relevant, because residues in magnitude of the residues in the plant matrices are below 0.01 mg/kg.~~
Magnitude of residues in processed commodities study is necessary for metabolites TA and TLA for matrices processed from oilseed rape..

zRMS comments:
No new data were submitted in the framework of this application.
zRMS does not agree with the Applicant that the residue results in the plant matrices are below 0.01 mg/kg (see Table 7.3-9).
Any studies on the magnitude of residues in processed commodities are not considered to be required for parent difenoconazole, TAA and 1,2,4-T as residues of these compounds are below 0.1 mg/kg in sugar beet root and rapeseed at commercial harvest after application of CHR/F/SCORPIO 325 SC according to the proposed GAP. However, the residue levels of TA and TLA in rapeseed were above 0.1 mg/kg. Therefore studies on industrial processing and/or household preparation for TA and TLA are required.
According to the EFSA Journal. 2024;22:e8987:
"No new studies on TDMs were submitted in the framework of this review. However, processing studies were assessed as confirmatory data evaluated by the United Kingdom (EFSA, 2018d; United Kingdom, 2018). It is noted that for TA, only two studies were available for processed commodities of tomatoes, apples, potatoes, soya beans (meal, hulls) and sugar beet (dried pulp, molasses), and according to the old data requirements, at least three studies are required. However, the information available is considered sufficient to derive robust processing factors since the individual factors do not deviate by more than 50%. On the other hand, tentative processing factors were derived for TA for grapes, soya beans (refined oil) and sugar beet (refined sugar). All processing factors derived for TAA are also tentative (not fully supported by data)".
Processing factors for crops under consideration, EFSA Journal. 2024;22:e8987:

Processed commodity	Number of studies	Processing factors		Compound covered	Reference
		Individual values	Median PF		
Soyabean, refined oil	1	<0.07	0.07	TA	tentative EFSA, 2018; UK, 2018
Soya bean, meal	2 1	0.97;1 1.5	0.99 1.5	TA TAA	 tentative EFSA, 2018; UK, 2018
Soya bean, hulls	2 1	0.33; 0.38 0.5	0.36 0.5	TA TAA	 tentative EFSA, 2018; UK, 2018
Sugar beet, refined sugar	2	<1;3.5	2.25	TA	tentative EFSA, 2018; UK, 2018
Sugar beet, molasses	2	6.0;9.5	7.75	TA	EFSA, 2018; UK, 2018
Sugar beet, dried pulp	2	<1; 3.5	2.25	TA	tentative EFSA, 2018; UK, 2018

Studies on industrial processing and/or household preparation for TA and TLA in rapeseed are required – data gap.

Applicant agree with received comment regarding necessity of presenting processing data for oilseed rape for metabolites TA and TLA exceeding threshold value of 0.1 mg/kg. 3 unprotected residue studies were published in *EFSA Journal 2018;16(7):5376*:

Processed commodity	Number of studies	Processing factors		Compound covered	Reference
		Individual values	Median PF		
Meal	3	0.52, 0.81, 1.9, ~~1.9~~, 2.9 NA, >1, >2, >3	1.9 2.0	TA TLA	EFSA, 2018; UK, 2018
Refined oil	3	< 0.02, < 0.03, < 0.03, < 0.04 3× NA	0.03 NA	TA TLA	EFSA, 2018; UK, 2018
Press cake	2	0.61, 0.78, 1.3 > 2, >2	0.78 2.0	TA TLA	EFSA, 2018; UK, 2018
Press oil	2	< 0.03, < 0.03, < 0.04	0.03	TA	EFSA, 2018; UK, 2018
Extraction oil	2	< 0.03, < 0.03, < 0.04	0.03	TA	EFSA, 2018; UK, 2018
Crude oil	2	< 0.03, < 0.03, < 0.04	0.03	TA	EFSA, 2018; UK, 2018
Pre-clarified oil	2	< 0.03, < 0.03, < 0.04	0.03	TA	EFSA, 2018; UK, 2018
Neutralised oil	2	< 0.03, < 0.03, < 0.04	0.03	TA	EFSA, 2018; UK, 2018

Default processing factor of 2.0 is proposed for oilseed rape meal in animal model 2017 and default value of 2.0 is proposed for oils in PRIMo 3.1 (OECD, 2008).
Considering that processing factors estimated based on unprotected processing studies in oilseed rape are equal or lower in comparison to default PF values in PRIMo and Animal model there is no need to include it in risk assessment for consumer or dietary burden, as presented calculations reflects the worst case scenario.
All necessary processed matrices were covered in unprotected studies presented on EU level, therefore no additional study is required.

zRMS comments, July 2025:
Any studies on the magnitude of residues in processed commodities are not considered to be required for parent difenoconazole, TAA and 1,2,4-T as residues of these compounds are below 0.1 mg/kg in sugar beet root and rapeseed at commercial harvest after application of CHR/F/SCORPIO 325 SC according to the proposed GAP. However, the residue levels of TA and TLA in rapeseed were above 0.1 mg/kg. Therefore studies on industrial processing and/or household preparation for TA and TLA are required. Magnitude of residues in processed commodities are part of the peer review of the TDMs confirmatory data (EFSA Journal 2018; 16(7):5736) and are out of data protection. Information about the fate of the triazole derived metabolites during oilseed processing was available from processing studies conducted with oilseed rape treated with prothioconazole (2 trials) and with prothioconazole and tebuconazole (1 trial). Information about the fate of the triazole derived metabolites during rice processing was available from processing studies conducted with rice treated with prothioconazole (1 trial). Information about the fate of the triazole derived metabolites during sugar beet processing was available from processing studies conducted with sugar beet treated with metconazole (4 trials), prothioconazole (1 trial) and Difenoconazole (2 trials).

According to EFSA Journal 2018; 16(7):5736: "The hydrolysis studies show that all four TDM are stable on processing. As a consequence the relevant residues in processed commodities are the TDM and no breakdown products need be considered. No processing factors have been applied to the consumer risk assessments. However, the processing factors determined do need to be considered for the dietary burden of livestock."

7.3.5.1 Available data for all crops under consideration

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

7.3.5.2 Conclusion on processing studies

7.3.6 Magnitude of residues in representative succeeding crops

Crops under evaluation are expected to be grown in rotation. Further investigation of residues in rotational crops is therefore required.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.
Data/information on residues in succeeding crops were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated.
In five available studies, total radioactive residues in rotational crops (wheat, sugar beet, maize, lettuce, turnips and mustard) planted 62 to 488 days after one application of difenoconazole applied to bare ground at a rates of 32.4, 125 and 750 g a.i./ha ranged from <0.0001 to 0.34 mg difenoconazole equivalents/kg. Following application equivalent to twice the maximum recommended rate for carrots in Northern and Southern Europe (3 x 125 g a.i./ha), residues of difenoconazole were below the LOD (<0.02 and <0.05 mg/kg). The exaggerated application rate of 750 g a.i./ha represents a worst-case for residues of difenoconazole in rotational crops and in commercial practice residues of difenoconazole will not be expected in succeeding crops.

Conclusion on rotational crops studies

No risk mitigation measures are necessary.

zRMS comments:
No new data were submitted in the framework of this application. The applicant did not provide any data on TDMs.

According to the EFSA Journal. 2024;22:e8987: "Several field rotational crop studies were available for this review. One of them was evaluated in the framework of the peer review (EFSA, 2011a; Sweden, 2006), while two new ones were submitted in the framework of this MRL review (Spain, 2022). Additional studies on the magnitude of TDMs were submitted as confirmatory data in the frame of the peer review for TDMs (EFSA, 2018d; United Kingdom, 2018), but were not considered in this review due to the data gap previously identified (the maximum storage time interval of the residue samples of the trials in primary and rotational crops is required to conclude on the validity of these trials).
In the first study, difenoconazole was applied at 750 g a.s./ha to bare soil, and root crops (carrots) and

leafy vegetables (spinaches) were planted 30 and 31 DAT, respectively. Rotational crops were sampled between 97 and 136 DAT for carrots and between 62 and 77 DAT for spinaches. Samples were analysed for difenoconazole and TA, and residues were always below the LOQ of 0.02 mg/kg and 0.05 mg/kg, respectively (EFSA, 2011a). Given the high persistence of difenoconazole in soil (see Section 1.1.2), the potential occurrence of residues following multiannual applications should also be investigated …
It cannot be concluded that no residues of difenoconazole above LOQ would be expected in rotational commodities when difenoconazole is applied in compliance with the most critical GAPs reported in Appendix A. Therefore, a field rotational crop study analysing for difenoconazole, covering the most critical GAP authorised on crops that can be rotated and the plateau following multiple years of consecutive applications is required (data gap). It is noted that this data gap is relevant only for the most critical indoor GAP for fodder beet (which is also not supported by residue trials, see Section 1.2.1), while all other most critical GAPs reported under this review are covered by the available study …
Consequently, field rotation crops studies, analysing for the TDMs, covering the most critical GAP authorised on crops that can be rotated and the plateau following multiple years of consecutive applications, are in principle still required (data gap). Nevertheless, considering the large margin of safety of the risk assessment performed with the TDMs resulting from the authorised uses of difenoconazole assessed in this MRL review (see Section 3), this data gap is not expected to be of concern for the authorised uses of difenoconazole, but might be relevant for the comprehensive assessment of all triazole fungicides.
Regarding metabolite CGA205375, given its high persistence in soil (see Section 1.1.2), the potential occurrence of residues following multiannual applications should also be investigated for this metabolite. Available studies do not allow a clear conclusion about possible residue levels of metabolite CGA205375 in rotational crops. According to the confined rotational crop study performed at 516 g a.s./ha (see Section 1.1.2), residues of CGA205375 occurred above 10% of the TRR in several plant matrices, but the actual levels of this metabolite in crops were below the trigger values of 0.01 mg/kg in food and 0.05 mg/kg in feed (EFSA, 2021). Nevertheless, the dose rate used in this study does not cover the maximum rate applied for the most critical GAP assessed under this review (indoor fodder beet). Therefore, this study considered sufficient to conclude on the nature of residues, cannot be relied on to conclude whether residues of metabolite CGA205375 above 0.01 mg/kg would occur in rotational crops. Moreover, available field studies did not analyse for this metabolite. Although metabolite CGA205375 is not currently included in the residue definition for risk assessment for rotational crops, a field rotational crops study analysing for this metabolite, covering the most critical GAP authorised on crops that can be rotated and the plateau following multiple years of consecutive applications, is still required to exclude the occurrence of this metabolite at significant levels in rotational crops (data gap). Pending the submission of field rotational crops studies covering the plateau following multiple years of consecutive applications for difenoconazole and metabolite CGA205375, Member States should consider implementing adequate risk mitigation measures to avoid significant residues to occur in rotational crops."

Data/information on difenoconazole residues in succeeding crops were reviewed at EU level and were considered to be acceptable, cover the proposed use.
Field rotation crops studies, analysing for the TDMs are required – data gap.

Applicant agree that the rotational crop studies for difenoconazole presented in EFSA Journal 2018;16(7):5376 (Gemrot, F., 2012, A7402T_10154 and A7402T_10149) lack proper storage stability to support the received results.
In accordance to documentation on EU level storage stability of 12 months would be required to cover the period from sampling to analysis. Applicant provided own storage stability study in which slighlty shorter period of 300 days was covered for oilseed rape (seed, plant, straw) and wheat (grain, plant, straw). In EFSA Journal 2018;16(7):5376 unprotected storage stability studies are evaluated in which stability for at least 15 months are concluded for high water , high starch, high oil and high protein matrices for TA, TAA and TLA. Shorter period were covered for 1,2,4,-T, but in applicant's opinion it has no impact considering that this metabolite degrade very quickly in presented magnitude of residue studies.

Additionally the mentioned studies resulted in similar conclusion to rotational studies performed for other triazole active substances and monitoring data:

Supervised field trials to investigate the residues in rotational crops after application of an EC formulation containing 250 g/L of difenoconazole were conducted at four test sites located in northern France, the United Kingdom, southern France and Spain. At each site, the product was applied once to bare soil at the rate of 375 g as/ha of difenoconazole and rotational crops from three crop groups (cereals represented by barley, root crops represented by carrot and leafy crops represented by lettuce) were planted at three plant-back intervals 29-36 days, 60-61 days and 322-375 days after application to simulate a crop failure, a normal rotation and an annual rotation, respectively. The study samples were analysed for residues of T, TA, TAA and TLA. A summary of the STMR and HR measured in each commodity for each main application scenario is given below:

Commo-dity	Application to	No of Trials	STMR (mg/kg)				HR (mg/kg)			
			T	TA	TAA	TLA	T	TA	TAA	TLA
Barley plant	Bare soil PBI 30-36 days	4	<0.01	0.06	0.03	0.14	<0.01	0.09	0.04	0.20
	Bare soil PBI 60-61 days	4	<0.01	0.06	0.04	0.12	<0.01	0.14	0.09	0.42
	Bare soil PBI 322-375 days	4	<0.01	0.09	0.02	0.13	<0.01	0.12	0.05	0.19
Barley (plant) worst case			<0.01	0.09	0.04	0.14	<0.01	0.14	0.09	0.42
Barley grain	Bare soil PBI 30-36 days	3	<0.01	0.18	0.16	0.01	<0.01	0.54	0.57	0.01
	Bare soil PBI 60-61 days	3	<0.01	0.23	0.22	<0.01	<0.01	0.31	0.33	<0.01
	Bare soil PBI 322-375 days	4	<0.01	0.28	0.27	0.01	<0.01	0.40	0.35	0.02
Barley (grain) worst case			<0.01	0.28	0.27	0.01	<0.01	0.54	0.57	0.02
Barley straw	Bare soil PBI 30-36 days	4	<0.01	0.11	0.13	0.07	<0.01	0.22	0.17	0.24
	Bare soil PBI 60-61 days	3	<0.01	0.05	0.16	0.07	<0.01	0.19	0.24	0.42
	Bare soil PBI 322-375 days	4	<0.01	0.04	0.13	0.07	<0.01	0.08	0.23	0.10
Barley (straw) worst case			<0.01	0.11	0.16	0.07	<0.01	0.22	0.24	0.42
Carrot tops	Bare soil PBI 30-36 days	4	<0.01	<0.01	<0.01	0.09	<0.01	0.01	<0.01	0.29
	Bare soil PBI 60-61 days	4	<0.01	<0.01	<0.01	0.06	<0.01	<0.01	<0.01	0.09
	Bare soil PBI 322-375 days	4	<0.01	<0.01	<0.01	0.06	<0.01	0.01	<0.01	0.07
Carrot (tops) worst case			<0.01	<0.01	<0.01	0.09	<0.01	0.01	<0.01	0.29
Carrot root	Bare soil PBI 30-36 days	4	<0.01	0.06	<0.01	0.01	<0.01	0.07	<0.01	0.03
	Bare soil PBI 60-61 days	4	<0.01	0.05	<0.01	<0.01	<0.01	0.05	<0.01	0.01
	Bare soil PBI 322-375 days	4	<0.01	0.03	<0.01	<0.01	<0.01	0.04	<0.01	0.01
Carrot (root) worst case			<0.01	0.06	<0.01	0.01	<0.01	0.07	<0.01	0.03
Lettuce	Bare soil PBI 29-36 days	4	<0.01	0.01	<0.01	0.03	<0.01	0.02	<0.01	0.05
	Bare soil PBI 60-61 days	4	<0.01	0.01	<0.01	0.03	<0.01	0.02	<0.01	0.08
	Bare soil PBI 322-375 days	4	<0.01	<0.01	<0.01	0.03	<0.01	0.02	<0.01	0.08
Lettuce worst case			<0.01	0.01	<0.01	0.03	<0.01	0.03	<0.01	0.08

Note: For the calculation of the STMRs and HRs the residue values measured in the control samples were taken into account whenever they exceeded the values measured in the corresponding treated samples. The STMRs were calculated based on the highest residue levels from each trial.

Studies presented in *EFSA Journal.* 2024;22:e8987 reflects similar observations:
For what concerns TDMs, two new studies investigating the magnitude of the residues of TDMs in rotational crops were provided (Spain, 2022), however not yet peer reviewed. In these studies, difenoconazole was applied to bare soil at a nominal rate of 375 g a.s./ha (0.4N the maximum rate

assessed under this review, considering crop interception). Barley (cereals), carrots (root crop) and lettuce (leafy crop) were planted at nominal PBI of 30, 60 and 365 DAT. Samples were analysed for the four TDMs; parent was not analysed for. In all rotated crops, 1,2,4-T was below the LOQ (0.01 mg/kg). *In lettuce, residues of TAA were always below or at the LOQ (0.01 mg/kg), while TA and TLA were measured in mature head lettuce at up to 0.02 mg/kg and 0.08 mg/kg, respectively. Highest residues were found in barley, with TA, TLA and TAA measured in grain up to 0.52, 0.44 and 0.02 mg/kg, respectively, and in straw up to 0.22, 0.24 and 0.42 mg/kg, respectively. In carrot roots, TAA residues were always below LOQ, while TA and TLA were found up to 0.07 mg/kg. In carrot tops only, TLA was measured above the LOQ, up to 0.29 mg/kg. No clear decline nor increase of residues with time was observed. No data on the residue concentrations in soil are available. It is concluded that residues of TA, TAA and TLA above 0.01 mg/kg in rotational crops cannot be excluded and that the present study is not expected to cover the concentrations of these metabolites in soil following annual and multiannual applications according to the most critical GAP currently authorised. Consequently, field rotation crops studies, analysing for the TDMs, covering the most critical GAP authorised on crops that can be rotated and the plateau following multiple years of consecutive applications, are in principle still required (data gap). Nevertheless, considering the large margin of safety of the risk assessment performed with the TDMs resulting from the authorised uses of difenoconazole assessed in this MRL review), this data gap is not expected to be of concern for the authorised uses of difenoconazole, but might be relevant for the comprehensive assessment of all triazole fungicides.*

Mentioned studies were presented in EFSA review of confirmatory data following the Article 12 MRL review of the existing maximum residue levels for difenoconazole EFSA Journal. 2024;22:e8987., therefore applicant can rely on this data, as it is unprotected.

As stated no clear decline or increase of residues is observed in all presented studies, therefore in applicant's opinion performing and presenting new studies will result in comparable results, which in fact will not, with high probability, have any significant impact on the final label of the product in comparision to the labels of competitive products.
Also the peer review of difenoconazole (*EFSA Journal 2011;9(1):1967*) classified missing rotational crop study as Data gap:
Data gaps were identified to provide information on the possible residues of TDM metabolites in primary crops, rotational crops, processed commodities and animal products
In the light of current requirements applicant is obligated to fulfill eventual missing points but only after active substance renewal.
Concluding argumentation provided above there is no need currently to present new rotational crop study for triazole metabolites, considering the large margin of safety of the risk assessment performed for triazole metabolites.

zRMS comments, July 2025:
zRMS took into account the additional data provided by the Applicant. Consequently, field rotation crops studies, analysing for the TDMs, on crops that can be rotated and the plateau following multiple years of consecutive applications, are in principle still required (data gap). Nevertheless, considering the large margin of safety of the risk assessment performed with the TDMs resulting from the authorised uses of difenoconazole assessed in this dossier, this data gap is not expected to be of concern for the authorised uses of difenoconazole, but might be relevant for the comprehensive assessment of all triazole fungicides. The position of zRMS is the same as that given in the EFSA Journal. 2024;22:e8987.

7.3.7 Other / special studies (KCA 6.10, 6.10.1)

The residue in honey are expected after pesticide application. (the zonal uses application from GAP table – on winter oilseed rape is during the flowering stage of a crop which is forage by bees.

The new study was conducted as four field trials in Germany (2 trials), Southern France (1 trial) and Spain (1 trial) in 2022/2023.

There were two applications, both at a nominal rate of 1000 mL formulated product/ha in 300 L water/ha (equivalent to 125 g difenoconazole/ha and 200 g azoxystrobin/ha).

Table 3: Summary of residues of Azoxystrobin, Difenoconazole and Metabolites of Difenoconazole (1,2,4 triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA)) Residues in Honey Samples

Sampling code	Trial No.	Sample timing	Treatment	Sample	Residues					
					Azoxy-strobin	Difeno-conazole	1,2,4-T	TA	TAA	TLA
					[mg/kg]					
S1	-01	04 May 2023	C	A1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
			T	A1	<0.01	<0.01	<0.01	0.02	<0.01	<0.01
S1	-02	24 Apr 2023	C	A1	<0.01	<0.01	<0.01	0.01	<0.01	<0.01
			T	A1	<0.01	<0.01	<0.01	0.01	<0.01	<0.01
S1	-04	04 May 2023	C	A1	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
			T	A1	<0.01	0.014	<0.01	0.01	<0.01	<0.01
S1	-05	13 Apr 2023	C	A1	<0.01	<0.01	<0.01	0.03	<0.01	<0.01
			T	A1	<0.01	0.012	<0.01	0.04	<0.01	<0.01

C: control sample; T: treated sample,
LOQ = Limit of quantification (0.01 mg/kg), LOD = Limit of detection (0.003 mg/kg)

No residues of Azoxystrobin, Difenoconazole, 1,2,4 triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) at or above 30 % of the LOQ were detected in any of the untreated honey samples. Residues of triazole alanine (TA) were detected in untreated honey samples of trial -02 with 0.01 mg/kg and of trial -05 at 0.03 mg/kg. No residues of Azoxystrobin, 1,2,4 triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) at or above 30 % of the LOQ were detected in any of the treated honey samples.
Results are below the MRL level – 0.05 mg/kg.

zRMS comments:
The applicant provided one study of which the objective was to determine residues of difenoconazole, azoxystrobin and triazole derivate metabolites (TDMs) in honey from winter oilseed rape collected by honeybees after two applications of CHR/F/SCORPIO 325 SC under semi-field conditions.
Four residue trial was conducted on winter oilseed rape during 2022/2023 in Central and Southern Europe.
Two trials were conducted in Germany, one trial in Southern France and one trial in Spain. Two applications of CHR/F/SCORPIO 325 SC were applied at a target rate of 1.00 L product/ha (125 g Difenoconazole/ha and 200 g azoxystrobin/ha) at an application spray volume of 300 L/ha per application.
The first application was conducted at BBCH 14-23. The second application was conducted at BBCH 63-64, 6-18 days before sampling.
It was reported in the study that a method validation was not performed within this analytical phase because the analytical methods were previously validated in honey with an LOQ of 0.01 mg/kg in accordance to SANTE/2020/12830, rev. 2 for the determination of difenoconazole and azoxystrobin in GLP study S22-08436 (MAHLOW S. 2023) and for 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA), triazole lactic acid (TLA) in GLP study S21- 05866 (MAHLOW S. 2022). However, study S21-05866 cannot be considered to cover method validation because it does not contain all the necessary data for validation, e.g. recovery study at LOQ level, see dRR Part B5.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for all analytes with a limit of detection (LOD) set at 0.003 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ).
For difenoconazole and azoxystrobin, the proof of stability of the analytes in/on fortified samples upon storage period of 104 days in deep frozen conditions was conducted in study S22-08436. The storage interval in study S22-08436 covers the max. storage time from sampling to extraction in the current study.
For 1,2,4-T, TA, TAA and TLA, the proof of stability of the analytes in fortified samples upon storage period of 15 months in deep frozen conditions was conducted in study S21-05867 (see dRR Part B5). The storage interval in study S21-05867 covers the max. storage time from sampling to extraction in the current study.
No residues of azoxystrobin, difenoconazole, 1,2,4 triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) at or above 30 % of the LOQ were detected in any of the untreated honey samples. Residues of triazole alanine (TA) were detected in untreated honey samples of trial -02 with 0.01 mg/kg and of trial -05 at 0.03 mg/kg. No residues of azoxystrobin, 1,2,4 triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) at or above 30 % of the LOQ were detected in any of the treated honey samples. Residues of difenoconazole were between <LOQ (trials -01 and -02), 0.014 mg/kg in trial -04 and 0.012 mg/kg in trial -05. Residues of triazole alanine were between 0.01 mg/kg and 0.04 mg/kg in treated honey samples.
The study is not accepted for TDMs due to the lack of necessary, complete validation data. Reported results:
TAA: 4 x < 0.01 mg/kg
TA: 2 x 0.01 mg/kg, 0.02 mg/kg, 0.04 mg/kg
TLA: 4 x < 0.01 mg/kg
1,2,4 -T: 4 x < 0.01 mg/kg
Difenoconazole: 2 x < 0.01 mg/kg, 0.012 mg/kg, 0.014 mg/kg
Azoxystrobin: 4 x < LOD

The currently established MRL for difenoconazole in honey is 0.05 mg/kg. The use of the CHR/F/SCORPIO 325 SC in accordance with the proposed GAP does not pose a risk of exceeding the currently established MRL in honey.

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

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

In the framework of the assessment of confirmatory data, an uncertainty factor (UF) of 1.3 was derived for all plant commodities, reflecting the tendency of a preferential degradation of trans isomers and a shift to the cis isomers of difenoconazole. For all livestock commodities, noting that difenoconazole-alcohol is a mixture of two isomers, an indicative UF of 2 was considered to accommodate for a possible shift in its isomer ratio, pending further information on the relative toxicity of the individual isomers. These two UFs were applied to the risk assessment calculations.

7.3.8.1 Input values for the consumer risk assessment

Table 7.3.8-1 Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue Difenoconazole				
Beetroots	0.0143	STMR×UF (1.3)	0.0247	HR×UF (1.3)
Celeriacs/turnip rooted celeries	0.0143	STMR×UF (1.3)	0.0247	HR×UF (1.3)
Horseradishes	0.0143	STMR×UF (1.3)	0.0247	HR×UF (1.3)
Swedes/rutabagas	0.0143	STMR×UF (1.3)	0.0247	HR×UF (1.3)
Turnips	0.0143	STMR×UF (1.3)	0.0247	HR×UF (1.3)
Linseeds	0.013	STMR×UF (1.3)	0.013	HR×UF (1.3)
Poppy seeds	0.013	STMR×UF (1.3)	0.013	HR×UF (1.3)
Sunflower seeds	0.013	STMR×UF (1.3)	0.013	HR×UF (1.3)
Rapeseeds/canola seeds	0.013	STMR×UF (1.3)	0.013	HR×UF (1.3)
Soyabeans	0.013	STMR×UF (1.3)	0.013	HR×UF (1.3)
Mustard seeds	0.013	STMR×UF (1.3)	0.013	HR×UF (1.3)
Pumpkin seeds	0.013	STMR×UF (1.3)	0.013	HR×UF (1.3)
Hemp seeds	0.013	STMR×UF (1.3)	0.013	HR×UF (1.3)
Sugar beet roots	0.0143	STMR×UF (1.3)	0.0247	HR×UF (1.3)
Chicory roots	0.0143	STMR×UF (1.3)	0.0247	HR×UF (1.3)
Swine: Muscle/meat	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Swine: Fat tissue	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Swine: Liver	0.04	STMR×UF (2.0)	0.06	HR×UF (2.0)
Swine: Kidney	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Swine: Edible offals (other than liver and kidney)	0.04	STMR×UF (2.0)	0.06	HR×UF (2.0)
Swine: Other products	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Bovine: Muscle/meat	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Bovine: Fat tissue	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Bovine: Liver	0.14	STMR×UF (2.0)	0.16	HR×UF (2.0)
Bovine: Kidney	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Bovine: Edible offals (other than liver and kidney)	0.14	STMR×UF (2.0)	0.16	HR×UF (2.0)
Bovine: Other products	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Sheep: Muscle/meat	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Sheep: Fat tissue	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Sheep: Liver	0.14	STMR×UF (2.0)	0.16	HR×UF (2.0)
Sheep: Kidney	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Sheep: Edible offals (other than liver and kidney)	0.14	STMR×UF (2.0)	0.16	HR×UF (2.0)
Sheep: other products	0.02	STMR×UF (2.0)	-	-
Goat: Muscle/meat	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Goat: Fat tissue	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Goat: Liver	0.14	STMR×UF (2.0)	0.16	HR×UF (2.0)
Goat: Kidney	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Goat: Edible offals (other tha liver and kindey)	0.14	STMR×UF (2.0)	0.16	HR×UF (2.0)
Goat: other products	0.02	STMR×UF (2.0)	-	-

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Equine: Muscle/meat	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Equine: Fat tissue	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Equine: Liver	0.14	STMR×UF (2.0)	0.16	HR×UF (2.0)
Equine: Kidney	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Equine: Edible offals (other than liver and kidney)	0.14	STMR×UF (2.0)	0.16	HR×UF (2.0)
Equine: Other products	0.02	STMR×UF (2.0)	-	-
Poultry: Muscle/meat	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Poultry: Fat tissue	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Poultry: Liver	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Poultry: Kidney	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Poultry: Edible offals (other than liver and kideny)	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Poultry: Other products	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Other farmed animals: Muscle/meat	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Other farmed animals: Fat tissue	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Other farmed animals: Liver	0.14	STMR×UF (2.0)	0.16	HR×UF (2.0)
Other farmed animals: Kidney	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Other farmed animals: Edible offals (other than liver and kidney)	0.14	STMR×UF (2.0)	0.16	HR×UF (2.0)
Other farmed animals: Other products	0.02	STMR×UF (2.0)	-	-
Milk: Cattle	0.01	STMR×UF (2.0)	0.01	HR×UF (2.0)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Milk: Sheep	0.01	STMR×UF (2.0)	0.01	HR×UF (2.0)
Milk: Goat	0.01	STMR×UF (2.0)	0.01	HR×UF (2.0)
Milk: Horse	0.01	STMR×UF (2.0)	0.01	HR×UF (2.0)
Milk: Others	0.01	STMR×UF (2.0)	0.01	HR×UF (2.0)
Eggs: Chicken	0.02	STMR×UF (2.0)	0.04	HR×UF (2.0)
Eggs: Duck	0.02	STMR×UF (2.0)	0.04	HR×UF (2.0)
Eggs: Goose	0.02	STMR×UF (2.0)	0.04	HR×UF (2.0)
Eggs: Quail	0.02	STMR×UF (2.0)	0.04	HR×UF (2.0)
Eggs: Others	0.02	STMR×UF (2.0)	0.04	HR×UF (2.0)
Honey and other apiculture products	0.02	STMR×UF (2.0)	0.02	HR×UF (2.0)
Commodity	**Chronic risk assessment**		**Acute risk assessment**	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue TAA				
Beetroots	0.002	STMR	0.002	HR
Celeriacs/turnip rooted celeries	0.002	STMR	0.002	HR
Horseradishes	0.002	STMR	0.002	HR
Swedes/rutabagas	0.002	STMR	0.002	HR
Turnips	0.002	STMR	0.002	HR
Linseeds	0.004	STMR	0.004	HR
Poppy seeds	0.004	STMR	0.004	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sunflower seeds	0.004	STMR	0.004	HR
Rapeseeds/canola seeds	0.004	STMR	0.004	HR
Soyabeans	0.004	STMR	0.004	HR
Mustard seeds	0.004	STMR	0.004	HR
Pumpkin seeds	0.004	STMR	0.004	HR
Hemp seeds	0.004	STMR	0.004	HR
Sugar beet roots	0.002	STMR	0.002	HR
Chicory roots	0.002	STMR	0.002	HR
Swine: Muscle/meat	0.003	STMR	0.004	HR
Swine: Fat tissue	0.003	STMR	0.01	HR
Swine: Liver	0.003	STMR	0.004	HR
Swine: Kidney	0.003	STMR	0.004	HR
Swine: Edible offals (other than liver and kidney)	0.003	STMR	0.004	HR
Swine: Other products	0.01	STMR	0.01	HR
Bovine: Muscle/meat	0.002	STMR	0.004	HR
Bovine: Fat tissue	0.003	STMR	0.01	HR
Bovine: Liver	0.002	STMR	0.004	HR
Bovine: Kidney	0.002	STMR	0.004	HR
Bovine: Edible offals (other than liver and kidney)	0.002	STMR	0.004	HR
Bovine: Other products	0.01	STMR	0.01	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sheep: Muscle/meat	0.01	STMR	0.01	HR
Sheep: Fat tissue	0.01	STMR	0.01	HR
Sheep: Liver	0.01	STMR	0.01	HR
Sheep: Kidney	0.01	STMR	0.02	HR
Sheep: Edible offals (other than liver and kidney)	0.01	STMR	0.02	HR
Sheep: other products	0.01	STMR	-	-
Goat: Muscle/meat	0.01	STMR	0.01	HR
Goat: Fat tissue	0.01	STMR	0.01	HR
Goat: Liver	0.01	STMR	0.01	HR
Goat: Kidney	0.01	STMR	0.02	HR
Goat: Edible offals (other tha liver and kindey)	0.01	STMR	0.02	HR
Goat: other products	0.01	STMR	-	-
Equine: Muscle/meat	0.01	STMR	0.01	HR
Equine: Fat tissue	0.01	STMR	0.01	HR
Equine: Liver	0.01	STMR	0.01	HR
Equine: Kidney	0.01	STMR	0.02	HR
Equine: Edible offals (other than liver and kidney)	0.01	STMR	0.02	HR
Equine: Other products	0.01	STMR	-	-
Poultry: Muscle/meat	0.01	STMR	0.01	HR
Poultry: Fat tissue	0.01	STMR	0.01	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Poultry: Liver	0.01	STMR	0.01	HR
Poultry: Kidney	0.01	STMR	0.02	HR
Poultry: Edible offals (other than liver and kideny)	0.01	STMR	0.02	HR
Poultry: Other products	0.01	STMR	-	-
Other farmed animals: Muscle/meat	0.01	STMR	0.01	HR
Other farmed animals: Fat tissue	0.01	STMR	0.01	HR
Other farmed animals: Liver	0.01	STMR	0.01	HR
Other farmed animals: Kidney	0.01	STMR	0.02	HR
Other farmed animals: Edible offals (other than liver and kidney)	0.01	STMR	0.02	HR
Other farmed animals: Other products	0.01	STMR	-	-
Milk: Cattle	0.002	STMR	0.002	HR
Milk: Sheep	0.002	STMR	0.002	HR
Milk: Goat	0.002	STMR	0.002	HR
Milk: Horse	0.002	STMR	0.002	HR
Milk: Others	0.002	STMR	0.002	HR
Eggs: Chicken	0.01	STMR	0.01	HR
Eggs: Duck	0.01	STMR	0.01	HR
Eggs: Goose	0.01	STMR	0.01	HR
Eggs: Quail	0.01	STMR	0.01	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Eggs: Others	0.01	STMR	0.01	HR
Honey and other apiculture products	0.01	STMR	0.01	HR
Risk assessment residue TA				
Beetroots	0.01	STMR	0.028	HR
Celeriacs/turnip rooted celeries	0.01	STMR	0.028	HR
Horseradishes	0.01	STMR	0.028	HR
Swedes/rutabagas	0.01	STMR	0.028	HR
Turnips	0.01	STMR	0.028	HR
Linseeds	0.47	STMR	0.47	HR
Poppy seeds	0.47	STMR	0.47	HR
Sunflower seeds	0.47	STMR	0.47	HR
Rapeseeds/canola seeds	0.47	STMR	0.47	HR
Soyabeans	0.47	STMR	0.47	HR
Mustard seeds	0.47	STMR	0.47	HR
Pumpkin seeds	0.47	STMR	0.47	HR
Hemp seeds	0.47	STMR	0.47	HR
Sugar beet roots	0.01	STMR	0.028	HR
Chicory roots	0.01	STMR	0.028	HR
Swine: Muscle/meat	0.01	STMR	0.02	HR
Swine: Fat tissue	0.01	STMR	0.01	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Swine: Liver	0.03	STMR	0.06	HR
Swine: Kidney	0.01	STMR	0.02	HR
Swine: Edible offals (other than liver and kidney)	0.03	STMR	0.06	HR
Swine: Other products	0.01	STMR	0.01	HR
Bovine: Muscle/meat	0.01	STMR	0.02	HR
Bovine: Fat tissue	0.01	STMR	0.01	HR
Bovine: Liver	0.03	STMR	0.05	HR
Bovine: Kidney	0.01	STMR	0.01	HR
Bovine: Edible offals (other than liver and kidney)	0.03	STMR	0.05	HR
Bovine: Other products	0.01	STMR	0.01	HR
Sheep: Muscle/meat	0.05	STMR	0.1	HR
Sheep: Fat tissue	0.02	STMR	0.06	HR
Sheep: Liver	0.16	STMR	0.26	HR
Sheep: Kidney	0.04	STMR	0.1	HR
Sheep: Edible offals (other than liver and kidney)	0.16	STMR	0.26	HR
Sheep: other products	0.01	STMR	-	-
Goat: Muscle/meat	0.05	STMR	0.1	HR
Goat: Fat tissue	0.02	STMR	0.06	HR
Goat: Liver	0.16	STMR	0.26	HR
Goat: Kidney	0.04	STMR	0.1	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Goat: Edible offals (other tha liver and kindey)	0.16	STMR	0.26	HR
Goat: other products	0.01	STMR	-	-
Equine: Muscle/meat	0.05	STMR	0.1	HR
Equine: Fat tissue	0.02	STMR	0.06	HR
Equine: Liver	0.16	STMR	0.26	HR
Equine: Kidney	0.04	STMR	0.1	HR
Equine: Edible offals (other than liver and kidney)	0.16	STMR	0.26	HR
Equine: Other products	0.01	STMR	-	-
Poultry: Muscle/meat	0.02	STMR	0.03	HR
Poultry: Fat tissue	0.03	STMR	0.05	HR
Poultry: Liver	0.08	STMR	0.12	HR
Poultry: Kidney	0.08	STMR	0.12	HR
Poultry: Edible offals (other than liver and kideny)	0.08	STMR	0.12	HR
Poultry: Other products	0.01	STMR	-	-
Other farmed animals: Muscle/meat	0.02	STMR	0.1	HR
Other farmed animals: Fat tissue	0.02	STMR	0.06	HR
Other farmed animals: Liver	0.16	STMR	0.26	HR
Other farmed animals: Kidney	0.04	STMR	0.1	HR
Other farmed animals: Edible offals (other than liver and kidney)	0.16	STMR	0.26	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Other farmed animals: Other products	0.01	STMR	-	-
Milk: Cattle	0.01	STMR	0.01	HR
Milk: Sheep	0.01	STMR	0.01	HR
Milk: Goat	0.01	STMR	0.01	HR
Milk: Horse	0.01	STMR	0.01	HR
Milk: Others	0.01	STMR	0.01	HR
Eggs: Chicken	0.01	STMR	0.02	HR
Eggs: Duck	0.01	STMR	0.02	HR
Eggs: Goose	0.01	STMR	0.02	HR
Eggs: Quail	0.01	STMR	0.02	HR
Eggs: Others	0.01	STMR	0.02	HR
Honey and other apiculture products	0.015	STMR	0.04	HR
Risk assessment residue 1,2,4-T				
Beetroots	0.002	STMR	0.002	HR
Celeriacs/turnip rooted celeries	0.002	STMR	0.002	HR
Horseradishes	0.002	STMR	0.002	HR
Swedes/rutabagas	0.002	STMR	0.002	HR
Turnips	0.002	STMR	0.002	HR
Linseeds	0.004	STMR	0.004	HR
Poppy seeds	0.004	STMR	0.004	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sunflower seeds	0.004	STMR	0.004	HR
Rapeseeds/canola seeds	0.004	STMR	0.004	HR
Soyabeans	0.004	STMR	0.004	HR
Mustard seeds	0.004	STMR	0.004	HR
Pumpkin seeds	0.004	STMR	0.004	HR
Hemp seeds	0.004	STMR	0.004	HR
Sugar beet roots	0.002	STMR	0.002	HR
Chicory roots	0.002	STMR	0.002	HR
Swine: Muscle/meat	0.01	STMR	0.01	HR
Swine: Fat tissue	0.01	STMR	0.01	HR
Swine: Liver	0.01	STMR	0.01	HR
Swine: Kidney	0.01	STMR	0.01	HR
Swine: Edible offals (other than liver and kidney)	0.01	STMR	0.01	HR
Swine: Other products	0.01	STMR	0.01	HR
Bovine: Muscle/meat	0.01	STMR	0.01	HR
Bovine: Fat tissue	0.01	STMR	0.01	HR
Bovine: Liver	0.01	STMR	0.01	HR
Bovine: Kidney	0.01	STMR	0.01	HR
Bovine: Edible offals (other than liver and kidney)	0.01	STMR	0.01	HR
Bovine: Other products	0.01	STMR	0.01	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sheep: Muscle/meat	0.01	STMR	0.01	HR
Sheep: Fat tissue	0.01	STMR	0.01	HR
Sheep: Liver	0.01	STMR	0.01	HR
Sheep: Kidney	0.01	STMR	0.01	HR
Sheep: Edible offals (other than liver and kidney)	0.01	STMR	0.01	HR
Sheep: other products	0.01	STMR	-	-
Goat: Muscle/meat	0.01	STMR	0.01	HR
Goat: Fat tissue	0.01	STMR	0.01	HR
Goat: Liver	0.01	STMR	0.01	HR
Goat: Kidney	0.01	STMR	0.01	HR
Goat: Edible offals (other tha liver and kindey)	0.01	STMR	0.01	HR
Goat: other products	0.01	STMR	-	-
Equine: Muscle/meat	0.01	STMR	0.01	HR
Equine: Fat tissue	0.01	STMR	0.01	HR
Equine: Liver	0.01	STMR	0.01	HR
Equine: Kidney	0.01	STMR	0.01	HR
Equine: Edible offals (other than liver and kidney)	0.01	STMR	0.01	HR
Equine: Other products	0.01	STMR	-	-
Poultry: Muscle/meat	0.01	STMR	0.01	HR
Poultry: Fat tissue	0.01	STMR	0.01	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Poultry: Liver	0.01	STMR	0.01	HR
Poultry: Kidney	0.01	STMR	0.01	HR
Poultry: Edible offals (other than liver and kideny)	0.01	STMR	0.01	HR
Poultry: Other products	0.01	STMR	-	-
Other farmed animals: Muscle/meat	0.01	STMR	0.01	HR
Other farmed animals: Fat tissue	0.01	STMR	0.01	HR
Other farmed animals: Liver	0.01	STMR	0.01	HR
Other farmed animals: Kidney	0.01	STMR	0.01	HR
Other farmed animals: Edible offals (other than liver and kidney)	0.01	STMR	0.01	HR
Other farmed animals: Other products	0.01	STMR	-	-
Milk: Cattle	0.01	STMR	0.01	HR
Milk: Sheep	0.01	STMR	0.01	HR
Milk: Goat	0.01	STMR	0.01	HR
Milk: Horse	0.01	STMR	0.01	HR
Milk: Others	0.01	STMR	0.01	HR
Eggs: Chicken	0.01	STMR	0.01	HR
Eggs: Duck	0.01	STMR	0.01	HR
Eggs: Goose	0.01	STMR	0.01	HR
Eggs: Quail	0.01	STMR	0.01	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Eggs: Others	0.01	STMR	0.01	HR
Honey and other apiculture products	0.01	STMR	0.01	HR
Risk assessment TLA				
Beetroots	0.002	STMR	0.01	HR
Celeriacs/turnip rooted celeries	0.002	STMR	0.01	HR
Horseradishes	0.002	STMR	0.01	HR
Swedes/rutabagas	0.002	STMR	0.01	HR
Turnips	0.002	STMR	0.01	HR
Linseeds	0.004	STMR	0.004	HR
Poppy seeds	0.004	STMR	0.004	HR
Sunflower seeds	0.004	STMR	0.004	HR
Rapeseeds/canola seeds	0.004	STMR	0.004	HR
Soyabeans	0.004	STMR	0.004	HR
Mustard seeds	0.004	STMR	0.004	HR
Pumpkin seeds	0.004	STMR	0.004	HR
Hemp seeds	0.004	STMR	0.004	HR
Sugar beet roots	0.004	STMR	0.23	HR
Chicory roots	0.004	STMR	0.23	HR
Swine: Muscle/meat	0.003	STMR	0.004	HR
Swine: Fat tissue	0.01	STMR	0.01	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Swine: Liver	0.003	STMR	0.004	HR
Swine: Kidney	0.003	STMR	0.004	HR
Swine: Edible offals (other than liver and kidney)	0.003	STMR	0.004	HR
Swine: Other products	0.01	STMR	0.01	HR
Bovine: Muscle/meat	0.002	STMR	0.004	HR
Bovine: Fat tissue	0.004	STMR	0.01	HR
Bovine: Liver	0.002	STMR	0.004	HR
Bovine: Kidney	0.002	STMR	0.004	HR
Bovine: Edible offals (other than liver and kidney)	0.002	STMR	0.004	HR
Bovine: Other products	0.01	STMR	0.01	HR
Sheep: Muscle/meat	0.01	STMR	0.01	HR
Sheep: Fat tissue	0.02	STMR	0.03	HR
Sheep: Liver	0.01	STMR	0.01	HR
Sheep: Kidney	0.01	STMR	0.01	HR
Sheep: Edible offals (other than liver and kidney)	0.01	STMR	0.01	HR
Sheep: other products	0.01	STMR	-	-
Goat: Muscle/meat	0.01	STMR	0.01	HR
Goat: Fat tissue	0.02	STMR	0.03	HR
Goat: Liver	0.01	STMR	0.01	HR
Goat: Kidney	0.01	STMR	0.01	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Goat: Edible offals (other tha liver and kindey)	0.01	STMR	0.01	HR
Goat: other products	0.01	STMR	-	-
Equine: Muscle/meat	0.01	STMR	0.01	HR
Equine: Fat tissue	0.02	STMR	0.03	HR
Equine: Liver	0.01	STMR	0.01	HR
Equine: Kidney	0.01	STMR	0.01	HR
Equine: Edible offals (other than liver and kidney)	0.01	STMR	0.01	HR
Equine: Other products	0.01	STMR	-	-
Poultry: Muscle/meat	0.01	STMR	0.01	HR
Poultry: Fat tissue	0.01	STMR	0.03	HR
Poultry: Liver	0.02	STMR	0.02	HR
Poultry: Kidney	0.02	STMR	0.02	HR
Poultry: Edible offals (other than liver and kideny)	0.02	STMR	0.02	HR
Poultry: Other products	0.01	STMR	-	-
Other farmed animals: Muscle/meat	0.02	STMR	0.01	HR
Other farmed animals: Fat tissue	0.02	STMR	0.03	HR
Other farmed animals: Liver	0.01	STMR	0.01	HR
Other farmed animals: Kidney	0.01	STMR	0.01	HR
Other farmed animals: Edible offals (other than liver and kidney)	0.01	STMR	0.01	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Other farmed animals: Other products	0.01	STMR	-	-
Milk: Cattle	0.002	STMR	0.002	HR
Milk: Sheep	0.002	STMR	0.002	HR
Milk: Goat	0.002	STMR	0.002	HR
Milk: Horse	0.002	STMR	0.002	HR
Milk: Others	0.002	STMR	0.002	HR
Eggs: Chicken	0.01	STMR	0.02	HR
Eggs: Duck	0.01	STMR	0.02	HR
Eggs: Goose	0.01	STMR	0.02	HR
Eggs: Quail	0.01	STMR	0.02	HR
Eggs: Others	0.01	STMR	-	-
Honey and other apiculture products	0.01	STMR	0.01	HR

Output values for animal matrices were calculated and presented in the tables 7.3-2-15, based on unprotected studies available on EU level. For metabolite 1,2,4-T risk for animals is acceptable, therefore livestock feeding study was not necessary. Considering lack of livestock study for each animal matrix default value of 0.01 mg/kg was used.

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3.8-2: Consumer risk assessment

Difenoconazole	
TMDI (% ADI) according to EFSA PRIMo	32% with 22% contribution from sugar beet roots (based on NL child)
IEDI (% ADI) according to EFSA PRIMo	8% with 22% contribution from milk: cattle(based on NL toddler)

IESTI (% ARfD) according to EFSA PRIMo	Unprocessed: 0.9% for celeriacs/turnip rooted (based on children) 0.5% for swedes/rutabagas (based on adults) Processed: 1% for sugar beets (root)/sugar (based on children) 0.4% for sugar beets (root)/sugar (based on adults)
TAA	
TMDI (% ADI) according to EFSA PRIMo	0.0% for soyabeans (based on GEMS/Food G11)
IEDI (% ADI) according to EFSA PRIMo	0.0% for milk cattle (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo	Unprocessed: 0.02 % for milk cattle (based on children) 0.01 % for poultry: muscle (based on adults) Processed: 0.0% for sugar beets (root)/ sugar (based on children) 0.0% for sugar beets (root)/ sugar (based on adults)
TA	
TMDI (% ADI) according to EFSA PRIMo	19% for soyabeans (GEMS/Food G10)
IEDI (% ADI) according to EFSA PRIMo	0.6% for soyabeans (GEMS/Food G10)
IESTI (% ARfD) according to EFSA PRIMo	Unprocessed: 0.5 % beetroots (based on children) 0.9 % soybeans (based on children) Processed: 0.7% Soya drink (based on children) 0.4% Beetroots/boiled (based on adults)
TLA	
TMDI (% ADI) according to EFSA PRIMo	0.7% for soybeans (GEMS/Food G10)
IEDI (% ADI) according to EFSA PRIMo	0.1% for milk:cattle (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo	Unprocessed: 0.2% for beetroots (based on children) 0.1% for sedes/rutabagas (based on children) Processed: 0.2% for turnips/boiled (based on children) 0.1% for beetroots/boiled (based on adults)
1,2,4-T	
TMDI (% ADI) according to EFSA PRIMo	3 % for milk cattle (NL child)
IEDI (% ADI) according to EFSA PRIMo	3 % for milk cattle (NL child)

IESTI (% ARfD) according to EFSA PRIMo	Unprocessed: 1 % for milk cattle (based on children) 0.4 % for milk cattle (based on children) Processed: 0.2 % for sugar beets (root)/sugar (based on children) 0.1 % for sugar beets (root)/sugar (based on adults)

* 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 CHR/F/SCORPIO 325 SC do not represent unacceptable risks for the consumer.

zRMS comments:

Difenoconazole
Taking into account that the STMR and HR for difenoconazole from this dossier are not higher than STMR and HR used as input values in risk assessment in the EFSA Journal. 2024;22:e8987 (see table below) it was considered that the assessment provided by EFSA covers the proposed uses and further calculations are not required.

Commodity	Chronic risk assessment		Acute risk assessment	
	STMR, Input value (mg/kg), EFSA 2024	STMR from studies in this dossier (mg/kg)	HR/STMR Input value (mg/kg), EFSA 2024	HR from studies in this dossier (mg/kg)
Sugar beet roots	0.06 STMR(tentative) × UF (1.3)	0.014 (0.011 x 1.3)	0.1 HR (tentative) × UF (1.3)	0.025 (0.019 x 1.3)
Turnips	0.1 STMR(tentative) × UF (1.3)	0.014 (0.011 x 1.3)	0.39 HR (tentative) × UF (1.3)	0.025 (0.019 x 1.3)
Chicory roots	0.26 STMR(tentative) × UF (1.3)	0.014 (0.011 x 1.3)	0.42 HR (tentative) × UF (1.3)	0.025 (0.019 x 1.3)
Beetroots	0.1 STMR(tentative) × UF (1.3)	0.014 (0.011 x 1.3)	0.39 HR (tentative) × UF (1.3)	0.025 (0.019 x 1.3)
Rutabagas	0.1 STMR(tentative) × UF (1.3)	0.014 (0.011 x 1.3)	0.39 HR (tentative) × UF (1.3)	0.025 (0.019 x 1.3)
Horseradish	0.1 STMR (CXL; tentative) × UF (1.3)	0.014 (0.011 x 1.3)	0.39 HR (CXL; tentative) × UF (1.3)	0.025 (0.019 x 1.3)
Celeriac	0.1 STMR(tentative) × UF (1.3)	0.014 (0.011 x 1.3)	0.39 HR (tentative) × UF (1.3)	0.025 (0.019 x 1.3)
Rapeseeds	0.03 STMR(tentative) × UF (1.3)	0.013 (0.01* x 1.3)	0.03 STMR(tentative) × UF (1.3)	0.013 (0.01* x 1.3)
Mustard seeds	0.03 STMR(tentative) × UF (1.3)	0.013 (0.01* x 1.3)	0.03 STMR(tentative) × UF (1.3)	0.013 (0.01* x 1.3)
Soybean	0.03 STMR(tentative) × UF (1.3)	0.013 (0.01* x 1.3)	0.03 STMR(tentative) × UF (1.3)	0.013 (0.01* x 1.3)
Sunflower seeds	0.01 STMR(tentative) × UF (1.3)	0.013 (0.01* x 1.3)	0.01 STMR(tentative) × UF (1.3)	0.013 (0.01* x 1.3)
Pumpkin seed	-	0.013 (0.01* x 1.3)	-	0.013 (0.01* x 1.3)
Hemp	-	0.013 (0.01* x 1.3)	-	0.013 (0.01* x 1.3)
Poppy seeds	0.03 STMR(tentative) × UF (1.3)	0.013 (0.01* x 1.3)	0.03 STMR(tentative) × UF (1.3)	0.013 (0.01* x 1.3)

*Residues below LOQ (0.01 mg/kg)

Consumer risk assessment without consideration of the existing CXLs, EFSA Journal. 2024;22:e8987

Highest IESTI, according to EFSA PRIMo (rev.3.1)	Scenario EU1 (without risk mitigation measures) Difenoconazole (RD-RA1): Lettuces: 204% of ARfD Escaroles: 111% of ARfD Kales: 110% of ARfD Celeries: 103% of ARfD Escaroles, processed: 183% of ARfD Witloofs, processed: 130% of ARfD Scenario EU2 (with risk mitigation measures) Difenoconazole: Celeries: 79% of ARfD Rhubarbs: 78% of ARfD Lettuces: 78% of ARfD Florence fennels, processed: 95% of ARfD Escaroles, processed: 81% of ARfD
Assumptions made for the calculations	Scenario EU1 (without risk mitigation measures): Difenoconazole (RD-RA1): The calculation is based on the highest residue levels (HR) expected in raw agricultural commodities, except for papaya and cucurbits with inedible peel where the respective derived peeling factors were applied, and for pulses, oilseeds, olives for oil production, cereal grains, ginger and milk where the median residue levels (STMR) expected in raw commodity was considered. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. To accommodate the shift in the isomer ratio for difenoconazole in plant commodities and for metabolite CGA205375 in livestock commodities uncertainty factors of 1.3 and 2, respectively, were applied for risk assessment calculations according to RD-RA1. Scenario EU2 (with risk mitigation measures): Difenoconazole (RD-RA1): Same assumptions as for scenario EU1, except that the highest residue level for lettuces, escaroles, kales, celeries and witloofs resulting from the GAPs of concern, were replaced by the highest residue levels resulting from the fall-back GAPs (assuming that the GAPs of concern will be withdrawn for these crops).
Highest IEDI, according to EFSA PRIMo (rev. 3.1)	Scenario EU1 (without risk mitigation measures): Difenoconazole (RD-RA1): 74% of ADI (NL toddler) Scenario EU2 (with risk mitigation measures): Difenoconazole (RD-RA1): 69% of ADI (NL toddler)
Assumptions made for the calculations	Scenario EU1 (without risk mitigation measures): Difenoconazole (RD-RA1): The calculation is based on the median residue levels (STMR) derived for raw agricultural commodities, except for papaya and cucurbits with inedible peel where the respective derived peeling factors were applied. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The contribution of commodities where no GAP was reported in the framework of the MRL review was not included in the calculation. To accommodate the possible shift in the isomer ratio for difenoconazole in

	plant commodities and for metabolite CGA205375 in livestock commodities uncertainty factors of 1.3 and 2, respectively, were applied for risk assessment calculations according to RD-RA1. Scenario EU2 (with risk mitigation measures): Difenoconazole (RD-RA1): Same assumptions as for scenario EU1, except that the median residue level for lettuces, escaroles, kales, celeries and witloofs resulting from the GAPs of concern, were replaced by the median residue levels resulting from the fallback GAPs (assuming that the GAPs of concern will be withdrawn for these crops).

The proposed uses of difenoconazole in the formulation CHR/F/SCORPIO 325 SC do not represent unacceptable acute and chronic risks for the consumer.

TDMs
zRMS did not recalculate chronic consumer risk assessment. STMR from this dossier are not higher than STMR detailed in the assessment of confirmatory data on TDMs (UK, 2018; (EFSA, 2018 amended 2019)).

Comparison of input values for risk assessment from confirmatory data assessment (UK, 2018 and (EFSA, 2018 amended 2019)) with values derived from studies provided in this dossier:

Commodity	Residue (mg/kg)							
	T		TA		TAA		TLA	
	STMR	HR	STMR	HR	STMR	HR	STMR	HR
Root & tuber vegetables Sugar beet roots Turnips Chicory roots Beetroots Rutabagas Horseradish Celeriac	0.01 (0.002*)	0.016 (0.002*)	0.184 (0.01)	0.239 (0.028)	0.010 (0.002*)	0.010 (0.002*)	0.021 (0.002)	0.131 (0.01)
Oilseeds Rapeseeds Mustard seeds Soybean Sunflower seeds Pumpkin seed Hemp Poppy seeds	0.050 (0.004*)	0.100 (0.004*)	1.039 (0.355)	2.826 (6.72)	0.120 (0.004)	0.680 (0.058)	0.065 (0.004)	0.192 (0.25)

Results from chronic risk assessment performed by EFSA (EFSA, 2018 amended 2019) are summarized below.

TMDI (% ADI) according to EFSA PRIMo 3	Not performed
IEDI (% ADI) according to EFSA PRIMo 3 (EFSA,	1,2,4-T: 93 % of ADI (NL toddler)

2018a, amended 2019)	TA and TLA: 7% of ADI (NL toddler) TAA: 1% of ADI (NL toddler)
IESTI (% ARfD) according to EFSA PRIMo 3	**1,2,4-T:** Unprocessed commodities: 0.7% based on the consumption of wheat by children Processed commodities: 0.6% based on the consumption of wheat/milling (flour) by children **TA and TLA:** Unprocessed commodities: 3.1% based on consumption of wheat by children Processed commodities: 3.1% based on consumption of wheat/milling (flour) by children **TAA:** Unprocessed commodities: 1% based on consumption of wheat by children Processed commodities: 1% based on consumption of wheat/milling (flour) by children

Input values for acute consumer risk assessment (TA and TLA);HR based on values from UK, 2018 with values derived from studies provided in this dossier:

Crop group	**TA**	**TLA**
	HR	**HR**
Root & tuber vegetables	0.239	0.131
Oilseeds	6.72 from this dossier	0.25 from this dossier
Sugar plants	0.078	0.010
Ruminant meat	0.62	0.04
Ruminant fat	0.34	0.1
Ruminant liver	1.36	0.04
Ruminant kidney	0.58	0.13
Ruminant milk	0.04	0.04
Sheep meat	0.68	0.04
Sheep fat	0.38	0.11
Sheet liver	1.80	0.04
Sheep kidney	0.65	0.13
Sheep milk	0.04	0.04
Swine meat	0.27	0.04
Swine fat	0.14	0.08
Swine liver	0.61	0.04
Swine kidney	0.27	0.08
Poultry meat	0.12	0.04
Poultry fat	0.11	0.04
Poultry liver	0.31	0.04
Poultry Eggs	0.06	0.04
Honey	0.04	0.01

IESTI (% ARfD) according to EFSA PRIMo 3.1	**TA** Unprocessed commodities: 5% based on consumption of beetroots by children Processed commodities: 4% based on consumption of turnips (boiled) by children **TAA:** Unprocessed commodities: 2% based on consumption of beetroots by children Processed commodities: 2% based on consumption of beetroots (boiled) by children

The exposure to difenoconazole and TDMs after use of CHR/F/SCORPIO 325 SC is not expected to present a consumer risk. No further refinement of the assessment is required.

TA

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

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

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

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

Show results for all crops

Unprocessed commodities

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

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

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Beetroots	0 / 0,24	14
4%	Celeriacs/turnip rooted	0 / 0,24	13
4%	Swedes/rutabagas	0 / 0,24	12
4%	Bovine: Liver	0 / 1,36	11
3%	Turnips	0 / 0,24	8,6
1%	Bovine: Muscle/meat	0 / 0,62	4,5
1%	Equine: Muscle/meat	0 / 0,68	4,1
1%	Sheep: Muscle/meat	0 / 0,68	3,7
1%	Swine: Muscle/meat	0 / 0,27	3,3
0,7%	Bovine: Kidney	0 / 0,58	2,2
0,7%	Poultry Muscle/meat	0 / 0,12	2,0
0,2%	Swine: Liver	0 / 0,61	0,75
0,2%	Eggs: Chicken	0 / 0,06	0,74
0,2%	Bovine: Fat tissue	0 / 0,34	0,71
0,1%	Swine: Kidney	0 / 0,27	0,34

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Swedes/rutabagas	0 / 0,24	8,2
2%	Beetroots	0 / 0,24	5,5
2%	Bovine: Liver	0 / 1,36	5,4
2%	Sheep: Liver	0 / 1,8	5,0
1%	Bovine: Muscle	0 / 0,62	3,5
1%	Equine: Muscle/meat	0 / 0,68	3,3
1%	Sheep: Muscle/meat	0 / 0,68	3,2
0,9%	Celeriacs/turnip rooted	0 / 0,24	2,8
0,9%	Turnips	0 / 0,24	2,7
0,6%	Horseradishes	0 / 0,24	1,7
0,5%	Poultry: Liver	0 / 0,31	1,5
0,5%	Poultry: Muscle	0 / 0,12	1,4
0,4%	Swine: Muscle/meat	0 / 0,27	1,3
0,4%	Bovine: Kidney	0 / 0,58	1,2
0,4%	Goat: Muscle	0 / 0,68	1,1

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

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

Processed commodities

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

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

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

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Turnips / boiled	0 / 0,24	12
4%	Beetroots / boiled	0 / 0,24	11
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

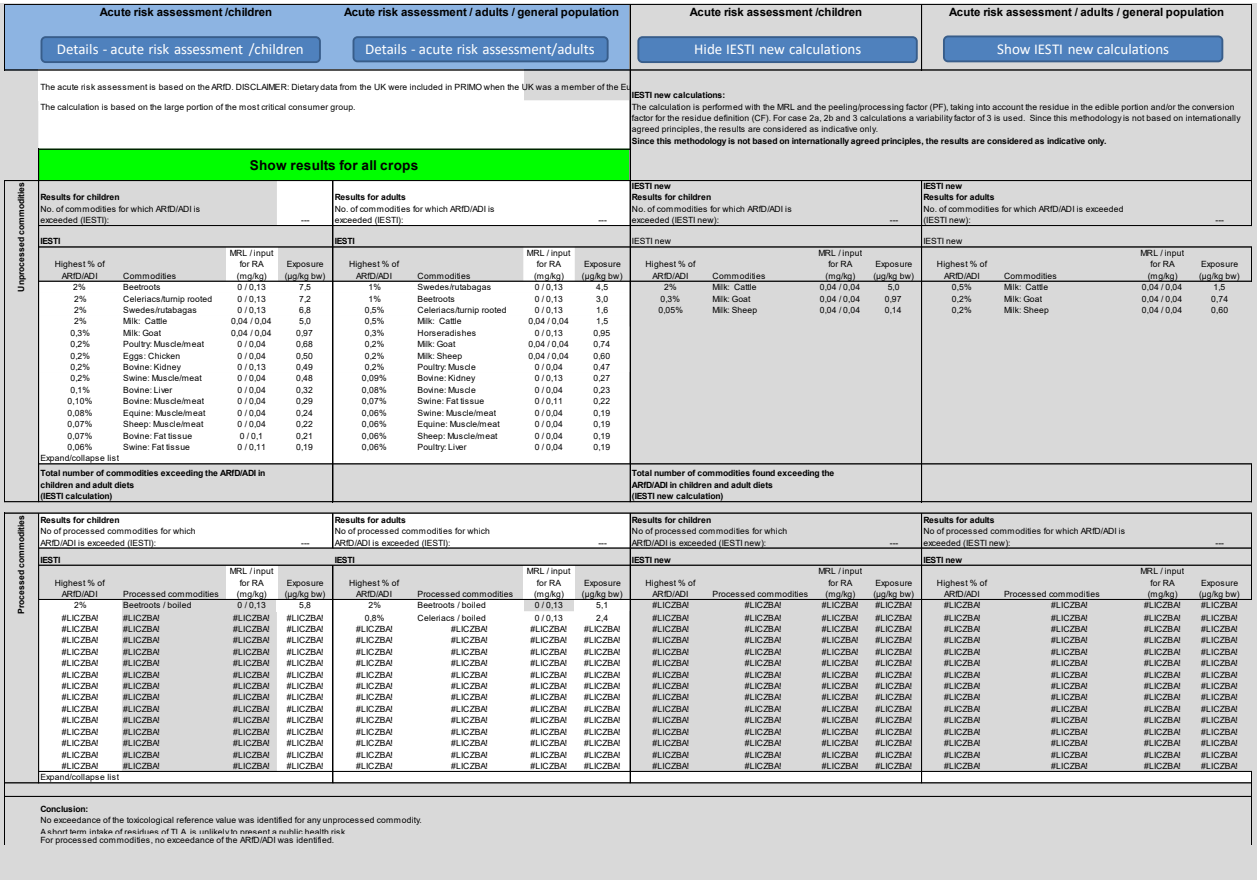
Expand/collapse list

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Beetroots / boiled	0 / 0,24	9,3
2%	Turnips / boiled	0 / 0,24	4,6
1%	Celeriacs / boiled	0 / 0,24	4,3
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

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

TLA



Acute risk assessment /children | Acute risk assessment / adults / general population | Acute risk assessment /children | Acute risk assessment / adults / general population

Details - acute risk assessment /children | Details - acute risk assessment/adults | Hide IESTI new calculations | Show IESTI new calculations

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

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

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

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				IESTI new Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---				IESTI new Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				IESTI				IESTI new				IESTI new			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Beetroots	0 / 0,13	7,5	1%	Swedes/rutabagas	0 / 0,13	4,5	2%	Milk: Cattle	0,04 / 0,04	5,0	0,5%	Milk: Cattle	0,04 / 0,04	1,5
2%	Celeriacs/turnip rooted	0 / 0,13	7,2	1%	Beetroots	0 / 0,13	3,0	0,3%	Milk: Goat	0,04 / 0,04	0,97	0,2%	Milk: Goat	0,04 / 0,04	0,74
2%	Swedes/rutabagas	0 / 0,13	6,8	0,5%	Celeriacs/turnip rooted	0 / 0,13	1,6	0,05%	Milk: Sheep	0,04 / 0,04	0,14	0,2%	Milk: Sheep	0,04 / 0,04	0,60
2%	Milk: Cattle	0,04 / 0,04	5,0	0,5%	Milk: Cattle	0,04 / 0,04	1,5								
0,3%	Milk: Goat	0,04 / 0,04	0,97	0,3%	Horseradishes	0 / 0,13	0,95								
0,2%	Poultry: Muscle/meat	0 / 0,04	0,68	0,2%	Milk: Goat	0,04 / 0,04	0,74								
0,2%	Eggs: Chicken	0 / 0,04	0,50	0,2%	Milk: Sheep	0,04 / 0,04	0,60								
0,2%	Bovine: Kidney	0 / 0,13	0,49	0,2%	Poultry: Muscle	0 / 0,04	0,47								
0,2%	Swine: Muscle/meat	0 / 0,04	0,48	0,09%	Bovine: Kidney	0 / 0,13	0,27								
0,1%	Bovine: Liver	0 / 0,04	0,32	0,08%	Bovine: Muscle	0 / 0,04	0,23								
0,10%	Bovine: Muscle/meat	0 / 0,04	0,29	0,07%	Swine: Fat tissue	0 / 0,11	0,22								
0,08%	Equine: Muscle/meat	0 / 0,04	0,24	0,06%	Swine: Muscle/meat	0 / 0,04	0,19								
0,07%	Sheep: Muscle/meat	0 / 0,04	0,22	0,06%	Equine: Muscle/meat	0 / 0,04	0,19								
0,07%	Bovine: Fat tissue	0 / 0,1	0,21	0,06%	Sheep: Muscle/meat	0 / 0,04	0,19								
0,06%	Swine: Fat tissue	0 / 0,11	0,19	0,06%	Poultry: Liver	0 / 0,04	0,19								
Expand/collapse list															
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)**							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				IESTI				IESTI new				IESTI new			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Beetroots / boiled	0 / 0,13	5,8	2%	Beetroots / boiled	0 / 0,13	5,1	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	0,8%	Celeriacs / boiled	0 / 0,13	2,4	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
Expand/collapse list															

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

7.4 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised "scientific methods accepted by the Authority to assess such effects are available."
Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

7.4.1 Chronic consumer risk assessment from combined exposure

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

7.5 References

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Denmark, 2010. Evaluation report on the review of the existing EU MRLs for clomazone prepared by the rapporteur Member State Denmark in the framework of Article 12 of Regulation (EC) No 396/2005, December 2010.

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EFSA (European Food Safety Authority), 2009b. Reasoned opinion on the modification of the existing MRL(s) for clomazone in herbs. EFSA Scientific Report (2009) 265, 1-22.

EFSA (European Food Safety Authority), 2011. Review of the existing maximum residue levels (MRLs) for clomazone according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011;9(8):2345. [44 pp.] doi:10.2903/j.efsa.2011.2345. Available online: www.efsa.europa.eu/efsajournal

FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.

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

EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Carrasco Cabrera, L.,Castellan, I., del Aguila, M., Ferreira, L., Greco, L., Jarrah, S., Leuschner, R., Mioč, A., Nave, S., Reich, H., Ruocco, S., Scarlato,A. P., Szot, M., Theobald, A., Tiramani, M., & Verani, A. (2024). Review of the existing maximum residue levels fordifenoconazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal, 22(8), e8987. https://doi.org/10.2903/j.efsa.2024.8987

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

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3	K. Wańczyk	2024	Magnitude of the azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) residues in Oil Seed Rape (Raw Agricultural Commodity) after two applications of CHR/F/SCORPIO 325 SC – one harvest study trial in Poland – 2022 Study number 22SGS48 SGS Polska Sp. z o. o. Jerozolimskie Business Park Al. Jerozolimskie 146A 02-305 Warszawa Poland GLP Not published	N	Chemirol
KCA 6.3	K. Wańczyk	2024	Magnitude of the azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) residues in Oil Seed Rape (Raw Agricultural Commodity) after two applications of CHR/F/SCORPIO 325 SC – one harvest study in Hungary – 2022 Study number 22SGS49 SGS Polska Sp. z o. o. Jerozolimskie Business Park Al. Jerozolimskie 146A 02-305 Warszawa Poland GLP Not published	N	Chemirol
KCA 6.3	K. Wańczyk	2024	Magnitude of the azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) residues in Oil Seed Rape (Raw Agricultural Commodity) after two applications of CHR/F/SCORPIO 325 SC – one harvest study trial in Poland – 2022 Study number 22SGS51 SGS Polska Sp. z o. o.	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Jerozolimskie Business Park Al. Jerozolimskie 146A 02-305 Warszawa Poland GLP Not published		
KCA 6.3	K. Wańczyk	2024	Magnitude of the azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) residues in Oil Seed Rape (Raw Agricultural Commodity) after two applications of CHR/F/SCORPIO 325 SC – one decline curve study trial in Poland – 2022 Study number 22SGS52 SGS Polska Sp. z o. o. Jerozolimskie Business Park Al. Jerozolimskie 146A 02-305 Warszawa Poland GLP Not published	N	Chemirol
KCA 6.3	K. Wańczyk	2024	Magnitude of the azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) residues in Oil Seed Rape (Raw Agricultural Commodity) after two applications of CHR/F/SCORPIO 325 SC – one decline curve study trial in Hungary – Study number 22SGS53 SGS Polska Sp. z o. o. Jerozolimskie Business Park Al. Jerozolimskie 146A 02-305 Warszawa Poland GLP Not published	N	Chemirol
KCA 6.3	K. Wańczyk	2024	Magnitude of the azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA),	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) residues in Oil Seed Rape (Raw Agricultural Commodity) after two applications of CHR/F/SCORPIO 325 SC – one decline curve study trial in Northern France – 2022 Study number 22SGS54 SGS Polska Sp. z o. o. Jerozolimskie Business Park Al. Jerozolimskie 146A 02-305 Warszawa Poland GLP Not published		
KCA 6.3	K. Wańczyk	2024	Magnitude of the azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) residues in Oil Seed Rape (Raw Agricultural Commodity) after two applications of CHR/F/SCORPIO 325 SC – one decline curve study trial in Germany – 2022 Study number 22SGS55 SGS Polska Sp. z o. o. Jerozolimskie Business Park Al. Jerozolimskie 146A 02-305 Warszawa Poland GLP Not published	N	Chemirol
KCA 6.3	T. Peda	2024	Magnitude of the azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) residues in Oil Seed Rape (Raw Agricultural Commodity) after two applications of CHR/F/SCORPIO 325 SC – one decline curve study trial in Germany – 2022 Study number 23SGS01 SGS Polska Sp. z o. o. Jerozolimskie Business Park Al. Jerozolimskie 146A	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			02-305 Warszawa Poland GLP Not published		
KCA 6.3	T. Peda	2024	Magnitude of residue of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T in sugar beet (Raw Agricultural Commodity) after one application of CHR/F/SCORPIO 325 SC – one harvest study trial in Hungary - 2023 Study number 23SGS02 SGS Polska Sp. z o. o. Jerozolimskie Business Park Al. Jerozolimskie 146A 02-305 Warszawa Poland GLP Not published	N	Chemirol
KCA 6.3	T. Peda	2024	Magnitude of residue of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T in sugar beet (Raw Agricultural Commodity) after one application of CHR/F/SCORPIO 325 SC – one harvest study trial in Germany - 2023 Study number 23SGS04 SGS Polska Sp. z o. o. Jerozolimskie Business Park Al. Jerozolimskie 146A 02-305 Warszawa Poland GLP Not published	N	Chemirol
KCA 6.3	T. Peda	2024	Magnitude of residue of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T in sugar beet (Raw Agricultural Commodity) after one application of CHR/F/SCORPIO 325 SC – one decline curve study trial in Poland - 2023 Study number 23SGS05	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			SGS Polska Sp. z o. o. Jerozolimskie Business Park Al. Jerozolimskie 146A 02-305 Warszawa Poland GLP Not published		
KCA 6.3	T. Peda	2024	Magnitude of residue of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T in sugar beet (Raw Agricultural Commodity) after one application of CHR/F/SCORPIO 325 SC – one decline curve study trial in Hungary - 2023 Study number 23SGS06 SGS Polska Sp. z o. o. Jerozolimskie Business Park Al. Jerozolimskie 146A 02-305 Warszawa Poland GLP Not published	N	Chemirol
KCA 6.3	T. Peda	2024	Magnitude of residue of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T in sugar beet (Raw Agricultural Commodity) after one application of CHR/F/SCORPIO 325 SC – one decline curve study trial in Northern France - 2023 Study number 23SGS07 SGS Polska Sp. z o. o. Jerozolimskie Business Park Al. Jerozolimskie 146A 02-305 Warszawa Poland GLP Not published	N	Chemirol
KCA 6.3	T. Peda	2024	Magnitude of residue of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T in sugar beet (Raw Agricultural Commodity) after one application of CHR/F/SCORPIO 325 SC – one	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			decline curve study trial in Denmark – 2023 Study number 23SGS08 SGS Polska Sp. z o. o. Jerozolimskie Business Park Al. Jerozolimskie 146A 02-305 Warszawa Poland GLP Not published		
KCA 6.3	T. Peda	2024	Magnitude of residue of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T in sugar beet (Raw Agricultural Commodity) after one application of CHR/F/SCORPIO 325 SC – one harvest study trial in Poland - 2023 Study number 23SGS46 SGS Polska Sp. z o. o. Jerozolimskie Business Park Al. Jerozolimskie 146A 02-305 Warszawa Poland GLP Not published	N	Chemirol
KCP 6.10 KCP 6.10.1	S. Mahlow C. Ezeobi-Chris	2023	Determination of Residues of Difenoconazole, Azoxystrobin and Triazole Derivate Metabolites (TDMs) in Honey after Two applications of CHR/F/SCORPIO 325 SC in Winter Oilseed Rape at Four Sites in Central and Southern Europe in 2022/2023 Study Code: S22-08279 Analytical Phase Code: S22-08279-L1 Eurofins Agroscience Services Ecotox GmbH Eutinger Str. 24 D-75223 Niefern-Öschelbronn Germany	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Not published		
KCP 6.1	S. Niewelt-Stasiak	2022	Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA) in wheat (grain, straw, plant) and Oilseed Rape (OSR) (seed, straw, plant) - stability study Study No: DPL/129/2021 SGS Polska Sp. z o.o. ul. Jana Kazimierza 3 01-248 Warszawa LABORATORIUM SGS POLSKA ul. Cieszyńska 52 A 43-200 Pszczyna, POLAND GLP	N	Chemirol
KCA 6.3	K. Wańczyk	2024	Magnitude of the azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) residues in Oil Seed Rape (Raw Agricultural Commodity) after two applications of CHR/F/SCORPIO 325 SC – one decline curve study trial in Poland – 2023 Study number 23SGS47 SGS Polska Sp. z o. o. Jerozolimskie Business Park Al. Jerozolimskie 146A 02-305 Warszawa Poland GLP Not published	N	Chemirol

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1	Beidler WT.	1991a	Stability of CGA-169374 residues in potatoes under freezer storage conditions for 2 years. Novartis Crop Protection AG, Basel, Switzerland.	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Ciba-Geigy Corp., Greensboro, United States Report No ABR-90070. GLP, Unpublished. Syngenta File No CGA 169374/0453		
KCP 6.1	Beidler WT.	1991b	Stability of CGA-169374 residues in potatoes under freezer storage conditions for 2 years. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-90069. GLP, Unpublished. Syngenta File No CGA 169374/0452	N	Syngenta
KCP 6.1	Beidler WT.	1992	Stability of CGA-169374 residues in lettuce, soybeans and wheat forage under freezer storage conditions for one year. Syngenta Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-91024. GLP, Unpublished. Syngenta File No CGA 169374/0617	N	Syngenta
KCP 6.1	Kühne-Thu H.	1994	Residue stability of CGA-169374 (difenoconazole) in banana (whole fruit) under freezer storage conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd. Basel, Switzerland. Report No 125/93. GLP, Unpublished. Syngenta File No CGA 169374/0934	N	Syngenta
KCP 6.1	Hayworth CG.	1998	Stability of CGA-169374 fortified into wheat and cotton substrates under freezer conditions. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection Inc., Greensboro, United States Report No ABR-98061. GLP, Unpublished. Syngenta File No CGA 169374/1644	N	Syngenta
KCP 6.1	Wurz REM.	1993a	Storage stability study of CGA-169374 in dairy and poultry tissues, eggs and milk under freezer storage conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-93012. GLP, Unpublished. Syngenta File No CGA 169374/0795	N	Syngenta
KCP 6.1 KCP 6.4.1	Tribolet R.	2000	Residue of difenoconazole (CGA 169374) and its metabolite CGA 205375 in milk, blood, and tissues (muscle, fat, liver, kidney) of dairy cattle resulting from feeding of difenoconazole at three dose levels.	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Novartis Crop Protection AG, Basel, Switzerland. Report No 202/99. GLP, Unpublished. Syngenta File No CGA 169374/2039		
KCP 6.2.1	Madrid SO. Huber MK	1987a	The distribution and characterization of phenyl-14C vs. triazole 14C-CGA 169374 on spray treated tomatoes – a side by side comparison study in greenhouse. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-87025. Not GLP, Unpublished. Syngenta File No CGA 169374/0043	N	Syngenta
KCP 6.2.1	Madrid SO. Huber MK	1987b	The distribution and characterization of phenyl-14C vs. triazole 14C-CGA 169374 on their metabolites in field grown tomatoes. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-87033. Not GLP, Unpublished. Syngenta File No CGA 169374/0044	N	Syngenta
KCP 6.2.1	Velagaleti PR.	1990a	Metabolism of triazole-14C-CGA 169374 in spray-treated tomatoes. Novartis Crop Protection AG, Basel, Switzerland. Battelle, Columbus, United States Report No N-0964-0600. GLP, Unpublished. Syngenta File No CGA 169374/0355	N	Syngenta
KCP 6.2.1	Schweitzer MG	1990a	Metabolism of phenyl-14C-CGA 169374 in spray-treated tomatoes. Novartis Crop Protection AG, Basel, Switzerland. Battelle, Columbus, United States Report No N-0964-0700. GLP, Unpublished. Syngenta File No CGA 169374/0356	N	Syngenta
KCP 6.2.1	Hubbard L.	1991a	Uptake and metabolism of 14C-CGA 169374 by wheat resulting from seed treatment application under field conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-90009. GLP, Unpublished. Syngenta File No CGA 169374/0415	N	Syngenta
KCP 6.2.1	Hubbard L.	1991b	Uptake and metabolism of 14C-CGA 169374 by wheat resulting from seed treatment application under greenhouse	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-90010. GLP, Unpublished. Syngenta File No CGA 169374/0416		
KCP 6.2.1	Hubbard L.	1991c	Uptake and metabolism of 14C-CGA 169374 by wheat resulting from foliar spray application under greenhouse environment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-90011. GLP, Unpublished. Syngenta File No CGA 169374/0417	N	Syngenta
KCP 6.2.1	Schweitzer MG	1990b	Metabolism of phenyl-14C-CGA 169374 in spray-treated potatoes. Novartis Crop Protection AG, Basel, Switzerland. Battelle, Columbus, United States Report No N-0964-0400. GLP, Unpublished. Syngenta File No CGA 169374/0357	N	Syngenta
KCP 6.2.1	Velagaleti PR.	1990b	Metabolism of triazole-14C-CGA 169374 in spray-treated potatoes. Novartis Crop Protection AG, Basel, Switzerland. Battelle, Columbus, United States Report No N-0964-0500. GLP, Unpublished. Syngenta File No CGA 169374/0489	N	Syngenta
KCP 6.2.1	Capps T.	1992	Uptake and metabolism of 14C-CGA 169374 by grapes from foliar spray treatment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-92003. GLP, Unpublished. Syngenta File No CGA 169374/0537	N	Syngenta
KCP 6.2.1	Neumann Ch.	1993a	Metabolism of [Phenyl-^{14}C] CGA-169374 in field grown spring rape. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd. Basel, Switzerland. Report No 11/93. GLP, Unpublished. Syngenta File No CGA 169374/0809	N	Syngenta
KCP 6.2.1	Neumann Ch.	1993b	Metabolism of [Triazole-^{14}C] CGA-169374 in field grown spring rape. Novartis Crop Protection AG, Basel, Switzerland.	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Ciba-Geigy Ltd. Basel, Switzerland. Report No 12/93. GLP, Unpublished. Syngenta File No CGA 169374/0810		
KCP 6.2.2	xxxxxx	1988	Metabolism of triazole and phenyl-14C-CGA 169374 in lactating goats dosed daily for ten consecutive days xxxxxx Report No. ABR-88087 Not GLP Unpublished Syngenta File No CGA 169374/0234	Y	Syngenta
KCP 6.2.2	xxxxxx	1990a	[14C] CGA169734 phenyl and triazole label distribution, elimination and metabolsim in goats xxxxxx Report No. ABR-89100 GLP Unpublished Syngenta File No CGA 169374/0379	Y	Syngenta
KCP 6.2.2	xxxxxx	1996	Metabolism of phenyl-14C-CGA 169374 in lactating goats xxxxxx Report No. ABR-95099 GLP Unpublished Syngenta File No CGA 169374/1232	Y	Syngenta
KCP 6.2.2	xxxxxx	1989	Metabolism of triazole and phenyl-14C-CGA 169374 in laying hens dosed daily for fourteen consecutive days xxxxxx Report No. ABR-89051 GLP Unpublished Syngenta File No CGA 169374/0234	Y	Syngenta
KCP 6.2.2	xxxxxx	1990b	[14C] CGA169734 phenyl and triazole label distribution, elimination and metabolsim in hens	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			xxxxxx Report No. ABR-89101 GLP Unpublished Syngenta File No CGA 169374/0364		
KCP 6.2.2	xxxxxx	2004	[triazole-14C] CGA-169374 – nature of the residue in laying hens xxxxxx Report No. 786-02 GLP Unpublished Syngenta File No CGA 169374/2441	Y	Syngenta
KCP 6.5.2	Muir GT.	2003	Difenoconazole: Aqueous hydrolysis at 90, 100 & 120 °C. Syngenta Crop Protection AG, Basel, Switzerland. Syngenta – Jealott´s Hill International, Bracknell, Berkshire, United Kingdom. Report No RJ3360B GLP, Unpublished. Syngenta File No CGA 169374/2312	N	Syngenta
KCP 6.5.2	Simon P.	2002c	Determination of residues of difenoconazole after application of Score in apples and processed commodities in Germany. Syngenta Crop Protection AG, Basel, Switzerland. Syngenta Agro GmbH, Maintal, Germany. Report No gap82901 GLP, unpublished. Syngenta File No CGA 169374/2282	N	Syngenta
KCP 6.5.2	Kühne-Thu H.	1997a	CGA-169374 (and metabolite CGA 205375), 250 EC, A-7402 G, apples and processed fractions, Chile. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection AG, Basel, Switzerland. Report No 2205/94 GLP, Unpublished. Syngenta File No CGA 169374/1424	N	Syngenta
KCP 6.5.2	Kühne-Thu H.	1997b	CGA-169374 (and metabolite CGA 205375), 250 EC, A-7402 G, apples and processed fractions, Chile. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection AG, Basel, Switzerland. Report No 2204/94 GLP, Unpublished. Syngenta File No CGA 169374/1426	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.5.2	Kühne-Thu H.	1997c	CGA-169374 (and metabolite CGA 205375), 250 EC, A-7402/780 A, apples and processed fractions, Brazil. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection AG, Basel, Switzerland. Report No 2195/94 GLP, Unpublished. Syngenta File No CGA 169374/1431	N	Syngenta
KCP 6.6.1	Walser M.	1994a	Outdoor confined accumulation study on rotational crops after bare ground soil application of [^{14}C-phenyl]-CGA-169374. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland. Report No 8/94. GLP, Unpublished. Syngenta File No CGA 169374/0924	N	Syngenta
KCP 6.6.1	Walser M.	1994b	Outdoor confined accumulation study on rotational crops after bare ground soil application of [^{14}C-triazole]-CGA-169374. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland. Report No 4/94. GLP, Unpublished. Syngenta File No CGA 169374/2395	N	Syngenta
KCP 6.6.1	Close C.	1995	14C-CGA-169374: Uptake and distribution of residues in confined rotational crops. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States Report No ABR-95057. GLP, Unpublished. Syngenta File No CGA 169374/1118	N	Syngenta
KCA 6.10	Heyer R.	1995a	CGA-169374 (metabolite CGA 131013), 250 EC, A-7402 G, rotational crop: carrot, soil, Germany. Novartis Crop Protection AG, Basel, Switzerland. RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany. Report No 488002. GLP, Unpublished. Syngenta File No CGA 169374/1215		
KCA 6.10	Heyer R.	1995b	CGA-169374 (metabolite CGA 131013), 250 EC, A-7402 G, rotational crop: spinach, soil, Germany. Novartis Crop Protection AG, Basel, Switzerland. RCC Umweltchemie GmbH & Co. KG, Rossdorf, Germany. Report No 488001. GLP, Unpublished. Syngenta File No CGA 169374/1216	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1/03	Burke, S.R.	1997	Azoxystrobin and R230310: storage stability in various crops stored deep frozen for up to two years. Final report Report RJ2404B ZENECA agrochemicals	N	Syngenta
KCP 6.1/04	Burke, S.R.	1995a	ICIA5504 and R230310: Storage stability in Various Crops Stored Deep Frozen for up to two years. Interim Report 1 (Cereals, Grapes and Wine) RJ1858B, RIP96-00140	N	Syngenta
KCP 6.2.1/05	Weeb, J. et al.	1995	ICIA5504: Metabolism in Peanuts RJ1807B RIP96-001006	N	Syngenta
KCP 6.2.1/06	Wilkinson, M.J.et al.	1994	ICIA5504: Metabolism in Winter Wheat RJ1682B RIP96-00103	N	Syngenta
KCP 6.2.1/07	Allin, R. et al.	1995	ICIA5504: Metabolism in Winter Wheat RJ1888B RIP96-00104	N	Syngenta
KCP 6.6.1/02	Goldsby, G. et al.	1995	ICIA5504 (14C-pyrimidinyl): Confined Rotatioanl Crop study RR 95-034B RIP96-00143	N	Syngenta
KCP 6.6.1/03	Miller, M.M and Wilson, W.	1995	ICIA5504-Cyanophenyl: Confined Rotational Crop Study RR 95-017B RIP96-00144	N	Syngenta
KCP 6.6.1/04	Rambling, D. D..R., Labatore, D.N. and Walker, F.H.	1995	ICIA5504 (14-phenylacrylate): Confined Rotational Crop Study RR 95-011B RIP96-00142	N	Syngenta
KCP 6.2.2/04	xxxxxx	1995	ICIA5504: Metablism of Orally Administered Multiple Doses in the Lactating Goat RJ1805B RIP96-00107	Y	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2.2/05	xxxxxx	1996	ICIA5504: Metabolism of orally Administered Multiple Doses in Lactating Goat RJ2083B Syngenta File No. IC15504/0739	Y	Syngenta
KCP 6.2.2/06	xxxxxx	1996	14C-ICIA5504: Metabolism of Orally Administered Multiple Doses in the Laying Hens RJ2084B Syngenta File No. ICI5504/0738	Y	Syngenta
KCP 6.3/08	Sapiets, A. Chamier, O. Dittrich, R..	1995	ICIA5504: Residue Levels in Wheat Grain and Milled Process Fractions from a Trial carried out in Germany drugin 1995 JR2065B, RIP96-00191	N	Syngenta
KCP 6.3/09	Sapiets, A. Chamier, O.	1997	ICIA5504: Residue Levels in Malting Barley and Process Fractions from Studies Conducted in Germany during 1996 RJ2382B GLP Unpublished	N	Syngenta
KCP 6.3/10	Sapiets, A. and Hall, G.	1998	ICIA5504: Residue Levels in Malting Barley and Brewing Fractions from a Trial conducted in the United Kingdom during 1996 RJ2452B GLP Unpublished	N	Syngenta
KCP 6.3/11	Simon, P.	2006	Azoxystrobin: Residue Study in or on Barley and Processed Barley Products in Germany 2005 (Test Product: A12705B) Report No. gba210004, Syngenta File No. ICI5504/3546 Syngenta Agro GMBH, Germany	N	Syngenta
KCP 6.3/12	Heillaut, C.	2008	Azoxystrobin (ICI5504): Residue Study on Wheat and Processed Wheat Products from Switzerland in 2006 Report No. T000676-06-REG. ADME, Syngneta File No. ICI5504/3940 Bioanalyses, France	N	Syngenta
KCP 6.5.2/01	Sapiets, A., Chamier, O. and Dittrich, R.	1996	Processing study: milling/baking of wheat RJ2065B ICI5504/0718	N	Syngenta
KCP	Clarke, D.M. and	1997	Processing study: milling/baking of wheat RJ2297B	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
6.5.2/02	Chamier, O.D.				
KCP 6.3/26	Sapiets, A. Bailey, A.	1997	Azoxystrobin and Flutriafol – Residua Levels in Oil Seed Rape from Trials conducted in the United Kingdom during 1996 Report No RJ2366B Zeneca Agrochemicals, Jealott's Hill, UK GLP Unpublished	N	Syngenta
KCP 6.3/27	Sapiets, A. Bailey, A.	1998	Azoxystrobin and Flutriafol – Residua Levels in Oil Seed Rape from Trials conducted in the France during 1996 Report No RJ2419B Zeneca Agrochemicals, Jealott's Hill, UK GLP Unpublished	N	Syngenta
KCP 6.3/28	Sapiets, A. Bailey, A.	1998	Azoxystrobin and Flutriafol – Residuea Levels in Oil Seed Rape from Trials conducted in the France during 1997 Report No RJ2524B Zeneca Agrochemicals, Jealott's Hill, UK GLP Unpublished	N	Syngenta
KCP 6.3/29	Sapiets, A. Bailey, A.	1998	Azoxystrobin and Flutriafol – Residuea Levels in Oil Seed Rape from Trials conducted in the United Kingdom during 1997 Report No RJ2591B Zeneca Agrochemicals, Jealott's Hill, UK GLP Unpublished	N	Syngenta

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Azoxystrobin and 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

~~Not required.~~

For Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA) in Oilseed Rape

A.2.1.1.1.1.1 Study 1

Comments of zRMS:	The objective of the study was to evaluate the stability of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in wheat - grain, straw, plant and in oilseed rape (OSR) - seed, straw, plant. Specimen extraction were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each compound. The method for determination of TDM (TAA, TA, 1,2,4-T, TLA) in oilseed rape was validated and results was summarized in study VAL/10/2021 (see dRR Part B5). For each analyte, one mass transition was evaluated and used for quantification. A second and third mass transition was monitored for confirmation of peak identity. Representative chromatograms are shown in the report. The study is accepted. Triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in oilseed rape are stable for 300 days.

Reference:	KCP 6.1
Report	Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA) in wheat (grain, straw, plant) and Oilseed Rape (OSR) (seed, straw, plant) - stability study, Study No: DPL/129/2021, S. Niewelt-Stasiak, 2022
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, SANTE/2020/12830 Rev.1, 24 February 2021
Deviations:	No
GLP:	Yes

Acceptability: Yes

For this documentation, the stability of Triazole Derivate Metabolites for oilseed is important, therefore this part will be described in this documentation.

STUDY OBJECTIVE

The objective of the study was to evaluate the stability of Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA) in wheat - grain, straw, plant and in oilseed rape (OSR) - seed, straw, plant.

Table 4. Scheme of study for oilseed rape - seed

Commodity	Analyte	Storage Period [days]	Samples for analysis
oilseed rape (OSR) - seed	Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA)	0	2 control samples (freshly fortified) + blank sample
oilseed rape (OSR) - seed	Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA)	303	3 storage samples + 2 freshly fortified samples + blank sample

Table 5. Scheme of study for oilseed rape - straw

Commodity	Analyte	Storage Period [days]	Samples for analysis
oilseed rape (OSR) - straw	Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA)	0	2 control samples (freshly fortified) + blank sample
oilseed rape (OSR) - straw	Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA)	300	3 storage samples + 2 freshly fortified samples + blank sample

Table 6. Scheme of study for oilseed rape - plant

Commodity	Analyte	Storage Period [days]	Samples for analysis
oilseed rape (OSR) - plant	Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA)	0	2 control samples (freshly fortified) + blank sample
oilseed rape (OSR) - plant	Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA)	301	3 storage samples + 2 freshly fortified samples + blank sample

ANALYTICAL METHOD

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

was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound.

Test item: Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA) Explanation of abbreviations:
TAA = triazole acetic acid
TA = triazole alanine 1
,2,4-T = 1,2,4-triazole
TLA = triazole lactic acid

METHOD VALIDATION

The method for determination of Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA) in oilseed rape (grain, whole plant without roots, straw) was validated at Test Site SGS Polska Sp. z o. o., ul. Cieszyńska 52A, Pszczyna, according to SANTE/2020/12830 Rev.1 guidelines. Validation criteria and results was summarized in study VAL/10/2021, entitled: ""Validation of an analytical method for the determination of residues of Triazole Derivative Metabolites (TAA, TA, 1,2,4-T, TLA) in Oilseed Rape (OSR) - seed, straw, plant".

INITIAL SAMPLE PREPARATION AND HOMOGENISATION

Untreated oilseed rape samples originated from previous GLP study. Samples were stored in a freezer at ≤ -18oC before analysis. After removal from the freezer the samples were homogenized using a knife grinder. Then prepared a series of spiked samples that were dedicated as storage samples. It was weighed 5 g (oilseed rape seed and plant) / 2 g (oilseed rape straw) samples into clean 50 mL centrifuge tubes. After adding 50 µL (oilseed rape seed and plant) / 20 µL (oilseed rape straw) of fortification solution at concentration 10.0 µg/mL, the samples were transferred to the freezer. The scheme was as follows:

Procedural scheme for oilseed rape seed

No.	Laboratory sample code	Treatment	Sample type	Preparation Date	Extraction/ Analysis Date
1	OSR grain, sample blank	blank sample (fresh)	oilseed rape seed	15.12.2021	15.12.2021
2	OSR grain, PK1 0,10 mg-kg	fresh fortified	oilseed rape seed	15.12.2021	15.12.2021
3	OSR grain, PK2 0,10 mg-kg	fresh fortified	oilseed rape seed	15.12.2021	15.12.2021
4	archival 1, OSR grain	storage sample	oilseed rape seed	15.12.2021*	14.10.2022
5	archival 2, OSR grain	storage sample	oilseed rape seed	15.12.2021*	14.10.2022
6	archival 3, OSR grain	storage sample	oilseed rape seed	15.12.2021*	14.10.2022
7	OSR grain, sample blank	blank sample (fresh)	oilseed rape seed	14.10.2022	14.10.2022
8	OSR grain, PK1 0,10 mg-kg	fresh fortified	oilseed rape seed	14.10.2022	14.10.2022
9	OSR grain, PK2 0,10 mg-kg	fresh fortified	oilseed rape seed	14.10.2022	14.10.2022

*only weighed and spiked, without extraction

Procedural scheme for oilseed rape plant

No.	Laboratory sample code	Treatment	Sample type	Preparation Date	Extraction/ Analysis Date
1	OSR plant. sample blank	blank sample (fresh)	oilseed rape plant	15.12.2021	15.12.2021
2	OSR plant. PK1 0,10 mg-kg	fresh fortified	oilseed rape plant	15.12.2021	15.12.2021
3	OSR plant. PK2 0,10 mg-kg	fresh fortified	oilseed rape plant	15.12.2021	15.12.2021
4	archival 1, OSR plant	storage sample	oilseed rape plant	15.12.2021*	12.10.2022
5	archival 2, OSR plant	storage sample	oilseed rape plant	15.12.2021*	12.10.2022
6	archival 3, OSR plant	storage sample	oilseed rape plant	15.12.2021*	12.10.2022
7	OSR plant, sample blank	blank sample (fresh)	oilseed rape plant	12.10.2022	12.10.2022
8	OSR plant, PK1 0,10 mg-kg	fresh fortified	oilseed rape plant	12.10.2022	12.10.2022
9	OSR plant, PK2 0,10 mg-kg	fresh fortified	oilseed rape plant	12.10.2022	12.10.2022

*only weighed and spiked, without extraction

Procedural scheme for oilseed rape straw

No.	Laboratory sample code	Treatment	Sample type	Preparation Date	Extraction/ Analysis Date
1	OSR straw, sample blank.lcd	blank sample (fresh)	oilseed rape straw	15.12.2021	15.12.2021
2	OSR straw, PK1 0,10 mg-kg.lcd	fresh fortified	oilseed rape straw	15.12.2021	15.12.2021
3	OSR straw, PK2 0,10 mg-kg.lcd	fresh fortified	oilseed rape straw	15.12.2021	15.12.2021
4	archival 1, OSR straw.lcd	storage sample	oilseed rape straw	15.12.2021*	11.10.2022
5	archival 2, OSR straw.lcd	storage sample	oilseed rape straw	15.12.2021*	11.10.2022
6	archival 3, OSR straw.lcd	storage sample	oilseed rape straw	15.12.2021*	11.10.2022
7	OSR, sample blank.lcd	blank sample (fresh)	oilseed rape straw	11.10.2022	11.10.2022
8	OSR, PK1 0,10 mg-kg.lcd	fresh fortified	oilseed rape straw	11.10.2022	11.10.2022
9	OSR, PK2 0,10 mg-kg.lcd	fresh fortified	oilseed rape straw	11.10.2022	11.10.2022

*only weighed and spiked, without extraction

All storage samples were further stored at ≤ -18°C until beginning of analysis.

EXTRACTION

5 g (grain/seed, plant)/ 2 g (straw) of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of water and 10 mL of acidified methanol (with 1 % of HCOOH) was added together with 50 µL of internal standard solution (IS WS I), and the mixture was shaken vigorously by hand for one minute, then centrifuged at 4700 rpm for 10 min for phase separation and finally subjected to a freezing process at ≤ -18°C for 2 h. After that, extract was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis.

FORTIFICATION AND CONTROL SAMPLES

For each analytical sequence one sample blank and two fresh procedural recoveries at the level of 10 x LOQ (0.10 mg/kg) were prepared. 5 g (grain/seed, plant)/ 2 g (straw) of the homogenized control sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Tables 13 and 14 for amounts and section “Preparation of Intermediate Calibration and Fortification

Solutions" for information on solution preparation) together with 50 µL of internal standard solution (IS WS I).

Table 13. Preparation of fortification and control samples – grain/seed, plant

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of internal standard solution IS-WS I added [µL]
Matrix blank	-	50
PK 0.10 mg/kg (10 x LOQ)	50.0	50

Table 14. Preparation of fortification and control samples – straw

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of internal standard solution IS-WS I added [µL]
Matrix blank	-	50
PK 0.10 mg/kg (10 x LOQ)	20.0	50

15.12.2021 (point ''0'' for oilseed rape) – it was extraction and analysis of one fresh blank sample and two fresh fortified samples in case of oilseed rape seed, oilseed rape plant and oilseed rape straw

11.10.2022 (end point for oilseed rape straw) - it was extraction and analysis of one fresh blank sample, two fresh fortified samples and three storage samples (that were spiked with triazole metabolites at the level of 10xLOQ 15.12.2021 (oilseed rape straw)) – separately for wheat straw and for oilseed rape straw

12.10.2022 (end point for oilseed rape plant) - it was extraction and analysis of one fresh blank sample, two fresh fortified samples and three storage samples (that were spiked with triazole metabolites at the level of 10xLOQ) 15.12.2021 (oilseed rape plant)) for oilseed rape plant

14.10.2022 (end point for oilseed rape seed) - it was extraction and analysis of one fresh blank sample, two fresh fortified samples and three storage samples (that were spiked with triazole metabolites at the level of 10xLOQ 15.12.2021

RESULTS AND CONCLUSIONS

The following residues concentration was determined in blank and fresh fortified samples analyzed on 14.12.2021 - 21.11.2022.

Results for analyzed samples on 15.12.2021 ("zero" study time for oilseed rape)

No	Commodity	Treatment	Sample number given by the laboratory	Result [mg/kg]			
				TAA	TA	TLA	1.2.4-T
1	oilseed rape seed	untreated	OSR grain, sample blank	<LOD	<LOD	<LOD	<LOD
2	oilseed rape seed	fresh fortified	OSR grain, PK1 0,10 mg-kg	0.092	0.094	0.091	0.093
3	oilseed rape seed	fresh fortified	OSR grain, PK2 0,10 mg-kg	0.10	0.10	0.098	0.10
4	oilseed rape plant	untreated	OSR plant. sample blank	<LOD	<LOD	<LOD	<LOD
5	oilseed rape plant	fresh fortified	OSR plant. PK1 0,10 mg-kg	0.10	0.081	0.085	0.097
6	oilseed rape plant	fresh fortified	OSR plant. PK2 0,10 mg-kg	0.12	0.094	0.10	0.12
7	oilseed rape straw	untreated	OSR straw, sample blank	<LOD	<LOD	<LOD	<LOD
8	oilseed rape straw	fresh fortified	OSR straw, PK1 0,10 mg-kg	0.098	0.080	0.094	0.094
9	oilseed rape straw	fresh fortified	OSR straw, PK2 0,10 mg-kg	0.098	0.079	0.10	0.097

Calculation based on unrounded values;
TAA – triazole acetic acid; TA – triazole alanine; TLA – triazole lactic acid; 1,2,4-T – 1,2,4-triazole

Results for analyzed samples on 14.10.2022 ("303 days" study time for oilseed rape seed)

No	Commodity	Treatment	Sample number given by the laboratory	Result [mg/kg]			
				TAA	TA	TLA	1.2.4-T
1	oilseed rape seed	untreated	OSR grain, sample blank	<LOD	<LOD	<LOD	<LOD
2	oilseed rape seed	fresh fortified	OSR grain, PK1 0,10 mg-kg	0.11	0.12	0.11	0.10
3	oilseed rape seed	fresh fortified	OSR grain, PK2 0,10 mg-kg	0.11	0.11	0.11	0.10
4	oilseed rape seed	treated (storage sample)	archival 1, OSR grain	0.10	0.12	0.11	0.083
5	oilseed rape seed	treated (storage sample)	archival 2, OSR grain	0.10	0.10	0.11	0.083
6	oilseed rape seed	treated (storage sample)	archival 3, OSR grain	0.10	0.11	0.11	0.080

Calculation based on unrounded values;
TAA – triazole acetic acid; TA – triazole alanine; TLA – triazole lactic acid; 1,2,4-T – 1,2,4-triazole

Results for analyzed samples on 12.10.2022 ("301 days" study time for oilseed rape plant)

No	Commodity	Treatment	Sample number given by the laboratory	Result [mg/kg]			
				TAA	TA	TLA	1.2.4-T
1	oilseed rape plant	untreated	OSR plant, sample blank	<LOD	<LOD	<LOD	<LOD
2	oilseed rape plant	fresh fortified	OSR plant, PK1 0,10 mg-kg	0.089	0.071	0.081	0.089
3	oilseed rape plant	fresh fortified	OSR plant, PK2 0,10 mg-kg	0.090	0.086	0.083	0.088
4	oilseed rape plant	treated (storage sample)	archival 1, OSR plant	0.11	0.12	0.10	0.10
5	oilseed rape plant	treated (storage sample)	archival 2, OSR plant	0.11	0.099	0.10	0.10
6	oilseed rape plant	treated (storage sample)	archival 3, OSR plant	0.098	0.088	0.10	0.10

Calculation based on unrounded values;
TAA – triazole acetic acid; TA – triazole alanine; TLA – triazole lactic acid; 1,2,4-T – 1,2,4-triazole

Results for analyzed samples on 11.10.2022 ("300 days" study time for oilseed rape straw)

No	Commodity	Treatment	Sample number given by the laboratory	Result [mg/kg]			
				TAA	TA	TLA	1.2.4-T
1	oilseed rape straw	untreated	OSR straw, sample blank	<LOD	<LOD	<LOD	<LOD
2	oilseed rape straw	fresh fortified	OSR straw, PK1 0,10 mg-kg	0.087	0.10	0.087	0.083
3	oilseed rape straw	fresh fortified	OSR straw, PK2 0,10 mg-kg	0.087	0.099	0.083	0.082
4	oilseed rape straw	treated (storage sample)	archival 1, OSR straw.lcd	0.090	0.091	0.093	0.081
5	oilseed rape straw	treated (storage sample)	archival 2, OSR straw.lcd	0.091	0.084	0.092	0.085
6	oilseed rape straw	treated (storage sample)	archival 3, OSR straw.lcd	0.099	0.10	0.10	0.092

Calculation based on unrounded values;
TAA – triazole acetic acid; TA – triazole alanine; TLA – triazole lactic acid; 1,2,4-T – 1,2,4-triazole

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. One sample blank matrix and two procedural recoveries at the level of 0.10 mg/kg per analytical set of respective matrix were analyzed during each of the sequence. The following results for fortified samples were obtained during analysis on 14.12.2021

OILSEED RAPE SEED
triazole-acetic acid (TAA)

Table 43. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR grain, sample blank.lcd	< LOD	-
OSR grain, PK1 0,10 mg-kg.lcd	0.092	91.8
OSR grain, PK2 0,10 mg-kg.lcd	0.10	101.3

triazole-alanine (TA)

Table 44. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR grain, sample blank.lcd	< LOD	-
OSR grain, PK1 0,10 mg-kg.lcd	0.094	94.0
OSR grain, PK2 0,10 mg-kg.lcd	0.10	102.9

triazole-lactic acid (TLA)

Table 45. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR grain, sample blank.lcd	< LOD	-
OSR grain, PK1 0,10 mg-kg.lcd	0.091	91.2
OSR grain, PK2 0,10 mg-kg.lcd	0.098	98.4

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

Table 46. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR grain, sample blank.lcd	< LOD	-
OSR grain, PK1 0,10 mg-kg.lcd	0.093	93.4
OSR grain, PK2 0,10 mg-kg.lcd	0.10	100.9

OILSEED RAPE PLANT

triazole-acetic acid (TAA)

Table 47. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant. sample blank.lcd	< LOD	-
OSR plant. PK1 0,10 mg-kg.lcd	0.10	103.9
OSR plant. PK2 0,10 mg-kg.lcd	0.12	117.5

triazole-alanine (TA)

Table 48. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant. sample blank.lcd	< LOD	-
OSR plant. PK1 0,10 mg-kg.lcd	0.081	81.5
OSR plant. PK2 0,10 mg-kg.lcd	0.094	94.3

triazole-lactic acid (TLA)

Table 49. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant. sample blank.lcd	< LOD	-
OSR plant. PK1 0,10 mg-kg.lcd	0.085	84.9
OSR plant. PK2 0,10 mg-kg.lcd	0.10	103.3

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

Table 50. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant. sample blank.lcd	< LOD	-
OSR plant. PK1 0,10 mg-kg.lcd	0.097	97.4
OSR plant. PK2 0,10 mg-kg.lcd	0.12	117.0

OILSEED RAPE STRAW

triazole-acetic acid (TAA)

Table 51. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR straw, sample blank.lcd	< LOD	-
OSR straw, PK1 0,10 mg-kg.lcd	0.098	98.2
OSR straw, PK2 0,10 mg-kg.lcd	0.098	98.3

triazole-alanine (TA)

Table 52. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR straw, sample blank.lcd	< LOD	-
OSR straw, PK1 0,10 mg-kg.lcd	0.080	79.6
OSR straw, PK2 0,10 mg-kg.lcd	0.079	79.1

triazole-lactic acid (TLA)

Table 53. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR straw, sample blank.lcd	< LOD	-
OSR straw, PK1 0,10 mg-kg.lcd	0.094	93.9
OSR straw, PK2 0,10 mg-kg.lcd	0.10	104.1

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

Table 54. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR straw, sample blank.lcd	< LOD	-
OSR straw, PK1 0,10 mg-kg.lcd	0.094	94.4
OSR straw, PK2 0,10 mg-kg.lcd	0.097	96.7

OILSEED RAPE PLANT

triazole-acetic acid (TAA)

Table 67. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant, sample blank.lcd	< LOD	-
OSR plant, PK1 0,10 mg-kg.lcd	0.089	89.1
OSR plant, PK2 0,10 mg-kg.lcd	0.090	89.7

triazole-alanine (TA)

Table 68. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant, sample blank.lcd	< LOD	-
OSR plant, PK1 0,10 mg-kg.lcd	0.071	70.5
OSR plant, PK2 0,10 mg-kg.lcd	0.086	86.2

triazole-lactic acid (TLA)

Table 69. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant, sample blank.lcd	< LOD	-
OSR plant, PK1 0,10 mg-kg.lcd	0.081	81.4
OSR plant, PK2 0,10 mg-kg.lcd	0.083	82.8

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

Table 70. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant, sample blank.lcd	< LOD	-
OSR plant, PK1 0,10 mg-kg.lcd	0.089	89.1
OSR plant, PK2 0,10 mg-kg.lcd	0.088	88.2

OILSEED RAPE STRAW

triazole-acetic acid (TAA)

Table 75. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR, sample blank.lcd	< LOD	-
OSR, PK1 0,10 mg-kg.lcd	0.087	86.6
OSR, PK2 0,10 mg-kg.lcd	0.087	86.7

triazole-alanine (TA)

Table 76. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR, sample blank.lcd	< LOD	-
OSR, PK1 0,10 mg-kg.lcd	0.10	103.3
OSR, PK2 0,10 mg-kg.lcd	0.099	98.7

triazole-lactic acid (TLA)

Table 77. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR, sample blank.lcd	< LOD	-
OSR, PK1 0,10 mg-kg.lcd	0.087	86.7
OSR, PK2 0,10 mg-kg.lcd	0.083	83.2

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

Table 78. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR, sample blank.lcd	< LOD	-
OSR, PK1 0,10 mg-kg.lcd	0.083	83.2
OSR, PK2 0,10 mg-kg.lcd	0.082	82.0

The following results for fortified samples were obtained during analysis on 14.10.2022

OILSEED RAPE SEED

triazole-acetic acid (TAA)

Table 79. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR grain, sample blank.lcd	< LOD	-
OSR grain, PK1 0,10 mg-kg.lcd	0.11	106.7
OSR grain, PK2 0,10 mg-kg.lcd	0.11	109.1

triazole-alanine (TA)

Table 80. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR grain, sample blank.lcd	< LOD	-
OSR grain, PK1 0,10 mg-kg.lcd	0.12	118.3
OSR grain, PK2 0,10 mg-kg.lcd	0.11	112.4

triazole-lactic acid (TLA)

Table 81. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR grain, sample blank.lcd	< LOD	-
OSR grain, PK1 0,10 mg-kg.lcd	0.11	113.4
OSR grain, PK2 0,10 mg-kg.lcd	0.11	113.0

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

Table 82. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR grain, sample blank.lcd	< LOD	-
OSR grain, PK1 0,10 mg-kg.lcd	0.10	101.9
OSR grain, PK2 0,10 mg-kg.lcd	0.10	102.6

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev.1

. The recovery values for PK 0.10 mg/kg (in the range of 70 – 120%) confirms the active substance stability during the analytical procedure.

15.12.2021 (point ''0'' for oilseed rape seed) – the duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 156 minutes (2.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day (about 7 h)

15.12.2021 (point ''0'' for oilseed rape plant) – the duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 156 minutes (2.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day (about 7 h)

15.12.2021 (point ''0'' for oilseed rape straw) – the duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 156 minutes (2.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day (about 7 h)

11.10.2022 (end point for oilseed rape straw) - the duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 180 minutes (3 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day (about 7 h)

12.10.2022 (end point for oilseed rape plant) - the duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 192 minutes (3.2 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day (less than 8 h)

14.10.2022 (end point for oilseed rape seed) - the duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 228 minutes (3.8 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day (about 8 h)

Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

CONCLUSIONS

The method was validated according to SANTE/2020/12830, Rev.1 guidelines.

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120%.

The limit of detection of the method was the lowest calibration standard (for each of compounds and each of the matrices) and the limit of quantification of the method was established at 0.010 mg/kg for each of compounds (TAA, TA, 1,2,4-T, TLA) in oilseed rape (seed, plant, straw).

There were no interfering signals at retention time of analyzed compound in examined control matrix.

The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in oilseed rape meets the criteria of SANTE/2020/12830, Rev.1 guidelines in terms of precision, accuracy and uncertainty.

Table 86. Reporting for a spike level of 0.10 mg/kg – oilseed rape seed

Commodity	Analyte	Storage Period [days]	Residue Level in Freezer Storage Stability Sample (mg/kg)	Residue Level in Freezer Storage Stability Sample (% of nominal spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)
oilseed rape seed	TAA – triazole acetic acid	0	-	-	91.8 101.3
oilseed rape seed	TAA – triazole acetic acid	303	0.10 0.10 0.10	103.8 104.1 103.9	106.7 109.1
oilseed rape seed	TA – triazole alanine	0	-	-	94.0 102.9
oilseed rape seed	TA – triazole alanine	303	0.12 0.10 0.11	119.8 103.8 107.0	118.3 112.4
oilseed rape seed	TLA – triazole lactic acid	0	-	-	91.2 98.4
oilseed rape seed	TLA – triazole lactic acid	303	0.11 0.11 0.11	109.6 109.8 109.2	113.4 113.0
oilseed rape seed	1,2,4- triazole	0	-	-	93.4 100.9
oilseed rape seed	1,2,4- triazole	303	0.083 0.083 0.080	82.8 82.9 80.4	101.9 102.6

Table 87. Reporting for a spike level of 0.10 mg/kg – oilseed rape plant

Commodity	Analyte	Storage Period [days]	Residue Level in Freezer Storage Stability Sample (mg/kg)	Residue Level in Freezer Storage Stability Sample (% of nominal spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)
oilseed rape plant	TAA – triazole acetic acid	0	-	-	103.9 117.5
oilseed rape plant	TAA – triazole acetic acid	301	0.11 0.11 0.098	106.5 106.1 98.2	89.1 89.7
oilseed rape plant	TA – triazole alanine	0	-	-	81.5 94.3
oilseed rape plant	TA – triazole alanine	301	0.12 0.099 0.088	116.5 99.0 87.9	70.5 86.2
oilseed rape plant	TLA – triazole lactic acid	0	-	-	84.9 103.3
oilseed rape plant	TLA – triazole lactic acid	301	0.10 0.10 0.10	103.9 102.9 101.1	81.4 82.8
oilseed rape plant	1,2,4- triazole	0	-	-	97.4 117.0
oilseed rape plant	1,2,4- triazole	301	0.10 0.10 0.10	101.2 100.7 99.8	89.1 88.2

Table 88. Reporting for a spike level of 0.10 mg/kg – oilseed rape straw

Commodity	Analyte	Storage Period [days]	Residue Level in Freezer Storage Stability Sample (mg/kg)	Residue Level in Freezer Storage Stability Sample (% of nominal spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)
oilseed rape straw	TAA – triazole acetic acid	0	-	-	98.2 98.3
oilseed rape straw	TAA – triazole acetic acid	300	0.090 0.091 0.099	90.3 90.5 98.7	86.6 86.7
oilseed rape straw	TA – triazole alanine	0	-	-	79.6 79.1
oilseed rape straw	TA – triazole alanine	300	0.091 0.084 0.10	90.6 84.2 102.1	103.3 98.7
oilseed rape straw	TLA – triazole lactic acid	0	-	-	93.9 104.1
oilseed rape straw	TLA – triazole lactic acid	300	0.093 0.092 0.10	92.9 91.9 101.0	86.7 83.2
oilseed rape straw	1,2,4- triazole	0	-	-	94.4 96.7
oilseed rape straw	1,2,4- triazole	300	0.081 0.085 0.092	81.2 84.7 91.9	83.2 82.0

A 2.1.1.1.2 Storage stability of residues in animal products

A 2.1.1.1.2.1 Study 1

Not required.

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

A 2.1.2.1.1.1 Study 1

Not required.

A 2.1.2.1.2 Nature of residue in rotational crops

Not required.

A 2.1.2.1.3 Nature of residues in processed commodities

Not required.

A 2.1.2.2 Nature of residues in livestock

Not required.

A 2.1.3 Magnitude of residues in plants

For Azoxystrobin and Difenoconazole and it's triazole metabolites (triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA)

A.2.1.3.1.1 Study 1

Comments of zRMS:	One residue field trial on oilseed rape was conducted in Poland (n=1) during 2022. Two applications (first at BBCH 20, second at BBCH 69) of CHR/F/SCORPIO 325 SC were performed at the target dose rate of 1,0 L/ha, equivalent to 200 g azoxystrobin and 125 g difenoconazole. Samples were stored frozen for max 7 months prior to analysis. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, in addition the total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in oilseed rape (seed) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.004 mg/kg for each compound. Specimen extraction and determination of residues of difenoconazole and azoxystrobin in oilseed rape (seed) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound. The methods used in the study were fully validated and accepted, see dRR Part B5 (VAL/10/2021 and VAL/22/2023). Procedural recoveries (at the level of LOQ and two at the level 10 x LOQ) were within acceptable range. No residues of TAA, TLA, 1,2,4-T, difenoconazole and azoxystrobin above the LOQ of the method were found. Residues of TA above the LOQ were found in samples taken from treated (0.054 mg/kg) and untreated (0.027 mg/kg) trial plot. The study is accepted. Results supporting the proposed GAP: TAA: 1 x < LOD TA: 1 x 0.054 mg/kg TLA: 1 x < LOD 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x < LOQ Azoxystrobin: 1 x < LOQ

Reference:	KCA 6.3/01
Report	Magnitude of the azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) residues in Oil Seed Rape (Raw Agricultural Commodity) after two applications of CHR/F/SCORPIO 325 SC – one harvest study trial in Poland – 2022, Study Number 22SG248 K. Wańczyk
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

	Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021) SANTE/2020/12830 Rev.2, 14 February 2023
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Residues concentration detected in analysed field samples:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]					
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1,2,4-triazole 1,2,4-T	Difenoconazole	Azoxystrobin
1	CH	22SGS48-01 1	oilseed rape (seeds)	DPL/81/2023/01U	<LOD	0.027	<LOD	<LOD	<LOD	<LOD
2		22SGS48-01 2	oilseed rape (seeds)	DPL/81/2023/02T	<LOD	0.054	<LOD	<LOD	<LOQ	<LOQ

CH – Commercial Harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values.
LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

The objective of the study was to determine the residue level of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T in winter oilseed rape RAC specimens in one harvest study following two applications of the formulated product CHR/F/SCORPIO 325 SC under cultural practice typical for winter oilseed rape production.

FORTIFICATION AND CONTROL SAMPLES

Metabolites (1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid)

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples. 5 g of the homogenized control sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 2 for amounts and section "Preparation of Intermediate Calibration and Fortification Solutions" for information on solution preparation) together with 50 µL of internal standard solution (IS WS I), and the samples were extracted as described in section 6.2.2. "Extraction".

Table 2. Preparation of fortification and control samples – oilseed rape (seeds)

Fortification level	Amount of standard solution 1.1 added [µL]	Amount of standard solution 1.3 added [µL]
Matrix blank	-	-
PK 0.01 mg/kg (LOQ)	-	50.0
PK 0.10 mg/kg (10xLOQ)	50.0	-

Extraction of all field samples as well as control and fortified samples was performed on 20.02.2024. After that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

Difenoconazole & azoxystrobin

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared. 5 g of the homogenized untreated sample was weighed into a 50 mL centrifuge tube. Appropriate active substance standard solution was added (see Table 3 for amounts and section 6.2.6 for information on solution preparation), and the sample was extracted as described above

Fortification level	Amount of standard solution 1.7 added [µL]	Amount of standard solution 1.8 added [µL]
Matrix blank	-	-
PK 0.010 mg/kg (LOQ)	-	50
PK 0.10 mg/kg (10 x LOQ)	50	-

Extraction of all field samples, as well as control and fortified samples was performed on 19.01.2024 and after that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

Conclusions

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery. The limit of quantification of the method was established at 0.010 mg/kg for oilseed rape (seed). There were no interfering signals at retention time of analyzed compound in examined control matrix. The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA), difenoconazole and azoxystrobin in oilseed rape (seed) meets the criteria of SANTE/2020/12830, Rev.2 guidelines in terms of precision, accuracy and uncertainty.

Active Substances:	Azoxystrobin, difenoconazole	**Commercial Product:**	CHR/F/SCORPIO 325 SC
Crop / crop group:	Winter Oilseed rape /*Brassicaceae* Burnett, *Cruciferae* Juss	**Producer:**	PUH Chemirol Sp. z o. o.
Responsible for reporting:	Katarzyna Wańczyk SGS Polska Sp. z o. o. Marszowice 19 55-200 Oława Poland		

Country:	Poland	**Indoor/outdoor:**	outdoor
Nominal Content of a. s.:	325 g/L	**Other active substance:**	NAP
Formulation:	SC	**Residue calculated for:**	difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T

1	2	3	4	5				6	7	8	9						10	11
				Actual application rate							Residues (1)						DALA or CH (2)	Remarks
Report No. 22SGS48	Commodity Variety	Date of 1-Sowing 2-flowering 3-Harvest	Method of Treatment	L f.p./ha	Water (L/ha)	g azoxystrobin (/ha)	g a difenoconazole (/ha)	Date of Treatment	BBCH at Treatment	Commodity analysed	Triazole-acetic Acid TAA	Triazole-alanine TA	Triazole-lactic Acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin		
Poland Wenecja (Kujawsko-Pomorskie) Harvest Study 22SGS48-01	Winter OSR Jurek	1 – 28/08/2022 2-01/05/2023 3-25/05/2023 3 – 26/07/2023	Foliar spray	0,977 0,984	195,3 196,7	195,4 196,8	122,1 123,0	08/11/2022 25/05/2023	20 69	Seeds Seeds	<LOD <LOD	0.027 0.054	<LOD <LOD	<LOD <LOD	<LOD <LOQ	<LOD <LOQ	62 62	Analytical Method: LC-MS/MS

*-diluted sample; (2) DALA – Days After Last Application; CH – Commercial Harvest; (1) Residues are not corrected for procedural recoveries; Calculation based on unrounded values, **LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites), LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)**

.2.1.3.1.2 Study 2

Comments of zRMS:	One residue field trial on oil seed rape was conducted in Hungary (n=1) during 2022. Two applications (first at BBCH 18-19, second at BBCH 69) of CHR/F/SCORPIO 325 SC were performed at the target dose rate of 1,0 L/ha, equivalent to 200 g azoxystrobin and 125 g difenoconazole. Samples were stored frozen for max 8 months prior to analysis. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, in addition the total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in oilseed rape (seed) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.004 mg/kg for each compound. Specimen extraction and determination of residues of difenoconazole and azoxystrobin in oilseed rape (seed) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound. The methods used in the study were fully validated and accepted, see dRR Part B5 (VAL/10/2021 and VAL/22/2023). Procedural recoveries (at the level of LOQ and two at the level 10 x LOQ) were within acceptable range. No residues of 1,2,4-T, difenoconazole and azoxystrobin above the LOQ of the method were found. Residues of TAA, TA and TLA above the LOQ were found in samples taken from treated (0.033 mg/kg, 3.58 mg/kg, 0.16 mg/kg respectively) and untreated (0.043 mg/kg, 4.84 mg/kg, 0.25 mg/kg respectively) trial plot. It should be noted that the residue results in a sample taken from an untreated field are higher than those from a treated field. Despite these uncertainties, these trials were considered with the purpose of performing a ‘worst case’ consumer dietary intake calculation. The study is accepted. Results supporting the proposed GAP: TAA: 1 x 0.043 mg/kg TA: 1 x 4.84 mg/kg TLA: 1 x 0.25 mg/kg 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x < LOQ Azoxystrobin: 1 x < LOQ

Reference:	KCA 6.3/01
Report	Magnitude of the azoxystrobin and difenoconazole and it’s triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) residues in Oil Seed Rape (Raw Agricultural Commodity) after two applications of CHR/F/SCORPIO 325 SC – one harvest study in Hungary – 2022 Study Number 22SGS49 K. Wańczyk
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October

2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997

OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021)

SANTE/2020/12830 Rev.2, 14 February 2023

Deviations: No

GLP: Yes

Acceptability: Yes

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]					
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1,2,4-triazole 1,2,4-T	Difenoconazole	Azoxystrobin
1	CH	22SGS49-01 1	oilseed rape (seeds)	DPL/93/2023/01U	0.043	4.84	0.25	<LOD	<LOD	<LOD
2		22SGS49-01 2	oilseed rape (seeds)	DPL/93/2023/02T	0.033	3.58	0.16	<LOD	<LOQ	<LOD

CH – Commercial Harvest
Residues are not corrected for procedural recoveries.
Calculation based on unrounded values.
LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

One single harvest study (HS) was established in Hungary. Trial consisted of one untreated plot U and one treated plot T. Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study. Two typical for fungicide applications of CHR/F/SCORPIO 325 SC were performed with boom sprayer on the treated plot at the target dose rate of 1,0 L/ha, equivalent to 200 g azoxystrobin and 125 g difenoconazole. Spray volume was 300 L/ha according to Good Agricultural Practice. The reported dose rate of test item was:

- A1: 1,022 L/ha (306,7 L/ha water), at BBCH stage 18-19
- A2: 1,033 L/ha (310,0 L/ha water), at BBCH stage 69

The objective of the study was to determine the residue level of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T in winter oilseed rape RAC specimens in one harvest study trial following two applications of the formulated product CHR/F/SCORPIO 325 SC under cultural practice typical for winter oilseed rape production.

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of

the fortification samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow. Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10 x LOQ per analytical set of respective matrix were analyzed during each of the sequence.

Analysis of samples 20.02.2024 – triazole metabolites in oilseed rape seed
triazole-acetic acid (TAA)

Table 16. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.010	103.1
OSR seed PK1 0,10 mg-kg.lcd	0.10	100.7
OSR seed PK2 0,010 mg-kg.lcd	0.011	105.4
OSR seed PK2 0,10 mg-kg.lcd	0.10	100.7

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.012	117.8
OSR seed PK1 0,10 mg-kg.lcd	0.099	99.2
OSR seed PK2 0,010 mg-kg.lcd	0.011	113.5
OSR seed PK2 0,10 mg-kg.lcd	0.095	95.2

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0082	82.5
OSR seed PK1 0,10 mg-kg.lcd	0.089	89.0
OSR seed PK2 0,010 mg-kg.lcd	0.0081	81.3
OSR seed PK2 0,10 mg-kg.lcd	0.093	93.2

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

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

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0081	80.7
OSR seed PK1 0,10 mg-kg.lcd	0.093	93.1
OSR seed PK2 0,010 mg-kg.lcd	0.0081	80.6
OSR seed PK2 0,10 mg-kg.lcd	0.095	94.8

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 19.01.2024 – difenoconazole and azoxystrobin in oilseed rape seed.

Difenoconazole

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.010	102.8
OSR seed PK1 0,10 mg-kg.lcd	0.11	105.2
OSR seed PK2 0,010 mg-kg.lcd	0.010	103.7
OSR seed PK2 0,10 mg-kg.lcd	0.10	101.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.010	101.2
OSR seed PK1 0,10 mg-kg.lcd	0.10	104.3
OSR seed PK2 0,010 mg-kg.lcd	0.010	104.4
OSR seed PK2 0,10 mg-kg.lcd	0.10	102.4

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev.2. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70 – 120% confirms the active substance stability during the analytical procedure.

19.01.2024 (difenoconazole and azoxystrobin in oilseed rape seed samples) - the duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 464 minutes (7.7

h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
20.02.2024 (triazole derivative metabolites in oilseed rape seed samples) - the duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 372 minutes (6.2 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.
Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery. The limit of quantification of the method was established at 0.010 mg/kg for oilseed rape (seed). There were no interfering signals at retention time of analyzed compound in examined control matrix. The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA), difenoconazole and azoxystrobin in oilseed rape (seed) meets the criteria of SANTE/2020/12830, Rev.2 guidelines in terms of precision, accuracy and uncertainty.

Active Substances:	Azoxystrobin, difenoconazole	**Commercial Product:**	CHR/F/SCORPIO 325 SC
Crop / crop group:	Winter Oilseed rape /*Brassicaceae* Burnett, *Cruciferae* Juss	**Producer:**	PUH Chemirol Sp. z o. o.
Responsible for reporting:	Katarzyna Wańczyk SGS Polska Sp. z o. o. Marszowice 19 55-200 Oława Poland		

Country:	Hungary	**Indoor/outdoor:**	outdoor
Nominal Content of a. s.:	325 g/L	**Other active substance:**	NAP
Formulation:	SC	**Residue calculated for:**	difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T

1	2	3	4	5				6	7	8	9						10	11
				Actual application rate							Residues (1)						DALA or CH (2)	Remarks
Report No. 22SGS49	Commodity Variety	Date of 1-Sowing 2-flowering 3-Harvest	Method of Treatment	L f.p./ha	Water (L/ha)	g azoxystrobin (/ha)	g a difenoconazole (/ha)	Date of Treatment	BBCH at Treatment	Commodity analysed	Triazole-acetic Acid TAA	Triazole-alanine TA	Triazole-lactic Acid TLA	1,2,4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin		
Hungary Monok (Borsod-abaúj-Zemplén) Harvest Study 22SGS49-01	Winter Oilseed Rape DK Excited	1 – 02.09.2022 2 – 02.05.2023-23.05.2023 3 – 15.07.2023	Foliar spray	1,022 1,033	306,7 310,0	204,4 206,6	127,8 129,1	08/12/2022 22/05/2023	18-19 69	Seeds Seeds	0.043 0.033	4.84 3.58	0.25 0.16	<LOD <LOD	<LOD <LOQ	<LOD <LOD	54	Analytical Method: LC-MS/MS

*-diluted sample;
(2) DALA – Days After Last Application; CH – Commercial Harvest;
(1) Residues are not corrected for procedural recoveries; Calculation based on unrounded values,
LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

A.2.1.3.1.3 Study 3

Comments of zRMS:	One residue field trial on oilseed rape was conducted in Poland (n=1) during 2022. Two applications (first at BBCH 22, second at BBCH 69) of CHR/F/SCORPIO 325 SC were performed at the target dose rate of 1,0 L/ha, equivalent to 200 g azoxystrobin and 125 g difenoconazole. Samples were stored frozen for max 7 months prior to analysis. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, in addition the total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in oilseed rape (seed) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.004 mg/kg for each compound. Specimen extraction and determination of residues of difenoconazole and azoxystrobin in oilseed rape (seed) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound. The methods used in the study were fully validated and accepted, see dRR Part B5 (VAL/10/2021 and VAL/22/2023). Procedural recoveries (at the level of LOQ and two at the level 10 x LOQ) were within acceptable range. No residues of TAA, TLA, 1,2,4-T, difenoconazole and azoxystrobin above the LOD of the method were found. Residues of TA above the LOQ were found in samples taken from treated (0.24 mg/kg) and untreated (0.11 mg/kg) trial plot. The study is accepted. Results supporting the proposed GAP: TAA: 1 x < LOD TA: 1 x 0.24 mg/kg TLA: 1 x < LOD 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x < LOD Azoxystrobin: 1 x < LOD

Reference:	KCA 6.3/01
Report	Magnitude of the azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) residues in Oil Seed Rape (Raw Agricultural Commodity) after two applications of CHR/F/SCORPIO 325 SC – one harvest study trial in Poland – 2022 Study Number 22SGS51 K. Wańczyk
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General

	Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021) SANTE/2020/12830 Rev.2, 14 February 2023
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Residues concentration detected in analysed field samples:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]					
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1,2,4-triazole 1,2,4-T	Difenoconazole	Azoxystrobin
1	CH	22SGS51-01 1	oilseed rape (seeds)	DPL/82/2023/01U	<LOD	0.11	<LOD	<LOD	<LOD	<LOD
2		22SGS51-01 2	oilseed rape (seeds)	DPL/82/2023/02T	<LOD	0.24	<LOD	<LOD	<LOD	<LOD

CH – Commercial Harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.

Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10 x LOQ per analytical set of respective matrix were analyzed during each of the sequence.

Analysis of samples 20.02.2024 – triazole metabolites in oilseed rape seed:

triazole-acetic acid (TAA)

Table 16. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.010	103.1
OSR seed PK1 0,10 mg-kg.lcd	0.10	100.7
OSR seed PK2 0,010 mg-kg.lcd	0.011	105.4
OSR seed PK2 0,10 mg-kg.lcd	0.10	100.7

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.012	117.8
OSR seed PK1 0,10 mg-kg.lcd	0.099	99.2
OSR seed PK2 0,010 mg-kg.lcd	0.011	113.5
OSR seed PK2 0,10 mg-kg.lcd	0.095	95.2

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0082	82.5
OSR seed PK1 0,10 mg-kg.lcd	0.089	89.0
OSR seed PK2 0,010 mg-kg.lcd	0.0081	81.3
OSR seed PK2 0,10 mg-kg.lcd	0.093	93.2

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

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

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0081	80.7
OSR seed PK1 0,10 mg-kg.lcd	0.093	93.1
OSR seed PK2 0,010 mg-kg.lcd	0.0081	80.6
OSR seed PK2 0,10 mg-kg.lcd	0.095	94.8

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 19.01.2024 – difenoconazole and azoxystrobin in oilseed rape seed:

Difenoconazole

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.010	102.8
OSR seed PK1 0,10 mg-kg.lcd	0.11	105.2
OSR seed PK2 0,010 mg-kg.lcd	0.010	103.7
OSR seed PK2 0,10 mg-kg.lcd	0.10	101.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.010	101.2
OSR seed PK1 0,10 mg-kg.lcd	0.10	104.3
OSR seed PK2 0,010 mg-kg.lcd	0.010	104.4
OSR seed PK2 0,10 mg-kg.lcd	0.10	102.4

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev.2.

The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70 – 120% confirms the active substance stability during the analytical procedure.

19.01.2024 (difenoconazole and azoxystrobin in oilseed rape seed samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 464 minutes (7.7 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

20.02.2024 (triazole derivative metabolites in oilseed rape seed samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 372 minutes (6.2 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

CONCLUSIONS

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for oilseed rape (seed).

There were no interfering signals at retention time of analyzed compound in examined control matrix.

The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA), difenoconazole and azoxystrobin in oilseed rape (seed) meets the criteria of SANTE/2020/12830, Rev.2 guidelines in terms of precision, accuracy and uncertainty.

Active Substances:	Azoxystrobin, difenoconazole	**Commercial Product:**	CHR/F/SCORPIO 325 SC
Crop / crop group:	Winter Oilseed rape /*Brassicaceae* Burnett, *Cruciferae* Juss	**Producer:**	PUH Chemirol Sp. z o. o.
Responsible for reporting:	Katarzyna Wańczyk SGS Polska Sp. z o. o. Marszowice 19 55-200 Oława Poland		

Country:	Poland	**Indoor/outdoor:**	outdoor
Nominal Content of a. s.:	325 g/L	**Other active substance:**	NAP
Formulation:	SC	**Residue calculated for:**	difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T

1	2	3	4	5				6	7	8	9						10	11
				Actual application rate							Residues (1)						DALA or CH (2)	Remarks
Report No. 22SGS51	Commodity Variety	Date of 1-Sowing 2-flowering 3-Harvest	Method of Treatment	L f.p./ha	Water (L/ha)	g azoxystrobin (/ha)	g a difenoconazole (/ha)	Date of Treatment	BBCH at Treatment	Commodity analysed	Triazole-acetic Acid TAA	Triazole-alanine TA	Triazole-lactic Acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin		
Poland Stoszowice (Dolnośląskie) Decline Curve Study Trial 22SGS51-01	Winter OSR Sienna	1 – 31/08/2022 2-27/04/2023 3-25/05/2023 3 – 20/07/2023	Foliar spray	0,984 1,007	295,3 302,1	196,8 201,4	123,0 125,9	08/11/2022 24/05/2023	22 69	Seeds Seeds	<LOD <LOD	0.11 0.24	<LOD <LOD	<LOD <LOD	<LOD <LOD	<LOD <LOD	58 58	Analytical Method: LC-MS/MS

*-diluted sample;(2) DALA – Days After Last Application; CH – Commercial Harvest; (1) Residues are not corrected for procedural recoveries; Calculation based on unrounded values,
LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

A.2.1.3.1.4 Study 4

Comments of zRMS:	One residue field trial (decline study) on oilseed rape was conducted in Poland (n=1) during 2022. Two applications (first at BBCH 22, second at BBCH 69) of CHR/F/SCORPIO 325 SC were performed at the target dose rate of 1,0 L/ha, equivalent to 200 g azoxystrobin and 125 g difenoconazole. Samples were stored frozen for max 7 months prior to analysis. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, in addition the total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in oilseed rape (seed) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.004 mg/kg for each compound. Specimen extraction and determination of residues of difenoconazole and azoxystrobin in oilseed rape (seed) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound. The methods used in the study were fully validated and accepted, see dRR Part B5 (VAL/10/2021 and VAL/22/2023). Procedural recoveries (at the level of LOQ and two at the level 10 x LOQ) were within acceptable range. No residues of TAA, TLA, 1,2,4-T, difenoconazole and azoxystrobin above the LOQ of the method were found in mature seeds (BBCH 89). Residues of TA above the LOQ were found in mature seeds samples taken from treated (0.47 mg/kg) and untreated (0.10 mg/kg) trial plot. The study is accepted. Results supporting the proposed GAP: TAA: 1 x < LOD TA: 1 x 0.47 mg/kg TLA: 1 x < LOD 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x < LOQ Azoxystrobin: 1 x < LOQ

Reference:	KCA 6.3/01
Report	Magnitude of the azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) residues in Oil Seed Rape (Raw Agricultural Commodity) after two applications of CHR/F/SCORPIO 325 SC – one decline curve study trial in Poland – 2022 Study Number 22SGS52 K. Wańczyk
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue

	Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021) SANTE/2020/12830 Rev.2, 14 February 2023
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue level of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T in winter oilseed rape RAC specimens in one decline curve study trial following two applications of the formulated product CHR/F/SCORPIO 325 SC under cultural practice typical for winter oilseed rape production.

The following residues concentration was determined in the field samples analyzed on 19.01.2024 (difenoconazole, azoxystrobin in seeds samples), 22.01.2024 (difenoconazole, azoxystrobin in plant samples), 15.02.2024 (difenoconazole, azoxystrobin in plant, diluted samples) 20.02.2024 (triazole metabolites in seeds samples) and 21.02.2024 (triazole metabolites in plant samples)

Table 15. Residue concentrations of difenoconazole, azoxystrobin and triazole derivative metabolites detected in analyzed field samples (Study No.: 22SGS52, Trial No.: 22SGS52-01 – Decline Study)

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]					
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1,2,4-triazole 1,2,4-T	Difenoconazole	Azoxystrobin
1	-0/0 DALA	22SGS52-01 1	oilseed rape (whole plants without roots)	DPL/79/2023/01U	<LOD	0.038	<LOD	<LOD	<LOD	<LOD
2		22SGS52-01 2	oilseed rape (whole plants without roots)	DPL/79/2023/02T	<LOD	0.082	<LOD	<LOD	1.45*	2.38*
3	14 DALA	22SGS52-01 3	oilseed rape (whole plants without roots)	DPL/79/2023/03T	<LOD	0.076	<LOD	<LOD	0.66*	1.26*
4	21 DALA	22SGS52-01 4	oilseed rape (whole plants without roots)	DPL/79/2023/04T	<LOD	0.12	<LOD	<LOD	0.18*	0.15*
5	28 DALA	22SGS52-01 5	oilseed rape (whole plants without roots)	DPL/79/2023/05T	<LOD	0.064	<LOD	<LOD	0.12	0.17
6	BBCH 89/CH	22SGS52-01 6	oilseed rape (seeds)	DPL/79/2023/06U	<LOD	0.10	<LOD	<LOD	<LOD	<LOD
7		22SGS52-01 7	oilseed rape (seeds)	DPL/79/2023/07T	<LOD	0.47	<LOD	<LOD	<LOQ	<LOQ

*- diluted samples
CH – Commercial Harvest; DALA – Days After Last Application
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.

Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10 x LOQ per analytical set of respective matrix were analyzed during each of the sequence.

Analysis of samples 20.02.2024 – triazole metabolites in oilseed rape seed:

triazole-acetic acid (TAA)

Table 16. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.010	103.1
OSR seed PK1 0,10 mg-kg.lcd	0.10	100.7
OSR seed PK2 0,010 mg-kg.lcd	0.011	105.4
OSR seed PK2 0,10 mg-kg.lcd	0.10	100.7

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.012	117.8
OSR seed PK1 0,10 mg-kg.lcd	0.099	99.2
OSR seed PK2 0,010 mg-kg.lcd	0.011	113.5
OSR seed PK2 0,10 mg-kg.lcd	0.095	95.2

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0082	82.5
OSR seed PK1 0,10 mg-kg.lcd	0.089	89.0
OSR seed PK2 0,010 mg-kg.lcd	0.0081	81.3
OSR seed PK2 0,10 mg-kg.lcd	0.093	93.2

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

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

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0081	80.7
OSR seed PK1 0,10 mg-kg.lcd	0.093	93.1
OSR seed PK2 0,010 mg-kg.lcd	0.0081	80.6
OSR seed PK2 0,10 mg-kg.lcd	0.095	94.8

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 19.01.2024 – difenoconazole and azoxystrobin in oilseed rape seed:

Difenoconazole

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.010	102.8
OSR seed PK1 0,10 mg-kg.lcd	0.11	105.2
OSR seed PK2 0,010 mg-kg.lcd	0.010	103.7
OSR seed PK2 0,10 mg-kg.lcd	0.10	101.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.010	101.2
OSR seed PK1 0,10 mg-kg.lcd	0.10	104.3
OSR seed PK2 0,010 mg-kg.lcd	0.010	104.4
OSR seed PK2 0,10 mg-kg.lcd	0.10	102.4

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 21.02.2024 – triazole metabolites in oilseed rape plant:

triazole-acetic acid (TAA)

Table 22. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	101.7
OSR plant PK1 0,10 mg-kg.lcd	0.097	96.8
OSR plant PK2 0,010 mg-kg.lcd	0.010	103.3
OSR plant PK2 0,10 mg-kg.lcd	0.10	100.6

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 23. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.0081	80.7
OSR plant PK1 0,10 mg-kg.lcd	0.093	92.8
OSR plant PK2 0,010 mg-kg.lcd	0.0097	96.7
OSR plant PK2 0,10 mg-kg.lcd	0.11	108.2

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 24. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.0079	79.2
OSR plant PK1 0,10 mg-kg.lcd	0.081	80.7
OSR plant PK2 0,010 mg-kg.lcd	0.0087	87.4
OSR plant PK2 0,10 mg-kg.lcd	0.083	83.1

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

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

Table 25. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.0090	89.7
OSR plant PK1 0,10 mg-kg.lcd	0.095	95.5
OSR plant PK2 0,010 mg-kg.lcd	0.0090	90.5
OSR plant PK2 0,10 mg-kg.lcd	0.097	97.5

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 22.01.2024 – difenoconazole and azoxystrobin in oilseed rape plant:

Difenoconazole

Table 26. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	104.3
OSR plant PK1 0,10 mg-kg.lcd	0.10	102.4
OSR plant PK2 0,010 mg-kg.lcd	0.010	104.3
OSR plant PK2 0,10 mg-kg.lcd	0.10	104.3

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 27. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	102.5
OSR plant PK1 0,10 mg-kg.lcd	0.11	105.3
OSR plant PK2 0,010 mg-kg.lcd	0.010	101.8
OSR plant PK2 0,10 mg-kg.lcd	0.11	105.9

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 15.02.2024 – difenoconazole and azoxystrobin in oilseed rape plant

Difenoconazole

Table 28. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	101.2
OSR plant PK1 0,10 mg-kg.lcd	0.10	101.5
OSR plant PK2 0,010 mg-kg.lcd	0.010	99.6
OSR plant PK2 0,10 mg-kg.lcd	0.10	99.6

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 29. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	100.7
OSR plant PK1 0,10 mg-kg.lcd	0.10	102.1
OSR plant PK2 0,010 mg-kg.lcd	0.010	103.6
OSR plant PK2 0,10 mg-kg.lcd	0.10	105.0

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev.2.
The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70 – 120% confirms the active substance stability during the analytical procedure.

19.01.2024 (difenoconazole and azoxystrobin in oilseed rape seed samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 464 minutes (7.7 h). The total analytical procedure, from sample extraction till analysis, was performed and completed

within 1 day.

22.01.2024 (difenoconazole and azoxystrobin in oilseed rape plant samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 544 minutes (9.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

15.02.2024 (difenoconazole and azoxystrobin in oilseed rape plant, diluted samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 416 minutes (6.9 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

20.02.2024 (triazole derivative metabolites in oilseed rape seed samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 372 minutes (6.2 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

21.02.2024 (triazole derivative metabolites in oilseed rape plant samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 348 minutes (5.8 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

CONCLUSIONS

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery. The limit of quantification of the method was established at 0.010 mg/kg for oilseed rape (seeds, whole plants without roots). There were no interfering signals at retention time of analyzed compound in examined control matrix. The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA), difenoconazole and azoxystrobin in oilseed rape (seeds, whole plants without roots) meets the criteria of SANTE/2020/12830, Rev.2 guidelines in terms of precision, accuracy and uncertainty

Active Substances:	Azoxystrobin, difenoconazole	**Commercial Product:**	CHR/F/SCORPIO 325 SC
Crop / crop group:	Winter Oilseed rape /*Brassicaceae* Burnett, *Cruciferae* Juss	**Producer:**	PUH Chemirol Sp. z o. o.
Responsible for reporting:	Katarzyna Wańczyk SGS Polska Sp. z o. o. Marszowice 19 55-200 Oława Poland		

Country:	Poland	**Indoor/outdoor:**	outdoor
Nominal Content of a. s.:	325 g/L	**Other active substance:**	NAP
Formulation:	SC	**Residue calculated for:**	difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T

1	2	3	4	5				6	7	8	9						10	11
				Actual application rate							Residues (1)						DALA or CH (2)	Remarks
Report No. 22SGS52	Commodity Variety	Date of 1-Sowing 2-flowering 3-Harvest	Method of Treatment	L f.p./ha	Water (L/ha)	g azoxystrobin (/ha)	g a difenoconazole (/ha)	Date of Treatment	BBCH at Treatment	Commodity analysed	Triazole-acetic Acid TAA	Triazole-alanine TA	Triazole-lactic Acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin		
Poland Chwastnica (Dolnośląskie) Decline Curve Study Trial 22SGS52-01	Winter OSR Sienna	1 – 30/08/2022 2-25/04/2023 3-26/05/2023 3 – 20/07/2023	Foliar spray	1,018 0,991	305,3 297,3	203,6 198,2	127,3 123,9	08/11/2022 24/05/2023	22 69	Whole plants w/o roots	<LOD	0.038	<LOD	<LOD	<LOD	<LOD	0	Analytical Method: LC-MS/MS
										Whole plants w/o roots	<LOD	0.082	<LOD	<LOD	1.45*	2.38*	0	
										Whole plants w/o roots	<LOD	0.076	<LOD	<LOD	0.66*	1.26*	14	
										Whole plants w/o	<LOD	0.12	<LOD	<LOD	0.18*	0.15*	21	

										roots								
										Whole plants w/o roots	<LOD	0.064	<LOD	<LOD	0.12	0.17	28	
										Seeds	<LOD	0.10	<LOD	<LOD	<LOD	<LOD	57	
										Seeds	<LOD	0.47	<LOD	<LOD	<LOQ	<LOQ	57	

*-diluted sample;
(2) DALA – Days After Last Application; CH – Commercial Harvest;
(1) Residues are not corrected for procedural recoveries; Calculation based on unrounded values,
LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

A.2.1.3.1.5 Study 5

Comments of zRMS:	One residue field trial (decline study) on oilseed rape was conducted in Hungary (n=1) during 2022. Two applications (first at BBCH 18, second at BBCH 69) of CHR/F/SCORPIO 325 SC were performed at the target dose rate of 1,0 L/ha, equivalent to 200 g azoxystrobin and 125 g difenoconazole. Samples were stored frozen for max 9 months prior to analysis. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, in addition the total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in oilseed rape (seed) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.004 mg/kg for each compound. Specimen extraction and determination of residues of difenoconazole and azoxystrobin in oilseed rape (seed) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound. The methods used in the study were fully validated and accepted, see dRR Part B5 (VAL/10/2021 and VAL/22/2023). Procedural recoveries (at the level of LOQ and two at the level 10 x LOQ) were within acceptable range. No residues of 1,2,4-T, difenoconazole and azoxystrobin above the LOQ of the method were found in mature seeds (BBCH 89). Residues of TAA, TA and TLA above the LOQ were found in mature seeds samples taken from treated (0.058 mg/kg, 6.72 mg/kg and 0.23 mg/kg respectively) and untreated (0.04 mg/kg, 4.81 mg/kg and 0.16 mg/kg respectively) trial plot. The study is accepted. Results supporting the proposed GAP: TAA: 1 x 0.058 mg/kg TA: 1 x 6.72 mg/kg TLA: 1 x 0.23 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x < LOQ Azoxystrobin: 1 x < LOQ

Reference:	KCA 6.3/01
Report	Magnitude of the azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) residues in Oil Seed Rape (Raw Agricultural Commodity) after two applications of CHR/F/SCORPIO 325 SC – one decline curve study trial in Hungary – 2022, Study Number 22SG253 K. Wańczyk
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

	Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021) SANTE/2020/12830 Rev.2, 14 February 2023
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Residue concentrations of difenoconazole, azoxystrobin and triazole derivative metabolites detected in analyzed field samples:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]					
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1,2,4-triazole 1,2,4-T	Difenoconazole	Azoxystrobin
1	-0/0 DALA	22SGS53-01 1	oilseed rape (whole plants without roots)	DPL/94/2023/01U	0.032	0.97	<LOD	<LOD	<LOD	<LOD
2		22SGS53-01 2	oilseed rape (whole plants without roots)	DPL/94/2023/02T	0.025	0.75	<LOD	<LOD	1.45*	2.15*
3	14 DALA	22SGS53-01 3	oilseed rape (whole plants without roots)	DPL/94/2023/03T	0.027	0.64	0.053	<LOD	0.41*	0.53*
4	21 DALA	22SGS53-01 4	oilseed rape (whole plants without roots)	DPL/94/2023/04T	0.036	0.59	0.093	<LOD	0.18*	0.11*
5	28 DALA	22SGS53-01 5	oilseed rape (whole plants without roots)	DPL/94/2023/05T	0.049	0.67	0.11	<LOD	0.16	0.14
6	BBCH 89/CH	22SGS53-01 6	oilseed rape (seeds)	DPL/94/2023/06U	0.040	4.81	0.16	<LOD	<LOD	<LOD
7		22SGS53-01 7	oilseed rape (seeds)	DPL/94/2023/07T	0.058	6.72*	0.23	<LOD	<LOQ	<LOQ

*- diluted samples
CH – Commercial Harvest; DALA – Days After Last Application
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

The objective of the study was to determine the residue of the azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) in oilseed rape (seeds, whole plants without roots), after two applications of CHR/F/SCORPIO 325 SC.

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active

substance stability during the analytical method workflow.

Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10 x LOQ per analytical set of respective matrix were analyzed during each of the sequence

Analysis of samples 21.02.2024 – triazole metabolites in oilseed rape seed

triazole-acetic acid (TAA)

Table 16. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0097	97.4
OSR seed PK1 0,10 mg-kg.lcd	0.098	98.2
OSR seed PK2 0,010 mg-kg.lcd	0.0099	98.8
OSR seed PK2 0,10 mg-kg.lcd	0.098	98.2

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.012	115.9
OSR seed PK1 0,10 mg-kg.lcd	0.11	106.8
OSR seed PK2 0,010 mg-kg.lcd	0.0098	98.3
OSR seed PK2 0,10 mg-kg.lcd	0.088	87.7

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0080	80.3
OSR seed PK1 0,10 mg-kg.lcd	0.082	81.6
OSR seed PK2 0,010 mg-kg.lcd	0.0079	79.0
OSR seed PK2 0,10 mg-kg.lcd	0.072	72.5

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

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

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0083	83.0
OSR seed PK1 0,10 mg-kg.lcd	0.092	92.1
OSR seed PK2 0,010 mg-kg.lcd	0.0083	83.4
OSR seed PK2 0,10 mg-kg.lcd	0.093	93.4

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 19.01.2024 – difenoconazole and azoxystrobin in oilseed rape seed:

Difenoconazole

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.010	102.8
OSR seed PK1 0,10 mg-kg.lcd	0.11	105.2
OSR seed PK2 0,010 mg-kg.lcd	0.010	103.7
OSR seed PK2 0,10 mg-kg.lcd	0.10	101.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.010	101.2
OSR seed PK1 0,10 mg-kg.lcd	0.10	104.3
OSR seed PK2 0,010 mg-kg.lcd	0.010	104.4
OSR seed PK2 0,10 mg-kg.lcd	0.10	102.4

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 21.02.2024 – triazole metabolites in oilseed rape plant:

triazole-acetic acid (TAA)

Table 22. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	101.7
OSR plant PK1 0,10 mg-kg.lcd	0.097	96.8
OSR plant PK2 0,010 mg-kg.lcd	0.010	103.3
OSR plant PK2 0,10 mg-kg.lcd	0.10	100.6

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 23. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.0081	80.7
OSR plant PK1 0,10 mg-kg.lcd	0.093	92.8
OSR plant PK2 0,010 mg-kg.lcd	0.0097	96.7
OSR plant PK2 0,10 mg-kg.lcd	0.11	108.2

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 24. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.0079	79.2
OSR plant PK1 0,10 mg-kg.lcd	0.081	80.7
OSR plant PK2 0,010 mg-kg.lcd	0.0087	87.4
OSR plant PK2 0,10 mg-kg.lcd	0.083	83.1

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

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

Table 25. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.0090	89.7
OSR plant PK1 0,10 mg-kg.lcd	0.095	95.5
OSR plant PK2 0,010 mg-kg.lcd	0.0090	90.5
OSR plant PK2 0,10 mg-kg.lcd	0.097	97.5

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 22.01.2024 – difenoconazole and azoxystrobin in oilseed rape plant:

Difenoconazole

Table 26. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	104.3
OSR plant PK1 0,10 mg-kg.lcd	0.10	102.4
OSR plant PK2 0,010 mg-kg.lcd	0.010	104.3
OSR plant PK2 0,10 mg-kg.lcd	0.10	104.3

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 27. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	102.5
OSR plant PK1 0,10 mg-kg.lcd	0.11	105.3
OSR plant PK2 0,010 mg-kg.lcd	0.010	101.8
OSR plant PK2 0,10 mg-kg.lcd	0.11	105.9

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 15.02.2024 – difenoconazole and azoxystrobin in oilseed rape plant:

Difenoconazole

Table 28. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	101.2
OSR plant PK1 0,10 mg-kg.lcd	0.10	101.5
OSR plant PK2 0,010 mg-kg.lcd	0.010	99.6
OSR plant PK2 0,10 mg-kg.lcd	0.10	99.6

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 29. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	100.7
OSR plant PK1 0,10 mg-kg.lcd	0.10	102.1
OSR plant PK2 0,010 mg-kg.lcd	0.010	103.6
OSR plant PK2 0,10 mg-kg.lcd	0.10	105.0

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev.2.

The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70 – 120% confirms the active substance stability during the analytical procedure.

19.01.2024 (difenoconazole and azoxystrobin in oilseed rape seed samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 464 minutes (7.7 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

22.01.2024 (difenoconazole and azoxystrobin in oilseed rape plant samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 544 minutes (9.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

15.02.2024 (difenoconazole and azoxystrobin in oilseed rape plant, diluted samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 416 minutes (6.9

h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

21.02.2024 (triazole derivative metabolites in oilseed rape seed samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 312 minutes (5.2 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

21.02.2024 (triazole derivative metabolites in oilseed rape plant samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 348 minutes (5.8 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

CONCLUSIONS

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for oilseed rape (seeds, whole plants without roots).

There were no interfering signals at retention time of analyzed compound in examined control matrix.

The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA), difenoconazole and azoxystrobin in oilseed rape (seeds, whole plants without roots) meets the criteria of SANTE/2020/12830, Rev.2 guidelines in terms of precision, accuracy and uncertainty

Active Substances:	Azoxystrobin, difenoconazole	**Commercial Product:**	CHR/F/SCORPIO 325 SC
Crop / crop group:	Winter Oilseed rape /*Brassicaceae* Burnett, *Cruciferae* Juss	**Producer:**	PUH Chemirol Sp. z o. o.
Responsible for reporting:	Katarzyna Wańczyk SGS Polska Sp. z o. o. Marszowice 19 55-200 Oława Poland		

Country:	Hungary	**Indoor/outdoor:**	outdoor
Nominal Content of a. s.:	325 g/L	**Other active substance:**	NAP
Formulation:	SC	**Residue calculated for:**	difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T

1	2	3	4	5				6	7	8	9						10	11
				Actual application rate							Residues (1)						DALA or CH (2)	Remarks
Report No. 22SGS53	Commodity Variety	Date of 1-Sowing 2-flowering 3-Harvest	Method of Treatment	L f.p./ha	Water (L/ha)	g azoxystrobin (/ha)	g a difenoconazole (/ha)	Date of Treatment	BBCH at Treatment	Commodity analysed	Triazole-acetic Acid TAA	Triazole-alanine TA	Triazole-lactic Acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin		
Hungary Nyiregyhaza (Szabolcs-Szatmár-Bereg) Decline Curve Study Trial 22SGS53-01	Winter OSR KWS Umberto	1 – 26/08/2022 2- 05/05/2023 3- 23/05/2023 3 – 15/07/2023 3- 16/07/2023	Foliar spray	0,994 0,964	298,3 289,2	198,8 192,8	124,3 120,5	08/12/2022 22/05/2023	18 69	Whole plants w/o roots	0.032	0.97	<LOD	<LOD	<LOD	<LOD	0	Analytical Method: LC-MS/MS
										Whole plants w/o roots	0.025	0.75	<LOD	<LOD	1,45*	2.15*	0	
										Whole plants w/o roots	0.27	0.64	0.053	<LOD	0.41*	0.53*	14	
										Whole plants w/o	0.036	0.59	0.093	<LOD	0.18*	0.11*	21	

										roots								
										Whole plants w/o roots	0.049	0.67	0.11	<LOD	0.16	0.14	28	
										Seeds	0.040	4.81	0.16	<LOD	<LOD	<LOD	54	
										Seeds	0.058	6.72	0.23	<LOD	<LOQ	<LOQ	54	

*-diluted sample;
(2) DALA – Days After Last Application; CH – Commercial Harvest;
(1) Residues are not corrected for procedural recoveries; Calculation based on unrounded values,
LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

A.2.1.3.1.6 Study 6

Comments of zRMS:	One residue field trial (decline study) on oilseed rape was conducted in Northern France (n=1) during 2022. Two applications (first at BBCH 19, second at BBCH 69) of CHR/F/SCORPIO 325 SC were performed at the target dose rate of 1,0 L/ha, equivalent to 200 g azoxystrobin and 125 g difenoconazole. Samples were stored frozen for max 9 months prior to analysis. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, in addition the total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in oilseed rape (seed) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.004 mg/kg for each compound. Specimen extraction and determination of residues of difenoconazole and azoxystrobin in oilseed rape (seed) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound. The methods used in the study were fully validated and accepted, see dRR Part B5 (VAL/10/2021 and VAL/22/2023). Procedural recoveries (at the level of LOQ and two at the level 10 x LOQ) were within acceptable range. No residues of TAA, TLA, 1,2,4-T and difenoconazole above the LOQ of the method were found in mature seeds (BBCH 89). Residues of TA and azoxystrobin above the LOQ were found in mature seeds samples taken from treated (0.2 mg/kg, and 0.02 mg/kg respectively) trial plot. The study is accepted. Results supporting the proposed GAP: TAA: 1 x < LOD TA: 1 x 0.2 mg/kg TLA: 1 x < LOD 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x < LOQ Azoxystrobin: 1 x 0.02 mg/kg

Reference:	KCA 6.3/01
Report	Magnitude of the azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) residues in Oil Seed Rape (Raw Agricultural Commodity) after two applications of CHR/F/SCORPIO 325 SC – one decline curve study trial in Northern France – 2022, Study Number 22SG254 K. Wańczyk

Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021) SANTE/2020/12830 Rev.2, 14 February 2023
Deviations:	No
GLP:	Yes

Residues concentration detected in analysed field samples:

The following residues concentration was determined in the field samples analyzed on 19.01.2024 (difenoconazole, azoxystrobin in seeds samples), 22.01.2024 (difenoconazole, azoxystrobin in plant samples), 15.02.2024 (difenoconazole, azoxystrobin in plant, diluted samples), 21.02.2024 (triazole metabolites in seeds samples) and 22.02.2024 (triazole metabolites in plant samples):

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]					
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1,2,4-triazole 1,2,4-T	Difenoconazole	Azoxystrobin
1	-0/0 DALA	22SGS54-01 1	oilseed rape (whole plants without roots)	DPL/106/2023/01U	<LOD	0.024	<LOD	<LOD	<LOD	<LOD
2		22SGS54-01 2	oilseed rape (whole plants without roots)	DPL/106/2023/02T	<LOD	0.036	<LOD	<LOD	3.50'	5.26'
3	21 DALA	22SGS54-01 4	oilseed rape (whole plants without roots)	DPL/106/2023/04T	<LOQ	0.070	<LOD	<LOD	1.14'	2.02'
4	28 DALA	22SGS54-01 5	oilseed rape (whole plants without roots)	DPL/106/2023/05T	<LOQ	0.052	<LOD	<LOD	0.36'	0.56'
5	BBCH 89/CH	22SGS54-01 6	oilseed rape (seeds)	DPL/106/2023/06U	<LOD	0.055	<LOD	<LOD	<LOD	<LOD
6		22SGS54-01 7	oilseed rape (seeds)	DPL/106/2023/07T	<LOD	0.20	<LOD	<LOD	<LOQ	0.020

'- diluted samples
CH – Commercial Harvest; DALA – Days After Last Application
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries

upon applying the test method.

Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.

Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10 x LOQ per analytical set of respective matrix were analyzed during each of the sequence.

Analysis of samples 21.02.2024 – triazole metabolites in oilseed rape seed:

triazole-acetic acid (TAA)

Table 16. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0097	97.4
OSR seed PK1 0,10 mg-kg.lcd	0.098	98.2
OSR seed PK2 0,010 mg-kg.lcd	0.0099	98.8
OSR seed PK2 0,10 mg-kg.lcd	0.098	98.2

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.012	115.9
OSR seed PK1 0,10 mg-kg.lcd	0.11	106.8
OSR seed PK2 0,010 mg-kg.lcd	0.0098	98.3
OSR seed PK2 0,10 mg-kg.lcd	0.088	87.7

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0080	80.3
OSR seed PK1 0,10 mg-kg.lcd	0.082	81.6
OSR seed PK2 0,010 mg-kg.lcd	0.0079	79.0
OSR seed PK2 0,10 mg-kg.lcd	0.072	72.5

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

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

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0083	83.0
OSR seed PK1 0,10 mg-kg.lcd	0.092	92.1
OSR seed PK2 0,010 mg-kg.lcd	0.0083	83.4
OSR seed PK2 0,10 mg-kg.lcd	0.093	93.4

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 19.01.2024 – difenoconazole and azoxystrobin in oilseed rape seed:

Difenoconazole

Difenoconazole

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.010	102.8
OSR seed PK1 0,10 mg-kg.lcd	0.11	105.2
OSR seed PK2 0,010 mg-kg.lcd	0.010	103.7
OSR seed PK2 0,10 mg-kg.lcd	0.10	101.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.010	101.2
OSR seed PK1 0,10 mg-kg.lcd	0.10	104.3
OSR seed PK2 0,010 mg-kg.lcd	0.010	104.4
OSR seed PK2 0,10 mg-kg.lcd	0.10	102.4

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 22.02.2024 – triazole metabolites in oilseed rape plant:

triazole-acetic acid (TAA)

Table 22. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.011	105.3
OSR plant PK1 0,10 mg-kg.lcd	0.099	99.3
OSR plant PK2 0,010 mg-kg.lcd	0.0099	99.2
OSR plant PK2 0,10 mg-kg.lcd	0.11	106.5

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 23. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.0086	85.6
OSR plant PK1 0,10 mg-kg.lcd	0.097	96.8
OSR plant PK2 0,010 mg-kg.lcd	0.0070	70.3
OSR plant PK2 0,10 mg-kg.lcd	0.11	106.4

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 24. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.0079	78.7
OSR plant PK1 0,10 mg-kg.lcd	0.078	78.4
OSR plant PK2 0,010 mg-kg.lcd	0.0076	75.7
OSR plant PK2 0,10 mg-kg.lcd	0.087	87.1

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

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

Table 25. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.0087	87.2
OSR plant PK1 0,10 mg-kg.lcd	0.096	95.6
OSR plant PK2 0,010 mg-kg.lcd	0.0084	84.2
OSR plant PK2 0,10 mg-kg.lcd	0.095	95.2

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 22.01.2024 – difenoconazole and azoxystrobin in oilseed rape plant:

Difenoconazole

Table 26. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	104.3
OSR plant PK1 0,10 mg-kg.lcd	0.10	102.4
OSR plant PK2 0,010 mg-kg.lcd	0.010	104.3
OSR plant PK2 0,10 mg-kg.lcd	0.10	104.3

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 27. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	102.5
OSR plant PK1 0,10 mg-kg.lcd	0.11	105.3
OSR plant PK2 0,010 mg-kg.lcd	0.010	101.8
OSR plant PK2 0,10 mg-kg.lcd	0.11	105.9

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 15.02.2024 – difenoconazole and azoxystrobin in oilseed rape plant:

Difenoconazole

Table 28. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	101.2
OSR plant PK1 0,10 mg-kg.lcd	0.10	101.5
OSR plant PK2 0,010 mg-kg.lcd	0.010	99.6
OSR plant PK2 0,10 mg-kg.lcd	0.10	99.6

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 29. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	100.7
OSR plant PK1 0,10 mg-kg.lcd	0.10	102.1
OSR plant PK2 0,010 mg-kg.lcd	0.010	103.6
OSR plant PK2 0,10 mg-kg.lcd	0.10	105.0

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev.2.

The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70 – 120% confirms the active substance stability during the analytical procedure.

19.01.2024 (difenoconazole and azoxystrobin in oilseed rape seed samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 464 minutes (7.7 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

22.01.2024 (difenoconazole and azoxystrobin in oilseed rape plant samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 544 minutes (9.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

15.02.2024 (difenoconazole and azoxystrobin in oilseed rape plant, diluted samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 416 minutes (6.9 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

21.02.2024 (triazole derivative metabolites in oilseed rape seed samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 312 minutes (5.2 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

22.02.2024 (triazole derivative metabolites in oilseed rape plant samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 336 minutes (5.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

CONCLUSIONS

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery. The limit of quantification of the method was established at 0.010 mg/kg for oilseed rape (seeds, whole plants without roots). There were no interfering signals at retention time of analyzed compound in examined control matrix. The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA), difenoconazole and azoxystrobin in oilseed rape (seeds, whole plants without roots) meets the criteria of SANTE/2020/12830, Rev.2 guidelines in terms of precision, accuracy and uncertainty.

Active Substances:	Azoxystrobin, difenoconazole	**Commercial Product:**	CHR/F/SCORPIO 325 SC
Crop / crop group:	Winter Oilseed rape /*Brassicaceae* Burnett, *Cruciferae* Juss	**Producer:**	PUH Chemirol Sp. z o. o.
Responsible for reporting:	Katarzyna Wańczyk SGS Polska Sp. z o. o. Marszowice 19 55-200 Oława Poland		

Country:	France N	**Indoor/outdoor:**	outdoor
Nominal Content of a. s.:	325 g/L	**Other active substance:**	NAP
Formulation:	SC	**Residue calculated for:**	difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T

1	2	3	4	5				6	7	8	9						10	11
				Actual application rate							Residues (1)						DALA or CH (2)	Remarks
Report No. 22SGS54	Commodity Variety	Date of 1-Sowing 2-flowering 3-Harvest	Method of Treatment	L f.p./ha	Water (L/ha)	g azoxystrobin (/ha)	g a difenoconazole (/ha)	Date of Treatment	BBCH at Treatment	Commodity analysed	Triazole-acetic Acid TAA	Triazole-alanine TA	Triazole-lactic Acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin		
France N Auménaucourt (Grand Est) Decline Curve Study Trial 22SGS54-01	Winter OSR CSZ19091	1 – 25/08/2022 2-15/04/2023-20/05/2023 3 – 03/07/2023-10/07/2023	Foliar spray	0,981 1,047	298,3 289,2	196,2 209,4	122,6 130,9	21/11/2022 26/05/2023	19 69	Whole plants w/o roots	<LOD	0.024	<LOD	<LOD	<LOD	<LOD	0	Analytical Method: LC-MS/MS
										Whole plants w/o roots	<LOD	0.036	<LOD	<LOD	3.50*	5.26*	0	
										Whole plants w/o roots	<LOQ	0.070	<LOD	<LOD	1.14*	2,02*	25	
										Whole plants w/o roots	<LOQ	0.052	<LOD	<LOD	0.36*	0.56*	28	
										Seeds	<LOD	0.055	<LOD	<LOD	<LOD	<LOD	45	

										Seeds	<LOD	0.20	<LOD	<LOD	<LOQ	0.020	45	

*-diluted sample;(2) DALA – Days After Last Application; CH – Commercial Harvest; (1) Residues are not corrected for procedural recoveries; Calculation based on unrounded values, **LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)**, **LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)**

A.2.1.3.1.7 Study 7

Comments of zRMS:	One residue field trial (decline study) on oilseed rape was conducted in Germany (n=1) during 2022. Two applications (first at BBCH 15, second at BBCH 69) of CHR/F/SCORPIO 325 SC were performed at the target dose rate of 1,0 L/ha, equivalent to 200 g azoxystrobin and 125 g difenoconazole. Samples were stored frozen for max 9 months prior to analysis. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, in addition the total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in oilseed rape (seed) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.004 mg/kg for each compound. Specimen extraction and determination of residues of difenoconazole and azoxystrobin in oilseed rape (seed) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound. The methods used in the study were fully validated and accepted, see dRR Part B5 (VAL/10/2021 and VAL/22/2023). Procedural recoveries (at the level of LOQ and two at the level 10 x LOQ) were within acceptable range. No residues of TAA, 1,2,4-T and difenoconazole above the LOD of the method were found in mature seeds (BBCH 89). Residues of TA and TLA above the LOQ were found in mature seeds samples taken from treated (0.53 mg/kg, and 0.078 mg/kg respectively) trial plot. The study is accepted. Results supporting the proposed GAP: TAA: 1 x < LOD TA: 1 x 0.53 mg/kg TLA: 1 x 0.078 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x < LOD Azoxystrobin: 1 x < LOD

Reference:	KCA 6.3/01
Report	Magnitude of the azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) residues in Oil Seed Rape (Raw Agricultural Commodity) after two applications of CHR/F/SCORPIO 325 SC – one decline curve study trial in Germany – 2022, Study Number 22SGS55 K. Wańczyk
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue

Trials, July 22, 1997

OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021)

SANTE/2020/12830 Rev.2, 14 February 2023

Deviations:	No
GLP:	Yes
Acceptability:	Yes

The following residues concentration was determined in the field samples analyzed on 19.01.2024 (difenoconazole, azoxystrobin in seeds samples), 22.01.2024 (difenoconazole, azoxystrobin in plant samples), 15.02.2024 (difenoconazole, azoxystrobin in plant, diluted samples), 21.02.2024 (triazole metabolites in seeds samples) and 22.02.2024 (triazole metabolites in plant samples)

Table 15. Residue concentrations of difenoconazole, azoxystrobin and triazole derivative metabolites detected in analyzed field samples (Study No.: 22SGS55, Trial No.: 22SGS55-01 – Decline Study)

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]					
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1,2,4-triazole 1,2,4-T	Difenoconazole	Azoxystrobin
1	-0/0 DALA	22SGS55-01 1	oilseed rape (whole plants without roots)	DPL/107/2023/01U	<LOD	0.054	<LOD	<LOD	<LOQ	<LOD
2		22SGS55-01 2	oilseed rape (whole plants without roots)	DPL/107/2023/02T	<LOD	0.037	<LOD	<LOD	1.44*	2.18*
3	14 DALA	22SGS55-01 3	oilseed rape (whole plants without roots)	DPL/107/2023/03T	<LOD	0.082	<LOD	<LOD	0.24*	0.088*
4	21 DALA	22SGS55-01 4	oilseed rape (whole plants without roots)	DPL/107/2023/04T	<LOD	0.081	<LOD	<LOD	0.12	0.037
5	28 DALA	22SGS55-01 5	oilseed rape (whole plants without roots)	DPL/107/2023/05T	<LOD	0.13	<LOD	<LOD	0.093	0.038
6	BBCH 89/CH	22SGS55-01 6	oilseed rape (seeds)	DPL/107/2023/06U	<LOD	0.47	0.050	<LOD	<LOD	<LOD
7		22SGS55-01 7	oilseed rape (seeds)	DPL/107/2023/07T	<LOD	0.53	0.078	<LOD	<LOD	<LOD

*- diluted samples
CH – Commercial Harvest; DALA – Days After Last Application
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

The objective of the study was to determine the residue level of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T in winter oilseed rape RAC specimens in one decline curve study trial following two applications of the formulated product CHR/F/SCORPIO 325 SC under cultural practice typical for winter oilseed rape production.

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

Procedural recoveries were handled and stored in the same way and for the same time period as the

samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.

Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10 x LOQ per analytical set of respective matrix were analyzed during each of the sequence.

Analysis of samples 21.02.2024 – triazole metabolites in oilseed rape seed

triazole-acetic acid (TAA)

Table 16. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0097	97.4
OSR seed PK1 0,10 mg-kg.lcd	0.098	98.2
OSR seed PK2 0,010 mg-kg.lcd	0.0099	98.8
OSR seed PK2 0,10 mg-kg.lcd	0.098	98.2

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.012	115.9
OSR seed PK1 0,10 mg-kg.lcd	0.11	106.8
OSR seed PK2 0,010 mg-kg.lcd	0.0098	98.3
OSR seed PK2 0,10 mg-kg.lcd	0.088	87.7

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0080	80.3
OSR seed PK1 0,10 mg-kg.lcd	0.082	81.6
OSR seed PK2 0,010 mg-kg.lcd	0.0079	79.0
OSR seed PK2 0,10 mg-kg.lcd	0.072	72.5

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

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

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0083	83.0
OSR seed PK1 0,10 mg-kg.lcd	0.092	92.1
OSR seed PK2 0,010 mg-kg.lcd	0.0083	83.4
OSR seed PK2 0,10 mg-kg.lcd	0.093	93.4

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 19.01.2024 – difenoconazole and azoxystrobin in oilseed rape seed:

Difenoconazole

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.010	102.8
OSR seed PK1 0,10 mg-kg.lcd	0.11	105.2
OSR seed PK2 0,010 mg-kg.lcd	0.010	103.7
OSR seed PK2 0,10 mg-kg.lcd	0.10	101.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.010	101.2
OSR seed PK1 0,10 mg-kg.lcd	0.10	104.3
OSR seed PK2 0,010 mg-kg.lcd	0.010	104.4
OSR seed PK2 0,10 mg-kg.lcd	0.10	102.4

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 22.02.2024 – triazole metabolites in oilseed rape plant:

triazole-acetic acid (TAA)

Table 22. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.011	105.3
OSR plant PK1 0,10 mg-kg.lcd	0.099	99.3
OSR plant PK2 0,010 mg-kg.lcd	0.0099	99.2
OSR plant PK2 0,10 mg-kg.lcd	0.11	106.5

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 23. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.0086	85.6
OSR plant PK1 0,10 mg-kg.lcd	0.097	96.8
OSR plant PK2 0,010 mg-kg.lcd	0.0070	70.3
OSR plant PK2 0,10 mg-kg.lcd	0.11	106.4

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 24. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.0079	78.7
OSR plant PK1 0,10 mg-kg.lcd	0.078	78.4
OSR plant PK2 0,010 mg-kg.lcd	0.0076	75.7
OSR plant PK2 0,10 mg-kg.lcd	0.087	87.1

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

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

Table 25. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.0087	87.2
OSR plant PK1 0,10 mg-kg.lcd	0.096	95.6
OSR plant PK2 0,010 mg-kg.lcd	0.0084	84.2
OSR plant PK2 0,10 mg-kg.lcd	0.095	95.2

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 22.01.2024 – difenoconazole and azoxystrobin in oilseed rape plant:

Difenoconazole

Table 26. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	104.3
OSR plant PK1 0,10 mg-kg.lcd	0.10	102.4
OSR plant PK2 0,010 mg-kg.lcd	0.010	104.3
OSR plant PK2 0,10 mg-kg.lcd	0.10	104.3

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 27. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	102.5
OSR plant PK1 0,10 mg-kg.lcd	0.11	105.3
OSR plant PK2 0,010 mg-kg.lcd	0.010	101.8
OSR plant PK2 0,10 mg-kg.lcd	0.11	105.9

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 15.02.2024 – difenoconazole and azoxystrobin in oilseed rape plant:

Difenoconazole

Table 28. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	101.2
OSR plant PK1 0,10 mg-kg.lcd	0.10	101.5
OSR plant PK2 0,010 mg-kg.lcd	0.010	99.6
OSR plant PK2 0,10 mg-kg.lcd	0.10	99.6

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 29. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	100.7
OSR plant PK1 0,10 mg-kg.lcd	0.10	102.1
OSR plant PK2 0,010 mg-kg.lcd	0.010	103.6
OSR plant PK2 0,10 mg-kg.lcd	0.10	105.0

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev.2.

The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70 – 120% confirms the active substance stability during the analytical procedure.

19.01.2024 (difenoconazole and azoxystrobin in oilseed rape seed samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 464 minutes (7.7 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

22.01.2024 (difenoconazole and azoxystrobin in oilseed rape plant samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 544 minutes (9.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

15.02.2024 (difenoconazole and azoxystrobin in oilseed rape plant, diluted samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 416 minutes (6.9 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

21.02.2024 (triazole derivative metabolites in oilseed rape seed samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 312 minutes (5.2 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

22.02.2024 (triazole derivative metabolites in oilseed rape plant samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 336 minutes (5.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

CONCLUSIONS

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for oilseed rape (seeds, whole plants without roots).

There were no interfering signals at retention time of analyzed compound in examined control matrix.

The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA), difenoconazole and azoxystrobin in oilseed rape (seeds, whole plants without roots) meets the criteria of SANTE/2020/12830, Rev.2 guidelines in terms of precision, accuracy and uncertainty.

Active Substances:	Azoxystrobin, difenoconazole	**Commercial Product:**	CHR/F/SCORPIO 325 SC
Crop / crop group:	Winter Oilseed rape /*Brassicaceae* Burnett, *Cruciferae* Juss	**Producer:**	PUH Chemirol Sp. z o. o.
Responsible for reporting:	Katarzyna Wańczyk SGS Polska Sp. z o. o. Marszowice 19 55-200 Oława Poland		
Country:	Germany	**Indoor/outdoor:**	outdoor
Nominal Content of a. s.:	325 g/L	**Other active substance:**	NAP
Formulation:	SC	**Residue calculated for:**	difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T

1	2	3	4	5				6	7	8	9						10	11
				Actual application rate							Residues (1)						DALA or CH (2)	Remarks
Report No. 22SGS55	Commodity Variety	Date of 1-Sowing 2-flowering 3-Harvest	Method of Treatment	L f.p./ha	Water (L/ha)	g azoxystrobin (/ha)	g a difenoconazole (/ha)	Date of Treatment	BBCH at Treatment	Commodity analysed	Triazole-acetic Acid TAA	Triazole-alanine TA	Triazole-lactic Acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin		
Germany Bahlingen (Oberrhein) Decline Curve Study Trial 22SGS55-01	Winter OSR RGT Cadran	1 – 20/09/2022 2- 14/04/2023- 06/05/2023 3 – 06/07/2023- 13/07/2023	Foliar spray	0,967 0,978	290,0 293,3	193,4 195,6	120,9 122,3	07/12/2022 03/05/2023	15 69	Whole plants w/o roots	<LOD	0.054	<LOD	<LOD	<LOQ	<LOD	0	Analytical Method: LC-MS/MS
										Whole plants w/o roots	<LOD	0.037	<LOD	<LOD	1,44*	2.18*	0	
										Whole plants w/o roots	<LOD	0.082	<LOD	<LOD	0.24*	0.088*	14	
										Whole plants w/o roots	<LOD	0.081	<LOD	<LOD	0.12	0.037	21	
										Whole	<LOD	0.13	<LOD	<LOD	0.093	0.038	28	

										plants w/o roots								
										Seeds	<LOD	0.47	0.050	<LOD	<LOD	<LOD	70	
										Seeds	<LOD	0.53	0.078	<LOD	<LOD	<LOD	70	

*-diluted sample;
(2) DALA – Days After Last Application; CH – Commercial Harvest;
(1) Residues are not corrected for procedural recoveries; Calculation based on unrounded values,
LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

A.2.1.3.1.8 Study 8

Comments of zRMS:	One residue field trial on sugar beet was conducted in Poland (n=1) during 2023. One application (at BBCH 49) of CHR/F/SCORPIO 325 SC were performed at the target dose rate of 1,3 L/ha, equivalent to 260 g azoxystrobin and 163 g difenoconazole. Samples were stored frozen for max 3 months prior to analysis. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, in addition the total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in sugar beet (leaves, roots) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound. Specimen extraction and determination of residues of difenoconazole and azoxystrobin in sugar beet (leaves, roots) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.001 mg/kg for each compound. The methods used in the study were fully validated and accepted, see dRR Part B5 (VAL/21/2023 and VAL/22/2023). Procedural recoveries (at the level of LOQ and two at the level 10 x LOQ) were within acceptable range. No residues of TAA, TLA, 1,2,4-T and azoxystrobin above the LOQ of the method were found in roots. Residues of TA and difenoconazole above the LOQ were found in roots samples taken from treated trial plot (0.028 mg/kg, and 0.019 mg/kg respectively). The study is accepted. Results supporting the proposed GAP (DALA 35): Roots: TAA: 1 x < LOD TA: 1 x 0.028 mg/kg TLA: 1 x < LOQ 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x 0.019 mg/kg Azoxystrobin: 1 x < LOQ Leaves: TAA: 1 x < LOQ TA: 1 x 0.029 mg/kg TLA: 1 x 0.083 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x 0.071 mg/kg Azoxystrobin: 1 x 0.054 mg/kg

Reference:	KCA 6.3/01
Report	Magnitude of residue of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T in sugar beet (Raw Agricultural Commodity) after one application of CHR/F/SCORPIO 325 SC – one harvest study trial in Poland - 2023 Study Number 23SGS01 T.~~Penda~~ Peda

Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021) SANTE/2020/12830 Rev.2, 14 February 2023
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue level of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T in sugar beet RAC specimens in one harvest study trial following one application of the formulated product CHR/F/SCORPIO 325 SC under cultural practice typical for sugar beet production.

Residues concentration detected in analysed field samples:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]					
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin
1	35(±1) DALA/CH	23SGS01-01 1	sugar beet (leaves with tops)	DPL/95/2023/01U	<LOQ	0.041	0.040	<LOD	<LOD	<LOD
2		23SGS01-01 2	sugar beet (roots)	DPL/95/2023/02U	<LOD	0.026	<LOQ	<LOD	<LOD	<LOD
3		23SGS01-01 3	sugar beet (leaves with tops)	DPL/95/2023/03T	<LOQ	0.029	0.083	<LOD	0.071	0.054
4		23SGS01-01 4	sugar beet (roots)	DPL/95/2023/04T	<LOD	0.028	<LOQ	<LOD	0.019	<LOQ

DALA – Days After Last Application; CH – Commercial Harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreates test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

Procedural recorveries were handled and stored In the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortitication samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.

Sample blank matrix, two procedural recoveries at the level of LOQ and the two at level 10x LOQ per analytical set of respective matrix were analyzed during each of sequence.

Analysis samples 15.12.2023 – triazole metabolites in sugar beet roots:

triazole-acetic acid (TAA)

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0092	91.7
sugar beet root PK1 0,10 mg-kg.lcd	0.10	100.9
sugar beet root PK2 0,010 mg-kg.lcd	0.0096	96.0
sugar beet root PK2 0,10 mg-kg.lcd	0.091	91.3

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

triazole-alanine (TA)

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0074	73.7
sugar beet root PK1 0,10 mg-kg.lcd	0.088	87.8
sugar beet root PK2 0,010 mg-kg.lcd	0.0087	86.9
sugar beet root PK2 0,10 mg-kg.lcd	0.084	83.9

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

triazole-lactic acid (TLA)

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0086	86.2
sugar beet root PK1 0,10 mg-kg.lcd	0.097	97.3
sugar beet root PK2 0,010 mg-kg.lcd	0.0092	92.1
sugar beet root PK2 0,10 mg-kg.lcd	0.087	87.4

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

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

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

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0095	95.1
sugar beet root PK1 0,10 mg-kg.lcd	0.10	100.3
sugar beet root PK2 0,010 mg-kg.lcd	0.011	107.3
sugar beet root PK2 0,10 mg-kg.lcd	0.091	91.2

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 15.12.2023 – difenoconazole and azoxystrobin in sugar beet roots

Difenoconazole

Difenoconazole

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0098	98.3
sugar beet root PK1 0,10 mg-kg.lcd	0.10	103.0
sugar beet root PK2 0,010 mg-kg.lcd	0.010	103.2
sugar beet root PK2 0,10 mg-kg.lcd	0.10	101.1

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Azoxystrobin

Table 22. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.010	103.2
sugar beet root PK1 0,10 mg-kg.lcd	0.10	102.0
sugar beet root PK2 0,010 mg-kg.lcd	0.0096	95.6
sugar beet root PK2 0,10 mg-kg.lcd	0.096	96.3

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 18.12.2023 – difenoconazole and azoxystrobin in sugar beet leaves

triazole-acetic acid (TAA)

triazole-acetic acid (TAA)

Table 23. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.011	111.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	104.7
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	104.8
sugar beet leaves PK2 0,10 mg-kg.lcd	0.100	100.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

triazole-alanine (TA)

Table 24. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.011	112.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.11	107.0
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	112.7
sugar beet leaves PK2 0,10 mg-kg.lcd	0.098	98.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

triazole-lactic acid (TLA)

Table 25. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.012	117.8
sugar beet leaves PK1 0,10 mg-kg.lcd	0.11	111.9
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	108.6
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	102.5

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

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

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

Table 26. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	104.8
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	104.9
sugar beet leaves PK2 0,010 mg-kg.lcd	0.0096	96.3
sugar beet leaves PK2 0,10 mg-kg.lcd	0.094	94.3

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 12.12.2023 – difenoconazole and azoxystrobin in sugar beet leaves:

Difenoconazole

Difenoconazole

Table 27. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	100.2
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	101.7
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	97.8

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Azoxystrobin

Table 28. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.3
sugar beet leaves PK1 0,10 mg-kg.lcd	0.099	98.7
sugar beet leaves PK2 0,010 mg-kg.lcd	0.0099	99.2
sugar beet leaves PK2 0,10 mg-kg.lcd	0.11	107.5

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev.2.

The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70 – 120% confirms the active substance stability during the analytical procedure.

15.12.2023 (difenoconazole and azoxystrobin in sugar beet roots samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 496 minutes (8.3 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

15.12.2023 (triazole derivative metabolites in sugar beet roots samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 312 minutes (5.2 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day

18.12.2023 (difenoconazole and azoxystrobin in sugar beet leaves samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 784 minutes (13.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

18.12.2023 (triazole derivative metabolites in sugar beet leaves samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 456 minutes (7.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

CONCLUSIONS

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for leaves with tops and roots.

There were no interfering signals at retention time of analyzed compound in examined control matrix.

The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA), difenoconazole and azoxystrobin in sugar beet (leaves with tops and roots) meets the criteria of SANTE/2020/12830, Rev.2 guidelines in terms of precision, accuracy and uncertainty.

Active Substances: Azoxystrobin, difenoconazole
Crop / crop group: Sugar beet / Root crops
Responsible for reporting: Tomasz Peda
SGS Polska Sp. z o. o.
ul. Poznańska 305B
05-850 Ołtarzew
Poland

Commercial Product: CHR/F/SCORPIO 325 SC
Producer: PUH Chemirol Sp. z o. o.

Country: Poland
Nominal Content of a. s.: 325 g/L
Formulation: SC

Indoor/outdoor: outdoor
Other active substance: NAP
Residue calculated for: difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T

1	2	3	4	5				6	7	8	9						10	11
				Actual application rate							Residues (1)						DALA or CH (2)	Remarks
Report No. 23SGS01	Commodity Variety	Date of 1-Sowing 2-Harvest	Method of Treatment	L a.s./ha	Water (L/ha)	g azoxystrobin (/ha)	g a difenoconazole (/ha)	Date of Treatment	BBCH at Treatment	Commodity analysed	Triazole-acetic Acid TAA	Triazole-alanine TA	Triazole-lactic Acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin		
Poland Cerekwica (Kujawsko-Pomorskie) Harvest Study Trial 23SGS01-01	Sugar beet Hubble	1 – 16/04/23 2 – 25/09/23	Foliar spray	1,247	293,3	249	163	21/08/2023	49	Leaves with tops Roots	<LOQ <LOD	0.029 0.028	0.083 <LOQ	<LOD <LOD	0.071 0.019	0.054 <LOQ	35	Analytical Method: LC-MS/MS

DALA – Days After Last Application; CH – Commercial Harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites), LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

A.2.1.3.1.9 Study 9

Comments of zRMS:	One residue field trial on sugar beet was conducted in Hungary (n=1) during 2023. One application (at BBCH 49) of CHR/F/SCORPIO 325 SC were performed at the target dose rate of 1,3 L/ha, equivalent to 260 g azoxystrobin and 163 g difenoconazole. Samples were stored frozen for max 3 months prior to analysis. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, in addition the total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in sugar beet (leaves, roots) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound. Specimen extraction and determination of residues of difenoconazole and azoxystrobin in sugar beet (leaves, roots) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.001 mg/kg for each compound. The methods used in the study were fully validated and accepted, see dRR Part B5 (VAL/21/2023 and VAL/22/2023). Procedural recoveries (at the level of LOQ and two at the level 10 x LOQ) were within acceptable range. No residues of TAA, TLA, 1,2,4-T, difenoconazole and azoxystrobin above the LOQ of the method were found in roots. Residues of TA above the LOQ were found in roots samples taken from treated trial plot (0.011 mg/kg). The study is accepted. Results supporting the proposed GAP (DALA 35): Roots: TAA: 1 x < LOD TA: 1 x 0.011 mg/kg TLA: 1 x < LOD 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x < LOD Azoxystrobin: 1 x < LOQ Leaves: TAA: 1 x < LOQ TA: 1 x 0.025 mg/kg TLA: 1 x 0.012 mg/kg 1,2,4 -T: 1 x < LOQ Difenoconazole: 1 x < LOQ Azoxystrobin: 1 x 0.012 mg/kg

Reference:	KCA 6.3/01
Report	Magnitude of residue of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4 T in sugar beet (Raw Agricultural Commodity) after one application of CHR/F/SCORPIO 325 SC – one harvest study trial in Hungary - 2023 Study Number 23SGS02 T.~~Penda~~ Peda

Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021) SANTE/2020/12830 Rev.2, 14 February 2023
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue of difenoconazole, azoxystrobin and Triazole Derivative Metabolites (triazole alanine, triazole acetic acid, triazole lactic acid and 1,2,4-triazole) in sugar beet RAC (leaves with tops and roots), following one application of CHR/F/SCORPIO 325 SC.
Residues concentration detected in analysed field samples:

Residues concentration detected in analysed field samples:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]					
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin
1	35(±1) DALA/CH	23SGS02-01 1	sugar beet (leaves with tops)	DPL/86/2023/01U	<LOD	<LOQ	<LOQ	<LOD	<LOD	<LOD
2		23SGS02-01 2	sugar beet (roots)	DPL/86/2023/02U	<LOD	<LOQ	<LOD	<LOD	<LOD	<LOD
3		23SGS02-01 3	sugar beet (leaves with tops)	DPL/86/2023/03T	<LOQ	0.025	0.012	<LOQ	<LOQ	0.012
4		23SGS02-01 4	sugar beet (roots)	DPL/86/2023/04T	<LOD	0.011	<LOD	<LOD	<LOD	<LOD

DALA – Days After Last Application; CH – Commercial Harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow. Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10 x LOQ per analytical set of respective matrix were analyzed during each of the sequence.

SUGAR BEET ROOTS

Analysis of samples 15.12.2023 – triazole metabolites in sugar beet roots:

triazole-acetic acid (TAA)

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0092	91.7
sugar beet root PK1 0,10 mg-kg.lcd	0.10	100.9
sugar beet root PK2 0,010 mg-kg.lcd	0.0096	96.0
sugar beet root PK2 0,10 mg-kg.lcd	0.091	91.3

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0074	73.7
sugar beet root PK1 0,10 mg-kg.lcd	0.088	87.8
sugar beet root PK2 0,010 mg-kg.lcd	0.0087	86.9
sugar beet root PK2 0,10 mg-kg.lcd	0.084	83.9

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0086	86.2
sugar beet root PK1 0,10 mg-kg.lcd	0.097	97.3
sugar beet root PK2 0,010 mg-kg.lcd	0.0092	92.1
sugar beet root PK2 0,10 mg-kg.lcd	0.087	87.4

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

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

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0095	95.1
sugar beet root PK1 0,10 mg-kg.lcd	0.10	100.3
sugar beet root PK2 0,010 mg-kg.lcd	0.011	107.3
sugar beet root PK2 0,10 mg-kg.lcd	0.091	91.2

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 15.12.2023 – difenoconazole and azoxystrobin in sugar beet roots:

Difenoconazole

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0098	98.3
sugar beet root PK1 0,10 mg-kg.lcd	0.10	103.0
sugar beet root PK2 0,010 mg-kg.lcd	0.010	103.2
sugar beet root PK2 0,10 mg-kg.lcd	0.10	101.1

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 22. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.010	103.2
sugar beet root PK1 0,10 mg-kg.lcd	0.10	102.0
sugar beet root PK2 0,010 mg-kg.lcd	0.0096	95.6
sugar beet root PK2 0,10 mg-kg.lcd	0.096	96.3

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

SUGAR BEET LEAVES

Analysis of samples 18.12.2023 – triazole metabolites in sugar beet leaves:

triazole-acetic acid (TAA)

Table 23. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.011	111.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	104.7
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	104.8
sugar beet leaves PK2 0,10 mg-kg.lcd	0.100	100.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 24. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.011	112.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.11	107.0
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	112.7
sugar beet leaves PK2 0,10 mg-kg.lcd	0.098	98.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 25. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.012	117.8
sugar beet leaves PK1 0,10 mg-kg.lcd	0.11	111.9
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	108.6
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	102.5

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

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

Table 26. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	104.8
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	104.9
sugar beet leaves PK2 0,010 mg-kg.lcd	0.0096	96.3
sugar beet leaves PK2 0,10 mg-kg.lcd	0.094	94.3

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 18.12.2023 – difenoconazole and azoxystrobin in sugar beet leaves:

Difenoconazole

Table 27. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	100.2
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	101.7
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	97.8

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 28. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.3
sugar beet leaves PK1 0,10 mg-kg.lcd	0.099	98.7
sugar beet leaves PK2 0,010 mg-kg.lcd	0.0099	99.2
sugar beet leaves PK2 0,10 mg-kg.lcd	0.11	107.5

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev.2.

The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70 – 120% confirms the active substance stability during the analytical procedure.

15.12.2023 (difenoconazole and azoxystrobin in sugar beet roots samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 496 minutes (8.3 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

15.12.2023 (triazole derivative metabolites in sugar beet roots samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 312 minutes (5.2 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day

18.12.2023 (difenoconazole and azoxystrobin in sugar beet leaves samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 784 minutes (13.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

18.12.2023 (triazole derivative metabolites in sugar beet leaves samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 456 minutes (7.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

19.12.2023 (difenoconazole and azoxystrobin in sugar beet leaves - diluted samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 448 minutes (7.5 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

CONCLUSIONS

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for leaves with tops and roots.

There were no interfering signals at retention time of analyzed compound in examined control matrix.

The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA), difenoconazole and azoxystrobin in sugar beet (leaves with tops and roots) meets the criteria of SANTE/2020/12830, Rev.2 guidelines in terms of precision, accuracy and uncertainty.

Active Substances:	Azoxystrobin, difenoconazole	**Commercial Product:**	CHR/F/SCORPIO 325 SC
Crop / crop group:	Sugar beet / Root crops	**Producer:**	PUH Chemirol Sp. z o. o.
Responsible for reporting:	Tomasz Peda		

SGS Polska Sp. z o. o.
ul. Poznańska 305B
05-850 Ołtarzew
Poland

Country:	Hungary	**Indoor/outdoor:**	outdoor
Nominal Content of a. s.:	325 g/L	**Other active substance:**	NAP
Formulation:	SC	**Residue calculated for:**	difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T

1	2	3	4	5				6	7	8	9						10	11
				Actual application rate							Residues (1)						DALA or CH (2)	Remarks
Report No. 23SGS02	Commodity Variety	Date of 1-Sowing 2-Harvest	Method of Treatment	L a.s./ha	Water (L/ha)	g azoxystrobin (/ha)	g a difenoconazole (/ha)	Date of Treatment	BBCH at Treatment	Commodity analysed	Triazole-acetic Acid TAA	Triazole-alanine TA	Triazole-lactic Acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin		
Hungary Hajdúnánás (Hajdú-Bihar) Harvest Study Trial 23SGS02-01	Sugar beet Gazeta	1 – 20/04/23 2 – 22/09/23	Foliar spray	1,314	303,3	263	165	18/08/2023	49	Leaves with tops Roots	<LOQ <LOD	0.025 0.011	0.012 <LOD	<LOQ <LOD	<LOQ <LOD	0.012 <LOQ	35	Analytical Method: LC-MS/MS

DALA – Days After Last Application; CH – Commercial Harvest
Residues are not corrected for procedural recoveries; Calculation based on unrounded values, **LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites), LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin**

A.2.1.3.1.10 Study 10

Comments of zRMS:	One residue field trial on sugar beet was conducted in Germany (n=1) during 2023. One application (at BBCH 49) of CHR/F/SCORPIO 325 SC were performed at the target dose rate of 1,3 L/ha, equivalent to 260 g azoxystrobin and 163 g difenoconazole. Samples were stored frozen for max 3 months prior to analysis. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, in addition the total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in sugar beet (leaves, roots) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound. Specimen extraction and determination of residues of difenoconazole and azoxystrobin in sugar beet (leaves, roots) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.001 mg/kg for each compound. The methods used in the study were fully validated and accepted, see dRR Part B5 (VAL/21/2023 and VAL/22/2023). Procedural recoveries (at the level of LOQ and two at the level 10 x LOQ) were within acceptable range. No residues of TAA, TLA, 1,2,4-T, TA, difenoconazole and azoxystrobin above the LOQ of the method were found in roots. The study is accepted. Results supporting the proposed GAP (DALA 36): Roots: TAA: 1 x < LOD TA: 1 x < LOQ TLA: 1 x < LOD 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x < LOQ Azoxystrobin: 1 x < LOQ Leaves: TAA: 1 x < LOQ TA: 1 x < LOQ TLA: 1 x 0.012 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x 0.064 mg/kg Azoxystrobin: 1 x 0.043 mg/kg

Reference:	KCA 6.3/01
Report	Magnitude of residue of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T in sugar beet (Raw Agricultural Commodity) after one application of CHR/F/SCORPIO 325 SC – one harvest study trial in Germany - 2023 Study Number 23SGS04 T.~~Penda~~ Peda

Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021) SANTE/2020/12830 Rev.2, 14 February 2023
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue of difenoconazole, azoxystrobin and Triazole Derivative Metabolites (triazole alanine, triazole acetic acid, triazole lactic acid and 1,2,4-triazole) in sugar beet (leaves with tops and roots), following one application of CHR/F/SCORPIO 325 SC.

Residues concentration detected in analysed field samples:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]					
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin
1	35(±1) DALA/CH	23SGS04-01 1	sugar beet (leaves with tops)	DPL/100/2023/01U	<LOD	<LOQ	<LOQ	<LOD	<LOD	<LOD
2		23SGS04-01 2	sugar beet (roots)	DPL/100/2023/02U	<LOD	<LOQ	<LOD	<LOD	<LOD	<LOD
3		23SGS04-01 3	sugar beet (leaves with tops)	DPL/100/2023/03T	<LOQ	<LOQ	0.012	<LOD	0.064	0.043
4		23SGS04-01 4	sugar beet (roots)	DPL/100/2023/04T	<LOD	<LOQ	<LOD	<LOD	<LOQ	<LOQ

DALA – Days After Last Application; CH – Commercial Harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.

Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10 x LOQ per analytical set of respective matrix were analyzed during each of the sequence.

SUGAR BEET ROOTS

Analysis of samples 16.12.2023 – triazole metabolites in sugar beet roots:

triazole-acetic acid (TAA)

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0091	91.3
sugar beet root PK1 0,10 mg-kg.lcd	0.094	93.6
sugar beet root PK2 0,010 mg-kg.lcd	0.0090	90.0
sugar beet root PK2 0,10 mg-kg.lcd	0.10	100.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0078	78.0
sugar beet root PK1 0,10 mg-kg.lcd	0.092	92.0
sugar beet root PK2 0,010 mg-kg.lcd	0.0080	79.7
sugar beet root PK2 0,10 mg-kg.lcd	0.095	95.5

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0087	87.4
sugar beet root PK1 0,10 mg-kg.lcd	0.092	91.8
sugar beet root PK2 0,010 mg-kg.lcd	0.0086	86.2
sugar beet root PK2 0,10 mg-kg.lcd	0.099	98.8

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

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

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0089	88.9
sugar beet root PK1 0,10 mg-kg.lcd	0.093	93.3
sugar beet root PK2 0,010 mg-kg.lcd	0.0091	90.7
sugar beet root PK2 0,10 mg-kg.lcd	0.10	100.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 16.12.2023 – difenoconazole and azoxystrobin in sugar beet roots:

Difenoconazole

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.010	100.4
sugar beet root PK1 0,10 mg-kg.lcd	0.10	103.4
sugar beet root PK2 0,010 mg-kg.lcd	0.010	102.4
sugar beet root PK2 0,10 mg-kg.lcd	0.097	97.3

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 22. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.011	108.0
sugar beet root PK1 0,10 mg-kg.lcd	0.11	110.0
sugar beet root PK2 0,010 mg-kg.lcd	0.010	104.6
sugar beet root PK2 0,10 mg-kg.lcd	0.10	102.4

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

SUGAR BEET LEAVES

Analysis of samples 18.12.2023 – triazole metabolites in sugar beet leaves:

triazole-acetic acid (TAA)

Table 23. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.011	111.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	104.7
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	104.8
sugar beet leaves PK2 0,10 mg-kg.lcd	0.100	100.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 24. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.011	112.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.11	107.0
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	112.7
sugar beet leaves PK2 0,10 mg-kg.lcd	0.098	98.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 25. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.012	117.8
sugar beet leaves PK1 0,10 mg-kg.lcd	0.11	111.9
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	108.6
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	102.5

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

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

Table 26. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	104.8
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	104.9
sugar beet leaves PK2 0,010 mg-kg.lcd	0.0096	96.3
sugar beet leaves PK2 0,10 mg-kg.lcd	0.094	94.3

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 18.12.2023 – difenoconazole and azoxystrobin in sugar beet leaves:

Difenoconazole

Table 27. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	100.2
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	101.7
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	97.8

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 28. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.3
sugar beet leaves PK1 0,10 mg-kg.lcd	0.099	98.7
sugar beet leaves PK2 0,010 mg-kg.lcd	0.0099	99.2
sugar beet leaves PK2 0,10 mg-kg.lcd	0.11	107.5

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev.2.

The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70 – 120% confirms the active substance stability during the analytical procedure.

16.12.2023 (difenoconazole and azoxystrobin in sugar beet roots samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 496 minutes (8.3 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

16.12.2023 (triazole derivative metabolites in sugar beet roots samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 312 minutes (5.2 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day

18.12.2023 (difenoconazole and azoxystrobin in sugar beet leaves samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 784 minutes (13.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

18.12.2023 (triazole derivative metabolites in sugar beet leaves samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 456 minutes (7.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

CONCLUSIONS

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for leaves with tops and roots.

There were no interfering signals at retention time of analyzed compound in examined control matrix.

The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA), difenoconazole and azoxystrobin in sugar beet (leaves with tops and roots) meets the criteria of SANTE/2020/12830, Rev.2 guidelines in terms of precision, accuracy and uncertainty.

Active Substances:	Azoxystrobin, difenoconazole	**Commercial Product:**	CHR/F/SCORPIO 325 SC
Crop / crop group:	Sugar beet / Root crops	**Producer:**	PUH Chemirol Sp. z o. o.
Responsible for reporting:	Tomasz Peda		
SGS Polska Sp. z o. o. ul. Poznańska 305B 05-850 Ołtarzew Poland			
Country:	Germany	**Indoor/outdoor:**	outdoor
Nominal Content of a. s.:	325 g/L	**Other active substance:**	NAP
Formulation:	SC	**Residue calculated for:**	difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T

1	2	3	4	5				6	7	8	9						10	11
				Actual application rate							Residues (1)						DALA or CH (2)	Remarks
Report No. 23SGS04	Commodity Variety	Date of 1-Sowing 2-Harvest	Method of Treatment	L a.s./ha	Water (L/ha)	g azoxystrobin (/ha)	g a difenoconazole (/ha)	Date of Treatment	BBCH at Treatment	Commodity analysed	Triazole-acetic Acid TAA	Triazole-alanine TA	Triazole-lactic Acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin		
Germany Höltinghausen (Lower Saxony) Harvest Study Trial 23SGS04-01	Sugar beet Annelaura	1 – 27/04/23 2 – 07/09/23	Foliar spray	1,307	301,7	261	164	02/08/2023	49	Leaves with tops Roots	<LOQ <LOD	<LOQ <LOQ	0.012 <LOD	<LOD <LOD	0.064 <LOQ	0.043 <LOQ	36	Analytical Method: LC-MS/MS

DALA – Days After Last Application; CH – Commercial Harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values, **LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites), LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)**

A.2.1.3.1.11 Study 11

Comments of zRMS:	One residue field trial (decline study) on sugar beet was conducted in Poland (n=1) during 2023. One application (at BBCH 49) of CHR/F/SCORPIO 325 SC were performed at the target dose rate of 1,3 L/ha, equivalent to 260 g azoxystrobin and 163 g difenoconazole. Samples were stored frozen for max 6 months prior to analysis. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, in addition the total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in sugar beet (leaves, roots) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound. Specimen extraction and determination of residues of difenoconazole and azoxystrobin in sugar beet (leaves, roots) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.001 mg/kg for each compound. The methods used in the study were fully validated and accepted, see dRR Part B5 (VAL/21/2023 and VAL/22/2023). Procedural recoveries (at the level of LOQ and two at the level 10 x LOQ) were within acceptable range. No residues of TAA, TA, TLA, 1,2,4-T and azoxystrobin above the LOQ of the method were found in roots. Residues of difenoconazole above the LOQ were found in roots samples taken from treated trial plot (0.013 mg/kg). The study is accepted. Results supporting the proposed GAP (DALA 35): Roots: TAA: 1 x < LOD TA: 1 x < LOQ TLA: 1 x < LOQ 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x 0.013 mg/kg Azoxystrobin: 1 x < LOQ Leaves: TAA: 1 x < LOQ TA: 1 x 0.016 mg/kg TLA: 1 x 0.011 mg/kg 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x 0.12 mg/kg Azoxystrobin: 1 x 0.082 mg/kg

Reference:	KCA 6.3/01
Report	Magnitude of residue of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T in sugar beet (Raw Agricultural Commodity) after one application of CHR/F/SCORPIO 325 SC – one decline curve study trial in Poland - 2023 Study Number 23SGS05

T.~~Penda~~ Peda

Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021) SANTE/2020/12830 Rev.2, 14 February 2023
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue of difenoconazole, azoxystrobin and Triazole Derivative Metabolites (triazole alanine, triazole acetic acid, triazole lactic acid and 1,2,4-triazole) in sugar beet RAC (leaves with tops and roots), following one application of CHR/F/SCORPIO 325 SC.

The following residues concentration was determined in the field samples analyzed on 15.12.2023 (difenoconazole, azoxystrobin and triazole metabolites in sugar beet roots samples), 18.12.2023 (difenoconazole, azoxystrobin and triazole metabolites in sugar beet leaves samples) and 19.12.2023 (difenoconazole and azoxystrobin in sugar beet leaves – diluted samples):

Residues concentration detected in analysed field samples:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]					
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin
1	0 DALA	23SGS05-01 1	sugar beet (leaves with tops)	DPL/96/2023/01U	<LOD	<LOQ	<LOQ	<LOD	<LOD	<LOD
2		23SGS05-01 2	sugar beet (roots)	DPL/96/2023/02U	<LOD	<LOQ	<LOD	<LOD	<LOD	<LOD
3		23SGS05-01 3	sugar beet (leaves with tops)	DPL/96/2023/03T	<LOD	<LOQ	<LOQ	<LOD	1.37*	2.48*
4		23SGS05-01 4	sugar beet (roots)	DPL/96/2023/04T	<LOD	<LOQ	<LOD	<LOD	0.056	0.11
5	7 DALA	23SGS05-01 5	sugar beet (leaves with tops)	DPL/96/2023/05U	<LOD	0.011	0.010	<LOD	<LOD	<LOD
6		23SGS05-01 6	sugar beet (roots)	DPL/96/2023/06U	<LOD	<LOQ	<LOD	<LOD	<LOD	<LOD
7		23SGS05-01 7	sugar beet (leaves with tops)	DPL/96/2023/07T	<LOD	<LOQ	<LOQ	<LOD	0.45*	0.66*
8		23SGS05-01 8	sugar beet (roots)	DPL/96/2023/08T	<LOD	<LOQ	<LOD	<LOD	0.068	0.051
9	35(±1) DALA/CH	23SGS05-01 9	sugar beet (leaves with tops)	DPL/96/2023/09U	<LOD	0.014	0.013	<LOD	<LOD	<LOD
10		23SGS05-01 10	sugar beet (roots)	DPL/96/2023/10U	<LOD	<LOQ	<LOD	<LOD	<LOD	<LOD
11		23SGS05-01 11	sugar beet (leaves with tops)	DPL/96/2023/11T	<LOQ	0.016	0.011	<LOD	0.12*	0.082*
12		23SGS05-01 12	sugar beet (roots)	DPL/96/2023/12T	<LOD	<LOQ	<LOD	<LOD	0.013	<LOQ

*- diluted samples;
DALA – Days After Last Application; CH – Commercial Harvest;
Residues are not corrected for procedural recoveries; Calculation based on unrounded values **LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)**
LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method. Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow. Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10 x LOQ per analytical set of respective matrix were analyzed during each of the sequence.

SUGAR BEET ROOTS

Analysis of samples 15.12.2023 – triazole metabolites in sugar beet roots:

triazole-acetic acid (TAA)

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0092	91.7
sugar beet root PK1 0,10 mg-kg.lcd	0.10	100.9
sugar beet root PK2 0,010 mg-kg.lcd	0.0096	96.0
sugar beet root PK2 0,10 mg-kg.lcd	0.091	91.3

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0074	73.7
sugar beet root PK1 0,10 mg-kg.lcd	0.088	87.8
sugar beet root PK2 0,010 mg-kg.lcd	0.0087	86.9
sugar beet root PK2 0,10 mg-kg.lcd	0.084	83.9

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0086	86.2
sugar beet root PK1 0,10 mg-kg.lcd	0.097	97.3
sugar beet root PK2 0,010 mg-kg.lcd	0.0092	92.1
sugar beet root PK2 0,10 mg-kg.lcd	0.087	87.4

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

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

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0095	95.1
sugar beet root PK1 0,10 mg-kg.lcd	0.10	100.3
sugar beet root PK2 0,010 mg-kg.lcd	0.011	107.3
sugar beet root PK2 0,10 mg-kg.lcd	0.091	91.2

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 15.12.2023 – difenoconazole and azoxystrobin in sugar beet roots:

Difenoconazole

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0098	98.3
sugar beet root PK1 0,10 mg-kg.lcd	0.10	103.0
sugar beet root PK2 0,010 mg-kg.lcd	0.010	103.2
sugar beet root PK2 0,10 mg-kg.lcd	0.10	101.1

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 22. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.010	103.2
sugar beet root PK1 0,10 mg-kg.lcd	0.10	102.0
sugar beet root PK2 0,010 mg-kg.lcd	0.0096	95.6
sugar beet root PK2 0,10 mg-kg.lcd	0.096	96.3

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

SUGAR BEET LEAVES

Analysis of samples 18.12.2023 – triazole metabolites in sugar beet leaves:

triazole-acetic acid (TAA)

Table 23. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.011	111.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	104.7
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	104.8
sugar beet leaves PK2 0,10 mg-kg.lcd	0.100	100.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 24. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.011	112.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.11	107.0
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	112.7
sugar beet leaves PK2 0,10 mg-kg.lcd	0.098	98.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 25. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.012	117.8
sugar beet leaves PK1 0,10 mg-kg.lcd	0.11	111.9
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	108.6
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	102.5

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

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

Table 26. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	104.8
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	104.9
sugar beet leaves PK2 0,010 mg-kg.lcd	0.0096	96.3
sugar beet leaves PK2 0,10 mg-kg.lcd	0.094	94.3

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 18.12.2023 – difenoconazole and azoxystrobin in sugar beet leaves:

Difenoconazole

Table 27. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	100.2
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	101.7
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	97.8

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 28. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.3
sugar beet leaves PK1 0,10 mg-kg.lcd	0.099	98.7
sugar beet leaves PK2 0,010 mg-kg.lcd	0.0099	99.2
sugar beet leaves PK2 0,10 mg-kg.lcd	0.11	107.5

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 19.12.2023 – difenoconazole and azoxystrobin in sugar beet leaves (for diluted samples)

Difenoconazole

Table 29. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.0099	99.0
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	101.2
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	102.0
sugar beet leaves PK2 0,10 mg-kg.lcd	0.096	96.5

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 30. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.0
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	100.6
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	107.3
sugar beet leaves PK2 0,10 mg-kg.lcd	0.11	105.4

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev.2.

The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70 – 120% confirms the active substance stability during the analytical procedure.

15.12.2023 (difenoconazole and azoxystrobin in sugar beet roots samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 496 minutes (8.3 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

15.12.2023 (triazole derivative metabolites in sugar beet roots samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 312 minutes (5.2 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day

18.12.2023 (difenoconazole and azoxystrobin in sugar beet leaves samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 784 minutes (13.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

18.12.2023 (triazole derivative metabolites in sugar beet leaves samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 456 minutes (7.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

19.12.2023 (difenoconazole and azoxystrobin in sugar beet leaves - diluted samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 448 minutes (7.5 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

CONCLUSIONS

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery.
The limit of quantification of the method was established at 0.010 mg/kg for leaves with tops and roots.

There were no interfering signals at retention time of analyzed compound in examined control matrix. The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA), difenoconazole and azoxystrobin in sugar beet (leaves with tops and roots) meets the criteria of SANTE/2020/12830, Rev.2 guidelines in terms of precision, accuracy and uncertainty.

Active Substances:	Azoxystrobin, difenoconazole	**Commercial Product:**	CHR/F/SCORPIO 325 SC
Crop / crop group:	Sugar beet / Root crops	**Producer:**	PUH Chemirol Sp. z o. o.
Responsible for reporting:	Tomasz Peda		
SGS Polska Sp. z o. o. ul. Poznańska 305B 05-850 Ołtarzew Poland			
Country:	Poland	**Indoor/outdoor:**	outdoor
Nominal Content of a. s.:	325 g/L	**Other active substance:**	NAP
Formulation:	SC	**Residue calculated for:**	difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T

1	2	3	4	5				6	7	8	9						10	11
				Actual application rate							Residues (1)							
Report No. 23SGS05	Commodity Variety	Date of 1-Sowing 2-Harvest	Method of Treatment	L a.s./ha	Water (L/ha)	g azoxystrobin (/ha)	g a difenoconazole (/ha)	Date of Treatment	BBCH at Treatment	Commodity analysed	Triazole-acetic Acid TAA	Triazole-alanine TA	Triazole-lactic Acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin	DALA or CH (2)	Remarks
Poland Krzelków (Dolnośląskie) Decline Curve Study Trial 23SGS05-01	Sugar beet Silesia	1 – 22/04/23 2 – 22/09/23	Foliar spray	1,318	405,6	264	165	18/08/2023	49	Leaves with tops	<LOD	<LOQ	<LOQ	<LOD	1.37	2.48	0	Analytical Method: LC-MS/MS
										Roots	<LOD	<LOQ	<LOD	<LOD	0.056	0.11	0	
										Leaves with tops	<LOD	<LOQ	<LOQ	<LOD	0.45	0.66	7	
										Roots	<LOD	<LOQ	<LOD	<LOD	0.068	0.051	7	
										Leaves with tops	<LOQ	0.016	0.011	<LOD	0.12	0.082	35	
										Roots	<LOD	<LOQ	<LOD	<LOD	0.013	<LOQ	35	

DALA – Days After Last Application; CH – Commercial Harvest; Residues are not corrected for procedural recoveries; Calculation based on unrounded values, **LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites), LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)**

A.2.1.3.1.12 Study 12

Comments of zRMS:	One residue field trial (decline study) on sugar beet was conducted in Hungary (n=1) during 2023. One application (at BBCH 49) of CHR/F/SCORPIO 325 SC were performed at the target dose rate of 1,3 L/ha, equivalent to 260 g azoxystrobin and 163 g difenoconazole. Samples were stored frozen for max 6 months prior to analysis. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, in addition the total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in sugar beet (leaves, roots) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound. Specimen extraction and determination of residues of difenoconazole and azoxystrobin in sugar beet (leaves, roots) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.001 mg/kg for each compound. The methods used in the study were fully validated and accepted, see dRR Part B5 (VAL/21/2023 and VAL/22/2023). Procedural recoveries (at the level of LOQ and two at the level 10 x LOQ) were within acceptable range. No residues of TAA, TA, TLA, 1,2,4-T, difenoconazole and azoxystrobin above the LOQ of the method were found in roots. The study is accepted. Results supporting the proposed GAP (DALA 36): Roots: TAA: 1 x < LOD TA: 1 x < LOQ TLA: 1 x < LOD 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x < LOQ Azoxystrobin: 1 x < LOQ Leaves: TAA: 1 x < LOQ TA: 1 x 0.016 mg/kg TLA: 1 x 0.04 mg/kg 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x 0.18 mg/kg Azoxystrobin: 1 x 0.34 mg/kg

Reference:	KCA 6.3/01
Report	Magnitude of residue of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4T in sugar beet (Raw Agricultural Commodity) after one application of CHR/F/SCORPIO 325 SC – one decline curve study trial in Hungary - 2023 Study Number 23SGS06

T.~~Penda~~ Peda

Guideline(s): Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997

OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021)

SANTE/2020/12830 Rev.2, 14 February 2023

Deviations: No

GLP: Yes

Acceptability: Yes

The objective of the study was to determine the residue of difenoconazole, azoxystrobin and Triazole Derivative Metabolites (triazole alanine, triazole acetic acid, triazole lactic acid and 1,2,4-triazole) in sugar beet RAC (leaves with tops and roots), following one application of CHR/F/SCORPIO 325 SC.

Residues concentration detected in analysed field samples:

Residues concentration detected in analysed field samples:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]					
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin
1	0 DALA	23SGS06-01 1	sugar beet (leaves with tops)	DPL/87/2023/01U	<LOD	<LOQ	0.016	<LOD	<LOD	<LOD
2		23SGS06-01 2	sugar beet (roots)	DPL/87/2023/02U	<LOD	<LOQ	<LOD	<LOD	<LOD	<LOD
3		23SGS06-01 3	sugar beet (leaves with tops)	DPL/87/2023/03T	<LOD	<LOQ	<LOQ	<LOD	3.87*	6.99*
4		23SGS06-01 4	sugar beet (roots)	DPL/87/2023/04T	<LOD	<LOQ	<LOD	<LOD	<LOQ	0.015
5	7 DALA	23SGS06-01 5	sugar beet (leaves with tops)	DPL/87/2023/05U	<LOD	<LOQ	<LOQ	<LOD	<LOD	<LOD
6		23SGS06-01 6	sugar beet (roots)	DPL/87/2023/06U	<LOD	<LOQ	<LOD	<LOD	<LOD	<LOD
7		23SGS06-01 7	sugar beet (leaves with tops)	DPL/87/2023/07T	<LOD	<LOQ	0.011	<LOD	1.86*	4.14*
8		23SGS06-01 8	sugar beet (roots)	DPL/87/2023/08T	<LOD	<LOQ	<LOD	<LOD	<LOQ	<LOQ
9	35(±1) DALA/CH	23SGS06-01 9	sugar beet (leaves with tops)	DPL/87/2023/09U	<LOD	<LOQ	<LOQ	<LOD	<LOD	<LOD
10		23SGS06-01 10	sugar beet (roots)	DPL/87/2023/10U	<LOD	<LOQ	<LOD	<LOD	<LOD	<LOD
11		23SGS06-01 11	sugar beet (leaves with tops)	DPL/87/2023/11T	<LOQ	0.016	0.040	<LOD	0.18*	0.34*
12		23SGS06-01 12	sugar beet (roots)	DPL/87/2023/12T	<LOD	<LOQ	<LOD	<LOD	<LOQ	<LOQ

*- diluted samples;
DALA – Days After Last Application; CH – Commercial Harvest;
Residues are not corrected for procedural recoveries; Calculation based on unrounded values.**LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)**
LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.

Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10 x LOQ per analytical set of respective matrix were analyzed during each of the sequence.

SUGAR BEET ROOTS

Analysis of samples 15.12.2023 – triazole metabolites in sugar beet roots:

triazole-acetic acid (TAA)

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0092	91.7
sugar beet root PK1 0,10 mg-kg.lcd	0.10	100.9
sugar beet root PK2 0,010 mg-kg.lcd	0.0096	96.0
sugar beet root PK2 0,10 mg-kg.lcd	0.091	91.3

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0074	73.7
sugar beet root PK1 0,10 mg-kg.lcd	0.088	87.8
sugar beet root PK2 0,010 mg-kg.lcd	0.0087	86.9
sugar beet root PK2 0,10 mg-kg.lcd	0.084	83.9

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0086	86.2
sugar beet root PK1 0,10 mg-kg.lcd	0.097	97.3
sugar beet root PK2 0,010 mg-kg.lcd	0.0092	92.1
sugar beet root PK2 0,10 mg-kg.lcd	0.087	87.4

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

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

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0095	95.1
sugar beet root PK1 0,10 mg-kg.lcd	0.10	100.3
sugar beet root PK2 0,010 mg-kg.lcd	0.011	107.3
sugar beet root PK2 0,10 mg-kg.lcd	0.091	91.2

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 15.12.2023 – difenoconazole and azoxystrobin in sugar beet roots:

Difenoconazole

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0098	98.3
sugar beet root PK1 0,10 mg-kg.lcd	0.10	103.0
sugar beet root PK2 0,010 mg-kg.lcd	0.010	103.2
sugar beet root PK2 0,10 mg-kg.lcd	0.10	101.1

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 22. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.010	103.2
sugar beet root PK1 0,10 mg-kg.lcd	0.10	102.0
sugar beet root PK2 0,010 mg-kg.lcd	0.0096	95.6
sugar beet root PK2 0,10 mg-kg.lcd	0.096	96.3

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

SUGAR BEET LEAVES

Analysis of samples 18.12.2023 – triazole metabolites in sugar beet leaves:

triazole-acetic acid (TAA)

Table 23. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.011	111.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	104.7
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	104.8
sugar beet leaves PK2 0,10 mg-kg.lcd	0.100	100.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 24. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.011	112.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.11	107.0
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	112.7
sugar beet leaves PK2 0,10 mg-kg.lcd	0.098	98.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 25. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.012	117.8
sugar beet leaves PK1 0,10 mg-kg.lcd	0.11	111.9
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	108.6
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	102.5

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

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

Table 26. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	104.8
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	104.9
sugar beet leaves PK2 0,010 mg-kg.lcd	0.0096	96.3
sugar beet leaves PK2 0,10 mg-kg.lcd	0.094	94.3

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 18.12.2023 – difenoconazole and azoxystrobin in sugar beet leaves:

Difenoconazole

Table 27. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	100.2
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	101.7
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	97.8

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 28. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.3
sugar beet leaves PK1 0,10 mg-kg.lcd	0.099	98.7
sugar beet leaves PK2 0,010 mg-kg.lcd	0.0099	99.2
sugar beet leaves PK2 0,10 mg-kg.lcd	0.11	107.5

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 19.12.2023 – difenoconazole and azoxystrobin in sugar beet leaves (for diluted samples):

Difenoconazole

Table 29. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.0099	99.0
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	101.2
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	102.0
sugar beet leaves PK2 0,10 mg-kg.lcd	0.096	96.5

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 30. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.0
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	100.6
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	107.3
sugar beet leaves PK2 0,10 mg-kg.lcd	0.11	105.4

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev.2.

The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70 – 120% confirms the active substance stability during the analytical procedure.

15.12.2023 (difenoconazole and azoxystrobin in sugar beet roots samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 496 minutes (8.3 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

15.12.2023 (triazole derivative metabolites in sugar beet roots samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 312 minutes (5.2 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day

18.12.2023 (difenoconazole and azoxystrobin in sugar beet leaves samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 784 minutes (13.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

18.12.2023 (triazole derivative metabolites in sugar beet leaves samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 456 minutes (7.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

19.12.2023 (difenoconazole and azoxystrobin in sugar beet leaves - diluted samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 448 minutes (7.5 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day

Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

CONCLUSIONS

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for leaves with tops and roots.

There were no interfering signals at retention time of analyzed compound in examined control matrix. The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA), difenoconazole and azoxystrobin in sugar beet (leaves with tops and roots) meets the criteria of SANTE/2020/12830, Rev.2 guidelines in terms of precision, accuracy and uncertainty.

Active Substances:	Azoxystrobin, difenoconazole	**Commercial Product:**	CHR/F/SCORPIO 325 SC
Crop / crop group:	Sugar beet / Root crops	**Producer:**	PUH Chemirol Sp. z o. o.
Responsible for reporting:	Tomasz Peda		

SGS Polska Sp. z o. o.
ul. Poznańska 305B
05-850 Ołtarzew
Poland

Country:	Hungary	**Indoor/outdoor:**	outdoor
Nominal Content of a. s.:	325 g/L	**Other active substance:**	NAP
Formulation:	SC	**Residue calculated for:**	difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T

1	2	3	4	5				6	7	8	9						10	11
				Actual application rate							Residues (1)						DALA or CH (2)	Remarks
Report No. 23SGS06	Commodity Variety	Date of 1-Sowing 2-Harvest	Method of Treatment	L a.s./ha	Water (L/ha)	g azoxystrobin (/ha)	g a difenoconazole (/ha)	Date of Treatment	BBCH at Treatment	Commodity analysed	Triazole-acetic Acid TAA	Triazole-alanine TA	Triazole-lactic Acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin		
Hungary Nyiregyhaza (Szabolcs-Szatmár-Bereg) Decline Curve Study Trial 23SGS06-01	Sugar beet Asketa	1 – 24/03/23 2 – 13/09/23	Foliar spray	1,348	311,1	270	169	08/08/2023	49	Leaves with tops	<LOD	<LOQ	<LOQ	<LOD	3.87*	6.99*	0	Analytical Method: LC-MS/MS
										Roots	<LOD	<LOQ	<LOD	<LOD	<LOQ	0.015	0	
										Leaves with tops	<LOD	<LOQ	0.011	<LOD	1.86*	4.14*	7	
										Roots	<LOD	<LOQ	<LOD	<LOD	<LOQ	<LOQ	7	
										Leaves with tops	<LOQ	0.016	0.040	<LOD	0.18*	0.34*	36	
										Roots	<LOD	<LOQ	<LOD	<LOD	<LOQ	<LOQ	36	

*-diluted sample; DALA – Days After Last Application; CH – Commercial Harvest; Residues are not corrected for procedural recoveries; Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

A.2.1.3.1.13 Study 13

Comments of zRMS:	One residue field trial (decline study) on sugar beet was conducted in Northern France (n=1) during 2023. One application (at BBCH 49) of CHR/F/SCORPIO 325 SC were performed at the target dose rate of 1,3 L/ha, equivalent to 260 g azoxystrobin and 163 g difenoconazole. Samples were stored frozen for max 5 months prior to analysis. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, in addition the total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in sugar beet (leaves, roots) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound. Specimen extraction and determination of residues of difenoconazole and azoxystrobin in sugar beet (leaves, roots) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.001 mg/kg for each compound. The methods used in the study were fully validated and accepted, see dRR Part B5 (VAL/21/2023 and VAL/22/2023). Procedural recoveries (at the level of LOQ and two at the level 10 x LOQ) were within acceptable range. No residues of TAA, TA, TLA, 1,2,4-T and azoxystrobin above the LOQ of the method were found in roots. Residues of difenoconazole above the LOQ were found in roots samples taken from treated trial plot (0.012 mg/kg). The study is accepted. Results supporting the proposed GAP (DALA 34): Roots: TAA: 1 x < LOD TA: 1 x < LOQ TLA: 1 x < LOD 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x 0.012 mg/kg Azoxystrobin: 1 x < LOQ Leaves: TAA: 1 x < LOQ TA: 1 x 0.011 mg/kg TLA: 1 x 0.013 mg/kg 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x 0.38 mg/kg Azoxystrobin: 1 x 0.51

Reference:	KCA 6.3/01
Report	Magnitude of residue of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4T in sugar beet (Raw Agricultural Commodity) after one application of CHR/F/SCORPIO 325 SC – one decline curve study trial in Northern France - 2023

	Study Number 23SGS07 T.~~Penda~~ Peda
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021) SANTE/2020/12830 Rev.2, 14 February 2023
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue of difenoconazole, azoxystrobin and Triazole Derivative Metabolites (triazole alanine, triazole acetic acid, triazole lactic acid and 1,2,4-triazole) in sugar beet (leaves with tops and roots), following one application of CHR/F/SCORPIO 325 SC.

The following residues concentration was determined in the field samples analyzed on 16.12.2023 (difenoconazole, azoxystrobin and triazole metabolites in sugar beet roots samples), 18.12.2023 (difenoconazole, azoxystrobin and triazole metabolites in sugar beet leaves samples) and 19.12.2023 (difenoconazole, azoxystrobin in sugar beet leaves - diluted samples):

Residues concentration detected in analysed field samples:

Residues concentration detected in analysed field samples:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]					
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin
1	0 DALA	23SGS07-01 1	sugar beet (leaves with tops)	DPL/102/2023/01U	<LOD	<LOD	<LOQ	<LOD	<LOD	<LOD
2		23SGS07-01 2	sugar beet (roots)	DPL/102/2023/02U	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
3		23SGS07-01 3	sugar beet (leaves with tops)	DPL/102/2023/03T	<LOD	<LOQ	0.010	<LOD	4.00*	7.26*
4		23SGS07-01 4	sugar beet (roots)	DPL/102/2023/04T	<LOD	<LOD	<LOD	<LOD	0.013	0.021
5	7 DALA	23SGS07-01 5	sugar beet (leaves with tops)	DPL/102/2023/05U	<LOD	<LOD	<LOQ	<LOD	<LOD	<LOD
6		23SGS07-01 6	sugar beet (roots)	DPL/102/2023/06U	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
7		23SGS07-01 7	sugar beet (leaves with tops)	DPL/102/2023/07T	<LOD	<LOQ	<LOQ	<LOD	1.01*	1.73*
8		23SGS07-01 8	sugar beet (roots)	DPL/102/2023/08T	<LOD	<LOQ	<LOD	<LOD	0.017	0.018
9	35(±1) DALA/ CH	23SGS07-01 9	sugar beet (leaves with tops)	DPL/102/2023/09U	<LOD	<LOD	<LOQ	<LOD	<LOD	<LOD
10		23SGS07-01 10	sugar beet (roots)	DPL/102/2023/10U	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
11		23SGS07-01 11	sugar beet (leaves with tops)	DPL/102/2023/11T	<LOQ	0.011	0.013	<LOD	0.38*	0.51*
12		23SGS07-01 12	sugar beet (roots)	DPL/102/2023/12T	<LOD	<LOQ	<LOD	<LOD	0.012	<LOQ

* diluted samples; DALA Days After Last Application; CH Commercial Harvest;
Residues are not corrected for procedural recoveries; Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.

Sample blank matrix, two (in case of roots samples) or three (in case of leaves samples) procedural recoveries at the level of LOQ and two (in case of roots samples) or three (in case of leaves samples) procedural at the level 10 x LOQ per analytical set of respective matrix were analyzed during each of the sequence.

SUGAR BEET ROOTS

Analysis of samples 16.12.2023 – triazole metabolites in sugar beet roots:

triazole-acetic acid (TAA)

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0091	91.3
sugar beet root PK1 0,10 mg-kg.lcd	0.094	93.6
sugar beet root PK2 0,010 mg-kg.lcd	0.0090	90.0
sugar beet root PK2 0,10 mg-kg.lcd	0.10	100.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0078	78.0
sugar beet root PK1 0,10 mg-kg.lcd	0.092	92.0
sugar beet root PK2 0,010 mg-kg.lcd	0.0080	79.7
sugar beet root PK2 0,10 mg-kg.lcd	0.095	95.5

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0087	87.4
sugar beet root PK1 0,10 mg-kg.lcd	0.092	91.8
sugar beet root PK2 0,010 mg-kg.lcd	0.0086	86.2
sugar beet root PK2 0,10 mg-kg.lcd	0.099	98.8

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

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

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0089	88.9
sugar beet root PK1 0,10 mg-kg.lcd	0.093	93.3
sugar beet root PK2 0,010 mg-kg.lcd	0.0091	90.7
sugar beet root PK2 0,10 mg-kg.lcd	0.10	100.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 16.12.2023 – difenoconazole and azoxystrobin in sugar beet roots:

Difenoconazole

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.010	100.4
sugar beet root PK1 0,10 mg-kg.lcd	0.10	103.4
sugar beet root PK2 0,010 mg-kg.lcd	0.010	102.4
sugar beet root PK2 0,10 mg-kg.lcd	0.097	97.3

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 22. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.011	108.0
sugar beet root PK1 0,10 mg-kg.lcd	0.11	110.0
sugar beet root PK2 0,010 mg-kg.lcd	0.010	104.6
sugar beet root PK2 0,10 mg-kg.lcd	0.10	102.4

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

SUGAR BEET LEAVES
Analysis of samples 18.12.2023 – triazole metabolites in sugar beet leaves:

triazole-acetic acid (TAA)

Table 23. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.011	111.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	104.7
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	104.8
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	100.1
sugar beet leaves PK3 0,010 mg-kg.lcd	0.011	105.6
sugar beet leaves PK3 0,10 mg-kg.lcd	0.10	100.5

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 24. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.011	112.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.11	107.0
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	112.7
sugar beet leaves PK2 0,10 mg-kg.lcd	0.098	98.1
sugar beet leaves PK3 0,010 mg-kg.lcd	0.012	115.8
sugar beet leaves PK3 0,10 mg-kg.lcd	0.10	99.6

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 25. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.012	117.8
sugar beet leaves PK1 0,10 mg-kg.lcd	0.11	111.9
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	108.6
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	102.5
sugar beet leaves PK3 0,010 mg-kg.lcd	0.011	106.6
sugar beet leaves PK3 0,10 mg-kg.lcd	0.10	102.2

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

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

Table 26. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	104.8
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	104.9
sugar beet leaves PK2 0,010 mg-kg.lcd	0.0096	96.3
sugar beet leaves PK2 0,10 mg-kg.lcd	0.094	94.3
sugar beet leaves PK3 0,010 mg-kg.lcd	0.0098	97.8
sugar beet leaves PK3 0,10 mg-kg.lcd	0.099	99.3

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 18.12.2023 – difenoconazole and azoxystrobin in sugar beet leaves:

Difenoconazole

Table 27. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	100.2
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	101.7
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	97.8
sugar beet leaves PK3 0,010 mg-kg.lcd	0.010	102.2
sugar beet leaves PK3 0,10 mg-kg.lcd	0.10	100.3

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 28. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.3
sugar beet leaves PK1 0,10 mg-kg.lcd	0.099	98.7
sugar beet leaves PK2 0,010 mg-kg.lcd	0.0099	99.2
sugar beet leaves PK2 0,10 mg-kg.lcd	0.11	107.5
sugar beet leaves PK3 0,010 mg-kg.lcd	0.010	101.2
sugar beet leaves PK3 0,10 mg-kg.lcd	0.095	94.7

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 19.12.2023 – difenoconazole and azoxystrobin in sugar beet leaves - diluted samples:

Difenoconazole

Table 29. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.0099	99.0
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	101.2
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	102.0
sugar beet leaves PK2 0,10 mg-kg.lcd	0.096	96.5

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 30. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.0
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	100.6
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	107.3
sugar beet leaves PK2 0,10 mg-kg.lcd	0.11	105.4

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev.2.

The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg, PK2 0.10 mg/kg and PK3 0.10 mg/kg in the range of 70 – 120% confirms the active substance stability during the analytical procedure.

16.12.2023 (difenoconazole and azoxystrobin in sugar beet roots samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 496 minutes (8.3 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

16.12.2023 (triazole derivative metabolites in sugar beet roots samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 312 minutes (5.2 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day

18.12.2023 (difenoconazole and azoxystrobin in sugar beet leaves samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 784 minutes (13.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

18.12.2023 (triazole derivative metabolites in sugar beet leaves samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 456 minutes (7.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

19.12.2023 (difenoconazole and azoxystrobin in sugar beet leaves - diluted samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 448 minutes (7.5 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

CONCLUSIONS

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery. The limit of quantification of the method was established at 0.010 mg/kg for sugar beet (leaves with tops and roots). There were no interfering signals at retention time of analyzed compound in examined control matrix. The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA), difenoconazole and azoxystrobin in sugar beet (leaves with tops and roots) meets the criteria of SANTE/2020/12830, Rev.2 guidelines in terms of precision, accuracy and uncertainty.

Active Substances:	Azoxystrobin, difenoconazole	**Commercial Product:**	CHR/F/SCORPIO 325 SC
Crop / crop group:	Sugar beet / Root crops	**Producer:**	PUH Chemirol Sp. z o. o.
Responsible for reporting:	Tomasz Peda		
SGS Polska Sp. z o. o. ul. Poznańska 305B 05-850 Ołtarzew Poland			
Country:	Northern France	**Indoor/outdoor:**	outdoor
Nominal Content of a. s.:	325 g/L	**Other active substance:**	NAP
Formulation:	SC	**Residue calculated for:**	difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T

1	2	3	4	5				6	7	8	9						10	11
				Actual application rate							Residues (1)						DALA or CH (2)	Remarks
Report No. 23SGS07	Commodity Variety	Date of 1-Sowing 2-Harvest	Method of Treatment	L a.s./ha	Water (L/ha)	g azoxystrobin (/ha)	g a difenoconazole (/ha)	Date of Treatment	BBCH at Treatment	Commodity analysed	Triazole-acetic Acid TAA	Triazole-alanine TA	Triazole-lactic Acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin		
Northern France Auménancourt (Grand Est.) Decline Curve Study Trial 23SGS07-01	Sugar beet Lunella KWS	1 – 04/04/23 2 – 26/09 - 15/10/23	Foliar spray	1,279	344,4	256	160	05/09/2023	49	Leaves with tops	<LOD	<LOQ	0.010	<LOD	4.00*	7.26*	0	Analytical Method: LC-MS/MS
										Roots	<LOD	<LOD	<LOD	<LOD	0.013	0.021	0	
										Leaves with tops	<LOD	<LOQ	<LOQ	<LOD	1.01*	1.73*	7	
										Roots	<LOD	<LOQ	<LOD	<LOD	0.017	0.018	7	
										Leaves with tops	<LOQ	0.011	0.013	<LOD	0.38*	0.51*	34	
										Roots	<LOD	<LOQ	<LOD	<LOD	0.012	<LOQ	34	

*-diluted sample; DALA – Days After Last Application; CH – Commercial Harvest; Residues are not corrected for procedural recoveries; Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites), LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

A.2.1.3.1.14 Study 14

Comments of zRMS:	One residue field trial (decline study) on sugar beet was conducted in Denmark (n=1) during 2023. One application (at BBCH 49) of CHR/F/SCORPIO 325 SC were performed at the target dose rate of 1,3 L/ha, equivalent to 260 g azoxystrobin and 163 g difenoconazole. Samples were stored frozen for max 5 months prior to analysis. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, in addition the total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in sugar beet (leaves, roots) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound. Specimen extraction and determination of residues of difenoconazole and azoxystrobin in sugar beet (leaves, roots) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.001 mg/kg for each compound. The methods used in the study were fully validated and accepted, see dRR Part B5 (VAL/21/2023 and VAL/22/2023). Procedural recoveries (at the level of LOQ and two at the level 10 x LOQ) were within acceptable range. No residues of TAA, TLA, 1,2,4-T, difenoconazole and azoxystrobin above the LOQ of the method were found in roots. Residues of TA above the LOQ were found in samples taken from treated (0.011 mg/kg) and untreated (0.016 mg/kg) trial plot. It should be noted that the residue results in a sample taken from an untreated field are higher than those from a treated field. Despite these uncertainties, these trials were considered with the purpose of performing a ‘worst case’ consumer dietary intake calculation. The study is accepted. Results supporting the proposed GAP (DALA 36): Roots: TAA: 1 x < LOD TA: 1 x 0.016 mg/kg TLA: 1 x < LOD 1,2,4 -T: 1 x 1 x < LOQ Difenoconazole: 1 x < LOQ Azoxystrobin: 1 x < LOQ Leaves: TAA: 1 x < LOQ TA: 1 x 0.027 mg/kg TLA: 1 x 0.023 mg/kg 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x 0.1 mg/kg Azoxystrobin: 1 x 0.087 mg/kg

Reference: KCA 6.3/01

Report	Magnitude of residue of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T in sugar beet (Raw Agricultural Commodity) after one application of CHR/F/SCORPIO 325 SC – one decline curve study trial in Denmark - 2023 Study Number 23SGS08 T.~~Penda~~
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021) SANTE/2020/12830 Rev.2, 14 February 2023
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue of difenoconazole, azoxystrobin and Triazole Derivative Metabolites (triazole alanine, triazole acetic acid, triazole lactic acid and 1,2,4-triazole) in sugar beet (leaves with tops and roots), following one application of CHR/F/SCORPIO 325 SC.

The following residues concentration was determined in the field samples analyzed on 16.12.2023 (difenoconazole, azoxystrobin and triazole metabolites in sugar beet roots samples), 18.12.2023 (difenoconazole, azoxystrobin and triazole metabolites in sugar beet leaves samples) and 19.12.2023 (difenoconazole, azoxystrobin in sugar beet leaves - diluted samples):

Residues concentration detected in analysed field samples:

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]					
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin
1	0 DALA	23SGS08-01 1	sugar beet (leaves with tops)	DPL/103/2023/01U	<LOQ	0.022	0.061	<LOD	<LOD	<LOD
2		23SGS08-01 2	sugar beet (roots)	DPL/103/2023/02U	<LOD	0.015	<LOD	<LOD	<LOD	<LOD
3		23SGS08-01 3	sugar beet (leaves with tops)	DPL/103/2023/03T	<LOQ	0.019	0.039	<LOD	1.99*	3.97*
4		23SGS08-01 4	sugar beet (roots)	DPL/103/2023/04T	<LOD	0.012	<LOD	<LOD	<LOQ	0.011
5	7 DALA	23SGS08-01 5	sugar beet (leaves with tops)	DPL/103/2023/05U	<LOQ	0.015	0.039	<LOD	<LOD	<LOD
6		23SGS08-01 6	sugar beet (roots)	DPL/103/2023/06U	<LOD	0.015	<LOD	<LOD	<LOD	<LOD
7		23SGS08-01 7	sugar beet (leaves with tops)	DPL/103/2023/07T	<LOQ	0.023	0.035	<LOD	0.33*	0.30*
8		23SGS08-01 8	sugar beet (roots)	DPL/103/2023/08T	<LOD	0.010	<LOD	<LOD	<LOQ	<LOQ
9	35(±1) DALA/ CH	23SGS08-01 9	sugar beet (leaves with tops)	DPL/103/2023/09U	<LOQ	0.025	0.018	<LOD	<LOD	<LOD
10		23SGS08-01 10	sugar beet (roots)	DPL/103/2023/10U	<LOD	0.016	<LOD	<LOD	<LOD	<LOD
11		23SGS08-01 11	sugar beet (leaves with tops)	DPL/103/2023/11T	<LOQ	0.027	0.023	<LOD	0.10*	0.087*
12		23SGS08-01 12	sugar beet (roots)	DPL/103/2023/12T	<LOD	0.011	<LOD	<LOD	<LOQ	<LOQ

*- diluted samples; DALA – Days After Last Application; CH – Commercial Harvest;
Residues are not corrected for procedural recoveries; Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.

Sample blank matrix, two (in case of roots samples) or three (in case of leaves samples) procedural recoveries at the level of LOQ and two (in case of roots samples) or three (in case of leaves samples) procedural at the level 10 x LOQ per analytical set of respective matrix were analyzed during each of the sequence.

SUGAR BEET ROOTS

Analysis of samples 16.12.2023 – triazole metabolites in sugar beet roots:

triazole-acetic acid (TAA)

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0091	91.3
sugar beet root PK1 0,10 mg-kg.lcd	0.094	93.6
sugar beet root PK2 0,010 mg-kg.lcd	0.0090	90.0
sugar beet root PK2 0,10 mg-kg.lcd	0.10	100.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0078	78.0
sugar beet root PK1 0,10 mg-kg.lcd	0.092	92.0
sugar beet root PK2 0,010 mg-kg.lcd	0.0080	79.7
sugar beet root PK2 0,10 mg-kg.lcd	0.095	95.5

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0087	87.4
sugar beet root PK1 0,10 mg-kg.lcd	0.092	91.8
sugar beet root PK2 0,010 mg-kg.lcd	0.0086	86.2
sugar beet root PK2 0,10 mg-kg.lcd	0.099	98.8

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

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

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0089	88.9
sugar beet root PK1 0,10 mg-kg.lcd	0.093	93.3
sugar beet root PK2 0,010 mg-kg.lcd	0.0091	90.7
sugar beet root PK2 0,10 mg-kg.lcd	0.10	100.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 16.12.2023 – difenoconazole and azoxystrobin in sugar beet roots:

Difenoconazole

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.010	100.4
sugar beet root PK1 0,10 mg-kg.lcd	0.10	103.4
sugar beet root PK2 0,010 mg-kg.lcd	0.010	102.4
sugar beet root PK2 0,10 mg-kg.lcd	0.097	97.3

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 22. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.011	108.0
sugar beet root PK1 0,10 mg-kg.lcd	0.11	110.0
sugar beet root PK2 0,010 mg-kg.lcd	0.010	104.6
sugar beet root PK2 0,10 mg-kg.lcd	0.10	102.4

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

SUGAR BEET LEAVES

Analysis of samples 18.12.2023 – triazole metabolites in sugar beet leaves:

triazole-acetic acid (TAA)

Table 23. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.011	111.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	104.7
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	104.8
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	100.1
sugar beet leaves PK3 0,010 mg-kg.lcd	0.011	105.6
sugar beet leaves PK3 0,10 mg-kg.lcd	0.10	100.5

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 24. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.011	112.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.11	107.0
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	112.7
sugar beet leaves PK2 0,10 mg-kg.lcd	0.098	98.1
sugar beet leaves PK3 0,010 mg-kg.lcd	0.012	115.8
sugar beet leaves PK3 0,10 mg-kg.lcd	0.10	99.6

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 25. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.012	117.8
sugar beet leaves PK1 0,10 mg-kg.lcd	0.11	111.9
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	108.6
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	102.5
sugar beet leaves PK3 0,010 mg-kg.lcd	0.011	106.6
sugar beet leaves PK3 0,10 mg-kg.lcd	0.10	102.2

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

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

Table 26. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	104.8
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	104.9
sugar beet leaves PK2 0,010 mg-kg.lcd	0.0096	96.3
sugar beet leaves PK2 0,10 mg-kg.lcd	0.094	94.3
sugar beet leaves PK3 0,010 mg-kg.lcd	0.0098	97.8
sugar beet leaves PK3 0,10 mg-kg.lcd	0.099	99.3

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 18.12.2023 – difenoconazole and azoxystrobin in sugar beet leaves:

Difenoconazole

Table 27. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	100.2
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	101.7
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	97.8
sugar beet leaves PK3 0,010 mg-kg.lcd	0.010	102.2
sugar beet leaves PK3 0,10 mg-kg.lcd	0.10	100.3

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 28. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.3
sugar beet leaves PK1 0,10 mg-kg.lcd	0.099	98.7
sugar beet leaves PK2 0,010 mg-kg.lcd	0.0099	99.2
sugar beet leaves PK2 0,10 mg-kg.lcd	0.11	107.5
sugar beet leaves PK3 0,010 mg-kg.lcd	0.010	101.2
sugar beet leaves PK3 0,10 mg-kg.lcd	0.095	94.7

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 19.12.2023 – difenoconazole and azoxystrobin in sugar beet leaves - diluted samples:

Difenoconazole

Table 29. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.0099	99.0
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	101.2
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	102.0
sugar beet leaves PK2 0,10 mg-kg.lcd	0.096	96.5

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 30. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.0
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	100.6
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	107.3
sugar beet leaves PK2 0,10 mg-kg.lcd	0.11	105.4

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev.2.

The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg, PK2 0.10 mg/kg and PK3 0.10 mg/kg in the range of 70 – 120% confirms the active substance stability during the analytical procedure.

16.12.2023 (difenoconazole and azoxystrobin in sugar beet roots samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 496 minutes (8.3 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

16.12.2023 (triazole derivative metabolites in sugar beet roots samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 312 minutes (5.2 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day

18.12.2023 (difenoconazole and azoxystrobin in sugar beet leaves samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 784 minutes (13.1

h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

18.12.2023 (triazole derivative metabolites in sugar beet leaves samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 456 minutes (7.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

19.12.2023 (difenoconazole and azoxystrobin in sugar beet leaves - diluted samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 448 minutes (7.5 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

CONCLUSIONS

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for sugar beet (leaves with tops and roots).

There were no interfering signals at retention time of analyzed compound in examined control matrix.

The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA), difenoconazole and azoxystrobin in sugar beet (leaves with tops and roots) meets the criteria of SANTE/2020/12830, Rev.2 guidelines in terms of precision, accuracy and uncertainty.

Active Substances:	Azoxystrobin, difenoconazole	**Commercial Product:**	CHR/F/SCORPIO 325 SC
Crop / crop group:	Sugar beet / Root crops	**Producer:**	PUH Chemirol Sp. z o. o.
Responsible for reporting:	Tomasz Peda		
SGS Polska Sp. z o. o. ul. Poznańska 305B 05-850 Ołtarzew Poland			
Country:	Denmark	**Indoor/outdoor:**	outdoor
Nominal Content of a. s.:	325 g/L	**Other active substance:**	NAP
Formulation:	SC	**Residue calculated for:**	difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T

1	2	3	4	5				6	7	8	9						10	11
				Actual application rate							Residues (1)						DALA or CH (2)	Remarks
Report No. 23SGS08	Commodity Variety	Date of 1-Sowing 2-Harvest	Method of Treatment	L a.s./ha	Water (L/ha)	g azoxystrobin (/ha)	g a difenoconazole (/ha)	Date of Treatment	BBCH at Treatment	Commodity analysed	Triazole-acetic Acid TAA	Triazole-alanine TA	Triazole-lactic Acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin		
Denmark Tinglev (Syddanmark) Decline Curve Study Trial 23SGS08-01	Sugar beet Strauß	1 – 10/04/23 2 – 17/10/23	Foliar spray	1,281	295,6	256	161	11/09/2023	49	Leaves with tops	<LOD	0.019	0.039	<LOD	1.99*	3.97*	0	Analytical Method: LC-MS/MS
										Roots	<LOD	0.012	<LOD	<LOD	<LOQ	0.011	0	
										Leaves with tops	<LOD	0.023	0.035	<LOD	0.33*	0.30*	7	
										Roots	<LOD	0.010	<LOD	<LOD	<LOQ	<LOQ	7	
										Leaves with tops	<LOQ	0.027	0.023	<LOD	0.10*	0.087*	36	
										Roots	<LOD	0.011	<LOD	<LOD	<LOQ	<LOQ	36	

*-diluted sample; DALA – Days After Last Application; CH – Commercial Harvest; Residues are not corrected for procedural recoveries; Calculation based on unrounded values, **LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites), LOD=0.001mg/kg,LOQ=0.010mg/kg(difenoconazole,azoxystrobin)**

A.2.1.3.1.15 Study 15

Comments of zRMS:	One residue field trial on sugar beet was conducted in Poland (n=1) during 2023. One application (at BBCH 49) of CHR/F/SCORPIO 325 SC were performed at the target dose rate of 1,3 L/ha, equivalent to 260 g azoxystrobin and 163 g difenoconazole. Samples were stored frozen for max 2 months prior to analysis. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, in addition the total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in sugar beet (leaves, roots) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound. Specimen extraction and determination of residues of difenoconazole and azoxystrobin in sugar beet (leaves, roots) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.001 mg/kg for each compound. The methods used in the study were fully validated and accepted, see dRR Part B5 (VAL/21/2023 and VAL/22/2023). Procedural recoveries (at the level of LOQ and two at the level 10 x LOQ) were within acceptable range. No residues of TAA, TA, TLA, 1,2,4-T and azoxystrobin above the LOQ of the method were found in roots. Residues of difenoconazole above the LOQ were found in samples taken from treated trial plot (0.013 mg/kg). The study is accepted. Results supporting the proposed GAP (DALA 35): Roots: TAA: 1 x < LOD TA: 1 x < LOQ TLA: 1 x < LOD 1,2,4 -T: 1 x 1 x < LOD Difenoconazole: 1 x 0.013 mg/kg Azoxystrobin: 1 x < LOQ Leaves: TAA: 1 x < LOQ TA: 1 x 0.015 mg/kg TLA: 1 x < LOQ 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x 0.087 mg/kg Azoxystrobin: 1 x 0.049 mg/kg

Reference: KCA 6.3/01

Report	Magnitude of residue of difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4T in sugar beet (Raw Agricultural Commodity) after one application of CHR/F/SCORPIO 325 SC – one harvest study trial in Poland - 2023 Study Number 23SGS46 T.~~Penda~~ Peda
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021) SANTE/2020/12830 Rev.2, 14 February 2023
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue of difenoconazole, azoxystrobin and Triazole Derivative Metabolites (triazole alanine, triazole acetic acid, triazole lactic acid and 1,2,4-triazole) in sugar beet (leaves with tops and roots), following one application of CHR/F/SCORPIO 325 SC.

The following residues concentration was determined in the field samples analyzed on 16.12.2023 (difenoconazole, azoxystrobin and triazole metabolites in sugar beet roots samples), 18.12.2023 (difenoconazole, azoxystrobin and triazole metabolites in sugar beet leaves samples) and 19.12.2023 (difenoconazole, azoxystrobin in sugar beet leaves - diluted samples):

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]					
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin
1	35(±1) DALA/CH	23SGS46-01 1	sugar beet (leaves with tops)	DPL/101/2023/01U	<LOQ	<LOQ	<LOQ	<LOD	<LOD	<LOD
2		23SGS46-01 2	sugar beet (roots)	DPL/101/2023/02U	<LOD	<LOQ	<LOD	<LOD	<LOD	<LOD
3		23SGS46-01 3	sugar beet (leaves with tops)	DPL/101/2023/03T	<LOQ	0.015	<LOQ	<LOD	0.087*	0.049*
4		23SGS46-01 4	sugar beet (roots)	DPL/101/2023/04T	<LOD	<LOQ	<LOD	<LOD	0.013	<LOQ

*- diluted samples;
DALA – Days After Last Application; CH – Commercial Harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values.
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.

Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10 x LOQ per analytical set of respective matrix were analyzed during each of the sequence.

SUGAR BEET ROOTS

Analysis of samples 16.12.2023 – triazole metabolites in sugar beet roots:

triazole-acetic acid (TAA)

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0091	91.3
sugar beet root PK1 0,10 mg-kg.lcd	0.094	93.6
sugar beet root PK2 0,010 mg-kg.lcd	0.0090	90.0
sugar beet root PK2 0,10 mg-kg.lcd	0.10	100.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0078	78.0
sugar beet root PK1 0,10 mg-kg.lcd	0.092	92.0
sugar beet root PK2 0,010 mg-kg.lcd	0.0080	79.7
sugar beet root PK2 0,10 mg-kg.lcd	0.095	95.5

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0087	87.4
sugar beet root PK1 0,10 mg-kg.lcd	0.092	91.8
sugar beet root PK2 0,010 mg-kg.lcd	0.0086	86.2
sugar beet root PK2 0,10 mg-kg.lcd	0.099	98.8

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

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

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.0089	88.9
sugar beet root PK1 0,10 mg-kg.lcd	0.093	93.3
sugar beet root PK2 0,010 mg-kg.lcd	0.0091	90.7
sugar beet root PK2 0,10 mg-kg.lcd	0.10	100.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 16.12.2023 – difenoconazole and azoxystrobin in sugar beet roots:

Difenoconazole

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.010	100.4
sugar beet root PK1 0,10 mg-kg.lcd	0.10	103.4
sugar beet root PK2 0,010 mg-kg.lcd	0.010	102.4
sugar beet root PK2 0,10 mg-kg.lcd	0.097	97.3

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 22. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet root sample blank.lcd	<LOD	-
sugar beet root PK1 0,010 mg-kg.lcd	0.011	108.0
sugar beet root PK1 0,10 mg-kg.lcd	0.11	110.0
sugar beet root PK2 0,010 mg-kg.lcd	0.010	104.6
sugar beet root PK2 0,10 mg-kg.lcd	0.10	102.4

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

SUGAR BEET LEAVES

Analysis of samples 18.12.2023 – triazole metabolites in sugar beet leaves:

triazole-acetic acid (TAA)

Table 23. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.011	111.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	104.7
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	104.8
sugar beet leaves PK2 0,10 mg-kg.lcd	0.100	100.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 24. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.011	112.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.11	107.0
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	112.7
sugar beet leaves PK2 0,10 mg-kg.lcd	0.098	98.1

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 25. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.012	117.8
sugar beet leaves PK1 0,10 mg-kg.lcd	0.11	111.9
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	108.6
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	102.5

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

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

Table 26. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	104.8
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	104.9
sugar beet leaves PK2 0,010 mg-kg.lcd	0.0096	96.3
sugar beet leaves PK2 0,10 mg-kg.lcd	0.094	94.3

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 18.12.2023 – difenoconazole and azoxystrobin in sugar beet leaves:

Difenoconazole

Table 27. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.2
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	100.2
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	101.7
sugar beet leaves PK2 0,10 mg-kg.lcd	0.10	97.8

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 28. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.3
sugar beet leaves PK1 0,10 mg-kg.lcd	0.099	98.7
sugar beet leaves PK2 0,010 mg-kg.lcd	0.0099	99.2
sugar beet leaves PK2 0,10 mg-kg.lcd	0.11	107.5

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 19.12.2023 – difenoconazole and azoxystrobin in sugar beet leaves - diluted samples:

Difenoconazole

Table 29. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.0099	99.0
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	101.2
sugar beet leaves PK2 0,010 mg-kg.lcd	0.010	102.0
sugar beet leaves PK2 0,10 mg-kg.lcd	0.096	96.5

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 30. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
sugar beet leaves sample blank.lcd	<LOD	-
sugar beet leaves PK1 0,010 mg-kg.lcd	0.010	102.0
sugar beet leaves PK1 0,10 mg-kg.lcd	0.10	100.6
sugar beet leaves PK2 0,010 mg-kg.lcd	0.011	107.3
sugar beet leaves PK2 0,10 mg-kg.lcd	0.11	105.4

LOD = 0.001 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev.2.

The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70 – 120% confirms the active substance stability during the analytical procedure.

16.12.2023 (difenoconazole and azoxystrobin in sugar beet roots samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 496 minutes (8.3 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

16.12.2023 (triazole derivative metabolites in sugar beet roots samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 312 minutes (5.2 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day

18.12.2023 (difenoconazole and azoxystrobin in sugar beet leaves samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 784 minutes (13.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

18.12.2023 (triazole derivative metabolites in sugar beet leaves samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 456 minutes (7.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

19.12.2023 (difenoconazole and azoxystrobin in sugar beet leaves - diluted samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 448 minutes (7.5 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day

Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

CONCLUSIONS

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for sugar beet (leaves with tops and roots).

There were no interfering signals at retention time of analyzed compound in examined control matrix.

The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA), difenoconazole and azoxystrobin in sugar beet (leaves with tops and roots) meets the criteria of SANTE/2020/12830, Rev.2 guidelines in terms of precision, accuracy and uncertainty.

Active Substances:	Azoxystrobin, difenoconazole	**Commercial Product:**	CHR/F/SCORPIO 325 SC
Crop / crop group:	Sugar beet / Root crops	**Producer:**	PUH Chemirol Sp. z o. o.
Responsible for reporting:	Tomasz Peda		
SGS Polska Sp. z o. o. ul. Poznańska 305B 05-850 Ołtarzew Poland			
Country:	Poland	**Indoor/outdoor:**	outdoor
Nominal Content of a. s.:	325 g/L	**Other active substance:**	NAP
Formulation:	SC	**Residue calculated for:**	difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T

1	2	3	4	5				6	7	8	9							10	11
				Actual application rate							Residues (1)							DALA or CH (2)	Remarks
Report No. 23SGS46	Commodity Variety	Date of 1-Sowing 2-Harvest	Method of Treatment	L a.s./ha	Water (L/ha)	g azoxystrobin (/ha)	g a difenoconazole (/ha)	Date of Treatment	BBCH at Treatment	Commodity analysed	Triazole-acetic Acid TAA	Triazole-alanine TA	Triazole-lactic Acid TLA	1.2.4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin			
Poland Miłonów (Dolnośląskie) Harvest Study Trial 23SGS46-01	Sugar beet Hubertus	1 – 20/04/23 2 – 02/11/23	Foliar spray	1,286	296,7	257	161	28/09/2023	49	Leaves with tops Roots	<LOQ <LOD	0.015 <LOQ	<LOQ <LOD	<LOD <LOD	0.087 0.013	0.049 <LOQ		35	Analytical Method: LC-MS/MS

DALA – Days After Last Application; CH – Commercial Harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites),
LOD=0.001mg/kg, LOQ=0.010mg/kg(difenoconazole,azoxystrobin)

A.2.1.3.1.15 Study 16

Comments of zRMS:	One residue field trial on oilseed rape was conducted in Poland (n=1) during 2023. Two applications (first at BBCH 22, second at BBCH 69) of CHR/F/SCORPIO 325 SC were performed at the target dose rate of 1,0 L/ha, equivalent to 200 g azoxystrobin and 125 g difenoconazole. Samples were stored frozen for max 3 months prior to analysis. The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, in addition the total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day. Specimen extraction and determination of residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA) in oilseed rape (seed) were performed according to the multi-residue QuPPe method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.004 mg/kg for each compound. Specimen extraction and determination of residues of difenoconazole and azoxystrobin in oilseed rape (seed) were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg for each compound. The limit of detection (LOD) of the analytical method was 0.002 mg/kg for each compound. The methods used in the study were fully validated and accepted, see dRR Part B5 (VAL/10/2021 and VAL/22/2023). Procedural recoveries (at the level of LOQ and two at the level 10 x LOQ) were within acceptable range. No residues of TAA, TLA, 1,2,4-T, difenoconazole and azoxystrobin above the LOQ of the method were found. Residues of TA above the LOQ were found in samples taken from treated (0.054 mg/kg) and untreated (0.027 mg/kg) trial plot. The study is accepted. Results supporting the proposed GAP: TAA: 1 x < LOD TA: 1 x 0.17 mg/kg TLA: 1 x < LOD 1,2,4 -T: 1 x < LOD Difenoconazole: 1 x < LOD Azoxystrobin: 1 x < LOD

Reference:	KCA 6.3/01
Report	Magnitude of residue of azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) residues in Oil Seed Rape (Raw Agricultural Commodity) after two applications of CHR/F/SCORPIO 325 SC – one decline curve study trial in Poland -2023 Study Number 23SGS47 T.Penda
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue

	Trials, July 22, 1997 OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published 14 June 2021) SANTE/2020/12830 Rev.2, 14 February 2023
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue of the azoxystrobin and difenoconazole and it's triazole metabolites: triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA), triazole lactic acid (TLA) in oilseed rape (seeds, whole plants without roots), after two applications of CHR/F/SCORPIO 325 SC.

The following residues concentration was determined in the field samples analyzed on 11.07.2024 (difenoconazole and azoxystrobin in plant samples), 16.07.2024 (triazole metabolites in plant samples), 24.07.2024 (difenoconazole and azoxystrobin in seed samples) and 26.07.2024 (triazole metabolites in seeds samples):

No	Timing	Sponsor's sample identification	Type of commodity	Sample number given by the laboratory	Result [mg/kg]					
					triazole-acetic acid TAA	triazole-alanine TA	triazole-lactic acid TLA	1,2,4-triazole 1,2,4-T	Difenoconazole	Azoxystrobin
1	-0/0 DALA	23SGS47-01 1	oilseed rape (whole plants without roots)	DPL/62/2024/01U	< LOD	< LOD	< LOD	< LOD	<LOD	<LOD
2		23SGS47-01 2	oilseed rape (whole plants without roots)	DPL/62/2024/02T	< LOD	< LOD	< LOD	< LOD	2.68*	2.92*
3	14 DALA	23SGS47-01 3	oilseed rape (whole plants without roots)	DPL/62/2024/03T	< LOD	< LOD	< LOD	< LOD	0.23*	0.48*
4	21 DALA	23SGS47-01 4	oilseed rape (whole plants without roots)	DPL/62/2024/04T	< LOD	< LOD	< LOD	< LOD	0.16*	0.31*
5	28 DALA	23SGS47-01 5	oilseed rape (whole plants without roots)	DPL/62/2024/05T	< LOD	< LOD	< LOD	< LOD	0.063	0.094
6	BBCH 89/CH	23SGS47-01 6R	oilseed rape (seeds)	DPL/62/2024/06U, R	< LOD	0.17	< LOD	<LOD	<LOD	<LOD
7		23SGS47-01 7R	oilseed rape (seeds)	DPL/62/2024/07T, R	< LOD	0.12	< LOD	<LOD	<LOD	<LOD

*- diluted samples
CH – Commercial Harvest; DALA – Days After Last Application
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg (triazole metabolites)
LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg (difenoconazole, azoxystrobin)

BLANK AND FORTIFICATION SAMPLES (QC SAMPLES)

For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.

Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.

Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level 10 x LOQ per analytical set of respective matrix were analyzed during each of the sequence.

OILSEED RAPE SEED

Analysis of samples 26.07.2024 – triazole metabolites in oilseed rape seed:

triazole-acetic acid (TAA)

Table 16. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0087	86.6
OSR seed PK1 0,10 mg-kg.lcd	0.10	100.5
OSR seed PK2 0,010 mg-kg.lcd	0.0085	85.2
OSR seed PK2 0,10 mg-kg.lcd	0.099	99.3

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 17. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0077	77.3
OSR seed PK1 0,10 mg-kg.lcd	0.12	116.0
OSR seed PK2 0,010 mg-kg.lcd	0.0079	78.6
OSR seed PK2 0,10 mg-kg.lcd	0.12	116.9

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 18. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0083	82.9
OSR seed PK1 0,10 mg-kg.lcd	0.080	79.5
OSR seed PK2 0,010 mg-kg.lcd	0.0078	78.4
OSR seed PK2 0,10 mg-kg.lcd	0.078	78.5

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

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

Table 19. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.0078	78.2
OSR seed PK1 0,10 mg-kg.lcd	0.080	80.1
OSR seed PK2 0,010 mg-kg.lcd	0.0079	79.0
OSR seed PK2 0,10 mg-kg.lcd	0.082	81.6

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 24.07.2024 – difenoconazole and azoxystrobin in oilseed rape seed

Difenoconazole

Table 20. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.010	101.7
OSR seed PK1 0,10 mg-kg.lcd	0.10	104.5
OSR seed PK2 0,010 mg-kg.lcd	0.010	103.5
OSR seed PK2 0,10 mg-kg.lcd	0.10	100.4

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 21. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR seed sample blank.lcd	<LOD	-
OSR seed PK1 0,010 mg-kg.lcd	0.010	101.4
OSR seed PK1 0,10 mg-kg.lcd	0.10	102.0
OSR seed PK2 0,010 mg-kg.lcd	0.011	110.8
OSR seed PK2 0,10 mg-kg.lcd	0.11	107.0

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

OILSEED RAPE PLANT

Analysis of samples 16.07.2024 – triazole metabolites in oilseed rape plant:

triazole-acetic acid (TAA)

Table 22. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.011	105.7
OSR plant PK1 0,10 mg-kg.lcd	0.10	104.2
OSR plant PK2 0,010 mg-kg.lcd	0.011	107.7
OSR plant PK2 0,10 mg-kg.lcd	0.098	97.8

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-alanine (TA)

Table 23. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.011	114.2
OSR plant PK1 0,10 mg-kg.lcd	0.11	112.0
OSR plant PK2 0,010 mg-kg.lcd	0.011	106.0
OSR plant PK2 0,10 mg-kg.lcd	0.096	96.1

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

triazole-lactic acid (TLA)

Table 24. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.0074	74.4
OSR plant PK1 0,10 mg-kg.lcd	0.091	90.7
OSR plant PK2 0,010 mg-kg.lcd	0.0075	74.6
OSR plant PK2 0,10 mg-kg.lcd	0.077	76.6

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

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

Table 25. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	99.8
OSR plant PK1 0,10 mg-kg.lcd	0.10	101.0
OSR plant PK2 0,010 mg-kg.lcd	0.011	110.2
OSR plant PK2 0,10 mg-kg.lcd	0.091	91.2

LOD = 0.004 mg/kg, LOQ = 0.010 mg/kg

Analysis of samples 11.07.2024 – difenoconazole and azoxystrobin in oilseed rape plant:

Difenoconazole

Table 26. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.010	101.3
OSR plant PK1 0,10 mg-kg.lcd	0.10	100.1
OSR plant PK2 0,010 mg-kg.lcd	0.010	100.5
OSR plant PK2 0,10 mg-kg.lcd	0.10	100.9

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

Azoxystrobin

Table 27. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
OSR plant sample blank.lcd	<LOD	-
OSR plant PK1 0,010 mg-kg.lcd	0.0096	95.6
OSR plant PK1 0,10 mg-kg.lcd	0.10	100.4
OSR plant PK2 0,010 mg-kg.lcd	0.0097	97.1
OSR plant PK2 0,10 mg-kg.lcd	0.098	98.0

LOD = 0.002 mg/kg, LOQ = 0.010 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830, Rev.2.

The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg in the range of 70 – 120% confirms the active substance stability during the analytical procedure.

11.07.2024 (difenoconazole and azoxystrobin in oilseed rape plant samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 368 minutes (6.1 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

16.07.2024 (triazole metabolites in oilseed rape plant samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 288 minutes (4.8 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

24.07.2024 (difenoconazole and azoxystrobin in retain oilseed rape seed samples) - The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 240 minutes (4 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

26.07.2024 (triazole derivative metabolites in retain oilseed rape seed samples) - The duration of the extraction process was about 4 hours, the duration of the chromatographic analysis was 276 minutes (4.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day.

Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

CONCLUSIONS

The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery.

The limit of quantification of the method was established at 0.010 mg/kg for oilseed rape (seeds, whole plants without roots).

There were no interfering signals at retention time of analyzed compound in examined control matrix.

The analytical method for determining the residues of triazole derivative metabolites (TAA, TA, 1,2,4-T, TLA), difenoconazole and azoxystrobin in oilseed rape (seeds, whole plants without roots) meets the criteria of SANTE/2020/12830, Rev.2 guidelines in terms of precision, accuracy and uncertainty.

After comparing the results of all the samples in this study and in analogous trials, it was found that the results of triazole metabolites for seed samples are questionable (in the untreated sample there was much more TA metabolite than in the treated sample). Therefore, on the request of Client, an analysis of retain samples were carried out to eliminate possibility of mistake on any step. After analysis it is confirmed that contamination occurred in the main samples and the results obtained from retain samples are considered as definitive results.

Active Substances: Azoxystrobin, difenoconazole **Commercial Product:** CHR/F/SCORPIO 325 SC
Crop / crop group: Winter Oilseed rape /Brassicaceae Burnett, Cruciferae Juss **Producer:** PUH Chemirol Sp. z o. o.
Responsible for reporting: Katarzyna Wańczyk
SGS Polska Sp. z o. o.
ul. Poznańska 305B
05-850 Ołtarzew
Poland
Country: Poland **Indoor/outdoor:** outdoor
Nominal Content of a. s.: 325 g/L **Other active substance:** NAP
Formulation: SC **Residue calculated for:** difenoconazole, azoxystrobin, TA, TAA, TLA, 1,2,4-T

1	2	3	4	5				6	7	8	9						10	11
				Actual application rate							Residues (1)						DALA or CH (2)	Remarks
Report No. 23SGS46	Commodity Variety	Date of 1-Sowing 2-Harvest	Method of Treatment	L a.s./ha	Water (L/ha)	g azoxystrobin (/ha)	g a difenoconazole (/ha)	Date of Treatment	BBCH at Treatment	Commodity analysed	Triazole-acetic Acid TAA	Triazole-alanine TA	Triazole-lactic Acid TLA	1,2,4-triazole 1.2.4-T	Difenoconazole	Azoxystrobin		
Poland Przylesie (Opolskie) Decline Curve Study Trial 23SGS47-01	Winter OSR Sienna	1 – 20/09/2023 2- 11/04/2024-03/05/2024 3 – 02/07/2024	Foliar spray	1,014 1,008	304,2 302,5	202,8 201,6	126,8 126,0	19/12/2023 30/04/2024	22 69	Whole plants w/o roots	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	0	Analytical Method: LC-MS/MS
										Whole plants w/o roots	<LOD	<LOD	<LOD	<LOD	2.68*	2.92*	0	
										Whole plants w/o roots	<LOD	<LOD	<LOD	<LOD	0.23*	0.48*	14	
										Whole plants w/o roots	<LOD	<LOD	<LOD	<LOD	0.16*	0.31*	21	

										Whole plants w/o roots	<LOD	<LOD	<LOD	<LOD	0.063	0.094	28	
										Seeds	<LOD	0.17	<LOD	<LOD	<LOD	<LOD	63	
										Seeds	<LOD	0.12	<LOD	<LOD	<LOD	<LOD	63	

DALA – Days After Last Application; CH – Commercial Harvest
Residues are not corrected for procedural recoveries;
Calculation based on unrounded values,
LOD= 0.002 mg/kg, LOQ= 0.010 mg/kg (difenoconazole, azoxystrobin)
LOD = 0.004 mg/kg, LOQ= 0.010 mg/kg (triazole metabolites)

A 2.1.4 Magnitude of residues in livestock

No additional studies were performed.

A 2.1.4.1 Livestock feeding studies

A 2.1.4.1.1 Livestock feeding study 1

Not required.

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

A 2.1.5.1 Distribution of the residue in peel/pulp

Not required.

A 2.1.5.1.1 Study 1

Not required.

A 2.1.5.2 Processing studies on a core set of representative processes

A 2.1.5.2.1 Study 1

A 2.1.6 Magnitude of residues in representative succeeding crops

Not required.

A 2.1.7 Other/Special Studies

A 2.1.7.1 Study 1

Comments of zRMS:	The objective of this study is the determination of residues of difenoconazole, azoxystrobin and triazole derivate metabolites (TDMs) in honey from winter oilseed rape collected by honeybees after two applications of CHR/F/SCORPIO 325 SC under semi-field conditions. Four residue trial was conducted on winter oilseed rape during 2022/2023 in Central and Southern Europe. Two trials were conducted in Germany, one trial in Southern France and one trial in Spain. Two applications of CHR/F/SCORPIO 325 SC were applied at a target rate of 1.00 L product/ha (125 g Difenoconazole/ha and 200 g azoxystrobin/ha) at an application spray volume of 300 L/ha per application. The first application was conducted at BBCH 14-23. The second application was conducted at BBCH 63-64, 6-18 days before sampling S1. The second Application was conducted in the morning before noon, with exception of trial -01 where spraying at application A2 ended slightly after noon at 12:05. Empty combs were inserted to the bee hive before the second application for later honey collection. The samples of honey from the untreated and treated plots were taken by hand using a spoon or a syringe or plastic pipette. A method validation was not performed within this analytical phase because the analytical methods were previously validated in honey with an LOQ of 0.01 mg/kg in accordance to SANTE/2020/12830, rev. 2 for the determination of difenoconazole and azoxystrobin in GLP study S22-08436 (MAHLOW S. 2023) and for 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA), triazole lactic acid (TLA) in GLP study S21- 05866 (MAHLOW S. 2022), ~~see dRR Part B5.~~ already evaluated and accepted in CHR/F/PROTAZO 375 SC final dossier. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for all analytes with a limit of detection (LOD) set at 0.003 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ). For difenoconazole and azoxystrobin, the proof of stability of the analytes in/on fortified samples upon storage period of 104 days in deep frozen conditions was conducted in study S22-08436. The storage interval in study S22-08436 covers the max. storage time from sampling to extraction in the current study. For 1,2,4-T, TA, TAA and TLA, the proof of stability of the analytes in fortified samples upon storage period of 15 months in deep frozen conditions was conducted in study S21-05867 (see dRR Part B5). The storage interval in study S21-05867 covers the max. storage time from sampling to extraction in the current study. No residues of Azoxystrobin, Difenoconazole, 1,2,4 triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) at or above 30 % of the LOQ were detected in any of the untreated honey samples. Residues of triazole alanine (TA) were detected in untreated honey samples of trial -02 with 0.01 mg/kg and of trial -05 at 0.03 mg/kg. No residues of Azoxystrobin, 1,2,4 triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) at or above 30 % of the LOQ were detected in any of the treated honey samples. Residues of Difenoconazole were between <LOQ (trials -01 and -02), 0.014 mg/kg in trial -04 and 0.012 mg/kg in trial -05. Residues of Triazole Alanine were between 0.01 mg/kg and 0.04 mg/kg in treated honey samples.

	The study is accepted. Results supporting the proposed GAP: TAA: 4 x < 0.01 mg/kg TA: 2 x 0.01 mg/kg, 0.02 mg/kg, 0.04 mg/kg TLA: 4 x < 0.01 mg/kg 1,2,4 -T: 4 x < 0.01 mg/kg Difenoconazole: 2 x < 0.01 mg/kg, 0.012 mg/kg, 0.014 mg/kg Azoxystrobin: 4 x < LOD

Reference:	KCA 6.3/46
Report	Determination of Residues of Difenoconazole, Azoxystrobin and Triazole Derivate Metabolites (TDMs) in Honey after Two applications of CHR/F/SCORPIO 325 SC in Winter Oilseed Rape at Four Sites in Central and Southern Europe in 2022/2023, Study Code: 22-08279, Analytical Phase Code: S22-08279-L1
Guideline(s):	Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC SANTE/2020/12830, rev.2
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes

Objective of the study

The objective was to analyse samples of honey for residues of difenoconazole, azoxystrobin and triazole derivate metabolites (TDMs). The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for honey in each analyte with a limit of detection (LOD) set at 0.003 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ).

Materials and methods

Sample Preparation

All samples were received at the test site for the analytical phase in frozen condition. After their arrival at the test site of the analytical phase the samples were stored at ≤ -18 °C until homogenisation. Samples were prepared according to the recommendations detailed in the test site's SOPs. Control samples were processed first, followed by samples with the lowest expected residue level to the highest expected residue level, if applicable. In order to avoid contamination, appropriate precautions and cleanings between samples were employed.

Matrix Type(s)	Laboratory Sample Preparation
Honey	The sample was homogenised by thoroughly stirring with a spatula before taking a representative sub-sample for analysis.

Matrix Type(s) Laboratory Sample Preparation Honey The sample was homogenised by thoroughly stirring with a spatula before taking a representative sub-sample for analysis. An aliquot of each

homogenised sample was stored at ≤ -18 °C so that multiple re-analyses would have been possible. The rest of the homogenised material was discarded.

Method Summary

Method for triazole metabolites was validated and summary of results presented in the report number S21-05866: *Prothioconazole – Residues of Triazole Metabolites in Honey Samples*. The study was already evaluated and accepted in CHR/F/PROTAZO 375 SC final dossier, therefore there is no need to present this data also in this dossier.
For the analysis of difenoconazole and azoxystrobin, samples of honey were extracted with acetonitrile after addition of water. The ratio was 10 mL of extraction solvent per g of matrix. Clean-up of the extract was performed by dispersive SPE with primary/secondary amine (PSA) and magnesium sulphate. The sample concentration in final extract was 0.05 g sample per mL of extract. Quantification was performed by use of LCMS/MS detection. For the analysis of triazole metabolites, samples of honey were extracted with methanol containing 1% formic acid after addition of water by shaking on a platform shaker for 15 min. An aliquot was transferred to a new 15 mL Sarstedt tube and isotopically labelled internal standards were added prior to evaporating the methanol phase of the extract. Quantification was performed by use of LC-DMS-MS/MS detection with isotopically labelled internal standard. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte with a limit of detection (LOD) set at 0.003 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ).

Results

The limit of quantification (LOQ) was 0.01 mg/kg with a limit of detection (LOD) of 0.003 mg/kg.

For honey, the maximum storage interval from sampling until extraction was 102 days for difenoconazole and azoxystrobin, and 98 for the triazole metabolites.

The storage temperature of the samples at the analytical test site was ≤ -18 °C.

The maximum storage interval of final sample extracts at typically 1 °C to 10 °C from extraction until injection to the detection system was 0 day for all analytes. All analysed samples are reported in this analytical phase report. Any result reported for a sample originates from single extraction and single injection to the detection system. Re-analysis in duplicate and/or analysis of any retain sample for result verification was not requested by the Study Director. Results in mg/kg are reported without correction for the obtained concurrent recoveries, i.e., no adjustments to hypothetical concurrent recoveries of 100 % were made.

The following residues were detected in the samples:

Sampling Code	Target Timing	Treatment	Sample Code	EAS (Chem) Internal Code	Sample Type	Residue of Difenoconazole (mg/kg)	Residue of Azoxystrobin (mg/kg)
Trial S22-08279-01 (Germany)							
S1	Maturity	C	L22-08279-01-C-S1-HO-A1	1	Honey	<0.01	<0.01
		T	L22-08279-01-T-S1-HO-A1	2	Honey	<0.01	<0.01
Trial S22-08279-02 (Germany)							
S1	Maturity	C	L22-08279-02-C-S1-HO-A1	3	Honey	<0.01	<0.01
		T	L22-08279-02-T-S1-HO-A1	4	Honey	<0.01	<0.01
Trial S22-08279-04 (France)							
S1	Maturity	C	L22-08279-04-C-S1-HO-A1	5	Honey	<0.01	<0.01
		T	L22-08279-04-T-S1-HO-A1	6	Honey	0.014	<0.01
Trial S22-08279-05 (Spain)							
S1	Maturity	C	L22-08279-05-C-S1-HO-A1	7	Honey	<0.01	<0.01
		T	L22-08279-05-T-S1-HO-A1	8	Honey	0.012	<0.01

T = treated; C = untreated.
Residues are not corrected for concurrent recoveries

Sampling Code	Target Timing	Treatment	Sample Code	EAS (Chem) Internal Code	Residue of 1,2,4-Triazole (mg/kg)	Residue of Triazole Alanine (mg/kg)	Residue of Triazole Acetic Acid (mg/kg)	Residue of Triazole Lactic Acid (mg/kg)
Trial S22-08279-01 (Germany)								
S1	Maturity	C	L22-08279-01-C-S1-HO-A1	1	<0.01	<0.01	<0.01	<0.01
		T	L22-08279-01-T-S1-HO-A1	2	<0.01	0.02	<0.01	<0.01
Trial S22-08279-02 (Germany)								
S1	Maturity	C	L22-08279-02-C-S1-HO-A1	3	<0.01	0.01	<0.01	<0.01
		T	L22-08279-02-T-S1-HO-A1	4	<0.01	0.01	<0.01	<0.01
Trial S22-08279-04 (France)								
S1	Maturity	C	L22-08279-04-C-S1-HO-A1	5	<0.01	<0.01	<0.01	<0.01
		T	L22-08279-04-T-S1-HO-A1	6	<0.01	0.01	<0.01	<0.01
Trial S22-08279-05 (Spain)								
S1	Maturity	C	L22-08279-05-C-S1-HO-A1	7	<0.01	0.03	<0.01	<0.01
		T	L22-08279-05-T-S1-HO-A1	8	<0.01	0.04	<0.01	<0.01

T = treated; C = untreated.
Residues are not corrected for concurrent recoveries

Conclusion

With regard to selectivity, accuracy and precision, the analytical method was applied successfully for each analytical set when analysing the samples of the study.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

Azoxystrobin

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.2	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	
Year of evaluation:	2010; 8 (4): 1542	Year of evaluation:	

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
22%	NL child	43.19	21%	Sugar beet roots	0.2%	Rapeseeds/canola seeds	0.1%	Milk: Cattle		22%
14%	NL toddler	27.93	13%	Sugar beet roots	0.3%	Rapeseeds/canola seeds	0.3%	Milk: Cattle		14%
12%	DE women 14-50 yr	23.21	11%	Sugar beet roots	0.1%	Milk: Cattle	0.0%	Celeriacs/turnip rooted celeries		12%
11%	DE general	21.38	11%	Sugar beet roots	0.1%	Milk: Cattle	0.0%	Celeriacs/turnip rooted celeries		11%
3%	FR child 3 15 yr	18.89	3%	Sugar beet roots	0.1%	Milk: Cattle	0.1%	Turnips		3%
8%	UK toddler	16.33	8%	Sugar beet roots	0.1%	Milk: Cattle	0.0%	Swedes/rutabagas		8%
7%	NL general	14.89	7%	Sugar beet roots	0.1%	Rapeseeds/canola seeds	0.1%	Sunflower seeds		7%
7%	FR toddler 2 3 yr	14.85	7%	Sugar beet roots	0.1%	Milk: Cattle	0.1%	Turnips		7%
4%	GEMS/Food G06	8.65	4%	Sugar beet roots	0.3%	Soybeans	0.1%	Pumpkins		4%
4%	UK infant	7.62	4%	Sugar beet roots	0.2%	Milk: Cattle	0.1%	Swedes/rutabagas		4%
4%	FR infant	7.30	3%	Sugar beet roots	0.1%	Turnips	0.1%	Milk: Cattle		4%
4%	RO general	7.08	3%	Sugar beet roots	0.2%	Sunflower seeds	0.1%	Milk: Cattle		4%
2%	FR adult	4.29	2%	Sugar beet roots	0.0%	Turnips	0.0%	Sunflower seeds		2%
1%	UK adult	2.88	1%	Sugar beet roots	0.0%	Milk: Cattle	0.0%	Swedes/rutabagas		1%
1%	GEMS/Food G11	2.83	0.9%	Soybeans	0.2%	Beetroots	0.1%	Celeriacs/turnip rooted celeries		1%
1%	UK vegetarian	2.72	1%	Sugar beet roots	0.0%	Milk: Cattle	0.0%	Beetroots		1%
1%	GEMS/Food G10	2.53	0.8%	Soybeans	0.1%	Pumpkins	0.1%	Rapeseeds/canola seeds		1%
1%	GEMS/Food G07	2.19	0.4%	Soybeans	0.2%	Rapeseeds/canola seeds	0.1%	Sunflower seeds		1%
1%	GEMS/Food G08	2.05	0.5%	Soybeans	0.1%	Turnips	0.1%	Sunflower seeds		1%
1%	GEMS/Food G15	2.02	0.4%	Soybeans	0.1%	Sunflower seeds	0.1%	Beetroots		1%
0.6%	ES child	1.14	0.4%	Sugar beet roots	0.1%	Milk: Cattle	0.0%	Sunflower seeds		0.6%
0.4%	IE adult	0.82	0.1%	Swedes/rutabagas	0.1%	Celeriacs/turnip rooted celeries	0.1%	Beetroots		0.4%
0.4%	ES adult	0.81	0.3%	Sugar beet roots	0.0%	Sunflower seeds	0.0%	Milk: Cattle		0.4%
0.2%	SE general	0.48	0.1%	Milk: Cattle	0.0%	Beetroots	0.0%	Beetroots		0.2%
0.2%	DE child	0.42	0.1%	Milk: Cattle	0.0%	Celeriacs/turnip rooted celeries	0.0%	Sunflower seeds		0.2%
0.2%	PT general	0.31	0.1%	Soybeans	0.1%	Sunflower seeds	0.0%	Turnips		0.2%
0.1%	PL general	0.27	0.1%	Beetroots	0.0%	Celeriacs/turnip rooted celeries	0.0%	Sunflower seeds		0.1%
0.1%	DK child	0.24	0.1%	Milk: Cattle	0.0%	Celeriacs/turnip rooted celeries	0.0%	Swine: Muscle/meat		0.1%
0.1%	LT adult	0.22	0.1%	Beetroots	0.0%	Milk: Cattle	0.0%	Sunflower seeds		0.1%
0.1%	FI 3 yr	0.21	0.0%	Beetroots	0.0%	Rapeseeds/canola seeds	0.0%	Swedes/rutabagas		0.1%
0.1%	FI 6 yr	0.19	0.1%	Beetroots	0.0%	Rapeseeds/canola seeds	0.0%	Swedes/rutabagas		0.1%
0.1%	FI adult	0.11	0.0%	Beetroots	0.0%	Swedes/rutabagas	0.0%	Soybeans		0.1%
0.1%	DK adult	0.10	0.0%	Milk: Cattle	0.0%	Celeriacs/turnip rooted celeries	0.0%	Swine: Fat tissue		0.1%
0.0%	IE child	0.08	0.0%	Milk: Cattle	0.0%	Turnips	0.0%	Swine: Fat tissue		0.0%
0.0%	IT toddler	0.05	0.0%	Pumpkins	0.0%	Sunflower seeds	0.0%	Turnips		0.0%
0.0%	IT adult	0.03	0.0%	Pumpkins	0.0%	Beetroots	0.0%	Sunflower seeds		0.0%

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

Difenoconazole

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.16
Source of ADI:	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 : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
32%	NL child	3.13	22%	Sugar beet roots	3%	Rapeseeds/canola seeds	2%	Milk: Cattle		32%
31%	NL toddler	3.13	14%	Sugar beet roots	6%	Rapeseeds/canola seeds	6%	Milk: Cattle		31%
21%	GEMS/Food G11	2.13	7%	Celeriacs/turnip rooted celeries	5%	Soybeans	3%	Chicory roots		21%
18%	FR child 3 15 yr	1.83	10%	Sugar beet roots	2%	Milk: Cattle	1%	Poultry: Muscle/meat		18%
16%	DE women 14-50 yr	1.58	12%	Sugar beet roots	1%	Milk: Cattle	0.9%	Celeriacs/turnip rooted celeries		16%
16%	GEMS/Food G07	1.55	4%	Rapeseeds/canola seeds	2%	Poultry: Muscle/meat	2%	Soybeans		16%
15%	FR toddler 2 3 yr	1.51	7%	Sugar beet roots	3%	Milk: Cattle	0.9%	Poultry: Muscle/meat		15%
15%	DE general	1.50	11%	Sugar beet roots	1%	Milk: Cattle	1.0%	Celeriacs/turnip rooted celeries		15%
14%	UK toddler	1.39	8%	Sugar beet roots	2%	Milk: Cattle	0.9%	Poultry: Muscle/meat		14%
14%	GEMS/Food G15	1.39	3%	Celeriacs/turnip rooted celeries	2%	Soybeans	2%	Poultry: Muscle/meat		14%
13%	NL general	1.31	7%	Sugar beet roots	2%	Rapeseeds/canola seeds	0.8%	Milk: Cattle		13%
13%	GEMS/Food G10	1.27	4%	Soybeans	3%	Poultry: Muscle/meat	2%	Rapeseeds/canola seeds		13%
13%	UK infant	1.26	4%	Milk: Cattle	4%	Sugar beet roots	1%	Eggs: Chicken		13%
12%	GEMS/Food G08	1.18	3%	Soybeans	2%	Rapeseeds/canola seeds	2%	Poultry: Muscle/meat		12%
11%	IE adult	1.09	3%	Celeriacs/turnip rooted celeries	2%	Sheep: Liver	1%	Swedes/rutabagas		11%
10%	GEMS/Food G06	1.01	4%	Sugar beet roots	2%	Soybeans	1%	Poultry: Muscle/meat		10%
8%	RO general	0.78	3%	Sugar beet roots	2%	Poultry: Muscle/meat	1%	Milk: Cattle		8%
7%	FR infant	0.72	4%	Sugar beet roots	2%	Milk: Cattle	0.9%	Turnips		7%
7%	ES child	0.70	3%	Poultry: Muscle/meat	1%	Milk: Cattle	0.8%	Bovine: Muscle/meat		7%
7%	DE child	0.67	2%	Milk: Cattle	1%	Poultry: Muscle/meat	1%	Celeriacs/turnip rooted celeries		7%
6%	SE general	0.64	3%	Bovine: Muscle/meat	1%	Milk: Cattle	0.9%	Eggs: Chicken		6%
6%	DK child	0.63	1%	Milk: Cattle	1%	Celeriacs/turnip rooted celeries	1%	Poultry: Muscle/meat		6%
6%	FR adult	0.58	2%	Sugar beet roots	0.6%	Poultry: Muscle/meat	0.4%	Milk: Cattle		6%
4%	ES adult	0.38	1%	Poultry: Muscle/meat	0.5%	Milk: Cattle	0.5%	Eggs: Chicken		4%
4%	UK adult	0.37	1%	Sugar beet roots	0.3%	Poultry: Muscle/meat	0.4%	Bovine: Muscle/meat		4%
3%	DK adult	0.28	0.5%	Milk: Cattle	0.5%	Poultry: Muscle/meat	0.4%	Eggs: Chicken		3%
3%	LT adult	0.27	0.6%	Beetroots	0.6%	Poultry: Muscle/meat	0.4%	Milk: Cattle		3%
2%	UK vegetarian	0.24	1%	Sugar beet roots	0.3%	Eggs: Chicken	0.3%	Milk: Cattle		2%
2%	PL general	0.21	1%	Beetroots	1.0%	Celeriacs/turnip rooted celeries	0.0%	Horseradishes		2%
2%	FI 3 yr	0.17	0.5%	Rapeseeds/canola seeds	0.5%	Celeriacs/turnip rooted celeries	0.5%	Beetroots		2%
1%	FI 6 yr	0.13	0.6%	Beetroots	0.4%	Rapeseeds/canola seeds	0.1%	Swedes/rutabagas		1%
1%	IE child	0.12	0.4%	Milk: Cattle	0.3%	Poultry: Muscle/meat	0.2%	Eggs: Chicken		1%
0.7%	FI adult	0.07	0.3%	Beetroots	0.2%	Celeriacs/turnip rooted celeries	0.1%	Swedes/rutabagas		0.7%
0.6%	PT general	0.06	0.4%	Soybeans	0.2%	Sunflower seeds	0.1%	Turnips		0.6%
0.1%	IT adult	0.01	0.1%	Celeriacs/turnip rooted celeries	0.0%	Beetroots	0.0%	Turnips		0.1%
0.1%	IT toddler	0.01	0.0%	Turnips	0.0%	Celeriacs/turnip rooted celeries	0.0%	Sunflower seeds		0.1%

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

TAA (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
0.0%	GEMS/Food G11	0.44	0.0%	Soyabeans	0.0%	Milk: Cattle	0.0%	Sunflower seeds		
0.0%	GEMS/Food G10	0.42	0.0%	Soyabeans	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds		
0.0%	NL toddler	0.40	0.0%	Milk: Cattle	0.0%	Rapeseeds/canola seeds	0.0%	Sugar beet roots		
0.0%	GEMS/Food G08	0.33	0.0%	Soyabeans	0.0%	Sunflower seeds	0.0%	Rapeseeds/canola seeds		
0.0%	GEMS/Food G07	0.32	0.0%	Soyabeans	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds		
0.0%	GEMS/Food G15	0.30	0.0%	Soyabeans	0.0%	Sunflower seeds	0.0%	Milk: Cattle		
0.0%	NL child	0.29	0.0%	Sugar beet roots	0.0%	Milk: Cattle	0.0%	Rapeseeds/canola seeds		
0.0%	GEMS/Food G06	0.18	0.0%	Soyabeans	0.0%	Sunflower seeds	0.0%	Sugar beet roots		
0.0%	FR child 3 15 yr	0.18	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Sunflower seeds		
0.0%	FR toddler 2 3 yr	0.17	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Sunflower seeds		
0.0%	UK infant	0.16	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Eggs: Chicken		
0.0%	RO general	0.14	0.0%	Sunflower seeds	0.0%	Milk: Cattle	0.0%	Sugar beet roots		
0.0%	NL general	0.13	0.0%	Sugar beet roots	0.0%	Rapeseeds/canola seeds	0.0%	Milk: Cattle		
0.0%	UK toddler	0.12	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Eggs: Chicken		
0.0%	DE women 14-50 yr	0.11	0.0%	Sugar beet roots	0.0%	Milk: Cattle	0.0%	Sunflower seeds		
0.0%	DE general	0.11	0.0%	Sugar beet roots	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat		
0.0%	DE child	0.10	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Sunflower seeds		
0.0%	ES child	0.09	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Sunflower seeds		
0.0%	FR infant	0.08	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Sunflower seeds		
0.0%	IE adult	0.08	0.0%	Sunflower seeds	0.0%	Linseeds	0.0%	Milk: Cattle		
0.0%	DK child	0.07	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Eggs: Chicken		
0.0%	SE general	0.07	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Eggs: Chicken		
0.0%	PT general	0.06	0.0%	Soyabeans	0.0%	Sunflower seeds	0.0%	Turnips		
0.0%	FR adult	0.06	0.0%	Milk: Cattle	0.0%	Sunflower seeds	0.0%	Sugar beet roots		
0.0%	ES adult	0.05	0.0%	Milk: Cattle	0.0%	Sunflower seeds	0.0%	Poultry: Muscle/meat		
0.0%	DK adult	0.03	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Eggs: Chicken		
0.0%	LT adult	0.03	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Sunflower seeds		
0.0%	UK adult	0.03	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Poultry: Muscle/meat		
0.0%	UK vegetarian	0.02	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Eggs: Chicken		
0.0%	IE child	0.02	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Poultry: Muscle/meat		
0.0%	FI 3 yr	0.01	0.0%	Rapeseeds/canola seeds	0.0%	Beetroots	0.0%	Sunflower seeds		
0.0%	FI 6 yr	0.01	0.0%	Rapeseeds/canola seeds	0.0%	Beetroots	0.0%	Sunflower seeds		
0.0%	FI adult	0.00	0.0%	Soyabeans	0.0%	Sunflower seeds	0.0%	Linseeds		
0.0%	PL general	0.00	0.0%	Beetroots	0.0%	Sunflower seeds	0.0%	Celeriacs/turnip rooted celeries		
0.0%	IT toddler	0.00	0.0%	Sunflower seeds	0.0%	Soyabeans	0.0%	Turnips		
0.0%	IT adult	0.00	0.0%	Sunflower seeds	0.0%	Soyabeans	0.0%	Beetroots		

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

TA (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
19%	GEMS/Food G11	57.73	19%	Soybeans	0.5%	Sunflower seeds	0.1%	Mustard seeds		
19%	GEMS/Food G10	56.70	16%	Soybeans	1%	Rapeseeds/canola seeds	1%	Sunflower seeds		
14%	GEMS/Food G08	42.13	10%	Soybeans	2%	Sunflower seeds	2%	Rapeseeds/canola seeds		
14%	GEMS/Food G07	40.93	9%	Soybeans	3%	Rapeseeds/canola seeds	2%	Sunflower seeds		
12%	GEMS/Food G15	37.47	9%	Soybeans	3%	Sunflower seeds	1%	Rapeseeds/canola seeds		
7%	GEMS/Food G06	22.43	6%	Soybeans	1%	Sunflower seeds	0.2%	Rapeseeds/canola seeds		
7%	NL toddler	22.00	5%	Rapeseeds/canola seeds	1%	Sunflower seeds	0.8%	Soybeans		
5%	NL child	16.23	2%	Rapeseeds/canola seeds	2%	Sunflower seeds	1%	Soybeans		
3%	RO general	10.27	3%	Sunflower seeds	0.0%	Milk: Cattle	0.0%	Sugar beet roots		
3%	NL general	9.24	1%	Rapeseeds/canola seeds	1%	Sunflower seeds	0.6%	Soybeans		
3%	PT general	8.90	2%	Soybeans	1%	Sunflower seeds	0.0%	Turnips		
2%	IE adult	5.51	1.0%	Sunflower seeds	0.7%	Linseeds	0.0%	Sheep: Liver		
2%	FR child 3 15 yr	5.06	1%	Sunflower seeds	0.2%	Soybeans	0.1%	Mustard seeds		
1%	FR toddler 2 3 yr	3.53	0.7%	Sunflower seeds	0.2%	Soybeans	0.1%	Milk: Cattle		
1.0%	DE child	3.00	0.5%	Sunflower seeds	0.2%	Soybeans	0.1%	Milk: Cattle		
0.8%	FR adult	2.33	0.5%	Sunflower seeds	0.1%	Soybeans	0.1%	Mustard seeds		
0.7%	DE women 14-50 yr	2.16	0.3%	Sunflower seeds	0.2%	Soybeans	0.1%	Sugar beet roots		
0.7%	ES child	2.12	0.6%	Sunflower seeds	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
0.7%	DE general	2.04	0.3%	Sunflower seeds	0.2%	Soybeans	0.1%	Rapeseeds/canola seeds		
0.6%	ES adult	1.70	0.5%	Sunflower seeds	0.0%	Milk: Cattle	0.0%	Soybeans		
0.5%	FI 3 yr	1.44	0.4%	Rapeseeds/canola seeds	0.0%	Sunflower seeds	0.0%	Soybeans		
0.3%	FI 6 yr	1.00	0.3%	Rapeseeds/canola seeds	0.0%	Sunflower seeds	0.0%	Soybeans		
0.3%	FR infant	0.92	0.1%	Sunflower seeds	0.1%	Milk: Cattle	0.0%	Soybeans		
0.2%	LT adult	0.74	0.2%	Sunflower seeds	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat		
0.2%	FI adult	0.61	0.1%	Soybeans	0.0%	Sunflower seeds	0.0%	Linseeds		
0.2%	UK infant	0.55	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Eggs: Chicken		
0.1%	UK toddler	0.41	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Eggs: Chicken		
0.1%	IT toddler	0.34	0.1%	Sunflower seeds	0.0%	Soybeans	0.0%	Turnips		
0.1%	DK child	0.28	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Eggs: Chicken		
0.1%	SE general	0.24	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Eggs: Chicken		
0.1%	IT adult	0.19	0.0%	Sunflower seeds	0.0%	Soybeans	0.0%	Beetroots		
0.1%	PL general	0.15	0.0%	Sunflower seeds	0.0%	Soybeans	0.0%	Beetroots		
0.0%	DK adult	0.12	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Eggs: Chicken		
0.0%	UK adult	0.10	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Poultry: Muscle/meat		
0.0%	UK vegetarian	0.07	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Eggs: Chicken		
0.0%	IE child	0.06	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Eggs: Chicken		

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

TLA (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
0.7%	GEMS/Food G11	2.01	0.6%	Soyabeans	0.0%	Sunflower seeds	0.0%	Poultry: Muscle/meat		
0.7%	GEMS/Food G10	1.98	0.5%	Soyabeans	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds		
0.5%	GEMS/Food G08	1.48	0.3%	Soyabeans	0.1%	Sunflower seeds	0.1%	Rapeseeds/canola seeds		
0.5%	GEMS/Food G07	1.45	0.3%	Soyabeans	0.1%	Rapeseeds/canola seeds	0.1%	Sunflower seeds		
0.4%	GEMS/Food G15	1.33	0.3%	Soyabeans	0.1%	Sunflower seeds	0.0%	Rapeseeds/canola seeds		
0.3%	NL toddler	0.98	0.2%	Rapeseeds/canola seeds	0.1%	Milk: Cattle	0.0%	Sunflower seeds		
0.3%	GEMS/Food G06	0.80	0.2%	Soyabeans	0.0%	Sunflower seeds	0.0%	Poultry: Muscle/meat		
0.2%	NL child	0.73	0.1%	Rapeseeds/canola seeds	0.1%	Sunflower seeds	0.0%	Soyabeans		
0.1%	RO general	0.44	0.1%	Sunflower seeds	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
0.1%	NL general	0.39	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds	0.0%	Soyabeans		
0.1%	FR child 3 15 yr	0.35	0.0%	Sunflower seeds	0.0%	Milk: Cattle	0.0%	Eggs: Chicken		
0.1%	PT general	0.30	0.1%	Soyabeans	0.0%	Sunflower seeds	0.0%	Turnips		
0.1%	FR toddler 2 3 yr	0.28	0.0%	Milk: Cattle	0.0%	Sunflower seeds	0.0%	Sugar beet roots		
0.1%	IE adult	0.24	0.0%	Sunflower seeds	0.0%	Linseeds	0.0%	Poultry: Muscle/meat		
0.1%	DE child	0.22	0.0%	Milk: Cattle	0.0%	Sunflower seeds	0.0%	Eggs: Chicken		
0.1%	UK infant	0.20	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Poultry: Muscle/meat		
0.1%	ES child	0.19	0.0%	Sunflower seeds	0.0%	Poultry: Muscle/meat	0.0%	Milk: Cattle		
0.1%	DE women 14-50 yr	0.17	0.0%	Sugar beet roots	0.0%	Milk: Cattle	0.0%	Sunflower seeds		
0.1%	DE general	0.17	0.0%	Sugar beet roots	0.0%	Milk: Cattle	0.0%	Sunflower seeds		
0.0%	UK toddler	0.15	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Eggs: Chicken		
0.0%	FR adult	0.13	0.0%	Sunflower seeds	0.0%	Milk: Cattle	0.0%	Eggs: Chicken		
0.0%	ES adult	0.12	0.0%	Sunflower seeds	0.0%	Poultry: Muscle/meat	0.0%	Milk: Cattle		
0.0%	DK child	0.11	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Poultry: Muscle/meat		
0.0%	FR infant	0.11	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Sunflower seeds		
0.0%	SE general	0.09	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Bovine: Muscle/meat		
0.0%	LT adult	0.07	0.0%	Sunflower seeds	0.0%	Poultry: Muscle/meat	0.0%	Milk: Cattle		
0.0%	FI 3 yr	0.05	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds	0.0%	Soyabeans		
0.0%	DK adult	0.05	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Poultry: Muscle/meat		
0.0%	UK adult	0.05	0.0%	Poultry: Muscle/meat	0.0%	Eggs: Chicken	0.0%	Milk: Cattle		
0.0%	FI 6 yr	0.04	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds	0.0%	Soyabeans		
0.0%	UK vegetarian	0.03	0.0%	Eggs: Chicken	0.0%	Milk: Cattle	0.0%	Sugar beet roots		
0.0%	IE child	0.03	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Eggs: Chicken		
0.0%	FI adult	0.02	0.0%	Soyabeans	0.0%	Sunflower seeds	0.0%	Linseeds		
0.0%	IT toddler	0.01	0.0%	Sunflower seeds	0.0%	Soyabeans	0.0%	Turnips		
0.0%	PL general	0.01	0.0%	Sunflower seeds	0.0%	Beetroots	0.0%	Celeriacs/turnip rooted celeries		
0.0%	IT adult	0.01	0.0%	Sunflower seeds	0.0%	Soyabeans	0.0%	Beetroots		

European Food Safety Authority
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1,2,4-T (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
3%	NL toddler	0.71	3%	Milk: Cattle	0.2%	Sugar beet roots	0.1%	Rapeseeds/canola seeds		
2%	UK infant	0.44	2%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Eggs: Chicken		
2%	NL child	0.38	1%	Milk: Cattle	0.4%	Sugar beet roots	0.0%	Swine: Muscle/meat		
2%	FR toddler 2 3 yr	0.37	1%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Bovine: Muscle/meat		
1%	FR child 3 15 yr	0.33	1.0%	Milk: Cattle	0.2%	Sugar beet roots	0.1%	Bovine: Muscle/meat		
1%	UK toddler	0.27	0.9%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Bovine: Muscle/meat		
1%	DE child	0.23	0.9%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Poultry: Muscle/meat		
0.9%	FR infant	0.20	0.7%	Milk: Cattle	0.1%	Sugar beet roots	0.0%	Swine: Muscle/meat		
0.8%	DE women 14-50 yr	0.19	0.5%	Milk: Cattle	0.2%	Sugar beet roots	0.0%	Swine: Muscle/meat		
0.8%	DE general	0.19	0.5%	Milk: Cattle	0.2%	Sugar beet roots	0.0%	Swine: Muscle/meat		
0.8%	ES child	0.18	0.5%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Poultry: Muscle/meat		
0.8%	SE general	0.18	0.5%	Milk: Cattle	0.2%	Bovine: Muscle/meat	0.0%	Eggs: Chicken		
0.8%	GEMS/Food G11	0.18	0.3%	Milk: Cattle	0.2%	Soybeans	0.1%	Swine: Muscle/meat		
0.8%	DK child	0.18	0.5%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.1%	Bovine: Muscle/meat		
0.7%	RO general	0.17	0.5%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Swine: Muscle/meat		
0.7%	GEMS/Food G10	0.15	0.2%	Milk: Cattle	0.2%	Soybeans	0.1%	Poultry: Muscle/meat		
0.7%	GEMS/Food G15	0.15	0.3%	Milk: Cattle	0.1%	Soybeans	0.1%	Swine: Muscle/meat		
0.6%	GEMS/Food G07	0.15	0.3%	Milk: Cattle	0.1%	Soybeans	0.1%	Poultry: Muscle/meat		
0.6%	NL general	0.15	0.4%	Milk: Cattle	0.1%	Sugar beet roots	0.0%	Swine: Muscle/meat		
0.6%	GEMS/Food G08	0.14	0.2%	Milk: Cattle	0.1%	Soybeans	0.1%	Swine: Muscle/meat		
0.4%	ES adult	0.08	0.2%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		
0.4%	FR adult	0.08	0.2%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Swine: Muscle/meat		
0.3%	GEMS/Food G06	0.08	0.1%	Milk: Cattle	0.1%	Soybeans	0.1%	Sugar beet roots		
0.3%	IE adult	0.08	0.2%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		
0.3%	DK adult	0.08	0.2%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
0.3%	LT adult	0.06	0.2%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Eggs: Chicken		
0.2%	UK adult	0.05	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Sugar beet roots		
0.2%	IE child	0.04	0.2%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Eggs: Chicken		
0.2%	UK vegetarian	0.04	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Eggs: Chicken		
0.0%	PT general	0.01	0.0%	Soybeans	0.0%	Sunflower seeds	0.0%	Turnips		
0.0%	FI 3 yr	0.00	0.0%	Rapeseeds/canola seeds	0.0%	Beetroots	0.0%	Swedes/rutabagas		
0.0%	PL general	0.00	0.0%	Beetroots	0.0%	Celeriacs/turnip rooted celeries	0.0%	Sunflower seeds		
0.0%	FI 6 yr	0.00	0.0%	Beetroots	0.0%	Rapeseeds/canola seeds	0.0%	Swedes/rutabagas		
0.0%	FI adult	0.00	0.0%	Beetroots	0.0%	Soybeans	0.0%	Swedes/rutabagas		
0.0%	IT toddler	0.00	0.0%	Sunflower seeds	0.0%	Soybeans	0.0%	Turnips		
0.0%	IT adult	0.00	0.0%	Sunflower seeds	0.0%	Beetroots	0.0%	Soybeans		

A 3.2 IEDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

Azoxystrobin

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.2	ARfD (mg/kg bw):	not necessary
Source of ADI:	EFSA	Source of ARfD:	
Year of evaluation:	2010; 8 (4): 1542	Year of evaluation:	

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
0.3%	NL toddler	0.70	0.3%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Bovine: Muscle/meat		0.3%
0.2%	UK infant	0.44	0.2%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Eggs: Chicken		0.2%
0.2%	NL child	0.37	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Swine: Muscle/meat		0.2%
0.2%	FR toddler 2 3 yr	0.37	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Bovine: Muscle/meat		0.2%
0.2%	FR child 3 15 yr	0.33	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Bovine: Muscle/meat		0.2%
0.1%	UK toddler	0.27	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Bovine: Muscle/meat		0.1%
0.1%	DE child	0.23	0.1%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Poultry: Muscle/meat		0.1%
0.1%	FR infant	0.20	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Swine: Muscle/meat		0.1%
0.1%	DE women 14-50 yr	0.19	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Swine: Muscle/meat		0.1%
0.1%	DE general	0.19	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Swine: Muscle/meat		0.1%
0.1%	SE general	0.18	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Eggs: Chicken		0.1%
0.1%	ES child	0.18	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Poultry: Muscle/meat		0.1%
0.1%	DK child	0.18	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		0.1%
0.1%	RO general	0.17	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Swine: Muscle/meat		0.1%
0.1%	GEMS/Food G11	0.16	0.0%	Milk: Cattle	0.0%	Soybeans	0.0%	Swine: Muscle/meat		0.1%
0.1%	NL general	0.15	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Swine: Muscle/meat		0.1%
0.1%	GEMS/Food G15	0.14	0.0%	Milk: Cattle	0.0%	Soybeans	0.0%	Swine: Muscle/meat		0.1%
0.1%	GEMS/Food G07	0.14	0.0%	Milk: Cattle	0.0%	Soybeans	0.0%	Poultry: Muscle/meat		0.1%
0.1%	GEMS/Food G10	0.13	0.0%	Milk: Cattle	0.0%	Soybeans	0.0%	Poultry: Muscle/meat		0.1%
0.1%	GEMS/Food G08	0.13	0.0%	Milk: Cattle	0.0%	Soybeans	0.0%	Swine: Muscle/meat		0.1%
0.0%	ES adult	0.08	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		0.0%
0.0%	FR adult	0.08	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Swine: Muscle/meat		0.0%
0.0%	IE adult	0.08	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		0.0%
0.0%	DK adult	0.08	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		0.0%
0.0%	GEMS/Food G06	0.07	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Soybeans		0.0%
0.0%	LT adult	0.06	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Eggs: Chicken		0.0%
0.0%	UK adult	0.05	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Sugar beet roots		0.0%
0.0%	IE child	0.04	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Eggs: Chicken		0.0%
0.0%	UK vegetarian	0.04	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Eggs: Chicken		0.0%
0.0%	PT general	0.01	0.0%	Soybeans	0.0%	Sunflower seeds	0.0%	Turnips		0.0%
0.0%	PL general	0.00	0.0%	Beetroots	0.0%	Celeriacs/turnip rooted celeries	0.0%	Sunflower seeds		0.0%
0.0%	FI 3 yr	0.00	0.0%	Beetroots	0.0%	Rapeseeds/canola seeds	0.0%	Swedes/rutabagas		0.0%
0.0%	FI 6 yr	0.00	0.0%	Beetroots	0.0%	Rapeseeds/canola seeds	0.0%	Swedes/rutabagas		0.0%
0.0%	FI adult	0.00	0.0%	Beetroots	0.0%	Swedes/rutabagas	0.0%	Soybeans		0.0%
0.0%	IT toddler	0.00	0.0%	Pumpkins	0.0%	Sunflower seeds	0.0%	Turnips		0.0%
0.0%	IT adult	0.00	0.0%	Pumpkins	0.0%	Beetroots	0.0%	Sunflower seeds		0.0%

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Difenoconazole

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.16
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2011	Year of evaluation:	2011

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	8%	NL toddler	0.78	6%	Milk: Cattle	0.8%	Sugar beet roots	0.2%	Bovine: Muscle/meat		8%
	5%	UK infant	0.51	4%	Milk: Cattle	0.3%	Eggs: Chicken	0.2%	Bovine: Muscle/meat		5%
	5%	NL child	0.46	2%	Milk: Cattle	1%	Sugar beet roots	0.2%	Swine: Muscle/meat		5%
	4%	FR toddler 2 3 yr	0.43	3%	Milk: Cattle	0.4%	Sugar beet roots	0.2%	Bovine: Muscle/meat		4%
	4%	FR child 3 15 yr	0.40	2%	Milk: Cattle	0.5%	Sugar beet roots	0.3%	Bovine: Muscle/meat		4%
	3%	UK toddler	0.32	2%	Milk: Cattle	0.5%	Sugar beet roots	0.3%	Bovine: Muscle/meat		3%
	3%	DE child	0.26	2%	Milk: Cattle	0.2%	Eggs: Chicken	0.1%	Poultry: Muscle/meat		3%
	2%	ES child	0.24	1%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.3%	Poultry: Muscle/meat		2%
	2%	DK child	0.24	1%	Milk: Cattle	0.4%	Swine: Muscle/meat	0.3%	Bovine: Muscle/meat		2%
	2%	DE women 14-50 yr	0.23	1%	Milk: Cattle	0.7%	Sugar beet roots	0.2%	Swine: Muscle/meat		2%
	2%	DE general	0.23	1%	Milk: Cattle	0.6%	Sugar beet roots	0.2%	Swine: Muscle/meat		2%
	2%	SE general	0.23	1%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.2%	Eggs: Chicken		2%
	2%	FR infant	0.22	2%	Milk: Cattle	0.2%	Sugar beet roots	0.1%	Swine: Muscle/meat		2%
	2%	GEMS/Food G11	0.21	0.8%	Milk: Cattle	0.5%	Soybeans	0.2%	Swine: Muscle/meat		2%
	2%	GEMS/Food G07	0.21	0.6%	Milk: Cattle	0.2%	Poultry: Muscle/meat	0.2%	Swine: Muscle/meat		2%
	2%	RO general	0.20	1%	Milk: Cattle	0.2%	Swine: Muscle/meat	0.2%	Sugar beet roots		2%
	2%	GEMS/Food G15	0.19	0.7%	Milk: Cattle	0.3%	Swine: Muscle/meat	0.2%	Soybeans		2%
	2%	NL general	0.19	0.8%	Milk: Cattle	0.4%	Sugar beet roots	0.2%	Swine: Muscle/meat		2%
	2%	GEMS/Food G10	0.19	0.5%	Milk: Cattle	0.4%	Soybeans	0.3%	Poultry: Muscle/meat		2%
	2%	GEMS/Food G08	0.18	0.6%	Milk: Cattle	0.4%	Swine: Muscle/meat	0.3%	Soybeans		2%
	1%	IE adult	0.14	0.4%	Milk: Cattle	0.3%	Sheep: Liver	0.1%	Sheep: Edible offals (other than liv		1%
	1%	ES adult	0.11	0.5%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Swine: Muscle/meat		1%
	1%	FR adult	0.11	0.4%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.1%	Bovine: Muscle/meat		1%
	1%	GEMS/Food G06	0.11	0.2%	Milk: Cattle	0.2%	Sugar beet roots	0.2%	Soybeans		1%
	1%	DK adult	0.10	0.5%	Milk: Cattle	0.2%	Swine: Muscle/meat	0.1%	Bovine: Muscle/meat		1%
	0.3%	LT adult	0.03	0.4%	Milk: Cattle	0.2%	Swine: Muscle/meat	0.1%	Eggs: Chicken		0.3%
	0.7%	UK adult	0.07	0.3%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Poultry: Muscle/meat		0.7%
	0.5%	IE child	0.05	0.4%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Eggs: Chicken		0.5%
	0.5%	UK vegetarian	0.05	0.3%	Milk: Cattle	0.1%	Sugar beet roots	0.1%	Eggs: Chicken		0.5%
	0.1%	PT general	0.01	0.0%	Soybeans	0.0%	Sunflower seeds	0.0%	Turnips		0.1%
	0.0%	PL general	0.00	0.0%	Beetroots	0.0%	Celeriacs/turnip rooted celeries	0.0%	Sunflower seeds		0.0%
	0.0%	FI 3 yr	0.00	0.0%	Beetroots	0.0%	Rapeseeds/canola seeds	0.0%	Swedes/rutabagas		0.0%
	0.0%	FI 6 yr	0.00	0.0%	Beetroots	0.0%	Rapeseeds/canola seeds	0.0%	Swedes/rutabagas		0.0%
	0.0%	FI adult	0.00	0.0%	Beetroots	0.0%	Swedes/rutabagas	0.0%	Soybeans		0.0%
	0.0%	IT toddler	0.00	0.0%	Sunflower seeds	0.0%	Turnips	0.0%	Soybeans		0.0%
	0.0%	IT adult	0.00	0.0%	Beetroots	0.0%	Sunflower seeds	0.0%	Turnips		0.0%

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TAA (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.0%	NL toddler	0.15	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Poultry: Muscle/meat		
	0.0%	UK infant	0.10	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Poultry: Muscle/meat		
	0.0%	NL child	0.09	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Poultry: Muscle/meat		
	0.0%	FR toddler 2 3 yr	0.09	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Sugar beet roots		
	0.0%	FR child 3 15 yr	0.09	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Sugar beet roots		
	0.0%	UK toddler	0.06	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Sugar beet roots		
	0.0%	DE child	0.06	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Poultry: Muscle/meat		
	0.0%	ES child	0.06	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Eggs: Chicken		
	0.0%	DK child	0.05	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Swine: Muscle/meat		
	0.0%	GEMS/Food G11	0.05	0.0%	Milk: Cattle	0.0%	Soyabeans	0.0%	Poultry: Muscle/meat		
	0.0%	RO general	0.05	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Eggs: Chicken		
	0.0%	GEMS/Food G10	0.05	0.0%	Poultry: Muscle/meat	0.0%	Soyabeans	0.0%	Milk: Cattle		
	0.0%	GEMS/Food G07	0.05	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Soyabeans		
	0.0%	DE women 14-50 yr	0.05	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Eggs: Chicken		
	0.0%	DE general	0.04	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Swine: Muscle/meat		
	0.0%	SE general	0.04	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Bovine: Muscle/meat		
	0.0%	FR infant	0.04	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Poultry: Muscle/meat		
	0.0%	GEMS/Food G15	0.04	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Soyabeans		
	0.0%	GEMS/Food G08	0.04	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Soyabeans		
	0.0%	NL general	0.04	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Poultry: Muscle/meat		
	0.0%	IE adult	0.03	0.0%	Milk: Cattle	0.0%	Sheep: Muscle/meat	0.0%	Poultry: Muscle/meat		
	0.0%	ES adult	0.03	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Eggs: Chicken		
	0.0%	FR adult	0.02	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Poultry: Muscle/meat		
	0.0%	GEMS/Food G06	0.02	0.0%	Poultry: Muscle/meat	0.0%	Milk: Cattle	0.0%	Soyabeans		
	0.0%	DK adult	0.02	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Swine: Muscle/meat		
	0.0%	LT adult	0.02	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Poultry: Muscle/meat		
	0.0%	UK adult	0.02	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Eggs: Chicken		
	0.0%	IE child	0.01	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Poultry: Muscle/meat		
	0.0%	UK vegetarian	0.01	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Sugar beet roots		
	0.0%	PT general	0.00	0.0%	Soyabeans	0.0%	Sunflower seeds	0.0%	Turnips		
	0.0%	FI 3 yr	0.00	0.0%	Rapeseeds/canola seeds	0.0%	Beetroots	0.0%	Honey and other apiculture products		
	0.0%	FI 6 yr	0.00	0.0%	Rapeseeds/canola seeds	0.0%	Beetroots	0.0%	Honey and other apiculture products		
	0.0%	PL general	0.00	0.0%	Beetroots	0.0%	Celeriacs/turnip rooted celeries	0.0%	Sunflower seeds		
	0.0%	FI adult	0.00	0.0%	Beetroots	0.0%	Soyabeans	0.0%	Swedes/rutabagas		
	0.0%	IT toddler	0.00	0.0%	Sunflower seeds	0.0%	Soyabeans	0.0%	Turnips		
	0.0%	IT adult	0.00	0.0%	Sunflower seeds	0.0%	Beetroots	0.0%	Soyabeans		

V

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TA (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
0.6%	GEMS/Food G11	1.94	0.6%	Soyabeans	0.0%	Milk: Cattle	0.0%	Sunflower seeds		
0.6%	GEMS/Food G10	1.88	0.5%	Soyabeans	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds		
0.5%	GEMS/Food G08	1.43	0.3%	Soyabeans	0.1%	Sunflower seeds	0.1%	Rapeseeds/canola seeds		
0.5%	GEMS/Food G07	1.42	0.3%	Soyabeans	0.1%	Rapeseeds/canola seeds	0.1%	Sunflower seeds		
0.5%	NL toddler	1.36	0.2%	Milk: Cattle	0.1%	Rapeseeds/canola seeds	0.0%	Sunflower seeds		
0.4%	GEMS/Food G15	1.30	0.3%	Soyabeans	0.1%	Sunflower seeds	0.0%	Rapeseeds/canola seeds		
0.3%	NL child	0.86	0.1%	Milk: Cattle	0.1%	Rapeseeds/canola seeds	0.1%	Sunflower seeds		
0.3%	GEMS/Food G06	0.78	0.2%	Soyabeans	0.0%	Sunflower seeds	0.0%	Milk: Cattle		
0.2%	RO general	0.48	0.1%	Sunflower seeds	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat		
0.2%	FR child 3 15 yr	0.48	0.1%	Milk: Cattle	0.0%	Sunflower seeds	0.0%	Sugar beet roots		
0.2%	FR toddler 2 3 yr	0.47	0.1%	Milk: Cattle	0.0%	Sunflower seeds	0.0%	Sugar beet roots		
0.1%	UK infant	0.44	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Eggs: Chicken		
0.1%	NL general	0.43	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds	0.0%	Milk: Cattle		
0.1%	DE child	0.32	0.1%	Milk: Cattle	0.0%	Sunflower seeds	0.0%	Soyabeans		
0.1%	IE adult	0.31	0.0%	Sunflower seeds	0.0%	Linseeds	0.0%	Milk: Cattle		
0.1%	PT general	0.28	0.0%	Soyabeans	0.0%	Sunflower seeds	0.0%	Turnips		
0.1%	UK toddler	0.27	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Bovine: Muscle/meat		
0.1%	ES child	0.26	0.0%	Milk: Cattle	0.0%	Sunflower seeds	0.0%	Poultry: Muscle/meat		
0.1%	DE women 14-50 yr	0.25	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Sunflower seeds		
0.1%	DE general	0.25	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Sunflower seeds		
0.1%	FR infant	0.22	0.1%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Sunflower seeds		
0.1%	DK child	0.19	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
0.1%	SE general	0.18	0.0%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Eggs: Chicken		
0.1%	FR adult	0.16	0.0%	Sunflower seeds	0.0%	Milk: Cattle	0.0%	Sugar beet roots		
0.0%	ES adult	0.14	0.0%	Milk: Cattle	0.0%	Sunflower seeds	0.0%	Poultry: Muscle/meat		
0.0%	LT adult	0.08	0.0%	Milk: Cattle	0.0%	Sunflower seeds	0.0%	Swine: Muscle/meat		
0.0%	DK adult	0.08	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
0.0%	UK adult	0.06	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Bovine: Muscle/meat		
0.0%	FI 3 yr	0.05	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds	0.0%	Soyabeans		
0.0%	IE child	0.05	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Swine: Muscle/meat		
0.0%	UK vegetarian	0.04	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Eggs: Chicken		
0.0%	FI 6 yr	0.03	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds	0.0%	Soyabeans		
0.0%	FI adult	0.02	0.0%	Soyabeans	0.0%	Sunflower seeds	0.0%	Linseeds		
0.0%	IT toddler	0.01	0.0%	Sunflower seeds	0.0%	Soyabeans	0.0%	Turnips		
0.0%	PL general	0.01	0.0%	Sunflower seeds	0.0%	Beetroots	0.0%	Soyabeans		
0.0%	IT adult	0.01	0.0%	Sunflower seeds	0.0%	Soyabeans	0.0%	Beetroots		

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TLA (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
0.1%	NL toddler	0.16	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Poultry: Muscle/meat		
0.0%	NL child	0.11	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Poultry: Muscle/meat		
0.0%	UK infant	0.10	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Sugar beet roots		
0.0%	FR child 3 15 yr	0.09	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Eggs: Chicken		
0.0%	FR toddler 2 3 yr	0.09	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Eggs: Chicken		
0.0%	UK toddler	0.07	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Eggs: Chicken		
0.0%	DE child	0.06	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Poultry: Muscle/meat		
0.0%	ES child	0.06	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Eggs: Chicken		
0.0%	DE women 14-50 yr	0.05	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Eggs: Chicken		
0.0%	DE general	0.05	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Swine: Muscle/meat		
0.0%	GEMS/Food G11	0.05	0.0%	Milk: Cattle	0.0%	Soyabeans	0.0%	Poultry: Muscle/meat		
0.0%	RO general	0.05	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Eggs: Chicken		
0.0%	DK child	0.05	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Swine: Muscle/meat		
0.0%	GEMS/Food G10	0.05	0.0%	Poultry: Muscle/meat	0.0%	Soyabeans	0.0%	Milk: Cattle		
0.0%	GEMS/Food G07	0.05	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Soyabeans		
0.0%	FR infant	0.05	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Poultry: Muscle/meat		
0.0%	GEMS/Food G15	0.04	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Soyabeans		
0.0%	NL general	0.04	0.0%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Poultry: Muscle/meat		
0.0%	SE general	0.04	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Bovine: Muscle/meat		
0.0%	GEMS/Food G08	0.04	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Soyabeans		
0.0%	IE adult	0.03	0.0%	Milk: Cattle	0.0%	Other farmed animals: Muscle/meat	0.0%	Sheep: Muscle/meat		
0.0%	ES adult	0.03	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Eggs: Chicken		
0.0%	FR adult	0.03	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Sugar beet roots		
0.0%	GEMS/Food G06	0.03	0.0%	Poultry: Muscle/meat	0.0%	Sugar beet roots	0.0%	Milk: Cattle		
0.0%	DK adult	0.02	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Swine: Muscle/meat		
0.0%	LT adult	0.02	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Poultry: Muscle/meat		
0.0%	UK adult	0.02	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Eggs: Chicken		
0.0%	IE child	0.01	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Swine: Fat tissue		
0.0%	UK vegetarian	0.01	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Sugar beet roots		
0.0%	PT general	0.00	0.0%	Soyabeans	0.0%	Sunflower seeds	0.0%	Turnips		
0.0%	FI 3 yr	0.00	0.0%	Rapeseeds/canola seeds	0.0%	Beetroots	0.0%	Honey and other apiculture products		
0.0%	FI 6 yr	0.00	0.0%	Rapeseeds/canola seeds	0.0%	Beetroots	0.0%	Honey and other apiculture products		
0.0%	PL general	0.00	0.0%	Beetroots	0.0%	Celeriacs/turnip rooted celeries	0.0%	Sunflower seeds		
0.0%	FI adult	0.00	0.0%	Beetroots	0.0%	Soyabeans	0.0%	Swedes/rutabagas		
0.0%	IT toddler	0.00	0.0%	Sunflower seeds	0.0%	Soyabeans	0.0%	Turnips		
0.0%	IT adult	0.00	0.0%	Sunflower seeds	0.0%	Beetroots	0.0%	Soyabeans		

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1,2,4-T (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

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

Input values

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

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
3%	NL toddler	0.65	3%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Bovine: Muscle/meat		
2%	UK infant	0.42	2%	Milk: Cattle	0.1%	Eggs: Chicken	0.1%	Bovine: Muscle/meat		
1%	FR toddler 2 3 yr	0.34	1%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Swine: Muscle/meat		
1%	NL child	0.30	1%	Milk: Cattle	0.1%	Sugar beet roots	0.0%	Swine: Muscle/meat		
1%	FR child 3 15 yr	0.29	1.0%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Swine: Muscle/meat		
1%	UK toddler	0.24	0.9%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	Eggs: Chicken		
1.0%	DE child	0.23	0.9%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Poultry: Muscle/meat		
0.8%	FR infant	0.18	0.7%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
0.8%	DK child	0.18	0.5%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.1%	Bovine: Muscle/meat		
0.8%	SE general	0.18	0.5%	Milk: Cattle	0.2%	Bovine: Muscle/meat	0.0%	Eggs: Chicken		
0.8%	ES child	0.18	0.5%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Poultry: Muscle/meat		
0.7%	DE general	0.16	0.5%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Sugar beet roots		
0.7%	DE women 14-50 yr	0.16	0.5%	Milk: Cattle	0.0%	Sugar beet roots	0.0%	Swine: Muscle/meat		
0.7%	RO general	0.15	0.5%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.0%	Poultry: Muscle/meat		
0.6%	GEMS/Food G11	0.13	0.3%	Milk: Cattle	0.1%	Soyabeans	0.1%	Swine: Muscle/meat		
0.5%	NL general	0.12	0.4%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
0.5%	GEMS/Food G15	0.12	0.3%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.0%	Poultry: Muscle/meat		
0.5%	GEMS/Food G07	0.12	0.3%	Milk: Cattle	0.1%	Poultry: Muscle/meat	0.1%	Swine: Muscle/meat		
0.5%	GEMS/Food G10	0.11	0.2%	Milk: Cattle	0.1%	Poultry: Muscle/meat	0.1%	Soyabeans		
0.5%	GEMS/Food G08	0.11	0.2%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.0%	Poultry: Muscle/meat		
0.3%	ES adult	0.08	0.2%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		
0.3%	DK adult	0.08	0.2%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
0.3%	FR adult	0.07	0.2%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		
0.3%	IE adult	0.07	0.2%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		
0.3%	LT adult	0.06	0.2%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Eggs: Chicken		
0.2%	GEMS/Food G06	0.05	0.1%	Milk: Cattle	0.0%	Poultry: Muscle/meat	0.0%	Soyabeans		
0.2%	UK adult	0.05	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Poultry: Muscle/meat		
0.2%	IE child	0.04	0.2%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Eggs: Chicken		
0.2%	UK vegetarian	0.04	0.1%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Sugar beet roots		
0.0%	PT general	0.00	0.0%	Soyabeans	0.0%	Sunflower seeds	0.0%	Turnips		
0.0%	FI 3 yr	0.00	0.0%	Rapeseeds/canola seeds	0.0%	Beetroots	0.0%	Honey and other apiculture products		
0.0%	FI 6 yr	0.00	0.0%	Rapeseeds/canola seeds	0.0%	Beetroots	0.0%	Honey and other apiculture products		
0.0%	PL general	0.00	0.0%	Beetroots	0.0%	Celeriacs/turnip rooted celeries	0.0%	Sunflower seeds		
0.0%	FI adult	0.00	0.0%	Beetroots	0.0%	Soyabeans	0.0%	Swedes/rutabagas		
0.0%	IT toddler	0.00	0.0%	Sunflower seeds	0.0%	Soyabeans	0.0%	Turnips		
0.0%	IT adult	0.00	0.0%	Sunflower seeds	0.0%	Beetroots	0.0%	Soyabeans		

A 3.3 IESTI calculations - Raw and processed commodities

For difenoconazole:

Acute risk assessment /children	ute risk assessment / adults / general populati	Acute risk assessment /children	Acute risk assessment / adults / general populatior
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.9%	Celeriac/turnip rooted	2 / 0.02	1.4
0.8%	Bovine: Liver	0.4 / 0.16	1.3
0.8%	Sugarbeet/rutabagas	0.4 / 0.02	1.3
0.8%	Milk: Cattle	0.01 / 0.01	1.2
0.7%	Bovine: Edible offals	0.2 / 0.16	1.2
0.7%	Beetroots	0.4 / 0.02	1.1
0.6%	Turnips	0.4 / 0.02	0.89
0.3%	Eggs: Chicken	0.05 / 0.04	0.50
0.2%	Poultry: Muscle/meat	0.1 / 0.02	0.34
0.2%	Suine: Muscle/meat	0.01 / 0.02	0.24
0.2%	Milk: Goat	0.01 / 0.01	0.24
0.1%	Suine: Edible offals (other	0.2 / 0.06	0.18
0.09%	Bovine: Muscle/meat	0.03 / 0.02	0.14
0.09%	Other farmed animals:	0.1 / 0.02	0.14
0.08%	Equine: Muscle/meat	0.05 / 0.02	0.12

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.5%	Sugarbeet/rutabagas	0.4 / 0.02	0.84
0.4%	Bovine: Liver	0.4 / 0.16	0.64
0.3%	Bovine: Edible offals (other	0.2 / 0.16	0.53
0.3%	Sheep: Liver	0.4 / 0.16	0.45
0.2%	Milk: Cattle	0.01 / 0.01	0.39
0.2%	Beetroots	0.4 / 0.02	0.30
0.2%	Celeriac/turnip rooted	2 / 0.02	0.29
0.2%	Turnips	0.4 / 0.02	0.28
0.1%	Poultry: Muscle	0.1 / 0.02	0.23
0.1%	Milk: Goat	0.01 / 0.01	0.18
0.1%	Horseradish	0.4 / 0.02	0.18
0.1%	Eggs: Chicken	0.05 / 0.04	0.17
0.1%	Poultry: Edible offals	0.1 / 0.02	0.17
0.10%	Suine: Edible offals (other	0.2 / 0.06	0.16
0.09%	Milk: Sheep	0.01 / 0.01	0.15

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
54%	Celeriac/turnip rooted	2 / 2.6	86

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
12%	Celeriac/turnip rooted celeries	2 / 2.6	18
7%	Sugarbeet/rutabagas	0.4 / 0.52	11
2%	Bovine: Liver	0.4 / 0.8	3.2
2%	Turnips	0.4 / 0.52	2.8
2%	Beetroots	0.4 / 0.52	2.8
1%	Poultry: Muscle	0.1 / 0.2	2.3
1%	Sheep: Liver	0.4 / 0.8	2.2
1%	Poultry: Edible offals (other than	0.1 / 0.2	1.7
1%	Horseradishes	0.4 / 0.52	1.6
0.8%	Bovine: Edible offals (other than	0.2 / 0.4	1.3
0.7%	Other farmed animals:	0.1 / 0.2	1.1
0.7%	Suine: Edible offals (other than	0.2 / 0.4	1.0
0.6%	Poultry: Liver	0.1 / 0.2	0.94
0.4%	Soybeans	0.1 / 0.13	0.72
0.4%	Suine: Other products	0.1 / 0.2	0.66

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1.0%	Sugar beets (root) / sugar	0.2 / 0.17	1.6
0.7%	Beetroots / boiled	0.4 / 0.02	1.1
0.1%	Celeriac / juice	2 / 0.01	0.21
0.0%	Soybeans / soy milk	0.1 / 0.01	0.05
0.0%	Sunflower seeds / oil	0.05 / 0.03	0.03
0.0%	Rapeseeds / processed (na	0.5 / 0.03	0.02
0.0%	Soybeans / boiled	0.1 / 0.01	0.02
0.0%	Chicory roots / processed (	0.6 / 0.01	0.01

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Sugar beets (root) / sugar	0.2 / 0.17	0.63
0.3%	Beetroots / boiled	0.4 / 0.02	0.55
0.3%	Turnips / boiled	0.4 / 0.02	0.47
0.3%	Celeriac / boiled	2 / 0.02	0.45
0.0%	Chicory roots / processed	0.6 / 0.01	0.00

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

IESTI new

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

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

IESTI new

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

For TAA:

Acute risk assessment /children | **ute risk assessment / adults / general populati** | **Acute risk assessment /children** | **Acute risk assessment / adults / general population**

Details - acute risk assessment /children | Details - acute risk assessment/adults | Hide IESTI new calculations | Show IESTI new calculations

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.02%	Milk: Cattle	0 / 0	0.25
0.02%	Poultry: Muscle/meat	0.01 / 0.01	0.17
0.01%	Eggs: Chicken	0.01 / 0.01	0.12
0.01%	Beetroots	0.01 / 0	0.11
0.01%	Celeriacs/turnip rooted	0.01 / 0	0.11
0.01%	Sweet potatoes	0.01 / 0	0.10
0.01%	Turnips	0.01 / 0	0.07
0.01%	Other farmed animals:	0.01 / 0.01	0.07
0.01%	Equine: Muscle/meat	0.01 / 0.01	0.06
0.01%	Sheep: Muscle/meat	0.01 / 0.01	0.05
0.00%	Suine: Muscle/meat	0.01 / 0	0.05
0.00%	Milk: Goat	0 / 0	0.05
0.00%	Honey and other	0.03 / 0.01	0.04
0.00%	Bovine: Liver	0 / 0	0.03
0.00%	Bovine: Edible offals	0 / 0	0.03

Expand / collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.01%	Poultry: Muscle	0.01 / 0.01	0.12
0.01%	Milk: Cattle	0 / 0	0.08
0.01%	Sweet potatoes	0.01 / 0	0.07
0.01%	Other farmed animals:	0.01 / 0.01	0.06
0.00%	Equine: Muscle/meat	0.01 / 0.01	0.05
0.00%	Sheep: Muscle/meat	0.01 / 0.01	0.05
0.00%	Poultry: Liver	0.01 / 0.01	0.05
0.00%	Beetroots	0.01 / 0	0.05
0.00%	Eggs: Chicken	0.01 / 0.01	0.04
0.00%	Milk: Goat	0 / 0	0.04
0.00%	Suine: Other products	0.01 / 0.01	0.03
0.00%	Milk: Sheep	0 / 0	0.03
0.00%	Sheep: Liver	0.01 / 0.01	0.03
0.00%	Celeriacs/turnip rooted	0.01 / 0	0.02
0.00%	Bovine: Muscle	0 / 0	0.02

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.04%	Milk: Cattle	0 / 0	0.37
0.03%	Celeriacs/turnip rooted	0.01 / 0.01	0.33
0.03%	Sunflower seeds	0.1 / 0.1	0.32
0.03%	Sweet potatoes	0.01 / 0.01	0.31
0.02%	Beetroots	0.01 / 0.01	0.24
0.02%	Soybeans	0.1 / 0.1	0.23
0.02%	Poultry: Muscle/meat	0.01 / 0.01	0.17
0.02%	Turnips	0.01 / 0.01	0.15
0.01%	Pumpkin seeds	0.1 / 0.1	0.15
0.01%	Rapeseeds/canola seeds	0.1 / 0.1	0.14
0.01%	Eggs: Chicken	0.01 / 0.01	0.12
0.01%	Honey and other	0.03 / 0.03	0.11
0.01%	Linseeds	0.1 / 0.1	0.11
0.01%	Other farmed animals:	0.01 / 0.02	0.10
0.01%	Mustard seeds	0.1 / 0.1	0.10

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.06%	Soybeans	0.1 / 0.1	0.55
0.02%	Sweet potatoes	0.01 / 0.01	0.20
0.02%	Pumpkin seeds	0.1 / 0.1	0.16
0.01%	Poultry: Muscle	0.01 / 0.01	0.12
0.01%	Milk: Cattle	0 / 0	0.12
0.01%	Beetroots	0.01 / 0.01	0.10
0.01%	Sunflower seeds	0.1 / 0.1	0.10
0.01%	Other farmed animals:	0.01 / 0.02	0.08
0.01%	Celeriacs/turnip rooted celeries	0.01 / 0.01	0.07
0.01%	Poppy seeds	0.1 / 0.1	0.07
0.01%	Poppy seeds	0.1 / 0.1	0.07
0.01%	Milk: Goat	0 / 0	0.06
0.01%	Turnips	0.01 / 0.01	0.05
0.01%	Equine: Muscle/meat	0.01 / 0.01	0.05
0.01%	Rapeseeds/canola seeds	0.1 / 0.1	0.05

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.0%	Sugar beets (root) / sugar	0.01 / 0.02	0.22
0.0%	Turnips / boiled	0.01 / 0	0.10
0.0%	Beetroots / boiled	0.01 / 0	0.09
0.0%	Celeriacs / juice	0.01 / 0	0.03
0.0%	Soybeans / soya drink	0.1 / 0	0.02
0.0%	Sunflower seeds / oils	0.1 / 0.01	0.01
0.0%	Soybeans / boiled	0.1 / 0	0.01
0.0%	Rapeseeds / oils	0.1 / 0.01	0.00
0.0%	Chicory roots / processed (	0.01 / 0	0.00
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Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.0%	Sugar beets (root) / sugar	0.01 / 0.02	0.09
0.0%	Beetroots / boiled	0.01 / 0	0.08
0.00%	Turnips / boiled	0.01 / 0	0.04
0.00%	Celeriacs / boiled	0.01 / 0	0.04
0.00%	Chicory roots / processed	0.01 / 0	0.00
$LICZBA!	$LICZBA!	$LICZBA!	$LICZBA!
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IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Sugar beets (root) / sugar	0.01 / 0.12	1.1
0.04%	Soybeans / soya drink	0.1 / 0.1	0.42
0.02%	Sunflower seeds / oils	0.1 / 0.2	0.23
0.02%	Turnips / boiled	0.01 / 0.01	0.22
0.02%	Beetroots / boiled	0.01 / 0.01	0.19
0.01%	Soybeans / boiled	0.1 / 0.04	0.15
0.01%	Celeriacs / juice	0.01 / 0.01	0.14
0.01%	Rapeseeds / oils	0.1 / 0.2	0.06
0.00%	Chicory roots / processed	0.01 / 0.01	0.01
$LICZBA!	$LICZBA!	$LICZBA!	$LICZBA!
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$LICZBA!	$LICZBA!	$LICZBA!	$LICZBA!

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.04%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
0.02%	Beetroots / boiled	0.01 / 0.01	0.17
0.01%	Celeriacs / boiled	0.01 / 0.01	0.11
0.01%	Turnips / boiled	0.01 / 0.01	0.09
0.00%	Chicory roots / processed (nat	0.01 / 0.01	0.00
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For TA:

Acute risk assessment /children | **Acute risk assessment / adults / general populatio** | **Acute risk assessment /children** | **Acute risk assessment / adults / general population**

Details - acute risk assessment /children | Details - acute risk assessment/adults | Hide IESTI new calculations | Show IESTI new calculations

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)
0.5%	Beetroots	0.04 / 0.03	1.6
0.5%	Celeriacs/turnip rooted	0.04 / 0.03	1.5
0.5%	Sunflower seeds	15 / 0.47	1.5
0.5%	Swedes/rutabagas	0.04 / 0.03	1.4
0.4%	Milk: Cattle	0 / 0.01	1.2
0.4%	Soyabeans	15 / 0.47	1.1
0.3%	Turnips	0.04 / 0.03	1.0
0.2%	Bovine: Liver	0 / 0.09	0.73
0.2%	Pumpkin seeds	15 / 0.47	0.68
0.2%	Bovine: Edible offals	0 / 0.09	0.65
0.2%	Rapeseeds/canola seeds	15 / 0.47	0.65
0.2%	Linseeds	15 / 0.47	0.50
0.2%	Mustard seeds	15 / 0.47	0.48
0.1%	Swine: Muscle/meat	0 / 0.03	0.36
0.08%	Milk: Goat	0 / 0.01	0.24

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)
0.3%	Soyabeans	15 / 0.47	2.6
0.3%	Swedes/rutabagas	0.04 / 0.03	0.96
0.3%	Pumpkin seeds	15 / 0.47	0.75
0.2%	Beetroots	0.04 / 0.03	0.64
0.2%	Sunflower seeds	15 / 0.47	0.47
0.1%	Milk: Cattle	0 / 0.01	0.39
0.1%	Bovine: Liver	0 / 0.09	0.36
0.1%	Sheep: Liver	0 / 0.12	0.34
0.1%	Celeriacs/turnip rooted	0.04 / 0.03	0.33
0.1%	Mustard seeds	15 / 0.47	0.33
0.1%	Poppy seeds	15 / 0.47	0.33
0.1%	Turnips	0.04 / 0.03	0.31
0.10%	Bovine: Edible offals	0 / 0.09	0.30
0.08%	Rapeseeds/canola seeds	15 / 0.47	0.25
0.08%	Linseeds	15 / 0.47	0.23

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

IESTI new

Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)
16%	Sunflower seeds	15 / 15	48
12%	Soyabeans	15 / 15	35
7%	Pumpkin seeds	15 / 15	22
7%	Rapeseeds/canola seeds	15 / 15	21
5%	Linseeds	15 / 15	16
5%	Mustard seeds	15 / 15	15
0.5%	Hemp seeds	15 / 15	1.5
0.4%	Celeriacs/turnip rooted	0.04 / 0.04	1.3
0.4%	Swedes/rutabagas	0.04 / 0.04	1.2
0.3%	Beetroots	0.04 / 0.04	0.98
0.2%	Turnips	0.04 / 0.04	0.62
0.10%	Honey and other	0.08 / 0.08	0.29
0.00%	Horseradishes	0.04 / 0.04	0.01

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)
28%	Soyabeans	15 / 15	83
8%	Pumpkin seeds	15 / 15	24
5%	Sunflower seeds	15 / 15	15
4%	Mustard seeds	15 / 15	11
4%	Poppy seeds	15 / 15	11
3%	Rapeseeds/canola seeds	15 / 15	7.9
2%	Linseeds	15 / 15	7.2
0.3%	Hemp seeds	15 / 15	0.90
0.3%	Swedes/rutabagas	0.04 / 0.04	0.82
0.1%	Beetroots	0.04 / 0.04	0.41
0.09%	Celeriacs/turnip rooted celeries	0.04 / 0.04	0.28
0.07%	Turnips	0.04 / 0.04	0.22
0.04%	Horseradishes	0.04 / 0.04	0.12
0.04%	Honey and other apiculture	0.08 / 0.08	0.11
0.01%	Chicory roots	0.04 / 0.04	0.02

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Soyabeans / soya drink	15 / 0.47	2.0
0.5%	Turnips / boiled	0.04 / 0.03	1.4
0.4%	Beetroots / boiled	0.04 / 0.03	1.2
0.4%	Sunflower seeds / oils	15 / 0.34	1.1
0.4%	Sugar beets (root) / sugar	0.04 / 0.12	1.1
0.2%	Soyabeans / boiled	15 / 0.19	0.68
0.1%	Rapeseeds / oils	15 / 0.34	0.28
0.0%	Celeriacs / juice	0.04 / 0.01	0.14
0.0%	Chicory roots / processed	0.04 / 0.01	0.01
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Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Beetroots / boiled	0.04 / 0.03	1.1
0.2%	Turnips / boiled	0.04 / 0.03	0.53
0.2%	Celeriacs / boiled	0.04 / 0.03	0.51
0.1%	Sugar beets (root) /	0.04 / 0.12	0.44
0.00%	Chicory roots /	0.04 / 0.01	0.00
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IESTI new
Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Processed commodities	input for RA (mg/kg)	Exposure (µg/kg bw)
21%	Soyabeans / soya drink	15 / 15	63
12%	Sunflower seeds / oils	15 / 30	35
7%	Soyabeans / boiled	15 / 6	22
3%	Rapeseeds / oils	15 / 30	8.8
1%	Sugar beets (root) /	0.04 / 0.48	4.4
0.3%	Turnips / boiled	0.04 / 0.04	0.87
0.3%	Beetroots / boiled	0.04 / 0.04	0.76
0.2%	Celeriacs / juice	0.04 / 0.04	0.58
0.01%	Chicory roots /	0.04 / 0.04	0.03
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	input for RA (mg/kg)	Exposure (µg/kg bw)
0.6%	Sugar beets (root) / sugar	0.04 / 0.48	1.8
0.2%	Beetroots / boiled	0.04 / 0.04	0.67
0.1%	Celeriacs / boiled	0.04 / 0.04	0.44
0.1%	Turnips / boiled	0.04 / 0.04	0.36
0.00%	Chicory roots / processed (not	0.04 / 0.04	0.01
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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For TLA:

Acute risk assessment /children | **ute risk assessment / adults / general populati** | **Acute risk assessment /children** | **Acute risk assessment / adults / general population**

Details - acute risk assessment /children | Details - acute risk assessment/adults | Hide IESTI new calculations | Show IESTI new calculations

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.2%	Beetroots	0.02 / 0.01	0.57
0.2%	Celeriacs/turnip rooted	0.02 / 0.01	0.55
0.2%	Swedes/rutabagas	0.02 / 0.01	0.52
0.1%	Turnips	0.02 / 0.01	0.36
0.08%	Milk: Cattle	0 / 0	0.25
0.08%	Eggs: Chicken	0.03 / 0.02	0.25
0.06%	Poultry: Muscle/meat	0.04 / 0.01	0.17
0.02%	Other farmed animals:	0.01 / 0.01	0.07
0.02%	Equine: Muscle/meat	0.01 / 0.01	0.06
0.02%	Sheep: Muscle/meat	0.01 / 0.01	0.05
0.02%	Suine: Muscle/meat	0.01 / 0	0.05
0.02%	Milk: Goat	0 / 0	0.05
0.01%	Honey and other	0.03 / 0.01	0.04
0.01%	Bovine: Liver	0 / 0	0.03
0.01%	Bovine: Edible offals	0 / 0	0.03

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Swedes/rutabagas	0.02 / 0.01	0.34
0.08%	Beetroots	0.02 / 0.01	0.23
0.04%	Celeriacs/turnip rooted	0.02 / 0.01	0.12
0.04%	Poultry: Muscle	0.04 / 0.01	0.12
0.04%	Turnips	0.02 / 0.01	0.11
0.03%	Poultry: Liver	0.15 / 0.02	0.09
0.03%	Chicory roots	0.01 / 0.23	0.09
0.03%	Eggs: Chicken	0.03 / 0.02	0.09
0.03%	Milk: Cattle	0 / 0	0.08
0.02%	Horses: dried	0.02 / 0.01	0.07
0.02%	Other farmed animals:	0.01 / 0.01	0.06
0.02%	Equine: Muscle/meat	0.01 / 0.01	0.05
0.02%	Sheep: Muscle/meat	0.01 / 0.01	0.05
0.01%	Milk: Goat	0 / 0	0.04
0.01%	Suine: Other products	0.01 / 0.01	0.03

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.5%	Sunflower seeds	0.5 / 0.5	1.6
0.4%	Soyabeans	0.5 / 0.5	1.2
0.2%	Pumpkin seeds	0.5 / 0.5	0.73
0.2%	Poultry: Muscle/meat	0.04 / 0.04	0.70
0.2%	Rapeseeds/canola seeds	0.5 / 0.5	0.69
0.2%	Linseeds	0.5 / 0.5	0.54
0.2%	Mustard seeds	0.5 / 0.5	0.51
0.2%	Celeriacs/turnip rooted	0.02 / 0.02	0.50
0.2%	Swedes/rutabagas	0.02 / 0.02	0.47
0.1%	Milk: Cattle	0 / 0	0.37
0.1%	Eggs: Chicken	0.03 / 0.03	0.37
0.1%	Beetroots	0.02 / 0.02	0.37
0.08%	Turnips	0.02 / 0.02	0.23
0.07%	Other farmed animals:	0.01 / 0.03	0.21
0.06%	Poultry: Liver	0.15 / 0.15	0.17

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.9%	Soyabeans	0.5 / 0.5	2.8
0.3%	Pumpkin seeds	0.5 / 0.5	0.80
0.2%	Poultry: Liver	0.15 / 0.15	0.71
0.2%	Sunflower seeds	0.5 / 0.5	0.50
0.2%	Poultry: Muscle	0.04 / 0.04	0.48
0.1%	Poppy seeds	0.5 / 0.5	0.35
0.1%	Poppy seeds	0.5 / 0.5	0.35
0.1%	Swedes/rutabagas	0.02 / 0.02	0.31
0.09%	Rapeseeds/canola seeds	0.5 / 0.5	0.26
0.08%	Linseeds	0.5 / 0.5	0.24
0.06%	Poultry: Kidney	0.15 / 0.15	0.19
0.06%	Other farmed animals:	0.01 / 0.03	0.17
0.05%	Beetroots	0.02 / 0.02	0.15
0.04%	Eggs: Chicken	0.03 / 0.03	0.13
0.04%	Milk: Cattle	0 / 0	0.12

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.2%	Turnips / boiled	0.02 / 0.01	0.51
0.1%	Beetroots / boiled	0.02 / 0.01	0.44
0.1%	Sugar beets (root) / sugar	0.01 / 0.05	0.44
0.0%	Celeriacs / juice	0.02 / 0	0.03
0.0%	Soyabeans / soya drink	0.5 / 0	0.02
0.0%	Sunflower seeds / oil	0.5 / 0.01	0.01
0.0%	Soyabeans / boiled	0.5 / 0	0.01
0.0%	Chicory roots / processed	0.01 / 0	0.00
0.0%	Rapeseeds / oil	0.5 / 0.01	0.00
$LICZBA!	$LICZBA!	$LICZBA!	$LICZBA!
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Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Beetroots / boiled	0.02 / 0.01	0.39
0.06%	Turnips / boiled	0.02 / 0.01	0.19
0.06%	Celeriacs / boiled	0.02 / 0.01	0.18
0.06%	Sugar beets (root) / sugar	0.01 / 0.05	0.18
0.00%	Chicory roots / processed	0.01 / 0	0.00
$LICZBA!	$LICZBA!	$LICZBA!	$LICZBA!
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IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Soyabeans / soya drink	0.5 / 0.5	2.1
0.4%	Sunflower seeds / oil	0.5 / 1	1.2
0.4%	Sugar beets (root) / sugar	0.01 / 0.12	1.1
0.2%	Soyabeans / boiled	0.5 / 0.2	0.73
0.1%	Turnips / boiled	0.02 / 0.02	0.33
0.10%	Rapeseeds / oil	0.5 / 1	0.29
0.10%	Beetroots / boiled	0.02 / 0.02	0.29
0.07%	Celeriacs / juice	0.02 / 0.02	0.22
0.00%	Chicory roots / processed	0.01 / 0.01	0.01
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IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
0.08%	Beetroots / boiled	0.02 / 0.02	0.25
0.05%	Celeriacs / boiled	0.02 / 0.02	0.16
0.05%	Turnips / boiled	0.02 / 0.02	0.14
0.00%	Chicory roots / processed (nat	0.01 / 0.01	0.00
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$LICZBA!	$LICZBA!	$LICZBA!	$LICZBA!
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For 1,2,4-T:

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

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Milk: Cattle	0.01 / 0.01	1.2
0.2%	Milk: Goat	0.01 / 0.01	0.24
0.2%	Poultry: Muscle/meat	0.01 / 0.01	0.17
0.1%	Eggs: Chicken	0.01 / 0.01	0.12
0.1%	Suine: Muscle/meat	0.01 / 0.01	0.12
0.1%	Beetroots	0.01 / 0	0.11
0.1%	Coleiacs/turnip rooted	0.01 / 0	0.11
0.1%	Suedes/rutabagas	0.01 / 0	0.10
0.08%	Bovine: Liver	0.01 / 0.01	0.08
0.07%	Bovine: Edible offals	0.01 / 0.01	0.07
0.07%	Bovine: Muscle/meat	0.01 / 0.01	0.07
0.07%	Turnips	0.01 / 0	0.07
0.07%	Other farmed animals:	0.01 / 0.01	0.07
0.06%	Equine: Muscle/meat	0.01 / 0.01	0.06
0.05%	Sheep: Muscle/meat	0.01 / 0.01	0.05

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Milk: Cattle	0.01 / 0.01	0.39
0.2%	Milk: Goat	0.01 / 0.01	0.18
0.2%	Milk: Sheep	0.01 / 0.01	0.15
0.1%	Poultry: Muscle	0.01 / 0.01	0.12
0.07%	Suedes/rutabagas	0.01 / 0	0.07
0.06%	Bovine: Muscle	0.01 / 0.01	0.06
0.06%	Other farmed animals:	0.01 / 0.01	0.06
0.05%	Suine: Muscle/meat	0.01 / 0.01	0.05
0.05%	Equine: Muscle/meat	0.01 / 0.01	0.05
0.05%	Sheep: Muscle/meat	0.01 / 0.01	0.05
0.05%	Poultry: Liver	0.01 / 0.01	0.05
0.04%	Beetroots	0.01 / 0	0.05
0.04%	Eggs: Chicken	0.01 / 0.01	0.04
0.04%	Bovine: Liver	0.01 / 0.01	0.04
0.03%	Bovine: Edible offals (other	0.01 / 0.01	0.03

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Milk: Cattle	0.01 / 0.01	1.2
0.3%	Coleiacs/turnip rooted	0.01 / 0.01	0.33
0.3%	Suedes/rutabagas	0.01 / 0.01	0.31
0.2%	Beetroots	0.01 / 0.01	0.24
0.2%	Milk: Goat	0.01 / 0.01	0.24
0.2%	Poultry: Muscle/meat	0.01 / 0.01	0.17
0.2%	Turnips	0.01 / 0.01	0.15
0.1%	Eggs: Chicken	0.01 / 0.01	0.12
0.1%	Suine: Muscle/meat	0.01 / 0.01	0.12
0.1%	Honey and other	0.03 / 0.03	0.11
0.08%	Bovine: Liver	0.01 / 0.01	0.08
0.07%	Bovine: Edible offals	0.01 / 0.01	0.07
0.07%	Bovine: Muscle/meat	0.01 / 0.01	0.07
0.07%	Other farmed animals:	0.01 / 0.01	0.07
0.06%	Equine: Muscle/meat	0.01 / 0.01	0.06

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Milk: Cattle	0.01 / 0.01	0.39
0.2%	Suedes/rutabagas	0.01 / 0.01	0.20
0.2%	Milk: Goat	0.01 / 0.01	0.18
0.2%	Milk: Sheep	0.01 / 0.01	0.15
0.1%	Poultry: Muscle	0.01 / 0.01	0.12
0.1%	Beetroots	0.01 / 0.01	0.10
0.08%	Soyabeans	0.02 / 0.02	0.08
0.07%	Coleiacs/turnip rooted celeries	0.01 / 0.01	0.07
0.06%	Bovine: Muscle	0.01 / 0.01	0.06
0.06%	Other farmed animals:	0.01 / 0.01	0.06
0.05%	Turnips	0.01 / 0.01	0.05
0.05%	Suine: Muscle/meat	0.01 / 0.01	0.05
0.05%	Equine: Muscle/meat	0.01 / 0.01	0.05
0.05%	Sheep: Muscle/meat	0.01 / 0.01	0.05
0.05%	Poultry: Liver	0.01 / 0.01	0.05

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.2%	Sugar beets (root) / sugar	0.01 / 0.02	0.22
0.1%	Turnips / boiled	0.01 / 0	0.10
0.1%	Beetroots / boiled	0.01 / 0	0.09
0.0%	Coleiacs / juice	0.01 / 0	0.03
0.0%	Soyabeans / soya drink	0.02 / 0	0.02
0.0%	Sunflower seeds / oil	0.02 / 0.01	0.01
0.0%	Soyabeans / boiled	0.02 / 0	0.01
0.0%	Rapeseeds / oil	0.02 / 0.01	0.00
0.0%	Chicory roots / processed (	0.01 / 0	0.00
$LICZBA!	$LICZBA!	$LICZBA!	$LICZBA!
$LICZBA!	$LICZBA!	$LICZBA!	$LICZBA!
$LICZBA!	$LICZBA!	$LICZBA!	$LICZBA!
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Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Sugar beets (root) / sugar	0.01 / 0.02	0.09
0.08%	Beetroots / boiled	0.01 / 0	0.08
0.04%	Turnips / boiled	0.01 / 0	0.04
0.04%	Coleiacs / boiled	0.01 / 0	0.04
0.00%	Chicory roots / processed	0.01 / 0	0.00
$LICZBA!	$LICZBA!	$LICZBA!	$LICZBA!
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$LICZBA!	$LICZBA!	$LICZBA!	$LICZBA!

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Sugar beets (root) / sugar	0.01 / 0.12	1.1
0.2%	Turnips / boiled	0.01 / 0.01	0.22
0.2%	Beetroots / boiled	0.01 / 0.01	0.19
0.1%	Coleiacs / juice	0.01 / 0.01	0.14
0.06%	Soyabeans / soya drink	0.02 / 0.02	0.06
0.04%	Sunflower seeds / oil	0.02 / 0.03	0.04
0.02%	Soyabeans / boiled	0.02 / 0.01	0.02
0.01%	Rapeseeds / oil	0.02 / 0.03	0.01
0.01%	Chicory roots / processed	0.01 / 0.01	0.01
$LICZBA!	$LICZBA!	$LICZBA!	$LICZBA!
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$LICZBA!	$LICZBA!	$LICZBA!	$LICZBA!

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Sugar beets (root) / sugar	0.01 / 0.12	0.44
0.2%	Beetroots / boiled	0.01 / 0.01	0.17
0.1%	Coleiacs / boiled	0.01 / 0.01	0.11
0.09%	Turnips / boiled	0.01 / 0.01	0.09
0.00%	Chicory roots / processed (not	0.01 / 0.01	0.00
$LICZBA!	$LICZBA!	$LICZBA!	$LICZBA!
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Appendix 4 Additional information provided by the applicant

Not required.