

FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: SIP 41061

Product name: SIP 41061

Chemical active substance:

Prothioconazole 400 g/L SC

Central zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization of use)

Applicant: Sipcam Oxon S.p.A.

Submission date: April 2022

MS Finalisation date: 01/2023; 03/2023; 06/2023

Version history

When	What
04/2022	First dossier submission
01/2023	Assessment
02/2023	dRR update following RMS comments. Addition of studies submitted by the applicant not finalised yet during first dossier submission. Revision and update of consumer risk assessments according to the new data. Changes are highlighted in green.
03/2023	Assessment of updated dRR part B7
06/2023	RR update following commenting phase. Changes are highlighted in yellow.

Table of Contents

7	Metabolism and residue data (KCA section 6).....	5
7.1	Summary and zRMS Conclusion.....	5
7.1.1	Critical GAP(s) and overall conclusion	15
7.1.2	Summary of the evaluation	20
7.1.2.1	Summary for Prothioconazole	21
7.1.2.2	Summary for active substance 2	22
7.1.2.3	Summary for SIP 41061.....	22
7.2	Prothioconazole.....	25
7.2.1.1	Stability of residues during storage of samples	26
7.2.1.2	Stability of residues in sample extracts (KCA 6.1).....	30
7.2.2	Nature of residues in plants, livestock and processed commodities	31
7.2.1.3	Nature of residue in primary crops (KCA 6.2.1)	31
7.2.1.4	Nature of residue in rotational crops (KCA 6.6.1).....	34
7.2.1.5	Nature of residues in processed commodities (KCA 6.5.1).....	35
7.2.1.6	Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)	36
7.2.1.7	Nature of residues in livestock (KCA 6.2.2-6.2.5)	36
7.2.1.8	Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)	40
7.2.2	Magnitude of residues in plants (KCA 6.3)	41
7.2.2.1	Summary of European data and new data supporting the intended uses	41
7.2.2.2	Conclusion on the magnitude of residues in plants	54
7.2.3	Magnitude of residues in livestock	63
7.2.3.1	Dietary burden calculation	63
7.2.3.2	Livestock feeding studies (KCA 6.4.1-6.4.3)	67
7.2.4	Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3).....	71
7.2.4.1	Available data for all crops under consideration	71
7.2.5	Magnitude of residues in representative succeeding crops.....	71
7.2.5.1	Field rotational crop studies (KCA 6.6.2).....	72
7.2.6	Other / special studies (KCA 6.10, 6.10.1)	73
7.2.7	Estimation of exposure through diet and other means (KCA 6.9).....	75
7.2.7.1	Input values for the consumer risk assessment	75
7.2.8.2	Conclusion on consumer risk assessment	81
7.3	Active substance 2	84
7.4	Combined exposure and risk assessment	84
7.5	References	85
Appendix 1	Lists of data considered in support of the evaluation.....	86
Appendix 2	Detailed evaluation of the additional studies relied upon	98
A 2.1	Prothioconazole.....	98
A 2.1.1	Stability of residues.....	98
A 2.1.2	Nature of residues in plants, livestock and processed commodities	110
A 2.1.3	Magnitude of residues in plants	111
A 2.1.4	Magnitude of residues in livestock	192

A 2.1.5	Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)	192
A 2.1.6	Magnitude of residues in representative succeeding crops.....	192
A 2.1.7	Other/Special Studies	193
Appendix 3	Pesticide Residue Intake Model (PRIMo).....	213
A 3.1	TMDI calculations	213
A 3.2	IEDI calculations	218
A 3.3	IESTI calculations - Raw commodities	219
A 3.4	IESTI calculations - Processed commodities.....	224
Appendix 4	Additional information provided by the applicant	229

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Storage stability

- High water content matrices (prothioconazole) in regard to following proposed uses: cucurbits edible peel (courgette, cucumber), pome fruits (apple, quince, medlar), pome fruits (pear), stone fruits (plum, apricot, cherries), carrot (other roots and tubers vegetables)

In the framework of the peer review, storage stability of prothioconazole and its metabolite prothioconazole-desthio residues was demonstrated at -18 °C for 18 months in wheat green matter and for 24 months in spinach, sugarbeet and in tomato.

According to OECD 506 if the stability of test substance in three diverse commodities in this category is confirmed, further examination with other crops that belong to this category is unnecessary.

- High starch content matrices (prothioconazole) in regard to following proposed uses: wheat (soft, durum), triticale, rye, barley and sugar beet.

In the framework of the peer review, storage stability of prothioconazole and its metabolite prothioconazole-desthio residues was demonstrated at -18 °C for 18 months in cereal grain and 24 month in sugar beet.

In the framework of the peer review, storage stability of prothioconazole and its metabolite prothioconazole-desthio residues was demonstrated at -18 °C for 18 months in cereal straw.

- High oil content

In the framework of the peer review, storage stability of prothioconazole and its metabolite prothioconazole-desthio residues was demonstrated at -18 °C for months in Canola seeds.

EFSA Journal 2020;18(2):5999 (confirmatory data following the Article 12 MRL review):

Hydroxylated metabolite included in the risk assessment residue definition:

Freezer storage stability of prothioconazole-a-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio was investigated in high water content (tomatoes), high starch content (potatoes), high oilcontent (soya beans, oilseed rape) and high acid content (oranges) commodities for a period of 24 months.

EFSA accepted the storage stability data on potatoes (high starch matrix) to address the storage stability in cereals.

Regarding prothioconazole, prothioconazole-desthio and its hydroxy metabolites, the available data sufficiently covers the maximum storage interval for commodities measured in the samples coming from residue trials.

TDMs

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

Plant products (Category)	Commodity	Stability (Months)			
		1,2,4-Triazole	TA	TAA	TLA

High water content	Apples, tomatoes, mustard leaves, wheat forage, radishes tops/roots, turnips roots, sugar beet roots, cabbages, lettuces	6	53	53	48 ((lettuce only)
High starch content	Barley, wheat	12	26	26	48
High oil content	Oilseed rape (seed), soya beans	12 (soya bean only; not stable in rape seed)	26 (soya bean only; not stable in rape seed)	53	48
High protein content	Peas, dry; Navy beans	No data	15	25	48
High acid content	Oranges	No data	No data	No data	48
Others	Cereal straw	12	53	40	No data
Animal	Animal commodity	Stability (Month/Year)			
	Muscle	18	No data	No data	No data
	Liver	12	No data	No data	No data
	Kidney	12	No data	No data	No data
	Milk	12	No data	No data	No data
	Egg	12	No data	No data	No data

New study - Freezer storage stability of Prothioconazole-desthio (M04) and its hydroxy metabolites M14, M15, M16, M17 and M18 in 5 different matrices: high water commodity (zucchini), high oil commodity (oilseed rape seeds), high acid commodity (grape), dry commodity (peas dry seeds) and high starch commodity (sugar beet root) is ongoing. 6 months checkpoint was presented.

Final Report was provided. In the new storage stability study submitted by the applicant, residues of prothioconazole-desthio (M04) and its hydroxy metabolites (M14, M15, M16, M17 and M18) which are all components included in the risk assessment residue definition, are stable in the 5 crop groups for 12 months when they are stored at -18°C. The only exceptions are the metabolites M14, M15 and M17 which degrade in high starch matrix after 6, 3 and 9 months respectively

Data gap: Storage stability data for 1,2,4-T and TA in rapeseeds.

A new storage stability study on 1,2,4 Triazole is ongoing in the various matrix groups to support 2020 residue trials. The stability will be evaluated once available the results of storage study, however according to the available data reported in the Interim report, no degradation of 1,2,4 Triazole is expected in high water and high starch matrix, while a strong degradation was observed in oil seed rape seed.

Final Report was provided. According to the available data, 1, 2 4 triazole is stable in high water (apple), high starch (sugar beet root) and dry commodity (peas dry seed) for 12 months when they are stored at -18°C. In grape samples a degradation was observed after 6 months.

Strong degradation was observed in high oil matrix (OSR seed) confirming the 1,2,4 triazole is not stable in this crop.

Metabolism in plants and animals

Plant residue definition for monitoring (RD-Mo): Prothioconazole: Prothioconazole-desthio (sum of isomers)

Plant residue definition for risk assessment (RD-RA):

a) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014)

b) TDMs (EFSA, 2018, SANCO/3923 /07 – final 10 December 2007, 26 January 2021), with separate assessment of:

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

Magnitude of residues in plants

Wheat (Soft, Durum), Triticale, Rye

Proposed GAP:

2 applications (14 days interval), BBCH 29-69; 200 g as/ha, PHI: 21 days

Prothioconazole

8 residue trials in Northern Europe were submitted for wheat. Residues measured in the trials are all < the LOQ except for one sample in which residue was above the LOQ but below the fixed MRL.

Trials GAP: 2x 200 g as/ha, BBCH 39-69, interval between appl. 14d; PHI 35d

Mo: 7x <0.01; 0.03 mg/kg

According to SANTE/2019/12752, wheat data could be extrapolated to rye and triticale.

The data submitted show that no exceedance of the current MRL of 0.1 mg/kg (wheat, triticale, durum, spelt) and 0.05 mg/kg (oat, rye) will occur when the PPP is applied according to the intended GAP.

With regard to Prothioconazole the use is considered acceptable with PHI=35.

TDMs:

Applicant's note: *An analytical method for the determination of triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) was validated in plant commodities. However, due to the difficulty related to the validation of the method, analysis of the samples coming from residue trials are still ongoing at the time of the first dossier submission. Once available all the data, a revised dRR Section B7 will be submitted, and an update consumer risk assessment will be provided.*

TDMs:

The proposed use can only be accepted after providing data on the TDMs residues after the use of PPP.

03/2023 Assessment of updated dRR part B7 (TDMs):

A reference has done to open data (4 NEU, 4 SEU trials).

EFSA Journal 2018;16(7):5376, United Kingdom, 2018. Triazole Derivative Metabolites Addendum – Confirmatory Data. United Kingdom, February 2018.

Trials GAP: 3x 187.5 g as/ha, BBCH 32-69, interval 14-35 d, PHI = 28d

No data is available for TLA, the applicant has planned with other Companies new residue trials on cereals in 2023 in order to analyse it. In any case, evaluating all the available TDMs data in the various crops, in particular to TLA measured in barley grain (HR = 0.01 mg/kg), residues expected in this matrix

are quite low and no consumer risk is expected. New residue trials on wheat are ongoing this year. The final report could be submitted as post registration data requirement at national level.

The data available are considered sufficient for risk assessment.

Uses are accepted.

Barley

Proposed GAP:

2 applications (14 days interval), BBCH 29-61; 200 g as/ha, PHI: 21 days

Prothioconazole

8 residue trials in Northern Europe were submitted for barley. Residues measured are all below the fixed MRL.

Trials GAP: 2x 200 g as/ha, BBCH 39-69, interval between appl. 14d; PHI 35d

Mo: <0.01; 0.08; 0.02; 0.11; 0.03; 0.02; 0.02; 0.01 mg/kg

According to SANTE/2019/12752, barley data could be extrapolated to oat.

The data submitted show that no exceedance of the current MRL of 0.2 mg/kg will occur when the PPP is applied according to the intended GAP.

Additionally open data on barley are available and can support the intended use.

With regard to Prothioconazole the use is considered acceptable with PHI=35.

TDMs:

Applicant's note: *An analytical method for the determination of triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) was validated in plant commodities. However, due to the difficulty related to the validation of the method, analysis of the samples coming from residue trials are still ongoing at the time of the first dossier submission. Once available all the data, a revised dRR Section B7 will be submitted, and an update consumer risk assessment will be provided.*

TDMs:

The proposed use can only be accepted after providing data on the TDMs residues after the use of PPP.

03/2023 Assessment of updated dRR part B7 (TDMs):

A reference has done to open data (4 NEU, 4 SEU trials).

EFSA Journal 2018;16(7):5376, United Kingdom, 2018. Triazole Derivative Metabolites Addendum – Confirmatory Data. United Kingdom, February 2018

Trials GAP: 2x 150/200 g as/ha, BBCH 37-61, interval 9/27 d, PHI = 28/35d

The data available are considered sufficient for risk assessment.

Use is accepted.

Oilseed rape

Proposed GAP:

2 applications (14 days interval), BBCH 30-71; 180 g as/ha, PHI: 50 days

Prothioconazole

8 residue trials in Northern Europe were submitted for Oil seed rape as it is a major crop in the EU.

Trials GAP: 2x 180 g as/ha, BBCH 30-71, interval between appl. 14d; PHI 50d

Residues (Mo): 6x <0.01; 0.01; 0.02 mg/kg

Residues measured in the trials conducted by the applicant showed results all below the LOQ except for two samples in which residues were above the LOQ but below the fixed MRL.

The data submitted show that no exceedance of the current MRL of 0.15 mg/kg will occur when the PPP is applied according to the intended GAP.

With regard to Prothioconazole the use is considered acceptable.

TDMs:

The proposed use can only be accepted after providing data on the TDMs residues after the use of PPP with prothioconazole in the protection of oilseed rape (from the new studies or unprotected EU data).

03/2023 Assessment of updated dRR part B7 (TDMs):

A reference has done to open data (20 NEU) and new trials (8 NEU).

Source	Residue zone	Evaluation GAP Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)
UK, 2018	20 NEU	GAP: 2x 125/150 g as/ha, BBCH 30-73/85, interval between appl. 14d; PHI nr	T: 0.01 TA: 0.24 TAA: 0.01 TLA: 0.015	T: 0.018 TA: 2.17 TAA: 0.062 TLA: 0.05
New trials	NEU	GAP: 2x 180 g as/ha, BBCH 30-71, interval between appl. 14d; PHI 50d RA: <ul style="list-style-type: none"> T: 8x <0.04 TA: 0.114; 0.18; 0.277; 0.297; 0.487; 0.81; 0.92; 6.23 TAA: 7x <0.04, 0.104 TLA: 5x <0.04, 0.056; 0.061; 0.204 	T: 0.04 TA: 0.39 TAA: 0.04 TLA: 0.04	T: 0.04 TA: 6.23 TAA: 0.1 TLA: 0.2

Strong degradation of TLA and TA was observed in oil seed rape seed (storage stability data).

According to that, new residue trials will be planned in 2023 with the aim to analyse the samples within 30 days from harvest to avoid storage stability issue. New trials could be sent as soon as finalised and/or as post registration requirement.

In any case, since no risk for consumers is expected when the PPP is applied according to the intended GAP, at the moment enough data is available to perform provisional consumer risk assessment. It is up to each Member State to decide on the need to provide the above-mentioned data prior to registration in a given country. This data can be submitted at national level.

It should be noted that Triazol Alanine is a common biological compound and can normally be found in the environment.

Although the evaluation is provisional, the use can be accepted.

TLA and TA in rape seed

New residue trials are ongoing in 2023 where samples will be analysed within 30 days from harvest to avoid storage stability issue. If required, the new report could be submitted as post registration data requirement at national level.

Residues of TMDs in honey

No data have been submitted for the residue situation of TDMs in honey (oilseed rape use).

It is up to each Member State to decide on the need to provide the above-mentioned data prior to registration in a given country. This data can be submitted at national level (see zRMS comment on

“Other / special studies” in this point and comments in the Reporting Table).

Sugar beet

Proposed GAP:

2 applications (14 days interval), BBCH 39-49; 160 g as/ha, PHI: 28 days

Prothioconazole

Four residue trials on sugar beet were conducted in Northern Europe on sugar beet. Residues measured are all below the LOQ.

According to SANTE 2019/12752 rev. 10.3 (Appendix d) and to Commission Regulation (EU) No 283/2013, the numbers of studies to be performed may be reduced if residue trials show that the residue levels in plant or plant products are lower than the LOQ. Four trials are sufficient to support sugar beet use.

Trials GAP: 2x 160 g as/ha, BBCH 39-49, interval between appl. 14d; PHI 28d

Residues: 4x <0.01 mg/kg

The data submitted show that no exceedance of the current MRL of 0.01 mg/kg will occur when the PPP is applied according to the intended GAP.

With regard to Prothioconazole the use is considered acceptable.

TDMs:

The proposed use can only be accepted after providing data on the TDMs residues after the use of PPP with prothioconazole in the protection of sugar beet (from the new studies or unprotected EU data).

03/2023 Assessment of updated dRR part B7 (TDMs):

A reference has done to new trials (7 NEU). Field phase and analytical method used are acceptable.

New trials	NEU	GAP: 2x 160 g as/ha, BBCH 39-49, interval between appl. 14d; PHI 28d RA:
		<ul style="list-style-type: none"> T: 7x <0.04 TA: 5x <0.04; 0.053; 0.08 TAA: 7x <0.04 TLA: 7x <0.04

T, TA, TAA:

All trials are acceptable with regard to storage stability data.

TLA

4 trials are acceptable with regard to storage stability data. The number of acceptable trials is sufficient since residues are below LOQ.

It should be noted that Triazol Alanine is a common biological compound and can normally be found in the environment.

Use is accepted.

Pome fruits (Apple, Quince, Medlar, Pear)

Proposed GAP:

Apple, Quince, Medlar: 2 applications (7-10 days interval), BBCH 39-85; 120 g as/ha, PHI: 14 days

Pear: 2 applications (7-10 days interval), BBCH 39-85; 120 g as/ha, PHI: 21 days

Prothioconazole

8 residue trials on apple conducted in Northern Europe have been submitted by the applicant.

Trials GAP: apple, 2x 120 g as/ha, BBCH 39-85, interval between appl. 7d; PHI 14d

Residues are above 0.01 mg/kg (MRL)

Considering the intended use on pome fruits, an exceedance of the MRL for prothioconazole is expected (0.01 mg/kg, Reg. (EU) 2019/552)

Assessment of application to modify the current EU MRL in various crops is ongoing. Approval for the use in protection of pome fruits will be possible after the change of the MRLs for this crops. Uses are not accepted.

TDMs

Data gap: TDMs residues after the use of PPP with prothioconazole in the protection of pome fruit (from the new studies or unprotected EU data).

03/2023 Assessment of updated dRR part B7 (TDMs):

Although new triazole residue trials have been provided, the use of the product in the protection of pome fruits cannot be accepted due to the risk of exceeding the MRL

Stone fruits (Plum, Apricot, Cherries)

Proposed GAP:

Plum, Apricot, Cherries: 2 applications (7 days interval), BBCH 51-85; 160 g as/ha, PHI: 3 days

Prothioconazole

6 residue trials on peaches, 8 residue trials on plums and 8 residue trials on cherries conducted in Northern Europe have been submitted by the applicant.

Trials GAP: 2x 160 g as/ha, BBCH 39-85, interval between appl. 7d; PHI 3d

Residues are above 0.01 mg/kg (MRL)

Considering the intended use on stone fruits, an exceedance of the MRL for prothioconazole is expected (0.01 mg/kg, Reg. (EU) 2019/552)

Assessment of application to modify the current EU MRL in various crops is ongoing. Approval for the use in protection of stone fruits will be possible after the change of the MRLs for this crops. Uses are not accepted.

TDMs

Data gap: TDMs residues after the use of PPP with prothioconazole in the protection of stone fruit (from the new studies or unprotected EU data).

03/2023 Assessment of updated dRR part B7 (TDMs):

Although new triazole residue trials have been provided, the use of the product in the protection of stone fruits cannot be accepted due to the risk of exceeding the MRL

Cucurbits with edible peel (courgette, cucumber)

Proposed GAP:

courgette, cucumber: 3 applications (10 days interval), BBCH 11-89; 200 g as/ha, PHI: 10 days

Prothioconazole

8 residue trials on zucchini (courgette in greenhouse conditions) conducted in Northern Europe have been submitted by the applicant

Trials GAP: 3x 120 g as/ha, BBCH 11-89, interval between appl. 10d; PHI 10d

The use cannot be accepted due to the possibility of exceeding the MRL.

Intended use is not sufficiently supported. At least 4 trials with residue levels below LOQ are required (reduced dataset). For a PHI of 10 days, residue levels are below LOQ, and no MRL exceedance is expected, but only 2 trials are available.

TDMs

Data gap: TDMs residues after the use of PPP with prothioconazole in the protection of cucurbits with edible peel (from the new studies or unprotected EU data).

03/2023 Assessment of updated dRR part B7 (TDMs):

Although new triazole residue trials have been provided, the use of the product in the protection of courgette, cucumber cannot be accepted due to the risk of exceeding the MRL.

Carrot (other roots and tubers vegetables)

Proposed GAP:

2 applications (21 days interval), BBCH 16-46; 200 g as/ha, PHI: 21 days

Prothioconazole

8 residue trials conducted in carrot have been submitted by the applicant.

Trials GAP

a) GAP: 2x 160 g as/ha, BBCH 16-46, interval between appl. 7-10d; PHI 21d

Mo: <0.01; 0.011; 0.024; 0.083

Proportionality approach: 1x 200 g as/ha:

Mo: <0.01; 0.01; 0.03; 0.1 mg/kg

The value of 0.1 mg/kg was presented by the applicant as an outlier. It does not exceed the MRL value, so it was taken into account by zRMS in the assessment.

b) GAP: 2x 200 g as/ha, BBCH 16-46, interval between appl. 7-10d; PHI 21d

Mo: <0.01; 0.0137; 0.03; 0.103 mg/kg

Number of trials is sufficient.

According to SANTE/2019/12752, carrot data could be extrapolated to Whole subgroup (c) other root and tuber vegetables except sugar beets (0213000) and except celeriacs/turnip rooted celeries (213030), jerusalem artichokes (213050) and radishes (213080) which EU MRLs are set at lower level.

The data submitted show that no exceedance of the current MRL of 0.1 mg/kg (beetroots, carrots, horseradishes, parsnips, parsley roots/hamburg roots parsley, salsifies, swedes/rutabagas and turnips) will occur when the PPP is applied according to the intended GAP.

With regard to Prothioconazole the uses in protection beetroots, carrots, horseradishes, parsnips, parsley roots/hamburg roots parsley, salsifies, swedes/rutabagas and turnips are considered acceptable.

TDMs

Data gap: TDMs residues after the use of PPP with prothioconazole in the protection of carrots (from the new studies or unprotected EU data)

03/2023 Assessment of updated dRR part B7 (TDMs):

A reference has done to open data (5 NEU) and new trials (4 NEU).

Source	Residue zone	Evaluation GAP Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)

UK, 2018	5 NEU	GAP: 3x 192 g as/ha, interval between application 14d, PHI 21d	T: 0.01 TA: 0.025 TAA: 0.01 TLA: 0.01	T: 0.016 TA: 0.029 TAA: 0.010 TLA: 0.010
New trials	NEU	GAP: 2x 200 g as/ha, BBCH 16-46, interval between appl. 7-10d; PHI 21d RA: <ul style="list-style-type: none"> T: 4x <0.04 TA: 4x <0.04 TAA: 4x <0.04 TLA: 4x <0.04 <p>⁺Only one year data package was analysed for NEU since all residues were found ND (not detectable, below LOD, <0.01 mg/kg)</p>	T: 0.04 TA: 0.04 TAA: 0.04 TLA: 0.04	T: 0.04 TA: 0.04 TAA: 0.04 TLA: 0.04

Applications for the protection of beetroots, carrots, horseradishes, parsnips, parsley roots/hamburg roots parsley, salsifies, swedes/rutabagas and turnips are considered acceptable.

Magnitude of residues in livestock

The calculated dietary burdens were found to exceed the trigger value of 0.004 mg/kg bw/day. Further investigation of residues in livestock is required. Applicant refers to out of protection EU data.

No exceedances of the existing EU MRLs for prothioconazole in animal commodities are anticipated as a result of the proposed uses.

TDMs

EFSA Journal 2018;16(7):5376:

The livestock exposure assessment cannot be finalised with regard to the outstanding data for acceptable residue trials in primary and rotational crops.

Data gap:

Poultry and ruminant feeding studies conducted with TLA or, alternatively, metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies to determine the magnitude of TLA residues in products of animal origin (data gap at EU level).

Industrial Processing and/or Household Preparation:

Prothiconazole

Studies are currently not required, as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI for the individual crops under assessment.

Such studies are not expected to affect the outcome of the risk assessment.

TDMs

The TDMs remained stable under the standard hydrolysis conditions simulating processing of pasteurisation, baking, brewing and boiling and sterilisation (EFSA Journal 2018;16(7):5376).

Additional data are not required.

Magnitude of residues in representative succeeding crops

Considering available data dealing with nature of residues, no study dealing with magnitude of residues in succeeding crops is needed

TDMs

Data gap: Rotational crops field residue trials supported by acceptable storage stability data on TDMs (data gap at EU level).

Other / special studies

The applicant has conducted a residue study on honey in order to determine the magnitude of residue of prothioconazole-desthio in this matrix.

2 residue trials were conducted in Northern Europe and 2 in Southern EU in tunnel conditions. As surrogate crop, phacelia was used. A worst case GAP has been selected for residue trials in order to cover all the uses in the intended GAP. The trials were done according to the Guideline SANTE/11956/2016 rev. 9, 14 September 2018. The analytical part of the study is still ongoing however, an Interim Report (KCA 6.10, Report N. QS21003) is available with the field data and the results of prothioconazole-desthio.

When prothioconazole-desthio is applied according to the intended GAP, no residue higher than MRL is expected.

No data have been submitted for the residue situation of TDMs in honey (oilseed rape use).

Applicant's comment:

“correct, unfortunately there was some issue with the development of the analytical method for the determination of TDMs in honey matrix. Please take note new residue trials on honey are ongoing in 2023, if needed, the final report could be submitted as post registration data requirement at national level.

However, no risk for consumer is expected when the PPP is applied according to the intended GAP. Please see EFSA 2023 (*Reasoned Opinion on the modification of the existing maximum residue levels for prothioconazole in garlic, onions and shallots. EFSA Journal 2023;21(1):7717, 48 pp.*), where new residue trials investigating the prothioconazole and TDM residues to honey from the use of prothioconazole on oilseed rape have been evaluated. The data indicates that residues of prothioconazole in honey would not exceed the existing MRL of 0.05 mg/kg (LOQ). Moreover, please consider according to EFSA, 2023 “the nature of prothioconazole in honey is not addressed to conclude on the relevant residues for enforcement purposes. Therefore, EFSA recommends considering this aspect further under the renewal assessment.” Following the above information, no new data is considered to be relevant in the Art. 33 context. If required, according to EFSA, if needed, after the active renewal new data on honey will be submitted by the applicant in Art. 43 dossier.”

Storage stability studies, neither for prothioconazole-desthio nor for TDMs in honey (oilseed rape use)

Applicant's comment:

“Storage stability study is ongoing for prothioconazole-desthio in honey. The final report could be submitted as soon as available (expected for September 2023), according to the preliminary data no degradation is expected. The final report could be submitted as post registration data requirement at national level. No data is needed for TDMs according to EFSA, 2023”.

zRMS: It is up to each Member State to decide on the need to provide the above-mentioned data prior to registration in a given country. This data can be submitted at national level.

Estimation of exposure through diet and other means

- Risk assessment for residue definition 1: Prothioconazole-desthio

Chronic and acute exposure calculations were performed using EFSA PRIMo revision 3.1 and calculated exposures were compared with the established toxicological reference values. The proposed uses of prothioconazole in the formulation SIP 41061 do not represent unacceptable acute and chronic risks for the consumer. All calculation provided by the Applicant are accepted.

- Risk assessment for residue definition 2: Triazole alanine and triazole lactic acid (data gap);

Risk assessment residue definition 3: Triazole acetic acid (data gap);

Risk assessment residue definition 4: 1,2,4-triazole (data gap)

03/2023 Assessment of updated dRR part B7 (TDMs):

Consumer risk assessment was performed separately for each definitions using and input values residue coming from applicant residue trials.

No risk to the consumer identified.

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 SIP 41061 are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central zone for wheat, rye, barley, oilseed rape, sugar beet, cucurbits with edible peel, pome fruits, stone fruits and carrot.

A list of all intended uses within the Central zone is given in Part B, Section 0.

Overall conclusion

The data available are considered not sufficient for risk assessment. An exceedance of the current MRL of

- wheat, 0.1 mg/kg
- barley, 0.2 mg/kg
- oil seed rape, 0.15 mg/kg
- sugar beet roots, 0.01 mg/kg
- cucurbits with edible peel, 0.01 mg/kg
- pome fruits, 0.01 mg/kg
- stone fruits, 0.01 mg/kg
- carrot and sub group (c), 0.1 mg/kg (except celeriacs/turnip rooted celeries (213030), jerusalem artichokes (213050) and radishes (213080))

for Prothioconazole as laid down in Reg. (EU) 396/2005 is not expected. However, for pome fruits and stone fruits, an exceedance of the current MRLs is expected. For this reason, the applicant in April 2022 submitted to Greece an Evaluation report in order to change the current MRLs. In addition a MRL dossier has been submitted as IUCLID dossier and it was uploaded on ECHA portal on 7th April 2022. No risk for consumers is expected with the new MRLs proposed.

MRLs exceedance is expected for pome fruits, stone fruits, cucurbits with edible peel, celeriacs/turnip rooted celeries, jerusalem artichokes and radishes. Intended use on cucurbits with edible peel is not sufficiently supported by field trials.

The chronic and the short-term intakes of Prothioconazole and its metabolites residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, zRMS agrees with the authorization of the following intended use(s):

Wheat (Soft, Durum), Triticale, Rye, Barley, Oilseed rape, Sugar beet, Carrot (0213020) and other roots and tuber vegetables (beetroots 0213010; horse radishes 0213040; parsnips 0213060; parsley roots

0213070; salsifies 0213090; swedes 0213100; turnips 0213110).

NOTE: It is up to each Member State to decide on the need to provide missing data for oil seed rape (data for TLA and TA in rape seed; residues of TMDs in honey) prior to registration in a given country. This data can be submitted as post registration requirement. In Poland use is accepted by the evaluator with post registration requirement.

Data gaps

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

Noticed data gaps are:

Data gap 1: MRLs existence is expected for pome fruits and stone fruits, cucurbits with edible peel. Cucurbits: Intended use is not sufficiently supported by field trials. At least 4 trials with residue levels below LOQ are required.

Data gap 2: No data is available for TLA in wheat. New residue trials on wheat are ongoing. The final report could be submitted as post registration data requirement at national level.

Data gap 3: Oilseed rape - TLA and TA in rape seed; Residues of TMDs in honey. It is up to each Member State to decide on the need to provide this data prior to registration in a given country. This data can be submitted as post registration requirement.

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

1	2	3	4	5	6	7	8					9			10	11
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	g as/ha min max		
1	Wheat (Soft, Durum), Triticale, Rye	CEU (DE, PL, CZ, RO, HU, BE, NL, AT, IE)	SIP 41061	F	<i>Septoria spp.</i> , <i>Fusarium spp.</i> , <i>Puccinia spp.</i> , <i>Erysiphe spp.</i>	SC	400 g/L	Spray	BBCH 29-69	2	14 days	0.06 - 0.1	200 - 600	200	24 35	A
2	Barley	CEU (DE, PL, CZ, RO, HU, BE, NL, AT, IE)	SIP 41061	F	<i>Rhynchosporium secalis</i> , <i>Puccinia hordei</i> , <i>Pyrenophora teres</i> (<i>Helminthosporium spp.</i>)	SC	400 g/L	Spray	BBCH 29-61	2	14 days	0.06 - 0.1	200 - 600	200	24 35	A
3	Oilseed rape	CEU (DE, CZ, PL, HU, RO, BE, AT, IE)	SIP 41061	F	<i>Sclerotinia</i> , <i>Phoma</i> , <i>Pyrenopeziza</i> , <i>Oidium</i>	SC	400 g/L	Spray	BBCH 30-71	2	14 days	0.06 - 0.09	200 - 600	180	50	R****
4	Sugar beet	CEU (DE, NL, BE, PL, CZ, AT, IE)	SIP 41061	F	<i>Cercospora beticola</i> , <i>Erysiphe betae</i>	SC	400 g/L	Spray	BBCH 39-49	2	14 days	0.05 - 0.08	200 - 600	160	28	A
5	Cucurbits edible peel (courgette, cucum-)	CEU (NL, DE, AT)	SIP 41061	G	<i>Oidium</i> (<i>Podosphaera xanthii</i> ,	SC	400 g/L	Spray	BBCH 11-89	3	10 days	0.06 - 0.1	200 - 600	200 120	10	N Intended

	ber)				<i>Golovinomyces cichoracearum</i> , <i>Sphaerotheca fuliginea</i> <i>Fusarium spp</i>											use is not sufficiently supported by field trials.
6a	Pome fruits (Apple, Quince, Medlar)	CEU (PL, HU, DE, BE, AT, IE)	SIP 41061	F	<i>Scab, Stem-phylidium, Oidium</i>	SC	400 g/L	Spray	BBCH 39-85	2	7-10 days	0.016 - 0.02	500 - 1500	120	14	N MRL exceedance is possible.
6b	Pome fruits (Pear)	CEU (PL, HU, DE, BE, AT, IE)	SIP 41061	F	<i>Scab, Stem-phylidium, Oidium</i>	SC	400 g/L	Spray	BBCH 39-85	2	7-10 days	0.016 - 0.02	500 - 1500	120 MRL exceedance is possible	21	N MRL exceedance is possible.
7	Stone fruits (Plum, Apricot, Cherries)	CEU (DE, PL, HU, AT)	SIP 41061	F	<i>Sphaerotheca spp</i> <i>Monilia spp.</i>	SC	400 g/L	Spray	BBCH 51-85	2	7 days	0.02 – 0.03	500 - 1500	160	3	N MRL exceedance is possible.
8	Carrot (0213020) and other roots and tuber vegetables (beetroots 0213010; horse radishes 0213040; parsnips 0213060; parsley roots 0213070; salsifies 0213090; swedes 0213100; turnips 0213110) (other roots and tubers vegetables)	CEU (PL, RO, NL, BE, AT, IE)	SIP 41061	F	Leaf blight (<i>Alternaria dauci</i>), Sclerotinia rot (<i>Sclerotinia sclerotiorum</i>), Powdery mildew (<i>Erysiphe heraclei</i>)	SC	400 g/L	Spray	BBCH 16-46	2	21 days	0.04	500 - 1000	200	21	A

	except celeriacs/turnip rooted celeries (213030), jerusalem artichokes (213050) and radishes (213080)															
--	---	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

* 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

**** NOTE: It is up to each Member State to decide on the need to provide missing data for oil seed rape (data for TLA and TA in rape seed; residues of TMDs in honey) prior to registration in a given country. This data can be submitted at national level. In Poland use is accepted by the evaluator with post registration requirement.

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 SIP 41061 is composed of Prothioconazole.

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Prothioconazole, parent					
ADI	EFSA	2007 ¹	0.05 mg/kg bw per d	Rat, 2 year study; dog, 1 year study	100
ARfD	EFSA	2007	0.2 mg/kg bw	Rat, developmental study	100
Prothioconazole-desthio					
ADI	EFSA	2007	0.01 mg/kg bw per d	Rat, carcinogenicity study	100
ARfD	EFSA	2007	0.01 mg/kg bw	Rat, developmental study	100
1,2,4-triazole, triazole acetic acid^(a) and triazole lactic acid^(a)					
ADI	PRAPeR 14	2007	0.02 mg/kg bw per d	Rat, multigeneration study	1000
ARfD	PRAPeR 14	2007	0.06 mg/kg bw	Rat, developmental study	500
Triazole alanine					
ADI	PRAPeR 14	2007	0.1 mg/kg bw per d	Rat, developmental study	1000
ARfD	PRAPeR 14	2007	0.1 mg/kg bw	Rat, developmental study	1000
1,2,4-triazole					
ADI	SANCO/3923 /07_rev Jan 2021 ²	2021	0.023 mg/kg bw per d	Rat, 12 month study	300
ARfD	SANCO/3923 /07_rev Jan 2021	2021	0.1 mg/kg bw	Rat, developmental study	300
Triazole alanine and Triazole lactic acid^{a)}					
ADI	SANCO/3923 /07_rev Jan 2021	2021	0.3 mg/kg bw per d	Rabbit, developmental study	100
ARfD	SANCO/3923 /07_rev Jan 2021	2021	0.3 mg/kg bw	Rabbit, developmental study	100

¹ EFSA, 2007. European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance prothioconazole. EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole

² Prothioconazole - SANCO/3923 /07 – final, 10 December 2007, rev 26 January 2021. Review report for the active substance prothioconazole, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 22 January 2008 in view of the inclusion of prothioconazole in Annex I of Directive 91/414/EEC and updated in the Standing Committee on Plants, Animals, Food and Feed on 26 January 2021

a) Triazole lactic acid bridging from TA.

Reference value	Source	Year	Value	Study relied upon	Safety factor
Triazole acetic acid					
ADI	SANCO/3923/07_rev Jan 2021	2021	1.0 mg/kg bw per d	Rat. 2 generation and rabbit development study	100
ARfD	SANCO/3923/07_rev Jan 2021	2021	1.0 mg/kg bw per d	Rat. 2 generation and rabbit development study	100

7.1.2.1 Summary for Prothioconazole

Table 7.1-3: Summary for Prothioconazole

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	Wheat, Triticale and Rye	Yes	Yes	Yes	Yes	Yes	No	No
2	Barley	Yes	Yes	Yes	Yes	Yes	No	No
3	Oilseed rape	Yes	Yes	Yes	Yes No	Yes	No	No
4	Sugar beet	Yes	Yes	Yes	Yes	Yes	No	No
5	Cucurbits edible peel	Yes	Yes No	Yes	Yes	Yes No	No	No
6a	Pome fruits (Apple, Quince, Medlar)	Yes	Yes	Yes	Yes	No (MRL change submitted and under evaluation)	No	No
6b	Pome fruits (Pear)	Yes	Yes	Yes	Yes	No (MRL change submitted and under evaluation)	No	No
7	Stone fruits (Plum, Apricot, Cherry)	Yes	Yes	Yes	Yes	No (MRL change submitted and under evaluation)	No	No
8	Carrot and other roots and tuber vegetables (beet-roots 0213010;	Yes	Yes	Yes	Yes	Yes	No	No

Use- No.*	Crop	Plant me- tabolism covered?	Sufficient residue trials?	PHI suffi- ciently supported?	Sample storage covered by sta- bility data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for con- sumers identified?
	horse rad- ishes 0213040; parsnips 0213060; parsley roots 0213070; salsifies 0213090; swedes 0213100; turnips 0213110)							

As residues of prothioconazole do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

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

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

7.1.2.2 Summary for active substance 2

Not relevant.

7.1.2.3 Summary for SIP 41061

Table 7.1-4: Information on SIP 41061 (KCA 6.8)

Crop	PHI for SIP 41061 proposed by applicant	PHI/ Withholding period* sufficiently supported for Prothioconazole	PHI for SIP 41061 proposed by zRMS	zRMS Comments (if different PHI proposed)
Wheat, Rye	21	Yes		
Barley	21	Yes		
Oilseed rape	50	Yes		
Sugar Beet	28	Yes		

Crop	PHI for SIP 41061 proposed by applicant	PHI/ Withholding period* sufficiently supported for Prothioconazole	PHI for SIP 41061 proposed by zRMS	zRMS Comments (if different PHI proposed)
Cucurbits edible peel	10	Yes		MRL exceedance is possible
Pome fruits (Apple, Quince, Med-lar)	14	Yes		MRL exceedance is possible
Pome fruits (Pear)	21	Yes		MRL exceedance is possible
Stone fruits (Apricot, Cherry, Plum)	3	Yes		MRL exceedance is possible
Carrot and other tuber vegetables (beetroots 0213010; horse radishes 0213040; parsnips 0213060; parsley roots 0213070; salsifies 0213090; swedes 0213100; turnips 0213110)	21	Yes		

NR: not relevant

* Purpose of withholding period to be specified

Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for SIP 41061
Crop group	Led by Prothioconazole	

NR: not relevant

Assessment

Prothioconazole is the ISO common name for (RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione (IUPAC). The active substance used in the pesticide formulations is a racemic mixture of the two stereoisomers (R- and S-enantiomer).

Prothioconazole is used as fungicide, it is a systemic compound which acts against a wide range of fungicidal diseases with protective, curative and eradicated activity. Its mode of action consists of a steroid demethylation in the ergosterol biosynthesis pathway. The technical active substance used in the pesticide formulations is a racemic mixture of the two stereoisomers (R – enantiomer and S – enantiomer).

Prothioconazole was evaluated in the framework of Council Directive 91/414/EEC with United Kingdom designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Commission Directive 2008/44/EC which entered into force on 1 August 2008 for use as a fungicide. In accordance with Commission Implementing Regulation (EU) No 540/20115 prothioconazole is approved under Regulation (EC) No 1107/2009. The EFSA conclusion is available (EFSA, 2007³).

The EU MRLs for prothioconazole are established as prothioconazole-desthio in Annex IIIA of Regulation (EC) No 396/2005. The review of prothioconazole MRLs according to Article 12 of Regulation (EC) No 396/2005 has been finalised (EFSA, 2014⁴). Current EU MRLs are set in the Reg. (EU) 2019/552.

According to Review Report on Prothioconazole, SANCO/3923/07 – final, 26 January 2021, EC agreed to include a second risk assessment residue definition for Triazole Derivate Metabolites (TDMs). An analytical method for the determination of triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) was validated in plant commodities (please refer to dRR Part B, Section 5). However, due to the difficulty related to the validation of the method, analysis of the samples coming from residue trials are still ongoing at the time of the first dossier submission. Since ~~Once available all the data~~ **is now available**, a revised dRR Section B7 ~~will be~~ **was** submitted, and an update consumer risk assessment ~~will be~~ **was** provided.

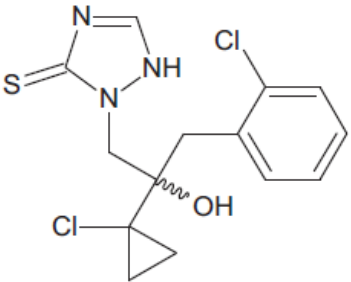
³ EFSA (European Food Safety Authority), 2007. Conclusion on the peer review of the pesticide risk assessment of the active substance prothioconazole. The EFSA Journal 2007, 106r, 1-98. doi:10.2903/j.efsa.2007.106r

⁴ EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for prothioconazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(5):3689, 72 pp. doi:10.2903/j.efsa.2014.3689

7.2 Prothioconazole

General data on Prothioconazole are summarized in the table below (last updated 2022/04/11)

Table 7.2-1: General information on Prothioconazole

Active substance (ISO Common Name)	Prothioconazole
IUPAC	(RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione
Chemical structure	
Molecular formula	C ₁₄ H ₁₅ Cl ₂ N ₃ OS
Molar mass	344.26 g/mol
Chemical group	Triazole group
Mode of action (if available)	Steroid demethylation in the ergosterol biosynthesis pathway
Systemic	Yes
Company (ies)	Notifier: Bayer Crop Science
Rapporteur Member State (RMS)	UK
Approval status	Approved Date of (01/08/2008) COMMISSION DIRECTIVE 2008/44/EC of 04 April 2008 - COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011 of 25 May 2011
Restriction (e.g. is restricted to use as "...")	Fungicide
Review Report	SANCO/3923 /07 - final 10 December 2007 26 January 2021
Current MRL regulation	Reg. (EU) 2019/552
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes EFSA, 2014 (EFSA Journal 2014;12(5):3689)
EFSA Journal : Conclusion on the peer review	Yes EFSA Scientific Report (2007) 106, 1-98
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	Yes Pome fruits Stone fruits Cucurbits with edible peel Cucurbits with inedible peel Rice

	<p>The applicant Sipcam Oxon S.p.A. created a pre-ID number on EFSA Portal, EFSA-ID-2021-000296, the aim is to modify the current EU MRL in various crops. MRL dossier has been submitted as IUCLID dossier and it was uploaded on ECHA portal on 7th April 2022:</p> <ul style="list-style-type: none"> • Submission type: EU PPP MRL application • Submission number: NRK209012-17 • Submitted by: SIPCAM OXON SPA, IUC5-b1756b6a-b256-466d-8949-e2fc536dcd8d • Dossier IUCLID: f2c7cfd0-e37e-4f61-8914-09c0fedbb6d4 <p>Status: Evaluation report submitted to Greece in April 2022, evaluation ongoing.</p>
--	---

7.2.1.1 Stability of residues during storage of samples

Available data

Please refer to United Kingdom 2004, United Kingdom 2007, EFSA 2007 and EFSA 2014.

In the framework of the peer review, storage stability of prothioconazole-desthio residues was demonstrated at -18 °C for 18 months in high water content matrices (wheat green matter), dry commodities (cereal grain) and straw.

In addition, storage stability of prothioconazole-desthio residues was demonstrated for a period of 24 months at – 18 °C in commodities with high water content (spinach, sugar beet, tomatoes), high oil content (canola seeds), dry commodities (dried peas) and canola straw.

For animal commodities in the framework of the feeding study, the storage stability of prothioconazole-desthio, M14 and M15 was demonstrated in all matrices for up to 1 month when stored deep frozen and was shown to cover the storage time interval of the residue samples of the feeding study.

A new stability study (~~Interim Report 6 months~~ Final report, Report N. RAU-026-20, KCA 6.1) has been submitted by the applicant in the framework of this application. Results are summarized in the Table below. The detailed assessment of this study is presented in Appendix 2.

Table 7.2-2a: Summary of stability data of prothioconazole metabolites achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Crop	Matrix group	Compound	Acceptable Maximum Storage duration at -18°C	Reference
Data relied on in EU				
Plant products				
Wheat green matter	High water content	Prothioconazole-desthio	18 months	UK, 2004 and UK, 2007
Cereal grain and straw	Dry/high protein commodity	Prothioconazole-desthio	18 months	UK, 2004 and UK, 2007
Spinach, Sugarbeet and Tomato	High water content	Prothioconazole-desthio	24 months	EFSA 2014
Canola seeds	High oil content	Prothioconazole-desthio	24 months	EFSA 2014
Dried Peas and Canola straw	Dry/high protein commodity	Prothioconazole-desthio	24 months	EFSA 2014
Animal Products				
Ruminant	Liver, kidney, muscle, fat	Prothioconazole-desthio, M14 and M15	1 month	UK, 2004 and UK, 2007
Ruminant	Milk	Prothioconazole-desthio, M14 and M15	1 month	UK, 2004 and UK, 2007
Pig	Liver, kidney, muscle, fat	Prothioconazole-desthio, M14 and M15	1 month	UK, 2004 and UK, 2007
New data				
Plant products				
Zucchini	High water content	Prothioconazole-desthio, M14, M15, M16, M17, M18	6 12 months	RAU-026-21, KCA 6.1
Oil seed rape	High oil content	Prothioconazole-desthio, M14, M15, M16, M17, M18	6 12 months	
Grape	High acid content	Prothioconazole-desthio, M14, M15, M16, M17, M18	6 12 months	
Sugar beet root	High starch commodity	Prothioconazole-desthio, M14, M16, M17, M18	6 12 months	
		M14	6 months	
		M15	3 months*	
		M17	9 months	

Crop	Matrix group	Compound	Acceptable Maximum Storage duration at -18°C	Reference
Peas dry seed	Dry/high protein commodity	Prothioconazole-desthio, M14, M15, M16, M17, M18	6 12 months	
		M17	3 months*	

* The study is still ongoing and further analysis are planned after 9 and 12 months of storage. The confirmation of the stability of these metabolites will be evaluated when the other data will be available.

In the new storage stability study submitted by the applicant, residues of prothioconazole-desthio (M04) and its hydroxy metabolites (M14, M15, M16, M17 and M18) which are all components included in the risk assessment residue definition, are stable in the 5 crop groups for 6 12 months when they are stored at -18°C. The only exceptions are the metabolite M14, M15 and M17 which degrades in high starch matrix after 6, 3 and 9 months respectively and M17 which degrades in high protein matrix. However, the study is still ongoing and further analysis are planned after 9 and 12 months of storage. The confirmation of the stability of these metabolites will be evaluated when the other data will be available.

In addition, according to the new residue definition for risk assessment, triazole metabolites, Triazole alanine (TA), triazole lactic acid (TLA), Triazole acetic acid (TAA) and 1,2,4-triazole (1,2,4-T) are still of interest.

Please refer to UK, 2018⁵ and to EFSA, 2018 2020⁶. In the below table the data coming from TDMs Confirmatory Data was summarised.

Table 7.2-3b: Summary of stability data of TDMs achieved at ≤ - 18°C (unless stated otherwise)

Matrix group	Crops	Compound	Acceptable Maximum Storage duration	Reference
Data relied on in EU				
Plant products				
High water content	Apple, tomato, mustard leave, wheat forage, radishes tops, cabbage, lettuce	1,2,4-Triazole	6 months	UK, 2018 and EFSA, 2018 2020
		TA	53 months	
		TAA	53 months	
		TLA	48 months	
High starch content	Barley, wheat grain	1,2,4-Triazole	12 months	
		TA	26 months	
		TAA	26 months	
		TLA	48 months	
High oil content	Soya bean	1,2,4-Triazole	12 months	
		TA	26 months	
		TAA	53 months	

⁵ United Kingdom, February 2018. Triazole Derivative Metabolites Addendum – Confirmatory Data

⁶ EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted. EFSA Journal 2018;16(7):5376, 20 pp

Matrix group	Crops	Compound	Acceptable Maximum Storage duration	Reference
		TLA	48 months	
High protein content	Peas dry seed, navy beans seed	1,2,4-Triazole	NA*	
		TA	15 months	
		TAA	25 months	
		TLA	48 months	
Dry matrix	Barley, wheat straw	1,2,4-Triazole	12 months	
		TA	53 months	
		TAA	40 months	
		TLA	NA	
High acid content	Oranges	1,2,4-Triazole	NA	
		TA	NA	
		TAA	NA	
		TLA	48 months	

*NA: no data available

Table 7.2-4c: Summary of stability data of 1,2,4 triazole achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

Matrix group	Crops	Compound	Acceptable Maximum Storage duration	Reference
New data				
High water content	Apple	1,2,4-Triazole	6 months	RAU-011-22 (interim report) KCA 6.1/02
High starch content	Sugar beet root		6 months	
High acid content	Grape		Not stable	
High oil content	OSR seed		Not stable	
High protein/dry commodity	Peas dry seed		6 months	

Conclusion on stability of residues during storage

Regarding prothioconazole, prothioconazole-desthio and its hydroxy metabolites, the available data sufficiently covers the maximum storage interval for commodities measured in the samples coming from residue trials.

~~Regarding prothioconazole-desthio and its hydroxy metabolites, the available data sufficiently covers the maximum storage interval for high water, high acid, high oil and high starch/dry commodities measured in the samples coming from residue trials conducted in year 2021. While the stability of samples coming from residue trials conducted in 2020, will be evaluated once available the results of 12 months of storage. However, according to the available data no degradation of prothioconazole desthio is expected in any crop group.~~

For TDMs, according to the available storage stability data, almost all samples coming from residue trials conducted in 2021 are covered, while samples from 2020 trials, exceeded the storage period for 1,2,4 Triazole only.

A new storage stability study on 1,2,4 Triazole is ongoing in the various matrix groups to support 2020 residue trials. The stability will be evaluated once available the results of storage study, however according to the available data reported in the Interim report, no degradation of 1,2,4 Triazole is expected in high water and high starch matrix, while a strong degradation was observed in oil seed rape seed.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

Storage stability in sample extracts can be assessed by the recovery samples. Recovery samples gave suitable recoveries within the acceptable range of 70-100 %, even after storage >24 hours. Because recoveries were good and samples of the corresponding field trials were treated alike and stored under the same conditions, the validity of the analysed sample extracts is proven.

Conclusion on stability of residues in sample extracts

Recoveries measured in the residue trials submitted in this document were within the acceptable range of 70-100 % within the 24 hours. Moreover, according to the SOP followed for residues analysis, extracts generated from field samples were always stored till the analysis at 4°C under dryness condition after removing the aqueous component of the matrix which might have led to degradation of residues.

These data of storage stability in sample extracts cover the residue trials presented in this application.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.1.3 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new metabolism study has been submitted in the framework of the MRL application.

Please refer to United Kingdom 2004, United Kingdom 2007 and to EFSA documents. The metabolism studies already considered during the peer review of the active substances (EFSA, 2007) and in EFSA reasoned opinion (EFSA, 2014) are briefly summarized below. An additional reference has done to FAO, 2008⁷.

Metabolism of prothioconazole was investigated for foliar application on root and tuber vegetables (sugar beet), pulses and oilseeds (peanut) and cereals (wheat) as well as for seed treatment on cereals (wheat) using [U-14C-phenyl]-labelled prothioconazole. In addition, the metabolism of prothioconazole-dethio was investigated for foliar application on cereals (wheat) using [3,5-14C-triazole]-labelled prothioconazole-dethio. Furthermore, three additional metabolism studies were conducted on root and tuber vegetables (sugar beet), pulses and oilseeds (peanut) and cereals (wheat) by foliar application using [3,5-14C-triazole]-labelled prothioconazole.

Table 7.2-5: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Root and tuber vegetables	Sugar beet	[U-14C-phenyl] prothioconazole	Foliar, F	0.29	4 (14 days)	Roots & Tops/leaves: 7		FAO, 2008; EFSA, 2014
		[3,5-14C-triazole] prothioconazole	Foliar, F	0.29	4 (14 days)	Roots & Tops/leaves: 7		FAO, 2008; EFSA, 2014
Pulses and oilseeds	Peanuts	[U-14C-phenyl] prothioconazole	Foliar, G	0.30	(21 days) (BBCH 66 -75)	Hay & nuts without shells: 14		DAR UK, 2004, 2007; EFSA 2007, EFSA 2014
		[3,5-14C-triazole] prothio	Foliar, G	0.30	(21 days) (BBCH	Hay & nuts without shells: 14		FAO 2008

⁷ FAO (Food and Agriculture Organization of the United Nations), 2008a. Prothioconazole. In: Pesticide residues in food – 2008. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 193.

		conazole			66 -75)			
Cereals	Wheat	[U-14C-phenyl] prothioconazole	Foliar, G	0.22	2 (BBCH 32-65)	Forage: 6 Hay: 26 Grain & straw: 48		DAR UK 2004, 2007; EFSA 2007; EFSA 2014
		[3,5-14C-triazole] prothioconazole	Foliar, G	0.25	2 (27 days) (BBCH 31-59)	Forage: 0, 14 Grain & straw: 48		DAR UK 2004, 2007; EFSA 2007; EFSA 2014
		[3,5-14C-triazole] prothioconazole	Foliar, F	0.18 and 0.19	2 (BBCH 32-65)	Forage, hay, grain, straw		FAO 2008
		[U-14C-phenyl] prothioconazole	Sees, G	0.02 or 0.10 kg/100 kg seeds (ca. 220 kg seeds/ha)	1	Forage: 57 Hay: 110 Grain & straw : 153		DAR UK 2004, 2007; EFSA 2007; EFSA 2014

Summary of plant metabolism studies reported in the EU

Following seed treatment on wheat with the phenyl labelled prothioconazole, very low levels of radioactive residues were recovered in wheat grain (TRR <0.01 mg/kg) and no metabolites' identification could be attempted. In straw, forage and hay, TRR accounted for 0.03 - 0.28, 0.02 - 0.07 and 0.02 - 0.09 mg eq/kg, after the 1X and 5X experiments, respectively. Identification procedures in these matrices were performed in the 5X experiment and showed that the metabolic pattern of prothioconazole in the wheat plant parts after seed treatment was similar to the one depicted following foliar applications. Indeed, parent compound was extensively metabolised: prothioconazole-desthio and its hydroxylated forms (including their glucosides) (M14, M15, M17) constituted the major compounds in all crop parts. Prothioconazole-desthio represented 10.9 % of the TRR (0.008 mg eq/kg) in forage, 6.6 % of the TRR (0.019 mg eq/kg) in straw and 6.4 % of the TRR (0.005 mg eq/kg) in hay. Its hydroxylated metabolites and their corresponding glucosides amounted together to 19.7 % of the TRR (0.055 mg eq/kg) in straw, 13.5 % of the TRR (0.011 mg eq/kg) in fodder and 5.6 % of the TRR (0.005 mg eq/kg) in hay. Parent and all other metabolites were below 10 % of the TRR.

In peanuts, following both labelling applications, the highest total radioactive residues were identified in peanut hay (47.4 - 107.5 mg eq/kg). In nutmeat, the total residues accounted for only 0.29 to 1.40 mg eq/kg. The level of identification of the total residues in hay and nutmeat for both labels ranged from 65.1 % to 82.7 % of the TRR. In peanut hay, following both labels, prothioconazole-desthio constituted the major component of the total radioactive residues (up to 28.2 % TRR, 30.4 mg eq/kg), whilst metabolite M27₂₄ was also recovered as a significant metabolite in hay after phenyl label application only (14.1 % TRR, 15.09 mg eq/kg). The hydroxylated derivative metabolites of prothioconazole-desthio (M14, M15) accounted together for 9.6 % of the TRR (up to 10.31 mg eq/kg). Parent compound and all other identified metabolites were recovered at levels below 10 % of the TRR. In nutmeat, after phenyl label application, M27 was the predominant compound of the total residues, accounting for up to 12.2% of the TRR (0.04 mg eq/kg). M24₂₅ was also identified and accounted for up to 9 % of the TRR (0.03 mg eq/kg). Neither parent compound nor prothioconazole-desthio were detected and the major part of the radioactivity was incorporated into the fatty acids matrix (up to 47.8 % TRR, 0.14 mg eq/kg). For the triazole labelling form, the major compounds identified in nutmeat were triazole lactic acid and triazole alanine (24.5 % and 47.8 % TRR, respectively) whilst other compounds amongst which the parent compound and prothioconazole-desthio were identified at a level below 10% of the TRR.

In sugar beets, for the phenyl and triazole labellings, TRR levels were higher in leaves (4.3 - 5.2 mg eq/kg) than in roots (0.12 - 0.13 mg eq/kg). Following phenyl labelled prothioconazole application, prothioconazole-desthio accounted for 28 % and 58 % of the TRR in leaves and roots, respectively. Metabolite M24 was also recovered in leaves at 10 % TRR (0.45 mg eq/kg). Regarding the triazole labelling moiety, besides prothioconazole-desthio that was identified in leaves (19 % TRR, 0.99 mg eq/kg) and in roots (25 % TRR, 0.03 mg eq/kg) and the metabolite M24 detected in leaves (10 % TRR, 0.51 mg eq/kg), triazole alanine was found to be the predominant compound of the total residues in roots (29 % TRR, 0.04 mg eq/kg). Prothioconazole was seen to be extensively degraded in both leaves and roots and accounted for less than 10 % of the TRR.

Summary of new plant metabolism studies

No new plant metabolism study has been submitted within the frame of this application.

Conclusion on metabolism in primary crops

EFSA, 2014: “Based on the available metabolism studies, prothioconazole is extensively metabolised and the metabolic pathway is similar in all crops investigated. The main metabolic pathway consisted in the formation of prothioconazole-desthio: the sulphur group of the triazolinethione ring of parent prothioconazole is firstly oxidized to the corresponding sulfonic acid with subsequent elimination of the sulfonic acid moiety. This metabolite subsequently undergoes different pathways either by hydroxylation on the chlorophenyl ring, forming various hydroxyl-desthio isomers (M14, M15, M17), dihydroxy-olefins (M27) and hydroxy-dienyl-cysteine (M24) isomers followed by a glucosidation step or by cleavage of the triazole moiety of prothioconazole-desthio resulting in the formation of ‘triazole derivative metabolites’ (TDMs), mainly triazole alanine, triazole lactic acid and triazole acetic acid.

According to the available data, no additional study is required and EFSA concludes a general residue definition for monitoring as prothioconazole-desthio (sum of isomers), for all plant commodities.

For risk assessment, EFSA proposes to take into account the metabolites which are structurally related to prothioconazole-desthio while the residue for risk assessment is defined as: sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). The proposed residue definitions apply for all plant commodities, for both foliar and seed treatments. During the peer review, it was assumed as a worst case that the toxicological end points allocated to prothioconazole-desthio should also be applied to these metabolites.

In the EFSA 2014 a second residue definition was prosed for Triazole Derivate Metabolites (TDMs); since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs:

The need to consider the second definition was confirmed in the Review Report on Prothioconazole, SANCO/3923/07 – final, 26 January 2021, EC where toxicological end points were fixed according to EFSA, 2018⁸

⁸ EFSA, 2018. Conclusion on the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted. EFSA Journal 2018;16(7):5376, 20 pp.
<https://doi.org/10.2903/j.efsa.2018.5376>

7.2.1.4 Nature of residue in rotational crops (KCA 6.6.1)

Available data

Please refer to United Kingdom 2004, United Kingdom 2007, EFSA 2007 and EFSA 2014.

According to the soil degradation studies evaluated in the framework of the peer review, DT90 field values of prothioconazole and prothioconazole-desthio range between 4.4 – 9.3 days (median: 5.5 days) and 54 – 240 days (median: 140 days), respectively. The DT90 field value of prothioconazole-desthio is therefore higher than the trigger value of 100 days and then further investigation of the nature of the residues in rotational crops is relevant.

The metabolism of prothioconazole in rotational crops has been evaluated in the context of Annex I first inclusion. The characteristics of the confined rotational crop study investigating the nature of residues were summarised in the below table.

Table 7.2-6: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Swiss chard	[U-14C-phenyl] prothioconazole	Bare Soil application	0.58	28, 146, 269	80, 188, 348		UK 2004, UK 2007
Root and tuber vegetables	Turnip	[U-14C-phenyl] prothioconazole	Bare Soil application	0.58	28, 146, 269	94, 201,349		
Cereals	spring wheat	[U-14C-phenyl] prothioconazole	Bare Soil application	0.58	28, 146, 269	Green material: 73, 178, 327 Hay: 111, 231, 377 Grain, straw: 145, 269, 412		

Summary of plant metabolism studies reported in the EU

EFSA: In wheat grain, the total radioactive residues were recovered at a trace level at all DATs (≤ 0.007 mg eq/kg) and no further metabolites' identification was attempted. In wheat green material, hay and straw, TRR ranged from 0.021 mg eq/kg (green material, DAT 28) to 0.450 mg eq/kg (straw, DAT 28). In turnip roots, tops and Swiss chard, the highest residue levels ranged from 0.043 mg eq/kg (turnip root, DAT 28) to 0.053 mg eq/kg (Swiss chard, DAT 146). No significant decline of the residue levels was observed for any crop part throughout the first, second and third rotation.

In the edible parts of the crops at harvest 61 to 87 % of the total residues were extracted and the level of identification ranged between 34.4 % TRR (Swiss chard, DAT 269) to 77.2 % TRR (turnip leaves, DAT 28). The major compounds of the total residues were identified as prothioconazole-desthio, its hydroxylated derivative metabolites, either free or conjugated (M14, M15, M16, M17), M27, free and conjugated and M0230. Residue levels of the main metabolites recovered in wheat were in general higher in straw

than in hay. In straw, they reached the following levels: prothioconazole-desthio (0.066 mg eq/kg) (DAT 28), M02 (0.063 mg eq/kg) (DAT 269), glucoside of M27 (0.056 mg eq/kg) (DAT 269) and glucosides of the hydroxylated metabolites of prothioconazole-desthio (0.097 mg eq/kg) (DAT 28). In Swiss chard, levels of prothioconazole-desthio reached 0.014 mg eq/kg at 28 DAT, while levels of M27 glucosides were below 0.01 mg eq/kg at all sowing intervals. In turnip roots and leaves, the residue levels of the identified major metabolites were always below 0.01 mg eq/kg.

Consequently, the metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

Regarding triazoles, please refer to EFSA, 2018 “based on the metabolism data in primary and rotational crops that were compiled from the assessment of the 18 triazole active substances the triazole active substances were shown to degrade into the common metabolites 1,2,4-T, TA, TLA and TAA, known as TDMs. Besides the parent compound that was identified at significant residue levels in all crop groups, TA was predominantly found in the organs of storage (79% total radioactive residue (TRR) in potato tuber, 31–88% TRR in oil seeds, 8–69% TRR in cereal grains) but also in cereal straw (1–16% TRR) and in fruit crops (up to 80% TRR). TAA was only detected at significant proportions in cereal grain and straw (5–35% and 7–41% TRR, respectively) and TLA in fruit crops (up to 67% TRR) and in cereal straw (up to 43% TRR). 1,2,4-T was detected at lower levels in all crop parts (up to 12% TRR).”

Summary of new plant metabolism studies

No new plant metabolism study was submitted in the frame of this application.

Conclusion on metabolism in rotational crops

Metabolism studies showed that prothioconazole has a similar behaviour in primary and rotational crops, therefore no residue definition for rotational crops was evaluated necessary. Also, for triazole similar metabolic patterns were depicted both in primary and in rotational crops.

Residue levels in rotational crops are expected to be covered by residue levels in primary crops and no additional study is required.

7.2.1.5 Nature of residues in processed commodities (KCA 6.5.1)

Available data

Please refer to United Kingdom 2004, United Kingdom 2007, EFSA 2007 and EFSA 2014.

The evaluation on the effect of processing on the nature of prothioconazole residues relies on studies assessed by the JMPR (FAO, 2008a, 2008b). In these studies conditions of 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) were tested. The conclusion of the studies was that the parent compound prothioconazole is stable under pasteurisation and baking/brewing/boiling, whilst it degrades to prothioconazole-desthio ($\leq 11\%$) under sterilisation conditions.

Considering that metabolites included in the risk assessment residue definition have a similar structure to parent compound prothioconazole and to prothioconazole desthio, it can be assumed that prothioconazole metabolites are expected to be stable under conditions tested above and to behave as in primary crops.

Conclusion on nature of residues in processed commodities

Referring to the results of the studies assessed by the JMPR, no additional study investigating magnitude of residues was evaluated necessary; moreover, as such studies are not expected to affect the risk assessment, they are not required.

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

Table 7.2-7: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (wheat), foliar and seed applications Oilseeds (peanut), foliar applications Root and tuber (Sugar beet), foliar
Rotational crops covered	Wheat / Swiss chard / Turnips
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	a.s. is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Reg. (EU) 2019/552: Prothioconazole-desthio (sum of isomers) (JAU 6476-desthio; M04)
Plant residue definition for risk assessment	EFSA, 2014; Review Report Prothioconazole, SANCO/3923 /07, rev2021 1. Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl) -2-hydroxypropyl-2H-1,2,4-triazole moiety, M14, M15, M16, M17 and M18) expressed as prothioconazole-desthio. 2. TDMs <ul style="list-style-type: none"> • TA and TLA • TAA • 1,2,4-T
CF	EFSA, 2007 2 in cereal grain, pulses and oilseeds, leafy vegetables, root and tuber vegetables; 3 in cereal straw

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

Available data

Please refer to United Kingdom 2004, 2007, EFSA 2007, 2014.

The nature of prothioconazole residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (United Kingdom, 2004, 2007). Metabolism studies investigating the nature of prothioconazole residues in commodities of animal origin are available; they include two studies in lactating goats using respectively [U-14C-phenyl]-labelled prothioconazole and prothioconazole-desthio and one study in laying hens using [U-14C-phenyl]-labelled prothioconazole. In addition, 2 stud-

ies were assessed by the JMPR (FAO, 2008a, 2008b) on lactating goats and laying hens, using both [3,5-¹⁴C-triazole]-labelled prothioconazole.

No new data submitted in the framework of this application.

Table 7.2-8: 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 sam-pling	
EU data								
Lactating ruminants	Goat	[U- ¹⁴ C-phenyl] prothioconazole ^(a)	1	10 (250 mg a.s./kg feed)	3	Milk	Twice daily	United Kingdom, 2004, 2007
						Urine and faeces	Daily And at sacrifice	
						Tissues	At sacrifice	
		[U- ¹⁴ C-phenyl] prothioconazole-desthio ^(a)	1	10 (195 mg a.s./kg feed)	3	Milk	Twice daily	
						Urine and faeces	Daily And at sacrifice	
						Tissues	At sacrifice	
		[3,5- ¹⁴ C-triazole] prothioconazole ^(b)	1	10	3	Milk	Twice daily	
						Urine and faeces	Daily And at sacrifice	
						Tissues	At sacrifice	
Laying poultry	Hens	[U- ¹⁴ C-phenyl] prothioconazole-desthio ^(a)	6	10	3	Eggs	Once daily	United Kingdom, 2004, 2007
						Excreta	At regular intervals	
						Tissues	At sacrifice (5 h after last administration)	
		[3,5- ¹⁴ C-triazole] prothioconazole ^(b)	6	10	3	Eggs	Once daily	
						Excreta	At regular intervals	
						Tissues	At sacrifice (5 h after last administration)	

(a): Sources: United Kingdom, 2004, 2007; JMPR, 2008a, 2008b

(b): Source: JMPR, 2008a, 2008b

Summary of animal metabolism studies reported in the EU

Metabolism studies on goat and hen were conducted.

EFSA: lactating goats were dosed with 10 mg/kg bw per d of prothioconazole or prothioconazole-desthio. The metabolism study conducted with prothioconazole was reported for information purposes only since the animals are mainly exposed to the prothioconazole-desthio residues. For prothioconazole-desthio, the

application rate was overdosed, corresponding to approximately 48 times the exposure of meat ruminants.

In the studies performed with both phenyl and triazole labellings of prothioconazole, the highest residue levels were found in kidney (6.8 - 4.5 mg eq/kg) and liver (6.1 - 6.2 mg eq/kg), respectively. Prothioconazole was rapidly adsorbed and extensively metabolised in all matrices but remained a significant compound of the residues in liver (13 – 17 % TRR), muscle, kidney and fat (7 - 20 % TRR) and to a minor extent in milk (0.9 % - 3 % TRR). Prothioconazole-desthio was detected at low levels in all matrices (< 5 % TRR), except in fat (19 % TRR, 0.032 mg eq/kg). The only identified triazole related metabolite was the thiocyanate metabolite: 41 % TRR (0.061 mg eq/kg) in milk, 30 % TRR (0.035 mg eq/kg) in muscle, 12 % TRR (0.022 mg eq/kg) in fat, 9 % TRR (0.41 mg eq/kg) in kidney and 2 % TRR (0.13 mg eq/kg) in liver. At the maximum dietary burden of meat ruminants, this metabolite is expected to occur at a trace level in all matrices (up to 0.004 mg eq/kg in kidney). There is therefore no need to further address its toxicological properties.

In the study performed with [U-14C-phenyl]-labelled prothioconazole-desthio, the highest residue levels were found in kidney and liver (up to 19 mg eq/kg). Total radioactive residues in milk, muscle and fat accounted for 0.286 mg eq/kg, 0.266 mg eq/kg and 0.231 mg eq/kg, respectively. Prothioconazole-desthio was the predominant compound of the total residues in liver (31.2 % TRR - 5.7 mg eq/kg) and in kidney both under its free and glucuronide conjugated forms (32 % TRR – 6 mg eq/kg) whilst it was extensively metabolised as glucuronide conjugates of the hydroxylated related metabolites in milk, muscle and fat. In milk, only prothioconazole-desthio under its glucuronide conjugated form was detected at a rather low level (6 % TRR – 0.017 mg eq/kg) whilst the sulphate conjugates of hydroxylated derivative prothioconazole-desthio metabolites (M14/M15/M16/M17/M2832/M3433/M3534) constituted the major part of the total residue in milk (44 % TRR, 0.126 mg eq/kg). All other compounds accounted for less than 10 % TRR.

Laying hens were dosed with 10 mg/kg bw per d of phenyl and triazole labelled prothioconazole, respectively. The major part of the total administered dose (AR) was recovered in excreta (66 % and 78 % AR for the triazole and phenyl labellings, respectively) and only trace amounts of radioactivity were detected both in eggs (0.01 % AR) and tissues (about 0.9 % AR). The total radioactive residues accounted for 4.0 – 3.5 mg eq/kg in liver, 0.036 – 0.05 mg eq/kg in eggs, 0.45 – 0.29 mg eq/kg in subcutaneous fat and 0.089 – 0.12 mg eq/kg in muscle, respectively for the phenyl and triazole labellings. Prothioconazole was the major compound of the total residues in liver (25 % - 31 % TRR, 1.0 - 1.1 mg/kg) and in fat (30 % - 16 % TRR, 0.14 - 0.046 mg/kg) for the phenyl and triazole labels, respectively. Prothioconazole-desthio (29 % - 27 % TRR, 0.13 - 0.08 mg eq/kg) and M0135 (20 % - 29 % TRR, 0.083 - 0.088 mg eq/kg) in fat as well as M0636 in liver (12 % - 15 % TRR, 0.48 - 0.53 mg eq/kg) were the only metabolites exceeding 10 % of the TRR in these commodities. In muscle, the major compounds were M4537 (28 % TRR, 0.035 mg eq/kg) and 1,2,4-triazole (19 % TRR, 0.023 mg eq/kg) specific to the triazole labelling, and M06 (16 % - 10 % TRR, 0.014 - 0.012 mg eq/kg) and parent prothioconazole (11 % - 2.5 % TRR, 0.01 - 0.003 mg eq/kg) for phenyl and triazole labelling, respectively. Prothioconazole-desthio accounted for only 7 % - 2.1 % TRR (0.006 - 0.003 mg eq/kg). In eggs, the major compounds of the total residues were M06 (24 % - 16 % TRR, 0.012 - 0.014 mg eq/kg) and prothioconazole-desthio (20 % - 6.2 % TRR, 0.007 - 0.003 mg eq/kg) for phenyl and triazole label, respectively. For the triazole labelling moiety, the metabolites M45 (15.6% TRR, 0.008 mg eq/kg) and 1,2,4-triazole (11 % TRR, 0.006 mg eq/kg) were also identified. Prothioconazole accounted for only 3.6 % - 3.4 % TRR (0.001 - 0.002 mg eq/kg), for phenyl and triazole label, respectively. All other metabolites identified were either glucuronic acid or sulphate conjugates of the hydroxylated prothioconazole and accounted for less than 10 % TRR.

Summary of new animal metabolism studies

No new animal metabolism study has been submitted within the frame of this application.

Conclusion on metabolism in livestock

According to the available data, the residue definition for enforcement in animal products was proposed as prothioconazole-desthio (sum of isomers) for all livestock matrices.

For risk assessment, the residue is defined in all commodities of animal origin as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).

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

Table 7.2-9: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating ruminants (goat)
	Laying hens (chicken)
Time needed to reach a plateau concentration	NA
	NA
Animal residue definition for monitoring	Prothioconazole-desthio (M04) (Reg. (EU) 2019/552)
Animal residue definition for risk assessment	Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety) expressed as prothioconazole-desthio. This definition is provisional and will need to be reconsidered regarding the triazole derivative metabolites (EFSA, 2007)
Conversion factor	10 Milk 2 Liver 10 Muscle 2 Kidney 4 Fat (EFSA, 2007)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes, Log Pow for prothioconazole-desthio = 3.04

7.2.2 Magnitude of residues in plants (KCA 6.3)

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

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

In the current MRL regulation (Reg. (EU) 2019/552), MRLs are set according to the monitoring residue definition: prothioconazole-desethio (M04) (sum of isomers).

For risk assessment definition, EFSA 2014, proposed the following RA definition:

- sum of prothioconazole-desethio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety (M14, M15, M16, M17 and M18), expressed as prothioconazole-desethio (sum of isomers).

In EFSA, 2007, considering that the residue definitions for enforcement and risk assessment are different, a conversion factors (CF) for enforcement to risk assessment was derived at on the basis of the available metabolism data.

The CF of 2 for cereal grain and 3 in cereal straw have been used for wheat and barley data as stated in EFSA, 2007 and 2014. On the contrary, for all the other crops, considering that in the new residue trails submitted by the applicant, residues have been analysed according to the risk assessment residue definition (all metabolite was analysed separately), no CF was used.

In addition, in the EFSA 2014 a second residue definition was proposed for Triazole Derivative Metabolites (TDMs); since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs. The need to consider the second definition was confirmed in the Review Report on Prothioconazole, SAN-CO/3923/07 – final, 26 January 2021, EC and in EFSA, 2018.

~~An analytical method for the determination of triazole alanine (TA), 1,2,4 triazole (1,2,4 T), triazole acetic acid (TAA) and triazole lactic acid (TLA) was validated in plant commodities. However, due to the difficulty related to the validation of the method, analysis of the samples coming from residue trials are still ongoing at the time of the first dossier submission. Once available all the data, a revised dRR Section B7 will be submitted, and an update consumer risk assessment will be provided.~~

Due to the long time needed for the analytical standards synthesis and the difficulty to validate an analytical method, analysis of the samples coming from residue trials were still ongoing at the time of the first dossier submission. The final reports with the analysis of TDMs are now available and the data were reported in the below tables 7.2-8b and summarized in Appendix 2.

In addition, in the table 7.2-8b open data from UK, 2018 (Triazole Derivative Metabolites Addendum – Confirmatory Data. United Kingdom, February 2018) was summarized joint to applicant new data.

Please take note in the table below, TDMs residues measured in samples collected in treated plots only were reported. Residues >LOQ were found in several control samples in the various matrices, in some cases they are in the same range of the respective treated samples while, in other case they were found at higher level. This is probably due to normal background level in the soil and in crops. The anomalous behavior was observed in particular for Triazole Alanine which is a common biological compound, and it may be normally available in the environment. Since the results are not easy to evaluate, the applicant decided to use for risk assessment the values measured in treated samples only which can be better compared each other's, no soctration was done.

Table 7.2-10: Summary of EU reported and new data supporting the intended uses of SIP41061 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
Residue definition for monitoring: prothioconazole-desthio (M04) (sum of isomers) A) Residue definition for risk assessment: sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety (M14, M15, M16, M17 and M18), expressed as prothioconazole-desthio (sum of isomers)								
Apple → extrapolated to whole pome fruits (130000)	New trials	N-EU	GAP: 2x 120 g as/ha, BBCH 39-85, interval between appl. 7d; PHI 14d Mo: <0.01; 0.0127; 0.017; 0.018; 0.0224; 0.0233; 0.039; 0.08 ¹ Mo: <0.01; 0.01; 4x 0.02; 0.04 RA: 7x <0.058 ^{B)} ¹ Residues measured in the residue No. RAU-008-21, F/PR21/AP01 are very anomalous according to the data came from the other trials. There was a deviation as a higher dose rate was applied respect the intended one, i.e. +14.7%. Moreover, according to OECD calculator it is an outlier. For these reasons it wasn't used in the calculation.	E: 0.02 RA: 0.058	E: 0.039 RA: 0.058	0.06	0.01	No, MRL change request under evaluation
Apricots*	New trials	NEU	GAP: 2x 160 g as/ha, BBCH 39-85, interval between appl. 7d; PHI 3d Mo: 0.080; 0.046; 0.088 Mo: 0.08; 0.05; 0.09 RA: 0.093; 0.06; 0.102					
Peaches*	New trials	NEU	GAP: 2x 160 g as/ha, BBCH 39-85, interval between appl. 7d; PHI 3d Mo: 0.064; 0.047; 0.077 Mo: 0.06; 0.05; 0.08					

			RA: 0.077; 0.061; 0.091					
Apricots and Peaches	Overall data ²	NEU	Mo: 0.046; 0.047; 0.064; 0.077; 0.080; 0.088 Mo: 0.05; 0.05; 0.06; 0.08; 0.08; 0.09 RA: 0.093; 0.06; 0.102; 0.077; 0.061; 0.091 ² According to SANTE/2019/12752, peaches (0140030) data could be extrapolated to apricots (0140010) and <i>vice versa</i> . Residues measured in the various trials are not statistically different, according to that, MRL calculation is based on the merged data.	E: 0.07 RA: 0.07	E: 0.088 RA: 0.1	0.2	0.01	No, MRL change request under evaluation
Plums*	New trials	NEU	GAP: 2x 160 g as/ha, BBCH 39-85, interval between appl. 7d; PHI 3d Mo: 3x <0.01; 0.011; 0.015; 0.022 0.043; 0.06 Mo: 3x <0.01; 0.01; 0.02; 0.02 0.04; 0.06 RA: 7x <0.058; 0.073	E: 0.013 RA: 0.058	E: 0.06 RA: 0.07	0.1	0.01	No, MRL change request under evaluation
Cherries*	New trials	NEU	GAP: 2x 160 g as/ha, BBCH 39-85, interval between appl. 7d; PHI 3d Mo: 0.15; 0.078, 0.26; 0.25; 0.085; 0.092; 0.095; 0.32 Mo: 0.15; 0.08, 0.26; 0.25; 0.09; 0.09; 0.10; 0.32 RA: 0.16; 0.092; 0.27; 0.26; 0.099; 2x 0.11; 0.34	E: 0.12 RA: 0.13	E: 0.32 RA: 0.34	0.6	0.01	No, MRL change request under evaluation
Courgette/ Zucchini → extrapolated to Whole sub-group (b) cucurbits with edible peel (0232000)	New trials	Indoor (GH)	GAP: 3x 120 g as/ha, BBCH 11-89, interval between appl. 10d; PHI 10d Mo: 2x <0.01 RA: 2x <0.058 Mo: 2x <0.01 RA: 2x <0.058 8 trials not acceptable	E: 0.01 RA: 0.058	E: 0.01 RA: 0.058	0.01	0.01	Yes
			GAP: 3x 120 g as/ha, BBCH 11-89, interval between appl. 10d; PHI 3d Mo: 3x <0.01; 0.0175; 0.0197; 0.0245; 0.034; 0.035 RA: 8x <0.058	E: 0.01 RA: 0.058	E: 0.02 RA: 0.058	0.07	0.01	No MRL change request under evaluation

Carrot → Whole subgroup (c) → other root and tuber vegetables except sugar beets (0213000) extrapolation to beetroots; horse radishes; parsnips; parsley roots; salsifies; swedes; turnips	New trials	NEU	<p>a) GAP: 2x 160 g as/ha, BBCH 16-46, interval between appl. 7-10d; PHI 21d Mo: <0.01; 0.011; 0.024; 0.083 RA: 3x <0.058; 0.097 → Proportionality approach ^{C)}: 1x 200 g as/ha: Mo: <0.01; 0.0137; 0.03; 0.10³ Mo: <0.01; 0.01; 0.03; 0.10 RA: 3x <0.058</p> <p>b) GAP: 2x 200 g as/ha, BBCH 16-46, interval between appl. 7-10d; PHI 21d Mo: <0.01; 0.021; 0.0287; 0.0336 Mo: <0.01; 0.02; 0.03; 0.03 RA: 4x <0.058</p> <p>³This residue is very high respect the other ones measured in residue trials, moreover, according to OECD calculator it is an outlier; for these reasons it wasn't used to derive the MRL and neither for RA</p>	E: 0.02 RA: 0.058	E: 0.034 RA: 0.058	0.06	0.1	Yes
Oil seed Rape - seed	New trials	NEU	<p>GAP: 2x 180 g as/ha, BBCH 30-71, interval between appl. 14d; PHI 50d Mo: 6x <0.01; 0.01; 0.022 Mo: 6x <0.01; 0.01; 0.02 RA: 8x <0.058</p>	E: 0.01 RA: 0.058	E: 0.022 RA: 0.058	0.03	0.15	Yes
Oil seed Rape – plant/straw	New trials	NEU	<p>GAP: 2x 180 g as/ha, BBCH 30-71, interval between appl. 14d; PHI 50d Mo: 0.172; 0.217; 0.025; 0.033; 0.0175; 0.033; 0.025; 0.017 RA: 0.34; 0.36; 0.075; 0.063; 0.09; <0.058; 0.092; 0.075</p>	RA: 0.08	RA: 0.36	-	-	No MRL set
Sugar beet root	New trials	NEU	<p>GAP: 2x 160 g as/ha, BBCH 39-49, interval between appl. 14d; PHI 28d Mo: 4x <0.01 RA: 4x <0.058</p>	E: 0.01 RA: 0.058	E: 0.01 RA: 0.058	0.01	0.01	Yes

Wheat grain → extrapolation to rye and triticale	New trials	NEU	GAP: 2x 200 g as/ha, BBCH 39-69, interval between appl. 14d; PHI 35d Mo: 7x <0.01; 0.031 Mo: 7x <0.01; 0.03 RA: 7x <0.02; 0.06	E: 0.01 RA: 0.02	E: 0.03 RA: 0.06	0.05	0.1	Yes
	Open data DAR (UK, 2005)	NEU	GAP: 3x 200 g as/ha, BBCH <69, interval between appl. 14/21d; PHI 35d Mo: 5x <0.01 RA: 5x <0.05 ⁺ *In these trials prothioconazole-desthio only was analysed. CF of 2 was used for cereal grain	E: 0.01 RA: 0.05	E: 0.01 RA: 0.05	0.03	0.2	Yes
	Open data DAR (UK, 2005)	NEU	GAP: 3x 200 g as/ha, BBCH <69, interval between appl. 14/21d; PHI 49/56d Mo: 5x <0.01 RA: 5x <0.05 ⁺ *In these trials prothioconazole-desthio only was analysed. CF of 2 was used for cereal grain	E: 0.01 RA: 0.05	E: 0.01 RA: 0.05	0.03	0.2	Yes
Wheat straw	New trials	NEU	GAP: 2x 200 g as/ha, BBCH 39-69, interval between appl. 14d; PHI 35d Mo: 0.0445; 0.175; 0.37; 0.94; 0.195; 0.42; 0.34; 0.19 RA: 0.133; 0.525; 1.11; 2.82; 0.585; 1.26; 1.02; 0.57	RA: 0.81	RA: 2.82	-	-	No MRL set
Barley grain → extrapolation to oat	New trials	NEU	GAP: 2x 200 g as/ha, BBCH 39-69, interval between appl. 14d; PHI 35d Mo: <0.01; 0.08; 0.0215; 0.11; 0.032; 0.019; 0.0233; 0.012 Mo: <0.01; 0.08; 0.02; 0.11; 0.03; 0.02; 0.02; 0.01 RA: <0.02; 0.16; 0.04; 0.22; 0.064; 0.038; 0.466; 0.024	E: 0.02 RA: 0.05	E: 0.11 RA: 0.47	0.2	0.2	Yes
	Open data DAR (UK, 2005)	NEU	GAP: 2x 200 g as/ha, BBCH <61, interval between appl. 14/21d; PHI 35d Mo: 2x <0.01; 0.01; 0.02 RA: 2x <0.05; 0.05; 0.10 ⁺	E: 0.01 RA: 0.05	E: 0.02 RA: 0.1	0.04	0.2	Yes

			*In these trials prothioconazole-desthio only was analysed. CF of 2 was used for cereal grain					
	Open data DAR (UK, 2005)	NEU	GAP: 2x 200 g as/ha, BBCH <61, interval between appl. 14/21d; PHI 48/61d Mo: 8x <0.01; 0.02 RA: 8x <0.05; 0.10 ⁺ *In these trials prothioconazole-desthio only was analysed. CF of 2 was used for cereal grain	E: 0.01 RA: 0.05	E: 0.02 RA: 0.1	0.03	0.2	Yes
Barley straw	New trials	NEU	GAP: 2x 200 g as/ha, BBCH 39-69, interval between appl. 14d; PHI 35d Mo: 0.2; 0.68; 2.02; 2.24; 0.42; 0.29; 0.65; 0.16 RA: 0.6; 2.04; 6.06; 6.72; 1.26; 0.87; 1.95; 0.48	RA: 1.45	RA: 6.72	-	-	No MRL set

A) Residue of sum of M04 and its hydroxy isomers (M14, M15, M16, M17, M18) expressed as M04 was calculated by the following formulae: *Residue of sum expressed as M04 (mg/kg) = residue of M04 + M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04*

Where the residue of *analyte* expressed as M04 (mg/kg) was calculated as follow =
$$\frac{\text{MW M04 (g/mol)} * \text{analyte residue measured (mg/kg)}}{\text{Analyte MW (g/mol)}}$$

The molecular weight (MW) of each analyte is:

M04: 312.29 g/mol,
M14: 328.19 g/mol,
M15: 328.19 g/mol,
M16: 328.19 g/mol,
M17: 328.19 g/mol,
M18: 328.19 g/mol

B) The LOQ for the sum expressed as M04 (0.058 mg/kg) was calculated using the same formulae: *LOQ of M04 + M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04*. It was calculated at 0.058 mg/kg

* Residues for stone fruits are expressed as whole fruit as requested by the guidance.

** Residues were analysed separately in peel and pulp. Results reported in the above tables are expressed as whole fruit as requested by the guidance.

*** Current EU MRLS are set in the Reg. (EU) 2019/552.

C) The proportionality approach was agreed at the 2013 CCPR meeting and endorsed by the Codex Alimentarius Commission at their 36th meeting in July 2013. Details are reported in Annex VIII of REP13/PR. It is also mentioned in the draft OECD guideline 509 on crop field trials. The proportionality concept assumes a linear relationship between application rates and residue levels. Therefore, residue data from trials conducted with variable application rates can be used for MRL calculations, assuming a scaling to the nominal application rate.

Table 7.2-8b: Summary of Triazole EU reported and new data supporting the intended uses of SIP41061

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
Residue definition for risk assessment: 1) 1,2,4-triazole (T) 2) Triazole alanine (TA) 3) Triazole acetic acid (TAA) 4) Triazole lactic acid (TLA)								
Apple → extrapolation to whole pome fruits	New trials	NEU	GAP: 2x 120 g as**/ha, BBCH 39-85, interval between appl. 7d; PHI 14d RA: <ul style="list-style-type: none"> T: 8x <0.04 TA: 8x <0.04 TAA: 8x <0.04 TLA: 8x <0.04 	T: 0.04 TA: 0.04 TAA: 0.04 TLA: 0.04	T: 0.04 TA: 0.04 0.059 TAA: 0.04 TLA: 0.04	-	-	No MRL set
Plum	New trials	NEU	GAP: 2x 160 g /ha, BBCH 39-85, interval between appl. 7d; PHI 3d RA: <ul style="list-style-type: none"> T: 8x <0.04 TA: 6x <0.04; 0.047; 0.059 TAA: 8x <0.04 TLA: 8x <0.04 	T: 0.04 TA: 0.04 TAA: 0.04 TLA: 0.04	T: 0.04 TA: 0.04 TAA: 0.04 TLA: 0.04	-	-	No MRL set
Peach and apricots →	New trials	NEU	GAP: 2x 160 g /ha, BBCH 39-85, interval between appl. 7d; PHI 3d	T: 0.04 TA: 0.1	T: 0.04 TA: 0.22	-	-	No MRL set

extrapolated to each other			RA: <ul style="list-style-type: none"> T: 6x <0.04 TA: 0.063; 0.10; 0.12; 0.156; 0.089; 0.22 TAA: 6x <0.04 TLA: 5x <0.04; 0.085 	TAA: 0.04 TLA: 0.04	TAA: 0.04 TLA: 0.085			
Cherry	New trials	NEU	GAP: 2x 160 g /ha, BBCH 39-85, interval between appl. 7d; PHI 3d RA: <ul style="list-style-type: none"> T: 8x <0.04 TA: 3x <0.04; 0.051; 0.054; 0.09; 0.97; 1.11 TAA: 7x <0.04; 0.095 TLA: 6x <0.04; 0.048; 0.157 	T: 0.04 TA: 0.06 TAA: 0.04 TLA: 0.04	T: 0.04 TA: 1.11 TAA: 0.095 TLA: 0.157	-	-	No MRL set
Sugar beet (root)	New trials	NEU	GAP: 2x 160 g as/ha, BBCH 39-49, interval between appl. 14d; PHI 28d RA: <ul style="list-style-type: none"> T: 7x <0.04 TA: 5x <0.04; 0.053; 0.08 TAA: 7x <0.04 TLA: 7x <0.04 	T: 0.04 TA: 0.04 TAA: 0.04 TLA: 0.04	T: 0.04 TA: 0.08 TAA: 0.04 TLA: 0.04	-	-	No MRL set
Zucchini → extrapolated to Whole sub-group (b) cucurbits with edible peel	New trials	GH	GAP: 3x 120 g as/ha, BBCH 11-89, interval between appl. 10d; PHI 3d RA: <ul style="list-style-type: none"> T: 6x <0.04 TA: 6x <0.04 TAA: 6x <0.04 TLA: 6x <0.04 	T: 0.04 TA: 0.04 TAA: 0.04 TLA: 0.04	T: 0.04 TA: 0.04 TAA: 0.04 TLA: 0.04	-	-	No MRL set
Wheat grain → extrapolation to rye and triticale	UK, 2018	4 NEU/ 4 SEU	GAP: 3x 187.5 g as/ha, BBCH 32-69, interval 14-35 d, PHI = 28d	T: 0.01 TA: 0.434 TAA: 0.189 TLA: na	T: 0.01 TA: 1.069 TAA: 0.517 TLA: na	-	-	No MRL set

Wheat straw	UK, 2018	4 NEU/ 4 SEU	GAP: 3x 187.5 g as/ha, BBCH 32-69, interval 14-35 d, PHI = 28d	T: 0.05 TA: 0.05 TAA: 0.058 TLA: na	T: 0.015 TA: 0.079 TAA: 0.307 TLA: na	-	-	No MRL set
Barley grain → extrapolation to oat	UK, 2018	4 NEU/ 4 SEU	GAP: 2x 150/200 g as/ha, BBCH 37-61, interval 9/27 days. PHI 28/35d	T: 0.01 TA: 0.208 TAA: 0.107 TLA: 0.01	T: 0.011 TA: 0.440 TAA: 0.320 TLA: 0.01	-	-	No MRL set
Barley straw	UK, 2018	4 NEU/ 4 SEU	GAP: 2x 150/200 g as/ha, BBCH 37-61, interval 9/27 days. PHI 28/35d	T: 0.050 TA: 0.50 TAA: 0.57 TLA: na	T: 0.05 TA: 0.050 TAA: 0.136 TLA: na	-	-	No MRL set
Oil seed Rape - seed	UK, 2018	20 NEU	GAP: 2x 125/150 g as/ha, BBCH 30-73/85, interval between appl. 14d; PHI nr	T: 0.01 TA: 0.24 TAA: 0.01 TLA: 0.015	T: 0.018 TA: 2.17 TAA: 0.062 TLA: 0.05	-	-	No MRL set
	New trials	NEU	GAP: 2x 180 g as/ha, BBCH 30-71, interval between appl. 14d; PHI 50d RA: <ul style="list-style-type: none"> T: 8x <0.04 TA: 0.114; 0.18; 0.277; 0.297; 0.487; 0.81; 0.92; 6.23 TAA: 7x <0.04, 0.104 TLA: 5x <0.04, 0.056; 0.061; 0.204 	T: 0.04 TA: 0.39 TAA: 0.04 TLA: 0.04	T: 0.04 TA: 6.23 TAA: 0.1 TLA: 0.2	-	-	No MRL set
Oil seed Rape - plant/straw	UK, 2018	20 NEU	GAP: 2x 125/150 g as/ha, BBCH 30-73/85, interval between appl. 14d; PHI nr	T: 0.01 TA: 0.077 TAA: 0.01 TLA: 0.01	T: 0.015 TA: 0.913 TAA: 0.034 TLA: 0.02	-	-	No MRL set
	New trials	NEU	GAP: 2x 180 g as/ha, BBCH 30-71, interval between appl. 14d; PHI 50d RA: <ul style="list-style-type: none"> T: 4x <0.06 TA: 4x <0.06 	T: 0.06 TA: 0.06 TAA: 0.06 TLA: 0.06	T: 0.06 TA: 0.06 TAA: 0.466 TLA: 0.236	-	-	No MRL set

			<ul style="list-style-type: none"> TAA: 3x <0.06; 0.466 TLA: 3x <0.06; 0.236 					
Carrot root→ extrapolation to beetroots; horse radishes; parsnips; parsley roots; salsifies; swedes; turnips	UK, 2018	5 NEU	GAP: 3x 192 g as/ha, interval between application 14d, PHI 21d	T: 0.01 TA: 0.025 TAA: 0.01 TLA: 0.01	T: 0.016 TA: 0.029 TAA: 0.010 TLA: 0.010			
	New trials	NEU	GAP: 2x 200 g as/ha, BBCH 16-46, interval between appl. 7-10d; PHI 21d RA: <ul style="list-style-type: none"> T: 4x <0.04 TA: 4x <0.04 TAA: 4x <0.04 TLA: 4x <0.04 <p>Only one year data package was analysed for NEU since all residues were found ND (not detectable, below LOD, <0.01 mg/kg)</p>	T: 0.04 TA: 0.04 TAA: 0.04 TLA: 0.04	T: 0.04 TA: 0.04 TAA: 0.04 TLA: 0.04	-	-	No MRL set

*No MRL are set for TMDs

**in the GAP the dose rate was expressed as prothioconazole

For the expert's convenience, please find below a short summary of the results reported in Confirmatory data UK, 2018 where the residues of TDMs were evaluated by UK coming from the application of various prothioconazole formulated products in various crops. All data are unpotrected.

Wheat

A total of 8 residue trials were conducted in northern and southern Europe in/on winter, spring or durum wheat with a emulsifiable concentrate (EC) containing 150 g/L of prothioconazole. The product was applied 3 times by foliar spray at the rate of 187.5 g as/ha of prothioconazole. The study samples were analysed for residues of 1,2,4-triazole (T), triazole alanine (TA) and triazole acetic acid (TAA). A summary of the median (STMR) and highest residues (HR) measured in the various sample materials is given below:

STMRs and HRs for the triazole derived metabolites in wheat commodities after three spray applications of an EC formulation containing prothioconazole

Commodity	No of Trials	STMR (mg/kg)				HR (mg/kg)			
		T	TA	TAA	TLA	T	TA	TAA	TLA
grain	8	0.010	0.434	0.189	NA	0.010	1.069	0.517	NA
plant	8	0.050	0.100	0.065	NA	0.050	0.524	0.434	NA
straw	8	0.050	0.050	0.058	NA	0.050	0.079	0.307	NA

NA: not analysed

Note: The STMRs were calculated based on the highest residue levels from each trial.

Barley

A total of 8 residue trials were conducted in northern and southern Europe in/on spring and winter barley with an emulsifiable concentrate (EC) containing 150 g/L of prothioconazole. The product was applied twice by foliar spray at the rate of 150 g as/ha of prothioconazole. The study samples were analysed for residues of 1,2,4-triazole (T), triazole alanine (TA) and triazole acetic acid (TAA). Further 4 residue trials were conducted in northern France in/on spring and winter barley with an emulsifiable concentrate (EC) containing 250 g/L of prothioconazole. The product was applied twice by foliar spray at the rate of 200 g as/ha of prothioconazole. The study samples were analysed for residues of 1,2,4-triazole (T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA). A summary of the median (STMR) and highest residues (HR) measured in the various sample materials is given below:

STMRs and HRs for the triazole derived metabolites in barley commodities after two spray applications with EC formulations containing prothioconazole

Commodity	No of Trials	STMR (mg/kg)				HR (mg/kg)			
		T	TA	TAA	TLA	T	TA	TAA	TLA
grain	12*	0.010	0.208	0.107	0.010	0.011	0.440	0.320	0.010
plant	8	0.050	0.061	0.050	NA	0.050	0.158	0.099	NA
straw	8	0.050	0.050	0.057	NA	0.050	0.050	0.136	NA

NA : not analysed * 4 trials for TLA

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.

Carrot

A total of 5 residue trials were conducted in northern Europe in/on carrot with a suspension concentrate (SC) containing 480 g/L of prothioconazole. The product was applied three times by foliar spray at the rate of 192 g as/ha of prothioconazole. The samples were analysed for residues of 1,2,4-triazole (T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA). A summary of the median (STMR) and highest residues (HR) measured in carrot is given below:

STMRs and HRs for the triazole derived metabolites in carrot after three spray applications with an SC formulation containing prothioconazole

Commodity	No of Trials	STMR (mg/kg)				HR (mg/kg)			
		T	TA	TAA	TLA	T	TA	TAA	TLA
root	5	0.010	0.025	0.010	0.010	0.016	0.029	0.010	0.010
leaf	5	0.021	0.010	0.010	0.025	0.070	0.010	0.010	0.125

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.

Oil seed rape

Overall summary of residues data for oilseed rape (prothioconazole)

A summary of the all 20 residue trials is outlined below:

STMRs and HRs for the triazole derived metabolites in oilseed rape commodities after foliar treatment with SC or EC formulations containing prothioconazole

Commodity	No of Trials	STMR (mg/kg)				HR (mg/kg)			
		T	TA	TAA	TLA	T	TA	TAA	TLA
plant	14 -20*	0.01	0.077	0.01	0.01	0.015	0.913	0.034	0.02
pod	8 – 13*	0.01	0.120	0.01	0.01	0.014	0.700	0.02	0.06
seed	14 -20*	0.01	0.24	0.01	0.015	0.018	2.17	0.062	0.05

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.

* The residues of T, TA and TAA were measured in 20 trials (including 13 trials with analysis of pods) while the residues of TLA were only measured in 14 trials (including 8 trials with analysis of pods).

7.2.2.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on pome fruits, stone fruits, wheat, rye, barley, oil seed rape, sugar beet (roots) and carrot for outdoor uses and on cucurbits edible peel in greenhouse are considered acceptable

According to the available data, the intended uses on pome fruits, apricot, cherries, plums, show an exceedance of the MRL. For this reason, the applicant in April 2022 submitted to Greece an Evaluation report in order to change the current MRLs; in addition a IUCLID dossier was submitted.

No risk for consumers is expected with the new MRLs proposed.

Pome fruits

Pome fruits are major crops in NEU for this reason 8 residue trials conducted in Northern Europe have been submitted by the applicant. Half of them are decline residue trials.

One decline residue trial conducted in NEU in 2021, give anomalous results, residues of M04 (prothioconazole-desthio) are higher than the ones measured in the other trials. Moreover, a degradation was not observed in this trial while in the other trials a degradation was clearly observed. No specific reason was found which can justify these results, the only difference is a higher dose rate was applied respected the intended GAP, +14.7%.

According to SANTE/2019/12752, apple (0130010) data could be extrapolated to Whole group Pome fruits (130000).

For pear to avoid any possible acute risk for consumer, a longer PHI was proposed for this crop, i.e. 21 days. Residues measured at this PHI are considered safe for consumers.

TDMs data is also available. Samples collected in applicant new residue trials have been analysed for the determination of the 4 triazoles.

8 samples were analysed and residues were all <LOQ. According to the available storage stability data (see Table 7.2-2b), storage data in high water matrix cover the analysis of TA and TAA (53 m) and TLA (48 m). For 1,2,4 triazole, four apple samples had been analysed within the acceptable maximum storage duration (6 months) while the others (trials conducted in 2020) went over that period.

Please find below the overview of the maximum storage interval of apple samples coming from residue trials conducted in 2021 (please see report RAU-008-21) and the one performed in 2020 (see report SPK-20-45305)

For samples extration and analysis of TDMs please refer to report RAU-029-21 and RAU-024-22:

Residue report Number	Trial number	Date of sampling	DLA of sampling (intended GAP)	Date of extraction and TDMs analysis	Time interval between sampling and sample extraction (days and months)
RAU-008-21	F/PR21/AP01/03T	14/09/2021	14 days	14/03/2022	182 d – 6 m
	H/PR21/AP02/09T	03/09/2021	14 days		193 d – 6.4 m
	P/PR21/AP03/15T	15/09/2021	14 days		183 d – 6 m
	P/PR21/AP04/21T	15/09/2021	14 days		183 d – 6 m
SPK-20-45305	SPK-20-45305 FR01 3	17/09/2020	14 days	19/07/2022	670 d – 22 m
	SPK-20-45305 HU02 7	14/09/2020	14 days		673 d – 22 m
	SPK-20-45305	26/08/2020	14 days		692 d – 23 m

	PL03 11				
	SPK-20-45305	15/09/2020	14 days		672 d – 22 m
	PL04 15				

A complete data package is available for TA, TAA and TLA.

In addition, a new storage stability study on 1,2,4 Triazole confirmed the stability in high water matrix for 12 months in frozen storage conditions.

All samples coming from 2021 residue trials were covered by storage stability data, while for 2020 data, an exceedance of storage period was found for 1,2,4 T.

For 1,2,4 triazole please take note 3 samples were analysed within 6 months, time covered by storage stability study, one was analysed a couple of weeks after but very close to the 6 months. Considering that 4 samples are available with residue <LOQ, a half data package can be considered as sufficient to support the use. Moreover, considering the 1,2,4 triazole residues were all <LOQ, the samples covered by storage stability data and the ones analysed after that period, it can be confirmed no residue of TDMs is expected when the PPP is applied according to the intended GAP.

In addition, please take note, a new storage stability study on 1,2,4 Triazole is ongoing in the various matrix groups to support residue trials done in 2020. As soon as the final report is available it will be submitted to RMS.

In conclusion enough TDMs data is available to support apple use and they could be used to run consumer risk assessment.

Sufficient residue data is available to set a MRL in pome fruits and the uses can be considered acceptable.

Apricots/Peaches

According to SANTE/2019/12752 Apricots and Peaches are minor crop in NEU. For this reason, 6 conducted in Northern Europe have been submitted by the applicant. Half of them are decline residue trials. According to SANTE/2019/12752, peaches (0140030) data could be extrapolated to apricots (0140010) and *vice versa*.

TDMs data is also available. Samples collected in applicant new residue trials have been analysed for the determination of the 4 triazoles.

6 samples were analysed and residues were all <LOQ for 1,2,4 T and TAA while residues >LOQ were found for TA and TLA. According to the available storage stability data (see Table 7.2-2b), storage data in high water matrix cover the analysis of TA and TAA (53 m) and TLA (48 m). For 1,2,4 triazole, no sample had been analysed within the acceptable maximum storage duration (6 months).

Please find below the overview of the maximum storage interval of apricot/peach samples coming from residue trials conducted in 2021 (please see report RAU-009-21) and the one performed in 2020 (see report SPK-20-45305)

For samples extration and analysis of TDMs please refer to report RAU-029-21 and RAU-024-22:

Residue report Number	Trial number	Date of sampling	DALA of sampling (intended GAP)	Date of extraction and TDMs analysis	Time interval between sampling and sample extraction (days and months)
RAU-009-21	H/PR21/PE01/03T	14/09/2021	3 days	01/06/2022	259 d – 8.6 m
	P/PR21/AR01/03T	03/09/2021	3 days		270 d – 9 m
SPK-20-45305	SPK-20-45307 HU01 3	25/06/2020	3 days	25/07/2022	760 d – 25.3 m
	SPK-20-45307 HU02 7	06/07/2020	3 days		749 d – 25 m
	SPK-20-45307	27/07/2020	3 days		728 d – 24.2 m

	PL03 11				
	SPK-20-45307	13/07/2020	3 days		742 d – 24.7 m
	PL04 15				

A complete data package is available for TA, TAA and TLA.

In addition, a new storage stability study on 1,2,4 Triazole confirmed the stability in high water matrix for 12 months in frozen storage conditions.

All samples coming from 2021 residue trials were covered by storage stability data, while for 2020 data, an exceedance of storage period was found for 1,2,4 T.

For 1,2,4 triazole, even if samples were analysed after the maximum acceptable storage period, no residue >LOQ is expected according to the overall data set.

To confirm this assumption please take note, a new storage stability study on 1,2,4 Triazole is ongoing in the various matrix groups to support residue trials. It will be provided to RMS as soon as finalised.

At the moment enough TDMs data is available to support apricot/peach use and they could be used to run consumer risk assessment.

Sufficient residue data is available to set a MRL in Apricots and the uses can be considered acceptable.

Plums

Plums are major crops in EU for this reason 8 residue trials conducted in Northern Europe have been submitted by the applicant. Half of them are decline residue trials.

TDMs data is also available. Samples collected in applicant new residue trials have been analysed for the determination of the 4 triazoles.

6 samples were analysed and residues were all <LOQ for 1,2,4 T and TAA while residues >LOQ were found for TA and TLA. According to the available storage stability data (see Table 7.2-2b), storage data in high water matrix cover the analysis of TA and TAA (53 m) and TLA (48 m). For 1,2,4 triazole, no sample had been analysed within the acceptable maximum storage duration (6 months).

Please find below the overview of the maximum storage interval of plum samples coming from residue trials conducted in 2021 (please see report RAU-010-21) and the one performed in 2020 (see report RAU-024-20)

For samples extration and analysis of TDMs please refer to report RAU-029-21 and RAU-024-22:

Residue report Number	Trial number	Date of sampling	DALA of sampling (intended GAP)	Date of extraction and TDMs analysis	Time interval between sampling and sample extraction (days and months)
RAU-010-21	H/PR21/PL01/03T	02/08/2021	3 days	06/04/2022	247 d – 8.2 m
	H/PR21/PL02/09T	26/08/2021			223 d – 7.4 m
	H/PR21/PL03/14T	02/08/2021			247 d – 8.2 m
	G/PR21/PL04/21T	23/07/2021			257 d – 8.5 m
RAU-024-20	F/PR20/PL01/02T	14/08/2020	3 days	21/07/2022	706 d – 23.5 m
	H/PR20/PL02/04T	17/07/2020			734 d – 24.5 m
	P/PR20/PL03/06T	03/09/2020			668 d – 22.2 m
	P/PR20/PL04/08T	26/08/2020			676 d – 22.5 m

A complete data package is available for TA, TAA and TLA.

In addition, a new storage stability study on 1,2,4 Triazole confirmed the stability in high water matrix for 12 months in frozen storage conditions.

All samples coming from 2021 residue trials were covered by storage stability data, while for 2020 data, an exceedance of storage period was found for 1,2,4 T.

For 1,2,4 triazole, even if samples were analysed after the maximum acceptable storage period, no residue >LOQ is expected according to the overall data set.

To confirm this assumption please take note, a new storage stability study on 1,2,4 Triazole is ongoing in the various matrix groups to support residue trials. It will be provided to RMS as soon as finalised.

At the moment enough TDMs data is available to support plum use and they could be used to run consumer risk assessment.

Sufficient residue data is available to set a MRL in plums and the use can be considered acceptable.

Cherries

According to SANTE/2019/12752 cherries are major crops in NEU, 8 residue trials conducted in Northern Europe. Half of them are decline residue trials.

Sufficient residue data is available to set a MRL in cherries and the uses can be considered acceptable.

TDMs data is also available. Samples collected in applicant new residue trials have been analysed for the determination of the 4 triazoles.

8 samples were analysed and residues were all <LOQ for 1,2,4 T while residues >LOQ were found for TA, TAA and TLA. According to the available storage stability data (see Table 7.2-2b), storage data in high water matrix cover the analysis of TA and TAA (53 m) and TLA (48 m). For 1,2,4 triazole, no sample had been analysed within the acceptable maximum storage duration (6 months).

Please find below the overview of the maximum storage interval of cherry samples coming from residue trials conducted in 2021 (please see report RAU-011-21) and the one performed in 2020 (see report RAU-017-20)

For samples extraction and analysis of TDMs please refer to report RAU-029-21 and RAU-024-22:

Residue report Number	Trial number	Date of sampling	DALA of sampling (intended GAP)	Date of extraction and TDMs analysis	Time interval between sampling and sample extraction (days and months)
RAU-011-21	H/PR21/CH01/03T	18/06/2021	3 days	31/03/2022	286 d – 9.5 m
	H/PR21/CH02/09T	19/06/2021			285 d – 9.5 m
	P/PR21/CH03/15T	22/07/2021			252 d – 8.4 m
	P/PR21/CH04/21T	15/07/2021			259 d – 8.6 m
RAU-017-20	H/PR20/CH01/02T	29/06/2020	3 days	19/07/2022	750 d – 25 m
	H/PR20/CH02/04T	12/06/2020			767 d – 25.5 m
	P/PR20/CH03/06T	27/07/2020			722 d – 24 m
	P/PR20/CH04/08T	10/07/2020			739 d – 24.6 m

A complete data package is available for TA, TAA and TLA.

In addition, a new storage stability study on 1,2,4 Triazole confirmed the stability in high water matrix for 12 months in frozen storage conditions.

All samples coming from 2021 residue trials were covered by storage stability data, while for 2020 data, an exceedance of storage period was found for 1,2,4 T.

For 1,2,4 triazole, even if samples were analysed after the maximum acceptable storage period, no residue >LOQ is expected according to the overall data set.

To confirm this assumption please take note, a new storage stability study on 1,2,4 Triazole is ongoing in the various matrix groups to support residue trials. It will be provided to RMS as soon as finalised.

At the moment enough TDMs data is available to support cherry use and they could be used to run consumer risk assessment.

Cucurbits with inedible peel

8 residue trials conducted in Melon in greenhouse conditions have been submitted by the applicant. 2 of them are decline residue trials and other 4 are multi RAC trials.

According to SANTE/2019/12752, melon (0232010) data could be extrapolated to Whole subgroup (c) cucurbits with inedible peel (0233000).

In the various trials a rapid degradation of prothioconazole desethio was observed. According to that, a PHI of 10days was proposed as at this interval, residues were all <LOQ.

No exceedance of current MRL is expected when the PPP is applied according to the intended GAP.

Cucurbits with edible peel

8 residue trials conducted in zucchini in greenhouse conditions have been submitted by the applicant. 2 of them are decline residue trials and other 6 are RAC trials.

The initial intended PHI was 3 days, however, according to the residue data, since at 3 days residues were found >LOQ in almost all samples, the applicant decided to support a longer PHI (i.e. 10 days). In fact, at 10 DALA residues were all <LOQ and then < current MRL for the group cucurbits edible peel (0.01 mg/kg).

According to SANTE/2019/12752, Courgettes (0232030) data could be extrapolated to Whole subgroup (c) cucurbits with edible peel (0231000).

Please take note the applicant submitted a MRL change application to increase the MRL in whole group cucurbits with edible peel, however as first instance, the applicant would support a PHI of 10 days, in fact at the intended GAP no current MRL exceedance is expected. Even if only 2 trials are available at PHI 10d, since a rapid degradation was observed from 1 to 10 DALA, no exceedance of current MRL is expected when the PPP is applied according to the intended GAP using a PHI of 10d.

TDMs data is also available. Samples collected in applicant new residue trials have been analysed for the determination of the 4 triazoles.

6 samples collected at 3 DALA were analysed and residues were all <LOQ. According to the available storage stability data (see Table 7.2-2b), storage data in high water matrix cover the analysis of TA and TAA (53 m) and TLA (48 m). For 1,2,4 triazole, no sample had been analysed within the acceptable maximum storage duration (6 months).

Please find below the overview of the maximum storage interval of zucchini samples coming from residue trials conducted in 2021 (please see report BIU-017-21) and the ones performed in 2020 (see report BIU-021-20)

For samples extration and analysis of TDMs please refer to report RAU-029-21 and RAU-024-22:

Residue report Number	Trial number	Date of sampling	DALA of sampling (intended GAP)	Date of extraction and TDMs analysis	Time interval between sampling and sample extraction (days and months)
BIU-017-21	I/PR21/ZU05/03T	08/07/2021	3 days	04/05/2022	300 d – 10 m
	I/PR21/ZU05/06T	15/07/2021	10 days		293 d – 9.7 m
	I/PR21/ZU06/09T	04/06/2021	3 days		334 d – 11 m
	I/PR21/ZU06/12T	10/06/2021	9 days		328 d – 11 m
	I/PR21/ZU07/14T	25/10/2021	3 days		191 d – 6 m
	I/PR21/ZU08/16T	04/06/2021	3 days		334 d – 11 m
BIU-021-20	I/PA20/ZU05/02T	04/06/2020	3 days	22/07/2022	778 d – 25.9 m
	I/PA20/ZU06/06T	02/11/2020			627 d – 20.9 m

A complete data package is available for TA, TAA and TLA.

In addition, a new storage stability study on 1,2,4 Triazole confirmed the stability in high water matrix for 12 months in frozen storage conditions.

All samples coming from 2021 residue trials were covered by storage stability data, while for 2020 data, an exceedance of storage period was found for 1,2,4 T.

For 1,2,4 triazole, even if samples were analysed after the maximum acceptable storage period, no residue >LOQ is expected according to the overall data set.

To confirm this assumption please take note, a new storage stability study on 1,2,4 Triazole is ongoing in the various matrix groups to support residue trials. It will be provided to RMS as soon as finalised.

At the moment enough TDMs data is available to support cucurbits edible peel greenhouse use and they could be used to run consumer risk assessment.

ntended use is not sufficiently supported. At least 4 trials with residue levels below LOQ are required (reduced dataset). For a PHI of 10 days, residue levels are below LOQ, and no MRL ex-ceedance is expected, but only 2 trials are available.

Carrot

8 residue trials conducted in Carrot have been submitted by the applicant. In one trial conducted in 2020, a high residue was measured, no specific reason was found for this anomalous data. Moreover, according to OECD calculator, it is an outlier. For these reasons it wasn't used to derive the MRL and neither for RA purpose.

According to SANTE/2019/12752, carrot data could be extrapolated to Whole subgroup (c) other root and tuber vegetables except sugar beets (0213000) and except also celeriac e radishes for which EU MRLs are set at lower level.

The data submitted show that no exceedance of the current MRL of 0.1 mg/kg will occur when the PPP is applied according to the intended GAP.

TDMs data is also available. The applicant refers to open data reported in UK, 2018. The available trials were conducted with a worst case GAP 3x 192 g as/ha instead of the intended SIP 41061 GAP, 2x 200 g as/ha. These data can be considered as supportive information. In addition, samples collected in applicant new residue trials have been analysed for the determination of the 4 triazoles.

4 carrot samples coming from 2021 trials were analysed and residues were all <LOQ. The available storage stability data in high starch matrix of 1,2,4 triazole (12 m), TA and TAA (26 m) and TLA (28 m), (see OECD 506 and Table 7.2-2b) cover the analysis of applicant samples.

Please find below the overview of the maximum storage interval of carrot samples coming from residue trials conducted in 2021 (please see report RAU-017-21), for samples extraction and analysis of TDMs please refer to report RAU-028-21:

Residue report Number	Trial number	Date of sampling	Date of extraction and TDMs analysis	Time interval between sampling and sample extraction (days and months)
RAU-017-21	F/PR21/CA01/02T	25/10/2021	28/04/2022	185 d – 6 m
	F/PR21/CA02/04T	13/10/2021		173 d – 5.7 m
	P/PR21/CA03/06T	20/10/2021		180 d – 6 m
	P/PR21/CA04/08T	12/08/2021		259 d – 8.6 m

Enough TDMs data is available to support carrot use and they could be used to run consumer risk assessment.

The use is considered acceptable.

Oil seed rape

8 residue trials in Northern Europe were submitted for Oil seed rape as it is a major crop in the EU.

Residues measured in the trials conducted by the applicant showed results all below the LOQ except for

two samples in which residues were above the LOQ but below the fixed MRL.

The data submitted show that no exceedance of the current MRL of 0.15 mg/kg will occur when the PPP is applied according to the intended GAP.

TDMs data is also available. The applicant refers to open data reported in UK, 2018. The available trials were conducted with a similar case GAP 2x 150 g as/ha, intended SIP 41061 GAP, 2x 180 g as/ha. These data can be considered as supportive information. In addition, samples collected in applicant new residue trials have been analysed for the determination of the 4 triazoles.

4 OSR samples coming from 2021 trials and 4 from 2020 trials were analysed. The available storage stability data in high starch matrix of TAA (53 m) and TLA (48 m) (see OECD 506 and Table 7.2-2b) cover the analysis of these compounds while 1,2,4 T and TA seems instable in this crop.

Please find below the overview of the maximum storage interval of OSR grain samples coming from residue trials conducted in 2021 (please see report RAU-014-21), for samples extration and analysis of TDMs please refer to report RAU-028-21 and RAU-024-22:

Residue report Number	Trial number	Date of sampling	Date of extraction and TDMs analysis	Time interval between sampling and sample extraction (days and months)
RAU-014-21	F/PR21/OS01/03T	16/07/2021	23/03/2022	250 d – 8.3 m
	H/PR21/OS02/07T	08/07/2021		258 d – 8.6 m
	P/PR21/OS03/11T	29/07/2021		237 d – 7.9 m
	P/PR21/OS04/15T	02/08/2021		233 d – 7.8 m
RAU-015-20	F/PA20/OS01/03T	09/07/2020	03/08/2022	755 d – 25 m
	F/PA20/OS02/07T	21/07/2020		743 d – 24.7 m
	P/PA20/OS03/11T	29/07/2020		735 d – 24 m
	P/PA20/OS04/15T	21/07/2020		743 d – 24.7 m

A new storage stability is ongoing but unfortunately according to the preliminary data, the instability of 1,2,4 T seems confirmed in oil seed rape matrix. According to that, new residue trials will be planned in 2023 with the aim to analyse the samples within 30 days from harvest to avoid storage stability issue. If RMS agrees, new trials could be sent as soon as finalised and/or as post registration requirement. In any case, since no risk for consumers is expected when the PPP is applied according to the intended GAP., at the moment enough data is available to perform consumer risk assessment.

The use is considered acceptable.

NOTE: It is up to each Member State to decide on the need to provide missing data for oil seed rape (data for TLA and TA in rape seed; residues of TMDs in honey) prior to registration in a given country. This data can be submitted at national level.

Sugar beet

Four residue trials on sugar beet were conducted in Northern Europe on sugar beet. Residues measured are all below the LOQ.

According to SANTE 2019/12752 rev. 10.3 (Appendix d) and to Commission Regulation (EU) No 283/2013, the numbers of studies to be performed may be reduced if residue trials show that the residue levels in plant or plant products are lower than the LOQ. Four trials are sufficient to support sugar beet use.

The data submitted show that no exceedance of the current MRL of 0.01 mg/kg will occur when the PPP is applied according to the intended GAP.

TDMs data is also available. Samples collected in applicant new residue trials have been analysed for the determination of the 4 triazoles.

4 sugar beet root sample coming from 2021 trials (please see RAU-015-21) and 3 from 2020 trials (please see report N. RAU-020-20) were analysed. Residues of 1,2,4 T, TAA and TLA were all <LOQ while TA was found >LOQ in 2 samples.

The available storage stability data in high starch matrix (see OECD 506 and Table 7.2-2b) cover the analysis of TA and TAA (26 m) and TLA (28 m). While for 1,2,4 triazole only the four trials performed in 2021 have been analysed within the acceptable storage interval (12 m).

Please find below the overview of the maximum storage interval of sugar beet samples coming from residue trials, for samples extraction and analysis of TDMs please refer to report RAU-028-21 and RAU-024-22.

Residue report Number	Trial number	Date of sampling	Date of extraction and TDMs analysis	Time interval between sampling and sample extraction (days and months)
RAU-020-20	U/PA20/SB01/03T	20/10/2020	22/07/2022	640 d – 21 m
	P/PA20/SB02/07T	23/09/2020		673 d – 22.4 m
	P/PA20/SB04/15T	23/09/2020		673 d – 22.4 m
RAU-015-21	P/PR21/SB02/04T	20/10/2021	28/04/2022	190 d – 6.3 m
	P/PR21/SB03/06T	21/11/2021		159 d – 5.3 m
	H/PR21/SB04/08T	16/09/2021		224 d – 7.4 m
	H/PR21/SB05/10T	17/10/2021		193 d – 6.3 m

In total 7 trials only were analysed, trial U/PR21/SB01 conducted in 2021 in United Kingdom was not analysed due to shipment issue. The delivery of crop sample from UK to an EU Country was stopped due to costume issue. However, 7 data can be considered enough to support the use and the available number are sufficient to perform consumer risk assessment.

Please take note for 1,2,4 triazole 4 samples only were analysed within 12 months, all of them were <LOQ. Considering that 4 samples are available with residue <LOQ, a half data package can be considered as sufficient to support the use. Moreover, considering the 1,2,4 triazole residues were all <LOQ, in the samples covered by storage stability data and the ones analysed after that period, it can be confirmed no residue of TDMs is expected when the PPP is applied according to the intended GAP.

The use is considered acceptable.

Wheat

8 residue trials in Northern Europe were submitted for wheat. Residues measured in the trials are all < the LOQ except for one sample in which residue was above the LOQ but below the fixed MRL.

According to SANTE/2019/12752, wheat data could be extrapolated to rye and triticale.

The data submitted show that no exceedance of the current MRL of 0.1 mg/kg will occur when the PPP is applied according to the intended GAP.

In addition, a reference has done to open data summarised in DAR, 2005. 10 residue trials have been conducted at a worst case GAP, 3 applications instead of 2 of the applicant intended GAP, however the dose rate is the same (i.e. 200 g as/ha). Residues measured in grain at 35 DALA are all <LOQ confirm no exceedance of current MRL is expected.

TDMs data is also available. The applicant refers to open data reported in UK, 2018. The available trials were conducted with a worst case GAP 3x 187.5 g as/ha, intended of SIP 41061 GAP, 2x 200 g as/ha. However, the dose rate is similar (187.5 is within 25% variability rule), and 3 applications can be considered as worst case respect the 2 of SIP 41061 GAP. Residues of 1,2,4 T, TA and TAA were analysed and enough storage stability data is available for this matrix.

No data is available for TLA, the applicant has planned with other Companies new residue trials on cereals in 2023 in order to analyse it. If RMS agrees, new trials could be sent as soon as finalised and/or as post registration requirement.

In any case, evaluating all the available TDMs data in the various crops, in particular to TLA measured in barley grain (HR = 0.01 mg/kg), residues expected in this matrix are quite low and no consumer risk is expected.

According to that, the applicant thinks enough TDMs data is available for wheat and the residue results can be used to perform the risk assessment and dietary burden calculation.

The use is considered acceptable.

Barley

8 residue trials in Northern Europe were submitted for barley. Residues measured are all below the fixed MRL.

According to SANTE/2019/12752, barley data could be extrapolated to oat.

The data submitted show that no exceedance of the current MRL of 0.2 mg/kg will occur when the PPP is applied according to the intended GAP.

In addition, a reference has done to open data summarised in DAR, 2005. 13 residue trials have been conducted according to the applicant intended GAP (2x 200 g as/ha), four of them with a PHI of 35 days while the other had a PHI of 48/61 d. Residues measured in grain at 35 DALA are all <MRL confirm no exceedance of current MRL is expected.

TDMs data is also available. The applicant refers to open data reported in UK, 2018. The available trials were conducted at the GAP 2x 150/200 g as/ha, in line with SIP 41061 GAP, 2x 200 g as/ha.

Residues of 1,2,4 T, TA, TLA and TAA were analysed in barley grain and enough storage stability data is available for this matrix.

Enough TDMs data is available for barley and the residue results can be used to perform the risk assessment and dietary burden calculation.

The use is considered acceptable.

7.2.3 Magnitude of residues in livestock

7.2.3.1 Dietary burden calculation

A dietary burden calculation has done using as input values:

- o for the crops related to the present application, the residues expressed according to the current residue definition for RA: sum of prothioconazole-desthio (M04) and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxy propyl-2H-1,2,4-triazole moiety (M14, M15, M16, M17, M18) expressed as prothioconazole-desthio (sum of isomers).
- o For other uses, input values reported in EFSA, 2014

In addition, dietary burden calculations have done separately for each TDMs using as input values:

- data from applicant residue trials for the crops analysed (oil seed rape, carrot, sugar beet, apple 63omace)
- for wheat and barley open data from UK, 2018. Please see Table 7.2-10b.

Table 7.2-11: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration) - Prothioconazole

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
<u>Risk assessment residue definition</u> : sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)				
Feed items related to previous evaluations				
Head cabbage	0.02	Median residue x CF	0.12	Highest residue x CF
Maize silage	0.01	Median residue	0.01	Highest residue
Maize grain	0.01	Median residue	0.01	Median residue
Potato	0.01	Median residue	0.01	Highest residue
Linseed meal	0.12	Median residue x CF	0.12	Highest residue x CF x 2
Peas and beans (dry)	0.02	Median residue	0.02	Highest residue
Feed items related to the current application				
Wheat/rye grain	0.02	Median residue	0.06	Highest residue
Wheat straw	0.81	Median residue	2.82	Highest residue
Barley/oat straw	1.45	Median residue	6.72	Highest residue
Barley/oat grain	0.05	Median residue	0.47	Highest residue
Sugar beet root	0.058	Median residue	0.058	Highest residue
Carrot root	0.058	Median residue	0.07	Highest residue
Turnip and swede root	0.058	Median residue	0.07	Highest residue
OSR grain (meal)	0.058	Median residue	0.058	Highest residue
OSR forage/plant	0.08	Median residue	0.36	Highest residue
Sugar beet root (dried pulp)	0.058	Median residue	0.058	Highest residue

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
<u>Risk assessment residue definition</u> : sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)				
Apple pomace, wet	0.058	Median residue	-	-

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

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Risk assessment residue definition: 1,2,4 Triazole				
Wheat/rye grain	0.01	Median residue	-	-
Wheat/rye straw	0.05	Median residue	0.015	Highest residue
Barley/oat grain	0.01	Median residue	-	-
Barley/oat straw	0.05	Median residue	0.05	Highest residue
Oil seed rape meal (grain)	0.04	Median residue	-	-
Oil seed rape forage/plant	0.06	Median residue	0.06	Highest residue
Sugar beet root	0.04	Median residue	0.04	Highest residue
Sugar beet root (dried pulp)	0.04	Median residue	-	-
Apple pomace	0.04	Median residue	-	-
Carrot root	0.04	Median residue	0.04	Highest residue
Turnip and swede root	0.04	Median residue	0.04	Highest residue
Risk assessment residue definition: Triazole Alanine				
Wheat/rye grain	0.434	Median residue	-	-
Wheat/rye straw	0.05	Median residue	0.079	Highest residue
Barley/oat grain	0.208	Median residue	-	-
Barley/oat straw	0.05	Median residue	0.05	Highest residue
OSR grain (meal)	0.39	Median residue	6.23	Highest residue
OSR forage/plant	0.06	Median residue	0.06	Highest residue
Sugar beet root	0.04	Median residue	-	-
Sugar beet root (dried pulp)	0.04	Median residue	-	-
Apple pomace	0.04	Median residue	-	-
Carrot root	0.04	Median residue	0.04	Highest residue
Turnip and swede root	0.04	Median residue	0.04	Highest residue

Risk assessment residue definition: Triazole acetic acid				
Wheat/rye grain	0.189	Median residue	-	-
Wheat straw	0.058	Median residue	0.307	Highest residue
Barley/oat grain	0.107	Median residue	-	-
Barley/oat straw	0.57	Median residue	0.136	Highest residue
OSR grain (meal)	0.04	Median residue	0.1	Highest residue
OSR forage/plant	0.06	Median residue	0.466	Highest residue
Sugar beet root	0.04	Median residue	0.04	Highest residue
Sugar beet root (dried pulp)	0.04	Median residue	-	-
Apple pomace	0.04	Median residue	-	-
Carrot root	0.04	Median residue	0.04	Highest residue
Turnip and swede root	0.04	Median residue	0.04	Highest residue
Risk assessment residue definition: Triazole lactic acid				
Wheat/rye grain	-		-	-
Wheat straw	-		-	-
Barley/oat grain	0.01	Median residue	-	-
Barley/oat straw	-		-	-
OSR grain (meal)	0.04	Median residue	0.2	Highest residue
OSR forage/plant	0.06	Median residue	0.236	Highest residue
Sugar beet root	0.04	Median residue	0.04	Highest residue
Sugar beet root (dried pulp)	0.04	Median residue	-	-
Apple pomace	0.04	Median residue	-	-
Carrot root	0.04	Median residue	0.04	Highest residue
Turnip and swede root	0.04	Median residue	0.04	Highest residue

Table 7.2-12: Results of the dietary burden calculation

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)	0.031	0.112	1.08	3.14	Dairy cattle	Barley	straw	Yes
Cattle (dairy only)	0.031	0.112	0.82	2.92	Dairy cattle	Barley	straw	Yes
Sheep (all diets)	0.041	0.213	1.15	5.20	Lamb	Barley	straw	Yes
Sheep (ewe only)	0.038	0.173	1.15	5.20	Ram/Ewe	Barley	straw	Yes
Swine (all diets)	0.015	0.016	0.60	0.71	Swine (breeding)	Potato	process waste	Yes
Poultry (all diets)	0.017	0.038	0.25	0.55	Poultry layer	Barley	straw	Yes
Poultry (layer only)	0.017	0.038	0.25	0.55	Poultry layer	Barley	straw	Yes
(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"								
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day"								

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

The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.004 mg/kg bw for all livestock groups. The results are in line with the calculation done in EFSA, 2014 where also in that case, the major compound was Barley straw.
Further investigation of residues is therefore required in all commodities of animal origin.

Table 7.2-11b: Results of the dietary burden calculation – 1,2,4 Triazole

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)	0.017	0.017	0.44	0.44	Dairy cattle	Beet, sugar	ensiled pulp	Yes
Cattle (dairy only)	0.017	0.017	0.44	0.44	Dairy cattle	Beet, sugar	ensiled pulp	Yes
Sheep (all diets)	0.022	0.022	0.51	0.51	Lamb	Beet, sugar	dried pulp	Yes
Sheep (ewe only)	0.009	0.017	0.26	0.51	Ram/Ewe	Beet, sugar	dried pulp	Yes
Swine (all diets)	0.010	0.010	0.37	0.37	Swine (finishing)	Beet, sugar	dried pulp	Yes
Poultry (all diets)	0.008	0.008	0.11	0.11	Poultry layer	Swede	roots	Yes
Poultry (layer only)	0.008	0.008	0.11	0.11	Poultry layer	Swede	roots	Yes
(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day".								
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".								

The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.004 mg/kg bw for all livestock groups. The maximum DM are lower than dietary burden calculated in UK, 2018 (TDMs confirmatory addendum) where the most critical commodity was potato process waste, DM maximum 3.75 mg/kg in Cattle (all diet).

Table 7.2-11c: Results of the dietary burden calculation – Triazole Alanine

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)	0.051	0.051	1.34	1.34	Dairy cattle	Wheat	milled bypdts	Yes
Cattle (dairy only)	0.051	0.051	1.32	1.32	Dairy cattle	Wheat	milled bypdts	Yes
Sheep (all diets)	0.083	0.083	1.95	1.95	Lamb	Wheat	milled bypdts	Yes
Sheep (ewe only)	0.055	0.055	1.65	1.65	Ram/Ewe	Wheat	milled bypdts	Yes
Swine (all diets)	0.059	0.059	1.96	1.96	Swine (finishing)	Wheat	milled bypdts	Yes
Poultry (all diets)	0.075	0.075	1.07	1.07	Poultry broiler	Wheat	milled bypdts	Yes
Poultry (layer only)	0.073	0.073	1.06	1.06	Poultry layer	Wheat	milled bypdts	Yes
(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day".								
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".								

The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.004 mg/kg bw for all livestock groups. The maximum DM are lower than dietary burden calculated in UK, 2018 (TDMs confirmatory addendum) where the most critical commodity was potato process waste, DM maximum 13.63 mg/kg in Cattle (all diet).

Table 7.2-11d: Results of the dietary burden calculation – Triazole Acetic Acid

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)	0.024	0.029	0.68	0.80	Dairy cattle	Wheat	milled bypdts	Yes
Cattle (dairy only)	0.024	0.029	0.63	0.77	Dairy cattle	Wheat	milled bypdts	Yes
Sheep (all diets)	0.039	0.060	0.91	1.41	Lamb	Rape	forage	Yes
Sheep (ewe only)	0.026	0.043	0.79	1.30	Ram/Ewe	Rape	forage	Yes
Swine (all diets)	0.028	0.028	0.93	1.18	Swine (finishing)	Wheat	milled bypdts	Yes
Poultry (all diets)	0.035	0.043	0.49	0.62	Poultry layer	Rape	forage	Yes
Poultry (layer only)	0.033	0.043	0.49	0.62	Poultry layer	Rape	forage	Yes
(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"								
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day"								

The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.004 mg/kg bw for all livestock groups. The maximum DM are lower than dietary burden calculated in UK, 2018 (TDMs confirmatory addendum) where the most critical commodity was potato process waste, DM maximum 4.29 mg/kg in Cattle (all diet).

Table 7.2-11e: Results of the dietary burden calculation – Triazole lactic acid

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)	0.016	0.019	0.42	0.48	Dairy cattle	Beet, sugar	ensiled pulp	Yes
Cattle (dairy only)	0.016	0.019	0.42	0.48	Dairy cattle	Beet, sugar	ensiled pulp	Yes
Sheep (all diets)	0.022	0.031	0.51	0.72	Lamb	Beet, sugar	dried pulp	Yes
Sheep (ewe only)	0.008	0.024	0.25	0.72	Ram/Ewe	Beet, sugar	dried pulp	Yes
Swine (all diets)	0.010	0.011	0.37	0.48	Swine (breeding)	Beet, sugar	dried pulp	Yes
Poultry (all diets)	0.005	0.009	0.08	0.14	Poultry layer	Rape	forage	Yes
Poultry (layer only)	0.005	0.009	0.08	0.14	Poultry layer	Rape	forage	Yes
(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"								
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".								

The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.004 mg/kg bw for all livestock groups. The maximum DM are lower than dietary burden calculated in UK, 2018 (TDMs confirmatory addendum) where the most critical commodity was Grass forage (fresh), DM maximum 4.61 mg/kg in Cattle (all diet).

7.2.3.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Please refer to United Kingdom 2004, 2007, EFSA 2007, 2014. No new data were submitted in the framework of this application.

Available data

The magnitude of prothioconazole residues was investigated in a feeding study with lactating cows (EFSA, 2007b; FAO, 2008a, 2008b; United Kingdom, 2004, 2007).

EFSA: *Three groups of lactating cows, each consisting of three animals, were dosed for 28 consecutive days with prothioconazole-desthio at levels of 4, 25, and 100 mg/kg in the diet (equivalent to 0.145, 0.909 and 3.636 mg/kg bw per d, respectively). The samples were analysed for prothioconazole-desthio, M14 and M15. In milk, a plateau level was reached after 1 or 2 days of exposure, according to the dose level group. Since neither the metabolites (free and conjugated) containing the common moiety and included in the residue definition for risk assessment nor the glucuronide conjugates of prothioconazole-desthio were analysed, EFSA reported the residue levels for enforcement only (prothioconazole-desthio) and considered the conversion factors for enforcement to risk assessment of 2 and 9 respectively for liver and kidney based on the goat metabolism study with administration of prothioconazole-desthio. No tentative CF was derived for milk, muscle and fat since the residue levels in these matrices are expected to be negligible (<0.01 mg/kg) at the calculated dietary burden. Furthermore, in the framework of the reported feeding study, the storage stability of prothioconazole-desthio, M14 and M15 was demonstrated in all matrices for up to 1 month when stored deep frozen and was shown to cover the storage time interval of the residue samples of the feeding study. Degradation of prothioconazole-desthio residues during storage of the feeding study residue samples is therefore not expected. Consequently, the available data allow deriving tentative MRLs in ruminants and pigs. These MRLs were derived in compliance with the latest recommendations on this matter (FAO, 2009b). Tentative MRLs in all commodities are established at the LOQ, except in liver and kidney of ruminants, where MRLs of 0.05 and 0.02 mg/kg respectively are proposed. EFSA notes that all the MRLs in ruminant and pig matrices can only be derived on a tentative basis, due to the data gaps, leading to a provisional dietary burden calculation and the missing livestock feeding study. Finally, although the maximum dietary burden for poultry exceeds the threshold of 0.1 mg/kg DM, no appropriate feeding study is available and is required, since based on the metabolism study, no residues above the LOQ are expected in poultry matrices at the calculated dietary burden. Therefore, tentative MRLs can be established at the LOQ in all poultry commodities and no default conversion factors for risk assessment need to be derived.*

Table 7.2-13: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) ^(b)	Highest residue (mg/kg) ^(c)	Calculated MRL (mg/kg)	CF for RA ^(d)		
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) ^(a)	No	Result for enforce-ment		Result for RA							
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)						
EU data (EFSA, 2014)														
Enforcement residue definition: prothioconazole-desthio (sum of isomers).														
Risk assessment residue definition: sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).														
Pig muscle	0.017	0.031	0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	1.0		
			0.91	3	<0.01	<0.01	n.a.	n.a.						
			3.64	3	<0.01	<0.01	n.a.	n.a.						
Pig fat					0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	1.0
					0.91	3	<0.01	0.01	n.a.	n.a.				
					3.64	3	0.02	0.04	n.a.	n.a.				
Pig liver					0.15	3	0.02	0.03	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	2.0
					0.91	3	0.14	0.18	n.a.	n.a.				
					3.64	3	0.68	1.20	n.a.	n.a.				
Pig kidney			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	9.0		
			0.91	3	0.03	0.03	n.a.	n.a.						
			3.64	3	0.13	0.24	n.a.	n.a.						
Milk	0.028	0.086	0.15	42	<0.005(f)	N/A	n.a.	n.a.	<0.005	<0.005	0.005* (tentative)	1.0		
			0.91	42	<0.005(f)	N/A	n.a.	n.a.						
			3.64	39	0.005(f)	N/A	n.a.	n.a.						

Ruminant muscle	0.069	0.208	0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	1.0
			0.91	3	<0.01	<0.01	n.a.	n.a.				
			3.64	3	<0.01	<0.01	n.a.	n.a.				
Ruminant fat			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01* (tentative)	1.0
			0.91	3	<0.01	0.01	n.a.	n.a.				
			3.64	3	0.02	0.04	n.a.	n.a.				
Ruminant liver			0.15	3	0.02	0.03	n.a.	n.a.	0.01	0.042	0.05 (tentative)	2.0
			0.91	3	0.14	0.18	n.a.	n.a.				
			3.64	3	0.68	1.20	n.a.	n.a.				
Ruminant kidney			0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	0.012	0.02 (tentative)	9.0
			0.91	3	0.03	0.03	n.a.	n.a.				
			3.64	3	0.13	0.24	n.a.	n.a.				

N/A: Not applicable.

n.a.: Not analysed.

(a): Based on a 560 kg animal consuming approximately 20 kg feed DM/day.

(b): In the feeding study, residues were not determined according to the residue definition for risk assessment. Indeed, only prothioconazole-desthio, M14 and M15 were analysed.

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

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

(e): The tentative conversion factors for enforcement to risk assessment in liver and kidney were derived on the basis of the available metabolism study on ruminants. For muscle, fat and milk, no CF was derived as residue levels are expected at the maximum meat ruminant dietary burden in these matrices are negligible (<0.01 mg/kg).

(f): Mean residue level from day 1 or 4 until day 29 (3 cows, 13 or 14 sampling days).

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

Conclusion on feeding studies

Based on the overall metabolic picture of prothioconazole and prothioconazole-desthio in animals, the residue definition for enforcement in animal products was set as prothioconazole-desthio (sum of isomers) for all the livestock matrices. This compound is fat soluble. For risk assessment, the residue was defined in all commodities of animal origin as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).

Feeding studies that have been evaluated (EFSA, 2007b; FAO, 2008a, 2008b; United Kingdom, 2004, 2007) and tentative MRLs were set at EU level.

Applicant uses are covered by these studies, therefore no additional feeding study needs to be conducted. No exceedance of current MRLs are expected when the PPP is applied according to the intended GAP.

In addition, for Triazole derivative metabolites, the intake calculations for the maximum dietary burden of livestock using applicant residues data and according to UK, 2018, demonstrate that residues of T, TA, TAA and TLA are significant in the diets of livestock (>0.1 mg/kg in the diets). Poultry and ruminant feeding studies have been conducted with TA and TAA. Based on these feeding studies the TDM arising in products of animal origin, when animal feed items contain either TA or TAA, have been determined. However, NEDIs and NESTIs are expected to be below the ADI and ARfD respectively. However, it is noted in EFSA, 2018 a data gap was identified: “Poultry and ruminant feeding studies conducted with TLA or, alternatively, metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies to determine the magnitude of TLA residues in products of animal origin.”

This is a data GAP at EU level not strictly related to prothioconazole active ingredient. Triazole are common metabolites coming from several active ingredients.

Reviewing the residues of TDMs measured in samples coming from residue trials conducted with prothioconazole, residues are very low, and dietary burden calculation indicate values lower than dietary burden calculated in UK, 2018. No residue higher MRLs is expected in animal matrix.

In conclusion no chronic or acute health concerns is expected when the PPP is applied according to the intended GAP, no further study is needed for the present dossier application. After the active ingredient renewal, additional information will be submitted in the context of Art. 43 if the data will be considered as essential for prothioconazole.

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

7.2.4.1 Available data for all crops under consideration

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

7.2.5 Magnitude of residues in representative succeeding crops

No study on magnitude of residue is available. According to the available data EFSA concluded that prothioconazole residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crop.

No new study was submitted by the applicant.

7.2.5.1 Field rotational crop studies (KCA 6.6.2)

Available data

No study on magnitude of residue is available. According to the available data EFSA concluded that prothioconazole residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crop.

No new study was submitted by the applicant.

In EFSA 2018 the following data gap was indicated: “*Rotational crops field residue trials supported by acceptable storage stability data on TDMs*”. Please consider this is a data GAP at EU level not strictly related to prothioconazole active ingredient. Triazole are common metabolites coming from several active ingredients. According to the available data, no residue is expected in rotational crops. No further study is needed for the present dossier application. After the active ingredient renewal, additional information will be submitted in the context of Art. 43 if the data will be considered as essential for prothioconazole.

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

The applicant has conducted a residue study on honey in order to determine the magnitude of residue of prothioconazole-desthio in this matrix.

The study summary was provided in Appendix 2, while a short summary was reported below.

2 residue trials were conducted in Northern Europe and 2 in Southern EU in tunnel conditions. As surrogate crop, *phacelia* was used.

A worst case GAP has been selected for residue trials in order to cover all the uses in the intended GAP.

The trials were done according to the Guideline SANTE/11956/2016 rev. 9, 14 September 2018.

The analytical part of the study is still ongoing however, an Interim Report (KCA 6.10, Report N. QS21003) is available with the field data and the results of prothioconazole-desthio.

Trial	Specimen (analysed fraction)	Sample	Plot	Planned No. of Appl.	Nominal Rate/ Appl. (a.s. kg/ha)	Prothioconazole-desthio (mg/kg)
1	Honey	QG21003-003	2	2	0.8	<0.005
2	Honey	QG21003-007	2	2	0.8	0.012
3	Honey	QG21003-011	2	2	0.8	<0.005
4	Honey	QG21003-015	2	2	0.8	<0.005

When prothioconazole-desthio is applied according to the intended GAP, no residue higher than MRL is expected.

Table 7.2-13: Summary of new data supporting the intended uses of SIP41061 in honey 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
Residue definition for monitoring: prothioconazole-desthio (M04) (sum of isomers)								
Honey (<i>phacelia</i>)	New trials	S-EU	GAP: 2x 200 g as/ha, BBCH 67-69, interval between appl. 14d; PHI 8d Mo: <0.01; 0.012					
	New trials	N-EU	GAP: 2x 200 g as/ha, BBCH 67-69, interval between appl. 14d; PHI 8d Mo: 2<0.01					
	Overall data	N-EU + S-EU	Mo: 3x <0.01; 0.012	E: 0.01	E: 0.012	0.02	0.05	Yes

* Current EU MRLs are set in the Reg. (EU) 2019/552.

7.2.7 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).

7.2.7.1 Input values for the consumer risk assessment

Consumer intake calculations should be performed using the EFSA PRIMo model rev 3.1.

In the below assessment, the following input values have been used:

Prothioconazole-desthio and its hydroxy metabolites

- for the crops related to the current application, the residues expressed according to the current residue definition for RA: sum of prothioconazole-desthio (M04) and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxy propyl-2H-1,2,4-triazole moiety (M14, M15, M16, M17, M18) expressed as prothioconazole-desthio (sum of isomers).
- For other uses considered in previous assessments and supporting the existing MRLs, median residue or highest residues coming from EFSA, 2014 x CF

For the chronic risk assessment, the following input values for chronic intake calculations were used:

1) Uses related to the **current** application:

→ The STMRs derived for plant commodities from the supervised residue trials listed in below Table 5.1: **Table 7.2 15**

2) Other uses considered in previous assessments and supporting the existing MRLs listed in Regulation (EC) No 396/2005.

→ The STMRs derived for plant commodities used in EFSA, 2014 (Please refer to Table 7.2-15: Input values for the consumer risk assessment, pages 35-37 of EFSA, 2014)

For the acute risk assessment, the following input values were used:

1) Uses related to the **current** application:

→ The HR derived for plant commodities from the supervised residue trials and listed in the below Table 7.2-15

Triazoles (TDMs)

Consumer risk assessment was performed separately for each triazole metabolites using and input values residue coming from applicant residue trials and as toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

In the trials performed by the applicant, residues of TMDs were found in several crops >LOQ in control samples. This was probably due to a field normal background or to a precedent triazole formulated product application on the plot. Since it is difficult to evaluate the data, as worst case approach, residues

measured in treated samples were used for consumer risk assessment without subtracting the residues found in the respective control plot.

For the chronic and acute risk assessment, the following input values were used:

1) Chronic risk assessment:

→ The STMRs of each TDMs derived for plant commodities from the supervised residue trials, please see below Table 7.2-15b

2) Acute risk assessment:

→ The HR derived for plant commodities from the supervised residue trials and listed in the below Table 7.2-15b

Table 7.2-14: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)				
Crops under considerations – applicant intended uses				
Apples	0.058	STMR from SRT**	0.058	HR from SRT
Pears	0.058	STMR from SRT	0.058	HR from SRT
Quinces	0.058	STMR from SRT	0.058	HR from SRT
Medlar	0.058	STMR from SRT	0.058	HR from SRT
Loquats/Japanese medlars	0.058	STMR from SRT	0.058	HR from SRT
Apricots, peaches	0.07	STMR from SRT	0.10	HR from SRT
Plums	0.058	STMR from SRT	0.073	HR from SRT
Cherries	0.13	STMR from SRT	0.34	HR from SRT
Cucumbers	0.058	STMR from SRT	0.058	HR from SRT
Gherkins	0.058	STMR from SRT	0.058	HR from SRT
Courgette/zucchini	0.058	STMR from SRT	0.058	HR from SRT
Carrot	0.058	STMR from SRT	0.058	HR from SRT
Beetroots	0.058	STMR from SRT	0.058	HR from SRT
Horseradishes	0.058	STMR from SRT	0.058	HR from SRT
Parsnips	0.058	STMR from SRT	0.058	HR from SRT
Parsley root	0.058	STMR from SRT	0.058	HR from SRT
Salsifies	0.058	STMR from SRT	0.058	HR from SRT
Swedes	0.058	STMR from SRT	0.058	HR from SRT
Turnips	0.058	STMR from SRT	0.058	HR from SRT
Rapeseed	0.058	STMR from SRT	0.058	HR from SRT

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sugar beet	0.058	STMR from SRT	0.058	HR from SRT
Wheat	0.02	STMR from SRT	0.06	HR from SRT
Rye	0.02	STMR from SRT	0.06	HR from SRT
Barley	0.05	STMR from SRT	0.47	HR from SRT
Oat	0.05	STMR from SRT	0.47	HR from SRT
Honey	0.01	STMR from SRT	0.012	HR from SRT
Input values EFSA, 2014				
Potatoes	0.01*	Median residue ^(a)	-	-
Onions	0.02	Median residue x CF (tentative) ^(b)	-	-
Broccoli	0.02	Median residue x CF (tentative) ^(b)	-	-
Cauliflower	0.02	Median residue x CF (tentative) ^(b)	-	-
Brussels sprouts	0.06	Median residue x CF (tentative) ^(b)	-	-
Head cabbage	0.02	Median residue x CF (tentative) ^(b)	-	-
Leek	0.02	Median residue x CF (tentative) ^(b)	-	-
Peas (dry seed)	0.02	Median residue x CF (tentative) ^(b)		
Beans (dry seed)	0.02	Median residue x CF (tentative) ^(b)		
Linseed	0.06	Median residue x CF (tentative) ^(b)	-	-
Poppy seed	0.06	Median residue x CF (tentative) ^(b)	-	-
Mustard seed	0.06	Median residue x CF (tentative) ^(b)	-	-
Gold of pleasure	0.02	Median residue x CF (tentative) ^(b)	-	-
Maize grain	0.01*	Median residue ^(a)	-	-
Swine meat	0.01*	0.8 x Median muscle + 0.2 x Median fat (tentative) ^(c)	0.01*	0.8 x Highest muscle + 0.2 x Highest fat (tentative) ^(c)
Swine fat (free of lean meat)	0.01*	Median residue (tentative) ^(c)	0.01*	Highest residue (tentative) ^(c)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Swine liver	0.02	Median residue x CF (tentative) (c)	0.02	Highest residue x CF (tentative) (c)
Swine kidney	0.09	Median residue x CF (tentative) (c)	0.09	Highest residue x CF (tentative) (c)
Ruminant meat	0.01*	0.8 x Median muscle + 0.2 x Median fat (tentative) (c)	0.01*	0.8 x Highest muscle + 0.2 x Highest fat (tentative) (c)
Ruminant fat	0.01*	Median residue (tentative) (c)	0.01*	Highest residue (tentative) (c)
Ruminant liver	0.02	Median residue x CF (tentative) (c)	0.09	Highest residue x CF (tentative) (c)
Ruminant kidney	0.09	Median residue x CF (tentative) (c)	0.11	Highest residue x CF (tentative) (c)
Poultry meat	0.01*	0.8 x Median muscle + 0.2 x Median fat (tentative) (c)	0.01*	0.8 x Highest muscle + 0.2 x Highest fat (tentative) (c)
Poultry fat	0.01*	Median residue (tentative) (c)	0.01*	Highest residue (tentative) (c)
Poultry liver	0.01*	Median residue (tentative) (c)	0.01*	Highest residue (tentative) (c)
Ruminant milk	0.005*	Median residue (tentative) (c)	0.005*	Highest residue (tentative) (c)
Birds' eggs	0.01*	Median residue (tentative) (c)	0.01*	Highest residue (tentative) (c)

*: Indicates that the input value is proposed at the limit of analytical quantification.

** SRT: Supervised Residue Trials submitted by the applicant

(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.

(b): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.

(c): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not fully supported by data; the risk assessment values derived in section 3 are used for indicative exposure calculations.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: 1,2,4 Triazole				
Carrot	0.04	STMR from SRT	0.04	HR from SRT
Beetroots	0.04	STMR from SRT	0.04	HR from SRT

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Horseradishes	0.04	STMR from SRT	0.04	HR from SRT
Parsnips	0.04	STMR from SRT	0.04	HR from SRT
Parsley root	0.04	STMR from SRT	0.04	HR from SRT
Salsifies	0.04	STMR from SRT	0.04	HR from SRT
Swedes	0.04	STMR from SRT	0.04	HR from SRT
Turnips	0.04	STMR from SRT	0.04	HR from SRT
Rapeseed	0.04	STMR from SRT	0.04	HR from SRT
Sugar beet	0.04	STMR from SRT	0.04	HR from SRT
Wheat	0.01	STMR from SRT	0.01	HR from SRT
Rye	0.01	STMR from SRT	0.01	HR from SRT
Barley	0.01	STMR from SRT	0.011	HR from SRT
Oat	0.01	STMR from SRT	0.011	HR from SRT
Apples	0.04	STMR from SRT	0.04	HR from SRT
Pears	0.04	STMR from SRT	0.04	HR from SRT
Quinces	0.04	STMR from SRT	0.04	HR from SRT
Medlar	0.04	STMR from SRT	0.04	HR from SRT
Loquats/Japanese medlars	0.04	STMR from SRT	0.04	HR from SRT
Apricots	0.04	STMR from SRT	0.04	HR from SRT
Peaches	0.04	STMR from SRT	0.04	HR from SRT
Plums	0.04	STMR from SRT	0.04	HR from SRT
Cherries	0.04	STMR from SRT	0.04	HR from SRT
Cucumbers	0.04	STMR from SRT	0.04	HR from SRT
Gherkins	0.04	STMR from SRT	0.04	HR from SRT
Courgette/zucchini	0.04	STMR from SRT	0.04	HR from SRT
Risk assessment residue definition: Triazole Alanine				
Carrot	0.04	STMR from SRT	0.04	HR from SRT
Beetroots	0.04	STMR from SRT	0.04	HR from SRT
Horseradishes	0.04	STMR from SRT	0.04	HR from SRT
Parsnips	0.04	STMR from SRT	0.04	HR from SRT
Parsley root	0.04	STMR from SRT	0.04	HR from SRT
Salsifies	0.04	STMR from SRT	0.04	HR from SRT
Swedes	0.04	STMR from SRT	0.04	HR from SRT
Turnips	0.04	STMR from SRT	0.04	HR from SRT
Rapeseed	0.39	STMR from SRT	6.23	HR from SRT
Sugar beet	0.04	STMR from SRT	0.08	HR from SRT
Wheat	0.434	STMR from SRT	1.07	HR from SRT

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Rye	0.434	STMR from SRT	1.07	HR from SRT
Barley	0.208	STMR from SRT	0.44	HR from SRT
Oat	0.208	STMR from SRT	0.44	HR from SRT
Apples	0.04	STMR from SRT	0.04	HR from SRT
Pears	0.04	STMR from SRT	0.04	HR from SRT
Quinces	0.04	STMR from SRT	0.04	HR from SRT
Medlar	0.04	STMR from SRT	0.04	HR from SRT
Loquats/Japanese medlars	0.04	STMR from SRT	0.04	HR from SRT
Apricots	0.1	STMR from SRT	0.22	HR from SRT
Peaches	0.1	STMR from SRT	0.22	HR from SRT
Plums	0.04	STMR from SRT	0.04	HR from SRT
Cherries	0.06	STMR from SRT	1.11	HR from SRT
Cucumbers	0.04	STMR from SRT	0.04	HR from SRT
Gherkins	0.04	STMR from SRT	0.04	HR from SRT
Courgette/zucchini	0.04	STMR from SRT	0.04	HR from SRT
Risk assessment residue definition: Triazole Acetic Acid				
Carrot	0.04	STMR from SRT	0.04	HR from SRT
Beetroots	0.04	STMR from SRT	0.04	HR from SRT
Horseradishes	0.04	STMR from SRT	0.04	HR from SRT
Parsnips	0.04	STMR from SRT	0.04	HR from SRT
Parsley root	0.04	STMR from SRT	0.04	HR from SRT
Salsifies	0.04	STMR from SRT	0.04	HR from SRT
Swedes	0.04	STMR from SRT	0.04	HR from SRT
Turnips	0.04	STMR from SRT	0.04	HR from SRT
Rapeseed	0.04	STMR from SRT	0.1	HR from SRT
Sugar beet	0.04	STMR from SRT	0.04	HR from SRT
Wheat	0.189	STMR from SRT	0.517	HR from SRT
Rye	0.189	STMR from SRT	0.517	HR from SRT
Barley	0.058	STMR from SRT	0.307	HR from SRT
Oat	0.058	STMR from SRT	0.307	HR from SRT
Apples	0.04	STMR from SRT	0.04	HR from SRT
Pears	0.04	STMR from SRT	0.04	HR from SRT
Quinces	0.04	STMR from SRT	0.04	HR from SRT
Medlar	0.04	STMR from SRT	0.04	HR from SRT
Loquats/Japanese medlars	0.04	STMR from SRT	0.04	HR from SRT
Apricots	0.04	STMR from SRT	0.04	HR from SRT

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Peaches	0.04	STMR from SRT	0.04	HR from SRT
Plums	0.04	STMR from SRT	0.04	HR from SRT
Cherries	0.04	STMR from SRT	0.095	HR from SRT
Cucumbers	0.04	STMR from SRT	0.04	HR from SRT
Gherkins	0.04	STMR from SRT	0.04	HR from SRT
Courgette/zucchini	0.04	STMR from SRT	0.04	HR from SRT
Risk assessment residue definition: Triazole Lactic Acid				
Carrot	0.04	STMR from SRT	0.04	HR from SRT
Beetroots	0.04	STMR from SRT	0.04	HR from SRT
Horseradishes	0.04	STMR from SRT	0.04	HR from SRT
Parsnips	0.04	STMR from SRT	0.04	HR from SRT
Parsley root	0.04	STMR from SRT	0.04	HR from SRT
Salsifies	0.04	STMR from SRT	0.04	HR from SRT
Swedes	0.04	STMR from SRT	0.04	HR from SRT
Turnips	0.04	STMR from SRT	0.04	HR from SRT
Rapeseed	0.04	STMR from SRT	0.2	HR from SRT
Sugar beet	0.04	STMR from SRT	0.04	HR from SRT
Barley	0.01	STMR from SRT	0.01	HR from SRT
Oat	0.01	STMR from SRT	0.01	HR from SRT
Apples	0.04	STMR from SRT	0.04	HR from SRT
Pears	0.04	STMR from SRT	0.04	HR from SRT
Quinces	0.04	STMR from SRT	0.04	HR from SRT
Medlar	0.04	STMR from SRT	0.04	HR from SRT
Loquats/Japanese medlars	0.04	STMR from SRT	0.04	HR from SRT
Apricots	0.04	STMR from SRT	0.08	HR from SRT
Peaches	0.04	STMR from SRT	0.08	HR from SRT
Plums	0.04	STMR from SRT	0.04	HR from SRT
Cherries	0.04	STMR from SRT	0.157	HR from SRT
Cucumbers	0.04	STMR from SRT	0.04	HR from SRT
Gherkins	0.04	STMR from SRT	0.04	HR from SRT
Courgette/zucchini	0.04	STMR from SRT	0.04	HR from SRT

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-15: Consumer risk assessment - Prothioconazole

TMDI (% ADI) according to EFSA PRIMo rev 3.1	19% NL Toddler (based on apples) 13% NL child (based on sugar beet roots)
IEDI (% ADI) according to EFSA PRIMo	NR
IESTI (% ARfD) according to EFSA PRIMo rev 3.1	Unprocessed commodities: - 80% Pears - 63% Apples Processed commodities: - 64% Sugar beet root/sugar - 31% Apple/juice
NESTI (% ARfD)	NR

Table 7.2-17: Consumer risk assessment – 1,2,4 Triazole

TMDI (% ADI) according to EFSA PRIMo rev 3.1	4% (based on NL toddler, apple) 3% (based on NL child, sugar beet)
IEDI (% ADI) according to EFSA PRIMo	NR
IESTI (% ARfD) according to EFSA PRIMo rev 3.1	Unprocessed commodities 6% pears 4% apple Processed commodities 4% sugar beet (root) / sugar 2% apple/juice

Table 7.2-18: Consumer risk assessment – Triazole Alanine

TMDI (% ADI) according to EFSA PRIMo rev 3.1	2% (based on DK child, rye) 1% (based on GEMS/Food G06, wheat)
IEDI (% ADI) according to EFSA PRIMo	NR
TESTI (% ARfD) according to EFSA PRIMo rev 3.1	Unprocessed commodities 7% peaches 5% cherry Processed commodities 2% peaches / canned

Table 7.2-19: Consumer risk assessment – Triazole Acetic acid

TMDI (% ADI) according to EFSA PRIMo rev 3.1	0.2% (based on DK child, rye) 0.2% (based on NL Toddler, wheat)
IEDI (% ADI) according to EFSA PRIMo	NR
TESTI (% ARfD) according to EFSA PRIMo rev 3.1	Unprocessed commodities 0.6% pears 0.4% apple Processed commodities 0.4% sugar beet (root) / sugar

Table 7.2-20: Consumer risk assessment – Triazole Lactic acid

TMDI (% ADI) according to EFSA PRIMo rev 3.1	0.3% (based on NL toddler, apples) 0.2% (based on NL child, sugar beet roots)
IEDI (% ADI) according to EFSA PRIMo	NR
TESTI (% ARfD) according to EFSA PRIMo rev 3.1	Unprocessed commodities 3% peaches 2% pears Processed commodities 1% sugar beet (root) / sugar

RMS comment: Triazole alanine (TA) and triazole lactic acid (TLA)

TA and TLA can be assigned to a common assessment group. Therefore a combined risk assessment for these TDM can be performed by simple addition of NEDIs and NESTIs of both metabolites.

Since there is a large margin of safety, no further calculations are required .

The proposed uses of prothioconazole in the formulation SIP41061 do not represent unacceptable acute and chronic risks for the consumer.

7.3 Active substance 2

Not relevant in the frame of this application/not applicable.

7.4 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.5 References

EFSA (European Food Safety Authority), 2007. Conclusion on the peer review of the pesticide risk assessment of the active substance prothioconazole. The EFSA Journal 2007, 106r, 1-98. doi:10.2903/j.efsa.2007.106r

EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for prothioconazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(5):3689, 72 pp. doi:10.2903/j.efsa.2014.3689

United Kingdom, 2004. Draft assessment report on the active substance Prothioconazole prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, October 2004.

United Kingdom, 2007. Final addendum to the additional report and the draft assessment report on the active substance prothioconazole prepared by the rapporteur Member State United Kingdom in the framework of Council Regulation (EC) No 33/2008, compiled by EFSA, May 2007.

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

FAO (Food and Agriculture Organization of the United Nations), 2008a. Prothioconazole. In: Pesticide residues in food – 2008. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 193.

FAO (Food and Agriculture Organization of the United Nations), 2008b. Prothioconazole. In: Pesticide residues in food – 2008. Evaluations. Part I. Residues. FAO Plant Production and Protection Paper 194.

FAO (Food and Agriculture Organization of the United Nations), 2009a. Prothioconazole. In: Pesticide residues in food – 2009. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 196.

United Kingdom, 2018. Triazole Derivative Metabolites Addendum – Confirmatory Data. United Kingdom, February 2018

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1	Massardi E.	2022	Freezer storage stability of Prothioconazole Metabolites in 5 different matrices: high water commodity (zucchini), high oil commodity (oilseed rape seeds), high acid commodity (grape), dry commodity (peas dry seeds) and high starch commodity (sugar beet root) – 6 months checkpoint Report RAU-026-21 Final report Research Center BioSphereS by Biotecnologie BT GLP, unpublished.	N	Sipcam Oxon SpA
KCA 6.1/02	Massardi E.	2022	Freezer storage stability of 1,2,4-Triazole in 5 different matrices: high water commodity (apple), high oil commodity (oilseed rape seeds), high acid commodity (grape), dry commodity (peas dry seeds) and high starch commodity (sugar beet root) - 6 months checkpoint Report RAU-011-21 Final report Research Center BioSphereS by Biotecnologie BT GLP, unpublished.	N	Sipcam Oxon SpA
KCA 6.3.1/01	Terranegra A.	2021	Prothioconazole – Residue study on apple in Northern Europe – 2020 Report N. SPK-20-45305 Staphyt GLP, unpublished.	N	Sipcam Oxon SpA
KCA	Massardi E.	2022	Determination of prothioconazole metabolites residues in raw agricultural commodity apple after	N	Sipcam Oxon SpA

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
6.3.1/02			two applications of SIP41061 (Prothioconazole 400 g/L SC) – Central Europe, 4 decline trials, year 2021 Report N. RAU-008-21 Research Center BioSphereS by Biotecnologie BT GLP, unpublished.		
KCA 6.3.2/01	Massardi E.	2021	Determination of prothioconazole metabolites residues in raw agricultural commodity plum after two applications of SIP41061 (Prothioconazole 400 g/L SC) - Northern Europe, 4 trials, year 2020 Report N. RAU-024-20 Research Center BioSphereS by Biotecnologie BT GLP, unpublished.	N	Sipcam Oxon SpA
KCA 6.3.2/02	Massardi E.	2022	Determination of Prothioconazole metabolites residues in raw agricultural commodity plum after two applications of SIP41061 (Prothioconazole 400 g/L SC) – (Central Europe, 4 decline trials, year 2021). Report N. RAU-010-21 BioTecnologie BT. GLP, unpublished	N	Sipcam Oxon SpA
KCA 6.3.3/01	Terranegra A.	2021	Prothioconazole – Residue study on apricot and peach in Northern Europe – 2020 Report N. SPK-20-45307 Staphyt GLP, unpublished.	N	Sipcam Oxon SpA
KCA 6.3.3/02	Massardi E.	2022	Determination of prothioconazole metabolites residues in raw agricultural commodity apricot and peach after two applications of SIP41061 (Prothioconazole 400 g/L SC) – Central Europe, 2 trials, year 2021 Report N. RAU-009-21 Research Center BioSphereS by Biotecnologie BT GLP, unpublished.	N	Sipcam Oxon SpA
KCA 6.3.4/01	Massardi E.	2021	Determination of prothioconazole metabolites residues in raw agricultural commodity cherry after two applications SIP41061 (Prothioconazole 400 g/L SC) in open field conditions - 4 trials, Northern Europe, year 2020	N	Sipcam Oxon SpA

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
			RAU-017-20 Research Center BioSphereS by Biotecnologie BT GLP, unpublished.		
KCA 6.3.4/02	Massardi E.	2021	Determination of prothioconazole metabolites residues in raw agricultural commodity cherry after two applications of SIP41061 (Prothioconazole 400 g/L SC) – Central Europe, 4 decline trials, year 2021 RAU-011-21 Research Center BioSphereS by Biotecnologie BT GLP, unpublished.	N	Sipcam Oxon SpA
KCA 6.3.5/01	Casalinuovo L.	2021	Determination of prothioconazole in raw agricultural commodity zucchini following three applications of SIP41099 (Prothioconazole 200 g/L + azoxystrobin 250 g/L SC) in greenhouse conditions - Southern Europe, 4 trials, year 2020 Report N. BIU-021-20 Research Center BioSphereS by Biotecnologie BT GLP, unpublished.	N	Sipcam Oxon SpA
KCA 6.3.5/02	Casalinuovo L.	2022	Determination of prothioconazole metabolites residues in raw agricultural commodity zucchini following three applications of SIP41061 (Prothioconazole 400 g/L) in greenhouse conditions - Southern Europe, 4 trials, year 2021 Report N. BIU-017-21 Research Center BioSphereS by Biotecnologie BT	N	Sipcam Oxon SpA
KCA 6.3.6/01	Massardi E.	2021	Determination of prothioconazole metabolites residues in raw agricultural commodity carrot after two applications of SIP41099 (Prothioconazole 200 g/L + azoxystrobin 250 g/L SC) in open field conditions - 4 trials, Northern Europe, year 2020 Report N. RAU-021-20 Research Center BioSphereS by Biotecnologie BT GLP, unpublished.	N	Sipcam Oxon SpA
KCA 6.3.6/02	Massardi E.	2022	Determination of Prothioconazole metabolites residues in raw agricultural commodity carrot after two applications of SIP41061 (Prothioconazole 400 g/L SC) – (Central Europe, 4 trials, year 2021). Report N. RAU-017-21	N	Sipcam Oxon SpA

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
			BioTecnologie BT. GLP, unpublished.		
KCA 6.3.7/01	Massardi E.	2021	Determination of prothioconazole metabolites residues in raw agricultural commodity oilseed rape after two applications of SIP41099 (Prothioconazole 200 g/L + azoxystrobin 250 g/L SC) in open field conditions - 4 trials, Northern Europe, year 2020 Report N. RAU-015-20 BioTecnologie BT. GLP, unpublished	N	Sipcam Oxon SpA
KCA 6.3.7/02	Massardi E.	2022	Determination of prothioconazole metabolites residues in raw agricultural commodity oilseed rape after two applications of SIP41061 (Prothioconazole 400 g/L SC) in open field conditions – Central Europe, 4 trials, year 2021 Report N. RAU-014-21 BioTecnologie BT. GLP, unpublished	N	Sipcam Oxon SpA
KCA 6.3.8/01	Massardi E.	2021	Determination of prothioconazole metabolites residues in raw agricultural commodity sugar beet after two applications of SIP41099 (Prothioconazole 200 g/L + azoxystrobin 250 g/L SC) in open field conditions - 3 trials, Northern Europe, year 2020 Report N. RAU-020-20 BioTecnologie BT. GLP, unpublished	N	Sipcam Oxon SpA
KCA 6.3.8/02	Massardi E.	2022	Determination of prothioconazole metabolites residues in raw agricultural commodity sugar beet (roots) after two applications of SIP41061 (Prothioconazole 400 g/L SC) in open field conditions – Central Europe, 5 trials, year 2021 Report N. RAU-015-21 BioTecnologie BT. GLP, unpublished	N	Sipcam Oxon SpA
KCA 6.3.9	Andrews G.	2022	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole- desthio Metabolites Following Two Applications of a 250 g/L EC Formulation to Wheat in Northern and Southern Europe, 2020. Interim report N. QG20005	N	Sipcam Oxon SpA, Jiangsu Rotam Chemistry Co Ltd., Barclay

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
			Battelle UK GLP, unpublished		chemicals, UPL Europe limited
KCA 6.3.10	Andrews G.	2022	Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole- desthio Metabolites Following Two Applications of a 250 g/L EC Formulation to Barley in Northern and Southern Europe, 2020. Interim report N. QG20006 Battelle UK GLP, unpublished	N	Sipcam Oxon SpA, Jiangsu Rotam Chemistry Co Ltd., Barclay chemicals, UPL Europe limited
KCA 6.10/01	Andrews G.	2022	Interim report - Magnitude of Residues of Prothioconazole-desthio and Hydroxy-prothioconazole-desthio Metabolites in Honey Following Two Tunnel Applications of a Prothioconazole 250 g/L EC Formulation (FF-065) to Phacelia in Northern and Southern Europe, 2021 Report N. QG21003 Battelle UK GLP, unpublished	N	Sipcam Oxon SpA, Jiangsu Rotam Chemistry Co Ltd., Barclay chemicals, UPL Europe limited
KCA 6.10/02	Massardi E.	2022	Determination of Triazole Derivative Metabolites (TDMs) residues in various crop matrices Report N. RAU-028-21 BioTecnologie BT. GLP, unpublished	N	Sipcam Oxon SpA
KCA 6.10/03	Massardi E.	2022	Determination of Triazole Derivative Metabolites (TDMs) residues in various crop matrices Report N. RAU-024-22 BioTecnologie BT. GLP, unpublished	N	Sipcam Oxon SpA

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 5.1.2/07	Heinemann O.	2000a	Analytical determination of residues of JAU 6476 and desthio-JAU 6476 in/on cereals by HPLC/MS/MS 00598 Bayer AG GLP published	N	Bayer AG
KCP 5.1.2/08	Heinemann O.	2000b	Analytical determination of residues of JAU 6476 and desthio-JAU 6476 in/on cereals and canola by HPLC/MS/MS (method modification 00598/M001) 00598/M001 Bayer AG GLP published	N	Bayer AG
KCP 5.1.2/09	Schramel O.	2000	Residue analytical method 00610 (MR-643/99) for the determination of JAU 6476 and the metabolites JAU 6476-desthio and JAU 6476-S-methyl in soil by HPLC/MS/MS 00610 Bayer AG GLP published	N	Bayer AG
KCP 5.1.2/10	Sommer H.	2001b	Enforcement method 00684 for determination of JAU 6476 and JAU 6476-desthio in drinking and surface water by HPLC/MS/MS 00684 Bayer AG GLP published	N	Bayer AG
KCP 5.1.2/11	Maasfeld W.	2002	Method for the determination of JAU 6476 in air by HPLC/MS/MS 00724 Bayer AG GLP published	N	Bayer AG
KCP 5.1.2/12	Heinemann O.	2001a	Analytical determination of residues of JAU6476-sulfonic acid and JAU6476-desthio in/on cereals and canola by HPLC/MS/MS (method modification 00598/M001) 00647 Bayer AG GLP	N	Bayer AG

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
			published		
KCP 5.1.2/13	Weeren R.D., Pelz S.	2000	Modification M033 of method 00086: validation of DFG method S 19 (extended revision) for the determination of residues of JAU 6476-desthio in materials of plant and animal origin 00684 Bayer AG GLP published	N	Bayer AG
KCP 5.1.2/14	Heinemann O.	2001b	Analytical determination of residues of JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio and JAU6476-desthio in/on matrices of animal origin by HPLC/MS/MS 00655 Bayer AG GLP published	N	Bayer AG
KCP 5.1.2/15	Heinemann O.	2001c	Analytical determination of residues of JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio and JAU6476-desthio in milk by HPLC/MS/MS 00655/M001 Bayer AG GLP published	N	Bayer AG
KCP 5.1.2/16	Steinhauer S.	2001	Enforcement method 00086/M038 for the determination of the residues of JAU 6476-desthio in soil - : validation of DFG method S 19 (extended revision) 00086/M038 Dr. Specht&Partner GLP published	N	Bayer AG
KCP 5.1.2/17	Sommer H.	1999	Method for the determination of JAU6476 in test water from aquatic toxicity tests by HPLC [Tox/Ecotox method] 00699 Bayer AG GLP published	N	Bayer AG
KCA 6.0	Heinemann, O.	2001a	18 months storage stability of residues of JAU 6476 and JAU 6476-Desthio during frozen storage in/on wheat matrices	N	Bayer AG

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
			Bayer AG, Report No.: MR-282/00,Date:2001-09-13		
KCA 6.1.1 /01	Haas, M.; Bornatsch, W.	2000	Metabolism of JAU6476 in spring wheat (after foliar application) Bayer AG, Report No.: MR-198/99, Date:2000-07-10	N	Bayer AG
KCA 6.1.1 /02	Haas, M.	2001a	Metabolism of JAU 6476 in spring wheat after seed dressing Bayer AG, Report No.: MR-467/99, Date:2001-05-10	N	Bayer AG
KCA 6.1.1 /03	Vogeler, K.; Sakamoto, H.; Brauner, A.	1993	Metabolism of SXX 0665 in summerwheat Bayer AG, Report No.: PF3906, Date:1993-08-13	N	Bayer AG
KCA 6.1.1.1 /01	Haas, M.	2001b	Extraction efficiency testing of the residue method (00647) for the determination of JAU 6476 residues inspring wheat using aged radioactive residues Bayer AG, Report No.: MR-084/01,Date:2001-05-15	N	Bayer AG
KCA 6.1.2 /01	...	2001	Metabolism of [phenyl-UL-14C]JAU6476 in peanuts, Date:2001-11-27	Y	Bayer AG
KCA 6.2.2.1 /01	...	2001a	[Phenyl-UL-14C]JAU6476 Absorption, distribution, excretion andmetabolism in the lactating goat ... Date:2001-09-19	Y	Bayer AG
KCA 6.2.2.2 /01	2002	[Phenyl-UL-14C]JAU6476-desthioAbsorption, distribution, excretion, and metabolism in the lactating goat, Date:2002-02-28	Y	Bayer AG
KCA 6.2.2.2.1 /01	Weber, H.; Weber,E.; Spiegel, K.	2002	Validation of the residue analyticalmethod for the determination of JAU6476-desthio, JAU6476-3-hydroxy-desthio and JAU6476-4- hydroxy-desthio residues in animal matrices using aged radioactive residues Bayer AG, Report No.: MR-091/01Part 2, Date:2002-02-28	N	Bayer AG
KCA 6.2.2.3 /01	2001b	[Phenyl-UL-14C]JAU6476 Absorption, distribution, excretion andmetabolism in laying hens, Date:2001-10-29	Y	Bayer AG

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 6.3.2.1.1 /01	Heinemann, O.	2001b	Determination of residues of JAU 6476-Desthio on spring wheat following seed treatment of JAU 6476200 FS in Great Britain, Germany and France Bayer AG, Report No.: RA-2010/99, Report includes Trial Nos.: R 1999 0173/9 R 1999 0174/7 R 1999 0175/5 R 1999 0176/3 Date: 2001-09-18	N	Bayer AG
KCA 6.3.2.1.1 /02	Heinemann, O.	2001c	Determination of residues of JAU 6476-desthio on spring wheat following seed treatment of JAU 6476200 FS in Germany and France Bayer AG, Report No.: RA-2091/00, Report includes Trial Nos.: R 2000 0002/2 R 2000 0424/9 Date: 2001-09-28	N	Bayer AG
KCA 6.3.2.1.1 /03	Heinemann, O.	2001d	Determination of residues of JAU 6476-desthio in/on spring wheat following seed treatment of JAU 6476200 FS in Italy and France Bayer AG, Report No.: RA-2090/00, Report includes Trial Nos.: R 2000 0003/0 R 2000 0423/0 Date: 2001-09-17	N	Bayer AG
KCA 6.3.2.1.2 /01	Heinemann, O.	2001h	Determination of residues of JAU 6476-desthio on spring wheat and winter wheat following seed treatment of JAU 6476 200 FS and spray application of JAU 6476 250 EC in Germany, Northern France, and Great Britain Bayer AG, Report No.: RA-2003/99, Report includes Trial Nos.: R 1999 0023/6 R 1999 0025/2 R 1999 0026/0 R 1999 0027/9 R 1999 0266/2 Date: 2001-10-04	N	Bayer AG
KCA 6.3.2.1.2 /02	Heinemann, O.	2001i	Determination of residues of JAU 6476-desthio on spring wheat after spray application of JAU 6476 250 EC in Sweden, Germany, Northern France and Great Britain Bayer AG, Report No.: RA-2104/00, Report includes Trial Nos.: R 2000 0454/0 R 2000 0457/5 R 2000 0474/5 R 2000 0475/3	N	Bayer AG

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
			R 2000 0476/1Date:2001-11-29		
KCA 6.3.2.1.2 /04	Heinemann, O.	2001 l	Determination of residues of JAU 6476-desthio in/on wheat and triticaeafter spray application of JAU 6476 250 EC in Spain and France Bayer AG, Report No.: RA-2105/00,Report includes Trial Nos.: R 2000 0482/6 R 2000 0479/6 R 2000 0478/8 R 2000 0455/9Date:2001-12-06	N	Bayer AG
KCA 6.3.2.1.3 /01	Heinemann, O.	2001e	Determination of residues of JAU 6476-desthio on spring barley following seed treatment of JAU 6476200 FS and spray application of JAU6476 250 EC in Germany Bayer AG, Report No.: RA-2150/98,Date:2001-09-24	N	Bayer AG
KCA 6.3.2.1.3 /03	Heinemann, O.	2001j	Determination of residues of JAU 6476-desthio on spring barley after spray application of JAU 6476 250 ECin Sweden, Germany, Northern France and Great Britain Bayer AG, Report No.: RA-2101/00,Report includes Trial Nos.: R 2000 0452/4 R 2000 0456/7 R 2000 0462/1 R 2000 0464/8 R 2000 0465/6Date:2001-11-21	N	Bayer AG
KCA 6.3.2.1.3 /05	Heinemann, O.; Elke, K.	2001b	Determination of residues of JAU 6476-desthio in/on winter barley after spray application of JAU 6476 250 ECin France, Italy and Portugal Bayer AG, Report No.: RA-2144/98,Report includes Trial Nos.: R 1998 1317/6 R 1998 1571/3 R 1998 1572/1Date:2001-09-24	N	Bayer AG
KCA 6.3.2.1.3 /06	Heinemann, O.	2001 k	Determination of residues of JAU 6476-desthio in/on spring barley after spray application of JAU 6476 250 ECin Spain, Italy and Southern France Bayer AG, Report No.: RA-2103/00, Report includes Trial Nos.: R 2000 0473/7 R 2000 0472/9 R 2000 0470/2 R 2000 0453/2Date:2001-11-21	N	Bayer AG
KCA 6.4 /01	2001	JAU 6476-desthio - Dairy cattle feeding study	Y	Bayer AG

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
			... Date:2001-10-15		
KCA 6.5 /01	Gilges, M.	2001	Hydrolysis of JAU 6476 under conditions of processing Bayer AG, Report No.: MR-166/00, Date:2001-01-29	N	Bayer AG
KCA 6.6 /01	Haas, M.	2001c	Confined rotational crop study with JAU6476 Bayer AG, Report No.: MR-159/00, Date:2001-05-14	N	Bayer AG

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Prothioconazole

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

A 2.1.1.1.1.1 Study RAU-026-20

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference	KCA 6.1
Study:	<p>Freezer storage stability of Prothioconazole Metabolites in 5 different matrices: high water commodity (zucchini), high oil commodity (oilseed rape seeds), high acid commodity (grape), dry commodity (peas dry seeds) and high starch commodity (sugar beet root) – Interim report, 6 months checkpoint</p> <p>Massardi E., 2022</p> <p>Report N. RAU-026-20</p> <p>Research Center BioSphereS by Biotechnologie BT</p>
Guideline(s):	<p>Yes</p> <p>OECD 506</p>
Deviations:	<p>Yes</p> <p>Deviation No. 1 to the Study Plan: 22/09/2021 Description: At 3 months checkpoint the retain samples were analysed for matrices Peas dry seed and Sugar Beet root. New recovery and untreated samples were weighted starting from the blank matrices stored in the same conditions of the samples and analysed. Reason: Due to a problem in the instrumental analysis, the retain samples were extracted to confirm the data obtained on stored samples. Impact: None, a more reliable results were provided.</p> <p>Deviation No. 2 to the Study Plan: 24/09/2021 Description: At 3 months checkpoint the matrix Sugar beet root was extracted at 3 months + 6 days (2 day more than the 4 days tolerance range set in the Study Plan). Reason: The time elapsed is due to the necessity to analyse the retain samples. Impact: None, it is a worst case</p> <p>Deviation No. 3 to the Study Plan: 20/12/2021</p>

Description: At 6 months checkpoint the retain samples were analysed for matrix Sugar beet root. New recovery and untreated samples were weighted starting from the blank matrix stored in the same conditions of the samples and analysed.

Reason: The retain samples were extracted to confirm the data obtained on stored samples.

Impact: None, a more reliable results were provided.

Deviation No. 4 to the Study Plan: 29/12/2021

Description: At 6 months checkpoint the retain samples were analysed for matrix Peas dry seed. New recovery and untreated samples were weighted starting from the blank matrix stored in the same conditions of the samples and analysed.

Reason: Due to a problem in the instrumental analysis of the stored samples, the retain samples were extracted and analysed.

Impact: None.

Deviation No. 5 to the Study Plan: 03/01/2022

Description: At 6 months checkpoint the matrix Peas dry seed was extracted at 6 months + 13 days (8 day more than the 5 days tolerance range set in the Study Plan).

Reason: The time elapsed is due to the necessity to analyse the retain samples.

Impact: None, it is a worst case.

Deviation No. 6 to the Study Plan: 06/04/2022

Description: At 9 months checkpoint the matrix:

- Sugarbeet root was extracted at 9 months + 16 days (9 days more than the 7 days tolerance range set in the Study Plan).

- Grape was extracted at 9 months + 15 days (8 days more than the 7 days tolerance range set in the Study Plan).

- Oilseed rape seeds was extracted at 9 months + 18 days (11 days more than the 7 days tolerance range set in the Study Plan).

- Peas dry seeds was extracted at 9 months + 16 days (9 days more than the 7 days tolerance range set in the Study Plan).

Reason: Internal organization.

Impact: None, they are worst cases.

Deviation No. 7 to the Study Plan: 11/04/2022

Description: At 9 months checkpoint the retain samples were analysed for matrix Zucchini. New recovery and untreated samples were weighed starting from the blank matrix stored in the same conditions of the samples and analysed.

Reason: The retain samples were extracted to confirm the data obtained on stored samples.

Impact: None, a more reliable results were provided

Deviation No. 8 to the Study Plan: 12/04/2022

Description: At 9 months checkpoint the matrix Zucchini was extracted at 9 months + 27 days (20 days more than the 7 days tolerance range set in the Study Plan).

Reason: The time elapsed was due to the necessity to analyse the retain samples.

Impact: None, a more reliable results were provided.

Deviation No. 9 to the Study Plan: 23/06/2022

Description: At 12 months checkpoint the retain samples were analysed for matrix Sugar beet root. New recovery and untreated samples were weighed starting from the blank matrix stored in the same conditions of the samples and analysed.

Reason: The retain samples were extracted to confirm the data obtained on stored samples.

Impact: None, a more reliable results were provided.

GLP: Yes

Validity of the study:

Materials and methods

The objective of this Study is to determine the stability of Prothioconazole-desthio (M04) and its hydroxy metabolites M14, M15, M16, M17 and M18 in different plant matrices (according to OECD 506 guideline):

- Zucchini: high water commodity
- Oilseed rape seeds: high oil commodity
- Grape: high acid commodity
- Peas dry seeds: dry/high protein commodity
- Sugar beet root: high starch commodity

stored at T = -18°C for 12 months.

5 checkpoints have been scheduled at: 0 days, 3, 6, 9 and 12 months after spiking procedure that was carried out at the study start.

In this Study the stability of Prothioconazole metabolites M04, M14, M15, M16, M17 and M18 will be evaluated in five different plant matrices during a 12 months storage period at -18°C (according to OECD 506 guideline).

With this purpose untreated samples of each matrix, devoid of Prothioconazole metabolites were spiked at 0.1 mg/kg spiking level (10xLOQ) with a mix of M04, M14, M15, M16, M17 and M18 analytical standards.

After fortification step, the samples identified as “0 days” was immediately analysed (within two hours after spiking) in order to determine the residue of analytes in fresh sample. A control sample (unspiked) and two recovery tests at 0.01 mg/kg and 0.1 mg/kg spiking levels were also analysed. All the other samples were stored immediately after spiking in freezer at the Residue Analysis Unit, at -18 °C, and analysed at scheduled time points. An unspiked control sample per check point was stored and analysed at same scheduled time points.

Two additional samples (retain samples) per each checkpoint were spiked at study start (except for 0 days checkpoint), to be analysed in case some storage or analysis problems occur to the scheduled samples (or upon sponsor request). Moreover, two recovery tests at 0.01 mg/kg and 0.1 mg/kg spiking levels were performed at each scheduled check point on fresh sample in order to verify the efficiency of the analytical method during the study. For any unsuspected events, the blank matrix used for the study was stored in the same storage conditions as samples.

At each sampling point, the samples for each matrix were:

- Untreated sample
- Recovery sample at 0.01 mg/kg
- Recovery sample at 0.1 mg/kg
- Two stored samples at 0.1 mg/kg
- Two retain samples (analysed only if necessary).

The Analytical Phase was conducted using the method validated in the GLP Study RAU-003-21. In addition, reference was done to the GLP study BIU-019-20 where a reduced validation was carried out on zucchini samples. The method consists in extraction using acetonitrile and purification by Dispersive Solid Phase Extraction (D-SPE). The purified samples were finally analyzed with a HPLC system coupled with a Triple Quadrupole Mass analyzer (LC-MS/MS). A mean recovery of 70% - 110% with a Relative Standard Deviation lower than 20% was adopted as acceptability criteria, SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000).

The limit of quantification (LOQ) of the method used is 0.01 mg/kg for each analyte in each matrix.

Results and discussions

No interferences from the matrix were observed and the analytical method worked adequately, all validity criteria were met.

Considering the MRL change is related to crops which are all part of high water (pome fruits, stone fruits and cucurbits) or dry commodities (rice), only the results of these 2 groups were summarised. Please see the full report for the other commodity groups data.

Commodity	Level (mg/kg)	Storage interval (months)	Fresh recovery (Individual, %)	residues after storage (mg/kg)		Recovery (% day 0) Individual value	Recovery (% day 0) mean
				Individual values	mean		
Zucchini (high water)	0.1	0	103, 96.2	0.104, 0.107	0.105	103.5, 107	105
		3	98.9, 92.5	0.096, 0.096	0.096	95.9, 95.8	95.7
		6	91.8, 96.2	0.104, 0.11	0.107	104.1, 110.8	107.4
		9	77.1, 90.6	0.11, 0.115	0.11	110, 115	112
		12	101.5, 103.8	0.117, 0.119	0.118	117, 118	117
Sugar beet root (high starch)	0.1	0	85.6, 96.84	0.102, 0.11	0.1	101.5, 109.9	106
		3	99.2, 99.01	0.072, 0.076	0.07	71.5, 76.2	73.85
		6	78.67, 103.1	0.107, 0.106	0.1	107.1, 105.8	106.4
		9	109.3, 116.3	0.118, 0.119	0.1	117.7, 118.4	117
		12	91.7, 105.4	0.12, 0.119	0.1	119.9, 119	119
Peas dry seed (high protein)	0.1	0	87.5, 105.2	0.11, 0.11	0.1	106.6, 106	106
		3	96.6, 106	0.078, 0.08	0.079	78.0, 82.3	80
		6	95.3, 97.7	0.09, 0.097	0.09	89.8, 96.7	93
		9	100.9, 101.8	0.071, 0.077	0.074	71.3, 76.9	74
		12	109, 113	0.09, 0.097	0.093	90.9, 96.9	93
Grape (high acid)	0.1	0	86.4, 90.18	0.09, 0.091	0.09	89.9, 90.9	90
		3	79.3, 94.03	0.087, 0.091	0.089	86.5, 91.3	88.9
		6	86.6, 99.99	0.079, 0.072	0.075	78.5, 72.4	75.4
		9	90.6, 108.2	0.084, 0.087	0.0865	83.6, 87.4	85.5
		12	89.3, 104	0.10, 0.10	0.10	99.7, 101	100
OSR (high oil)	0.1	0	81.45, 83.0	0.086, 0.081	0.084	86.0, 80.8	83.4
		3	97.2, 91.4	0.10, 0.088	0.094	100.3, 87.8	94
		6	94.4, 98.8	0.099, 0.091	0.095	99.3, 91.2	95.2
		9	111.5, 104.7	0.10, 0.093	0.96	102.1, 92.9	97.5
		12	104.1, 98.5	0.10, 0.092	0.096	100.7, 91.5	96

Commodity	Level (mg/kg)	Storage interval (months)	Fresh recovery (Individual, %)	residues after storage (mg/kg)		Recovery (% day 0) Individual value	Recovery (% day 0) mean
				Individual values	mean		
Zucchini (high water)	0.1	0	101.7, 101	0.106, 0.109	0.107	105.8, 108.9	107
		3	119, 91.5	0.11, 0.083	0.096	110.7, 83.1	96.9
		6	101.1, 92.8	0.106, 0.11	0.108	105.7, 113.8	109.7
		9	94.8, 95.6	0.088, 0.090	0.089	88.2, 89.6	88.9
		12	106.7, 104.4	0.095, 0.098	0.097	94.6, 98.1	96

Table C.3.5.1.-2 Stability of M14 residues following storage at -18°C.							
Commodity	Level (mg/kg)	Storage interval (months)	Fresh recovery (Individual, %)	residues after storage (mg/kg)		Recovery (% day 0) Individual value	Recovery (% day 0) mean
				Individual values	mean		
Sugar beet root (high starch)	0.1	0	82.8, 90.1	0.095, 0.105	0.1	94.7, 104.9	99.8
		3	118.8, 84.9	0.09, 0.07	0.08	89.7, 71.3	80.5
		6	78.67, 103	0.073, 0.071	0.07	72.5, 70.5	71.5
		9	102.8, 116.1	0.065, 0.062	0.064	64.9, 61.8	63
		12	102.9, 101.6	0.049, 0.043	0.046	48.6, 43.2	46
Peas dry seed (high protein)	0.1	0	88.2, 96.8	0.097, 0.11	0.1	97.4, 107	102
		3	73.7, 82.2	0.099, 0.092	0.09	98.9, 91.7	94
		6	98, 95.6	0.089, 0.09	0.09	88.7, 89.6	89
		9	119.9, 106.9	0.078, 0.08	0.079	77.7, 79.9	78.8
		12	114, 104.8	0.084, 0.093	0.088	83.5, 92.9	88
Grape (high acid)	0.1	0	78.8, 95.1	0.09, 0.096	0.09	91.2, 95.4	93.3
		3	76.5, 97.3	0.11, 0.104	0.107	114.2, 103.6	108.9
		6	80.04, 100	0.085, 0.085	0.085	85.3, 85.4	85
		9	95.11, 104.9	0.075, 0.081	0.078	74.7, 80.6	77.6
		12	96.7, 105.4	0.086, 0.085	0.0855	86.3, 84.9	85.6
OSR (high oil)	0.1	0	81.5, 84.6	0.087, 0.085	0.086	86.5, 85.3	85.9
		3	119.7, 112.5	0.11, 0.103	0.106	114.3, 102.4	108.3
		6	97.6, 100.2	0.098, 0.0977	0.098	97.9, 97.6	97.7
		9	110.3, 96.5	0.117, 0.11	0.113	116.6, 110.9	113.7
		12	99.5, 97.3	0.10, 0.094	0.097	100.3, 94.1	97

Table C.3.5.1.-3 Stability of M15 residues following storage at -18°C.							
Commodity	Level (mg/kg)	Storage interval (months)	Fresh recovery (Individual, %)	residues after storage (mg/kg)		Recovery (% day 0) Individual value	Recovery (% day 0) mean
				Individual values	mean		
Zucchini (high water)	0.1	0	100.7, 103.5	0.106, 0.108	0.107	106.4, 108.3	107.3
		3	91.5, 82.5	0.096, 0.078	0.087	95.6, 78.1	86.8
		6	96.1, 95.08	0.10, 0.105	0.102	101.3, 105.5	103.4
		9	66.9, 89.1	0.093, 0.098	0.096	92.9, 97.6	95
		12	100.1, 101	0.11, 0.10	0.105	108, 100	104
Sugar beet root (high starch)	0.1	0	82.7, 85.9	0.092, 0.106	0.099	92.14, 106.2	99.2
		3	106, 85.5	0.086, 0.074	0.8	86.46, 73.77	80.1
		6	78.2, 102.6	0.037, 0.036	0.0365	37.49, 35.5	36.5
		9	101.5, 117	0.037, 0.038	0.0375	36.8, 38.1	37
		12	98.99, 103.7	0.024, 0.025	0.0245	24.44, 25	24.5
Peas dry seed (high protein)	0.1	0	84.2, 102	0.10, 0.11	0.1	102, 109.8	106
		3	72.4, 74.5	0.098, 0.08	0.09	98.5, 83.4	91
		6	98.3, 98.4	0.09, 0.097	0.09	92.2, 96.7	94
		9	109, 98.7	0.076, 0.075	0.075	76.1, 75.1	75.6
		12	106.8, 108.8	0.09, 0.09	0.09	91.3, 90.6	91
Grape (high acid)	0.1	0	86.25, 94.5	0.096, 0.098	0.097	95.6, 98.1	96.8
		3	82.4, 96.7	0.079, 0.082	0.080	78.99, 82.0	80.5
		6	81.7, 103.4	0.075, 0.078	0.076	75.5, 77.98	76.7
		9	91.7, 115.5	0.065, 0.063	0.064	64.9, 63.4	64
		12	98.45, 99.8	0.078, 0.074	0.076	77.86, 74.1	75.9

Table C.3.5.1.-3 Stability of M15 residues following storage at -18°C.							
Commodity	Level (mg/kg)	Storage interval (months)	Fresh recovery (Individual, %)	residues after storage (mg/kg)		Recovery (% day 0) Individual value	Recovery (% day 0) mean
				Individual values	mean		
OSR (high oil)	0.1	0	83.9, 77.3	0.085, 0.082	0.083	84.66, 82.4	83.5
		3	116.0, 108.5	0.106, 0.095	0.10	105.7, 95.2	100.4
		6	92.0, 98.1	0.106, 0.105	0.105	106.4, 105.2	105.8
		9	105.6, 87.9	0.107, 0.0998	0.10	107.1, 99.77	103
		12	87.9, 104.2	0.107, 0.105	0.106	106.7, 105	105.8

Table C.3.5.1.-4 Stability of M16 residues following storage at -18°C.							
Commodity	Level (mg/kg)	Storage interval (months)	Fresh recovery (Individual, %)	residues after storage (mg/kg)		Recovery (% day 0) Individual value	Recovery (% day 0) mean
				Individual values	mean		
Zucchini (high water)	0.1	0	101.4, 95.6	0.099, 0.097	0.098	98.7, 96.9	97.8
		3	83.05, 86.5	0.11, 0.08	0.095	109.6, 87.7	98.65
		6	98.9, 94.8	0.109, 0.11	0.11	108.7, 112	110.3
		9	66.3, 88.5	0.097, 0.10	0.099	97.5, 100	98.7
		12	119.8, 101	0.11, 0.10	0.105	108.7, 103	105.8
Sugar beet root (high starch)	0.1	0	71.5, 89.86	0.094, 0.105	0.099	93.84, 105.3	99.6
		3	116, 88.2	0.083, 0.075	0.079	83.1, 74.96	79
		6	77.9, 101.8	0.093, 0.089	0.091	92.6, 88.7	90.6
		9	101.5, 116.6	0.093, 0.088	0.09	92.8, 87.7	90
		12	80.05, 108.8	0.089, 0.09	0.09	89.1, 90.3	90
Peas dry seed (high protein)	0.1	0	86.9, 96.3	0.1, 0.11	0.1	104, 106.7	105
		3	74.3, 81.7	0.11, 0.094	0.1	106.6, 93.8	100
		6	102.5, 101.6	0.098, 0.11	0.1	97.6, 108.7	103
		9	92.4, 94.97	0.082, 0.082	0.08	81.7, 81.8	82
		12	87.5, 112	0.087, 0.092	0.09	87.2, 92.0	90
Grape (high acid)	0.1	0	80.3, 93.9	0.095, 0.094	0.094	94.76, 94.2	94.5
		3	82.2, 97.8	0.098, 0.10	0.099	97.88, 101.1	99.5
		6	84.9, 100.2	0.085, 0.091	0.088	85.1, 90.7	87.9
		9	75.3, 114.1	0.082, 0.082	0.082	81.7, 82.4	82
		12	92.2, 99.2	0.092, 0.095	0.0935	91.7, 94.5	93.1
OSR (high oil)	0.1	0	79.4, 83.36	0.086, 0.086	0.086	86.1, 86.3	86.2
		3	117.2, 106.4	0.11, 0.104	0.107	113.3, 104.4	108.8
		6	91.8, 100.7	0.11, 0.11	0.11	114.8, 111.7	113.2
		9	98.3, 103	0.117, 0.11	0.113	117, 108.7	112.5
		12	107.1, 91.36	0.11, 0.098	0.10	106.6, 97.6	102

Table C.3.5.1.-5 Stability of M17 residues following storage at -18°C.							
Commodity	Level (mg/kg)	Storage interval (months)	Fresh recovery (Individual, %)	residues after storage (mg/kg)		Recovery (% day 0) Individual value	Recovery (% day 0) mean
				Individual values	mean		

Table C.3.5.1.-5 Stability of M17 residues following storage at -18°C.							
Commodity	Level (mg/kg)	Storage interval (months)	Fresh recovery (Individual, %)	residues after storage (mg/kg)		Recovery (% day 0) Individual value	Recovery (% day 0) mean
				Individual values	mean		
Zucchini (high water)	0.1	0	105.1, 105	0.108, 0.109	0.108	108.1, 109.3	108.7
		3	93.9, 90.4	0.097, 0.093	0.095	97.2, 93.04	95.1
		6	93.0, 77.4	0.073, 0.072	0.07	72.6, 72.1	72.3
		9	80.4, 82.2	0.072, 0.071	0.0705	72.35, 70.7	71.5
		12	108, 101	0.064, 0.072	0.068	64.3, 72.36	68.3
Sugar beet root (high starch)	0.1	0	83.4, 92.86	0.097, 0.107	0.1	96.6, 106.8	101.7
		3	76.7, 109.3	0.071, 0.071	0.07	70.5, 70.48	70.5
		6	90.9, 99.9	0.077, 0.075	0.076	76.8, 75	75.9
		9	107.4, 112.5	0.072, 0.069	0.106	105.6, 106	106
		12	95.88, 103.3	0.091, 0.088	0.06	56.3, 63.2	56
Peas dry seed (high protein)	0.1	0	86.1, 101.3	0.1, 0.1	0.1	99.6, 103.1	101.3
		3	67.1, 92.7	0.11, 0.12	0.11	109.6, 120	115
		6	101.5, 91.6	0.048, 0.04	0.04	48.4, 44.7	46
		9	107.7, 104.9	0.072, 0.069	0.07	71.87, 69.4	70.6
		12	101.5, 107	0.091, 0.088	0.089	90.6, 87.9	89.2
Grape (high acid)	0.1	0	92.7, 91.2	0.09, 0.094	0.092	92.4, 93.88	93.1
		3	85.8, 87.4	0.093, 0.095	0.094	82.96, 94.6	88.78
		6	78.7, 97.8	0.078, 0.073	0.075	73.4, 73.2	73.3
		9	82.6, 103.8	0.074, 0.078	0.076	74.3, 78.1	76
		12	95, 101	0.065, 0.065	0.065	65, 64.6	65
OSR (high oil)	0.1	0	80.5, 81.57	0.084, 0.082	0.083	98.9, 81.7	90.3
		3	105.8, 91.7	0.103, 0.094	0.098	102.7, 94.3	98.5
		6	97.48, 96.76	0.107, 0.104	0.105	106.7, 103.5	105
		9	109.7, 98	0.105, 0.099	0.076	104.6, 98.4	103
		12	99.6, 102.3	0.10, 0.10	0.065	102.1, 102	102

Table C.3.5.1.-6 Stability of M18 residues following storage at -18°C.							
Commodity	Level (mg/kg)	Storage interval (months)	Fresh recovery (Individual, %)	residues after storage (mg/kg)		Recovery (% day 0) Individual value	Recovery (% day 0) mean
				Individual values	mean		
Zucchini (high water)	0.1	0	103.9, 101.4	0.105, 0.105	0.105	105.5, 105.2	105
		3	82.9, 96.05	0.103, 0.084	0.93	102.9, 83.68	93.3
		6	100.4, 96.11	0.11, 0.11	0.11	110.9, 115.7	113.3
		9	90.4, 90.7	0.098, 0.11	0.099	97.6, 106.9	102
		12	103.8, 101	0.11, 0.12	0.115	111, 117	114
Sugar beet root (high starch)	0.1	0	84.3, 85.6	0.09, 0.106	0.098	90.1, 106.3	98.2
		3	118.4, 82.9	0.085, 0.07	0.078	85.3, 73.4	79.35
		6	73.4, 99.8	0.11, 0.11	0.11	111, 113	112
		9	96.76, 118	0.117, 0.117	0.117	117.2, 116.8	117
		12	108.8, 104.4	108.8, 104.4	106	120, 116.2	118
Peas dry seed (high protein)	0.1	0	83.8, 101.8	0.1, 0.11	0.1	101.4, 108	105
		3	82.2, 88.3	0.099, 0.099	0.099	98.9, 99.3	99
		6	97, 96.3	0.09, 0.099	0.09	91.0, 99.2	95
		9	95.5, 100	0.078, 0.080	0.079	77.9, 80.2	79
		12	107, 108	0.089, 0.094	0.09	88.9, 93.7	91

Commodity	Level (mg/kg)	Storage interval (months)	Fresh recovery (Individual, %)	residues after storage (mg/kg)		Recovery (% day 0) Individual value	Recovery (% day 0) mean
				Individual values	mean		
Grape (high acid)	0.1	0	85.5, 94.44	0.094, 0.097	0.096	93.7, 97.1	95.4
		3	73.24, 78.7	0.073, 0.095	0.084	73.0, 95.2	84.1
		6	80.03, 92.8	0.084, 0.085	0.084	84.3, 84.7	84.5
		9	108.9, 104.4	0.078, 0.08	0.079	77.5, 80.5	79.0
		12	100.8, 104	0.097, 0.095	0.096	96.6, 95.3	95.9
OSR (high oil)	0.1	0	85.1, 83.8	0.082, 0.08	0.081	82.1, 80.5	81.3
		3	77.3, 70.9	0.11, 0.12	0.11	115.0, 118.9	116.9
		6	96.3, 100.8	0.108, 0.105	0.106	108.1, 105.1	106.6
		9	106, 106.8	0.112, 0.11	0.11	117.6, 112.5	115
		12	114.3, 100.4	0.105, 0.104	0.104	104.7, 104	104

According to the above tables:

- prothioconazole-desthio (M04) in the 5 commodities is stable for 6-12 months when they are stored at -18°C.
- M14 is stable for 6-12 months when they are stored at -18°C in all crops. A low degradation was observed in sugar beet root (high starch) however, the recoveries are still acceptable at 6 months (mean recovery 71.5%). A degradation was observed in sugar beet root (high starch), the storage stability is confirmed at 6 months of frozen condition in this matrix.
- M15 is stable for 6-12 months when they are stored at -18°C in zucchini (high water), peas dry seed (high protein), grape (high acid) and Oil seed rape (high oil). On the contrary at 6 months, a degradation was observed in sugar beet root (high starch), the recoveries are <70% (mean recovery 36.5%). The storage stability is confirmed at 3 months of frozen condition in high starch matrix.

The study is still ongoing and further analysis are planned after 9 and 12 months of storage. The confirmation of the degradation of this metabolite will be evaluated when the other data are available.

- M16 in the 5 commodities is stable for 6-12 months when they are stored at -18°C.
- M17:
 - is stable for 6-12 months when they are stored at -18°C in zucchini (high water), sugar beet root (high starch), grape (high acid) and Oil seed rape (high oil). Even if a degradation was observed in zucchini and grape samples, a good recovery was measured in both crops (>65%) confirmed a storage stability of 12 months in these matrices.
 - On the contrary at 6 months, a degradation was observed in peas dry seed (high protein), the recoveries are <70% (mean recovery 36.5%). However, the analysis performed after 9 and 12 months of storage, confirmed a good stability of this metabolite in frozen conditions. Probably there was some issue with the analytical method at the 6 months interval.
 - The study is still ongoing and further analysis are planned after 9 and 12 months of storage. The confirmation of the degradation of this metabolite will be evaluated when the other data are available.
- M18 in the 5 commodities is stable for 6-12 months when they are stored at -18°C.

Conclusion

M04 and all its hydroxy metabolites (M14, M15, M16, M17 and M18 which are all components included in the risk assessment residue definition) are stable in the 5 crop groups for 6 months when they are stored at -18°C. The only exceptions are the metabolites M14, M15 and M17 which degrade in high starch matrix (sugar beet root) after 6, 3 and 9 months respectively.

~~The only exceptions are the metabolite M15 which degrades in high starch matrix and M17 which degrades in high protein matrix.~~
~~The study is still ongoing and further analysis are planned after 9 and 12 months of storage. The confirmation of the stability of these metabolites will be evaluated when the other data will be available.~~

A 2.1.1.1.2 Study RAU-026-20

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference

KCA 6.1/02

Study:

Freezer storage stability of 1,2,4-Triazole in 5 different matrices: high water commodity (apple), high oil commodity (oilseed rape seeds), high acid commodity (grape), dry commodity (peas dry seeds) and high starch commodity (sugar beet root) - 6 months checkpoint

Report RAU-011-21

Massardi E., 2022

Report N. RAU-026-20

Research Center BioSphereS by Biotechnologie BT

Guideline(s):

Yes

OECD 506

Deviations:

Yes

Deviation No. 1 to the Study Plan: 22/09/2021

Description: At 6 months checkpoint the retain samples were analysed for matrix peas dry seeds. A recovery sample at 10XLOQ level was weighted starting from the blank matrix stored in the same conditions of the samples and analysed.

Reason: sponsor request.

Impact: None.

Deviation No. 2 to the Study Plan: 25/01/2023

Description: At 9 months checkpoint the retain samples were analysed for matrix peas dry seeds. A recovery sample at 10XLOQ level was weighted starting from the blank matrix stored in the same conditions of the samples and analysed.

Reason: To confirm the data obtained on stored samples.

Impact: None.

Deviation No. 3 to the Study Plan: 22/03/2023

Description: At 11 months checkpoint the retain samples were analysed for matrix apple. A recovery sample at 10XLOQ level was weighted starting from the blank matrix stored in the same conditions of the samples and analysed.

Reason: To confirm the data obtained on stored samples.

Impact: None.

Deviation No. 4 to the Study Plan: 26/04/2023

Description: At 12 months checkpoint the retain samples were analysed for matrix apple. A recovery sample at 10XLOQ level was weighted starting from the blank matrix stored in the same conditions of the samples and analysed.

Reason: To confirm the data obtained on stored samples.
Impact: None.

GLP:

Yes

Validity of the study:

Materials and methods

The objective of this Study is to determine the stability of 1,2,4-Triazole in different plant matrices according to OECD 506 guideline:

- Apple: high water commodity
- Oilseed rape seeds: high oil commodity
- Grape: high acid commodity
- Peas dry seeds: dry commodity
- Sugar beet root: high starch commodity

stored at T = -18°C for 24 months.

5 checkpoints have been scheduled at: 0 days, 6, 12, 18 and 24 months after spiking procedure that was carried out at the study start.

In this Study the stability of 1,2,4-Triazole will be evaluated in five different plant matrices during a 24 months storage period at -18°C according to OECD 506 guideline. With this purpose untreated samples of each matrix, devoid of 1,2,4-Triazole, were spiked at 0.40 mg/kg spiking level (10xLOQ) with the analytical standard.

After fortification step, the samples identified as “0 days” was immediately analysed (within two hours after spiking) in order to determine the residue of analyte in fresh sample. A control sample (unspiked) and two recovery tests at 0.04 mg/kg and 0.40 mg/kg spiking levels were also analysed. All the other samples were stored immediately after spiking in freezer at the Residue Analysis Unit, at -18 °C, and analysed at scheduled time points. An unspiked control sample per check point was stored and analysed at same scheduled time points.

Two additional samples (retain samples) per each checkpoint were spiked at study start (except for 0 days checkpoint), to be analysed in case some storage or analysis problems occur to the scheduled samples (or upon sponsor request). Moreover, two recovery tests at 0.04 mg/kg and 0.40 mg/kg spiking levels were performed at each scheduled check point on fresh sample in order to verify the efficiency of the analytical method during the study. For any unsuspected events, the blank matrix used for the study was stored in the same storage conditions as samples

At each sampling point, the samples for each matrix were:

- Untreated sample
- Recovery sample at 0.04 mg/kg
- Recovery sample at 0.4 mg/kg
- Two stored samples at 0.4 mg/kg
- Two retain samples (analysed only if necessary).

The Analytical Phase was conducted using the method validated in the GLP Study RAU-027-21 “Validation of the analytical method to determine Triazole Derivative Metabolites (TDMs) in high water commodity (apple), high acid commodity (grapes), oil commodity (oilseed rape seeds), and dry commodity (peas dry seeds)”, Sponsor Sipcam Oxon S.p.A., Study Director Elisa Massardi, year 2021.

In addition, reference was done to the GLP study RAU-028-21 “Determination of Triazole Derivative Metabolites (TDMs) residues in various crop matrices”, Sponsor Sipcam Oxon S.p.A., Study Director Elisa Massardi, year 2021, where a reduced validation was carried out on sugar beet roots samples. The

method consists in extraction using methanol with 1% formic acid and, if necessary, a purification step by C18-sorbent (Discovery DSC-18). The extracted samples were finally analyzed with a HPLC system coupled with a Triple Quadrupole Mass analyzer with Differential Mobility Spectrometry (LC-DMS/MS/MS)

The limit of quantification (LOQ) of the method used is 0.04 mg/kg for the analyte in each matrix.

Results and discussions

No interferences from the matrix were observed and the analytical method worked adequately, all validity criteria were met.

Table C.3.5.1. 7 — Stability of 1,2,4 triazole residues following storage at -18°C							
Commodity	Level (mg/kg)	Storage interval (months)	Fresh recovery (Individual, %)	residues after storage (mg/kg)		Recovery (% day 0) Individual value	Recovery (% day 0) mean
				Individual values	mean		
Apple (high water)	0.4	0 6	103.3, 93.77 82.4, 91.73	0.375, 0.378 0.29, 0.288	0.37 0.29	93.5, 94.22 72.6, 71.7	93.85 72.1
Sugar beet root (high starch)	0.4	0 6	93.8, 93.1 101.8, 87.6	0.394, 0.391 0.298, 0.296	0.39 0.29	98.2, 97.5 74.36, 73.86	97.8 74
Grape (high acid)	0.4	0 6	95.9, 100.9 100.7, 100.2	0.396, 0.386 0.253, 0.223	0.39 0.24	98.6, 96.3 63.0, 55.5	97 59.2
OSR seed (high oil)	0.4	0 6	101.8, 100.1 84.3, 78.56	0.38, 0.35 0.084, 0.098	0.365 0.09	94.8, 87.22 20.9, 24.5	91 22.7
Peas dry seed (high protein/dry)	0.4	0 6	73.58, 90.54 93.36, 79.54	0.389, 0.37 0.283, 0.267*	0.38 0.27	96.95, 92.49 70.57, 66.45	94.7 68.5

*retain samples

Conclusion

1, 2 4 triazole is stable in apple, sugar beet root and peas dry seed for 6 months when they are stored at -18°C. The stability of grape (high acid) will be evaluated once available the analysis of 9 months of storage. At the moment a degradation is observed. According to the available data, the instability of 1,2,4 triazole is confirmed in OSR grain matrix. After 6 months of storage, a strong degradation was observed. The study is still ongoing and further analysis are planned after 9 and 12 months of storage. The confirmation of the stability of these metabolites will be evaluated when the other data will be available.

Table C.3.5.1.-7 Stability of 1,2,4 triazole residues following storage at -18°C.

Commodity	Level (mg/kg)	Storage interval (months)	Fresh recovery (Individual, %)	residues after storage (mg/kg)		Recovery (% fortification level Nominal 0.4 mg/kg) Individual value	Recovery (% day 0) mean
				Individual values	mean		
Apple (high water)	0.4	0	103.3, 93.77	0.375, 0.378	0.37	93.5, 94.22	100.0
		6	82.4, 91.73	0.29, 0.288	0.29	72.6, 71.7	78.38
		9	100.3, 96.6	0.26, 0.247	0.25	65.5, 61.6	67.57
		11	89.9, 93.9, 80.0	0.25, 0.276, 0.24, 0.27	0.26	61.2, 68.7, 60.9, 67.7	70.27
		12	108.7, 100.9, 104.5	0.26, 0.28, 0.29, 0.28	0.277	64.6, 70.2, 73.4, 70.0	74.86
Sugar beet root (high starch)	0.4	0	93.8, 93.1	0.394, 0.391	0.39	98.2, 97.5	100.0
		6	101.8, 87.6	0.298, 0.296	0.29	74.36, 73.86	74.36
		9	109.4, 87.3	0.328, 0.33	0.33	81.78, 83.3	84.62
		11	108.9, 109	0.38, 0.326	0.35	95.6, 81.37	89.74
		12	104.9, 109.3	0.36, 0.32	0.34	89.1, 79.3	87.18
Grape (high acid)	0.4	0	95.9, 100.9	0.396, 0.386	0.39	98.6, 96.3	100.0
		6	100.7, 100.2	0.253, 0.223	0.24	63.0, 55.5	61.54
		9	110, 91.3	0.26, 0.24	0.25	65.4, 60.4	64.10
		11	79.8, 97.3	0.225, 0.25	0.25	56.0, 62.37	64.10
		12	100.7, 100.2	0.24, 0.27	0.255	60.99, 62.37	65.38
OSR seed (high oil)	0.4	0	101.8, 100.1	0.38, 0.35	0.365	94.8, 87.22	100.0
		6	84.3, 78.56	0.084, 0.098	0.09	20.9, 24.5	24.66
		9	83.79, 82.1	0.076, 0.08	0.078	19.0, 20.0	21.37
		11	95.6, 88.9	0.10, 0.10	0.10	25.8, 26.0	27.40
		12	111.2, 88.3	0.088, 0.096	0.09	21.89, 24.0	24.66
Peas dry seed (high pro- tein/dry)	0.4	0	73.58, 90.54	0.389, 0.37	0.38	96.95, 92.49	100.00
		6	93.36, 79.54, 89.9	0.27, 0.25, 0.28, 0.27	0.267	67.0, 61.7, 70.57, 66.45	70.26
		9	79.7, 71.5, 107	0.28, 0.20, 0.28, 0.27	0.257	69.8, 50.7, 70.3, 67.6	67.63
		11	94.0, 84.5	0.287, 0.25	0.268	71.5, 61.3	70.53
		12	78.3, 75.6	0.25, 0.30	0.275	62.3, 75.6	72.37

Conclusion:

According to the available data, 1, 2 4 triazole is stable in high water (apple), high starch (sugar beet root) and dry commodity (peas dry seed) for 12 months when they are stored at -18°C.

In grape samples a degradation was observed after 6 months of frozen storage condition, however after that period, the 1,2,4 triazole remain stable in this crop with recoveries measured at each storage interval >60%. Considering that after 12 months of storage the mean recovery was found at 65%, the 1,2,4 T was considers stable in high acid matrix.

On the contrary a strong degradation was observed in high oil matrix (OSR seed) confirming the 1,2,4 triazole is not stable in this crop.

A 2.1.1.1.2 Storage stability of residues in animal products

No new study is submitted as 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

No new studies are submitted as not required.

A 2.1.2.1.1 Nature of residue in primary crops

No new studies are submitted as not required.

A 2.1.2.1.2 Nature of residue in rotational crops

No new studies are submitted as not required.

A 2.1.2.1.3 Nature of residues in processed commodities

No new studies are submitted as not required.

A 2.1.2.2 Nature of residues in livestock

No new studies are submitted as not required.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Apple

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2014)	-	-	-	-	-
Intended cGAP (number 6a)	2	120 g as/Ha	7-10 days	BBCH 39-85	14
Intended cGAP (number 6b)	2	120 g as/Ha	7-10 days	BBCH 39-85	21

A 2.1.3.1.1 Study SPK-20-4505

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference: KCA 6.3.1/01

Report Prothioconazole – Residue Study on Apple in Northern Europe – 2020.
Terranegra A., 2021
Report N. SPK-20-45305
Staphyt Italia S.R.L.

Guideline(s): GLP Guidelines:
The Italian GLP guidelines indicated by “Decreto Legislativo N° 50 del 2/03/2007”.
The OECD Principles of Good Laboratory Practice (as Revised in 1997), OECD Series on Principles of GLP and Compliance Monitoring Number 1, ENV/MC/CHEM(98)17.
The national requirements are compatible with Good Laboratory Practice regulations specified by regulatory authorities throughout the European Community, the United States of America (EPA and FDA) and Japan (MHLW, MAFF and METI).
The Application of GLP Principles to Field Studies, OECD Series on Principles of GLP and Compliance Monitoring Number 6 (Revised 1999), ENV/JM/MONO(99)22.
Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, OECD Series on Principles of GLP and Compliance Monitoring Number 13, ENV/JM/MONO(2002)9.
Field guidelines:
General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95 rev.5, 22 July 1997).

OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published on 7 September 2009).

Analytical guidelines:

EC - Guidance documents on residual analytical methods SAN-TE/2020/12830 rev.1

Guidance Documents on Pesticide Residue Analytical Methods (SAN-CO/825/00 rev.8.1, 16 Nov. 2010).

OECD (2007): Guidance Document on Pesticide Residue Analytical Methods

ENV/JM/MONO (2007)17.

Deviations:

Deviation n° 1: 22/04/2021

Description: The Internal code of delegate phase RAU-022-20 is not in compliance with SOP

MNG005-03, however the internal code was leaved as RAU-022-20 even if, due to internal

laboratory organisation, the analytical phase was conducted in 2021 instead of 2020.

Reason: The code has been taken before 2021.

Impact: None

Deviation n° 2: 29/04/2021

Description: The flow changed from 0.25 mL/min to 0.4 mL/min.

Reason: A different column (Kinetex 2.6 µm F5 100A 100 x 3.00 mm), with the same characteristic of previous one (Kinetex 2.6 µm PFP 100A 100 x 2.10 mm), has been used.

Impact: None.

Deviation n° 3:

Description: Test item storage temperature reached 28.5°C as maximum temperature.

Impact: None.

Deviation n° 4:

Description: Internal code not in compliance with internal SOP.

Impact: None.

Deviation n° 5:

Description: The flow changed from 0.25 mL/min to 0.4 mL/min.

Impact: None.

GLP:

Yes

Acceptability:

Table A 21: Summary of the study SPK-20-45305 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or 2.Flowering 3. Harvest	Application rate per treat- ment				Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI (days)	Remarks
			App. N.	g a.s./ ha	Water (l/ha)	g a.s./hl				M04	M14, M15, M16, M17, M18	Sum as M04*		
France Centre Val de Loire 37110 Dame Marie les Bois Trial number SPK-20- 45305 FR01	Apple Golden	1- 2011 2- From 12 to 25/04/2020 3- - From 15 to 22/09/2020	A1	122	785	16	27/08/2020	85	Fruits	0.0172	N.D.	N.D.	14	The analytical method was validated in study RAU- 003-20. Mean recovery fruit: M04: 91.29% M14: 95.24% M15: 95.24% M16: 95.59% M17: 97.54% M18: 94.83%
			A2	122	781		03/09/2020							
Hungary Csongrad county 6795 Bordány Trial number SPK-20- 45305 HU02	Apple Jonagored	1- before 2008 2- From 12 to 29/04//2020 3- - 16/09/2020	A1	125	1003	12	24/08/2020	85	Fruits	<0.01 (0.0083)	N.D.	N.D.	14	RSD M04: 5.43% M14: 5.52% M15: 5.95% M16: 5.01% M17: 4.45% M18: 6.05%
			A2	125	1000		31/08/2020							
Poland Wielkopolska 62-310 Pyzdry Trial number SPK-20- 45305 PL03	Apple Red gala	1- 04/03/2019 2- From 20/04 to 09/05/2020 3- - 26/08/2020	A1	127	1021	12	05/08/2020	85	Fruits	0.0390	N.D.	N.D.	14	Time interval between sampling and sample extraction: 246 days
			A2	127	1019		12/08/2020							
Poland Warmińsko – Mazurskie 11-010 Bark	Apple Antonovka	1- 15/09/2004 2- From 04 to 27/05/2020	A1	123	989	12	25/08/2020	85	Fruits	0.0224	N.D.	N.D.	14	LOQ single analyte: 0.01 mg/kg
			A2	122	975		01/09/2020							

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treat- ment				Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI (days)	Remarks
			App. N.	g a.s./ ha	Water (l/ha)	g a.s./hl				M04	M14, M15, M16, M17, M18	Sum as M04*		
Trial number SPK-20- 45305 PL04		3- - 15/09/2020												LOD single analyte: 0.003 mg/kg

(a) According to Codex Classification/Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

N.A.- Not Available N.D.= Not Detectable (lower than Limit of Detection)

*Residue of sum expressed as M04 (mg/kg) = residue of M04+ M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04

A 2.1.3.1.2 Study RAU-008-21

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference: KCA 6.3.1/02
Determination of Prothioconazole metabolites residues in raw agricultural commodity apple after two applications of SIP41061 (Prothioconazole 400 g/L SC) – (Central Europe, 4 decline trials, year 2021 Massardi E., 2022
Report N. RAU-008-21
Research Center BioSphereS by Biotechnologie BT

Guideline(s): Yes
OECD 509
SANTE/2019/12752

Deviations: Yes
Deviation No. 1 for the trial F/PR21/AP01: 01/09/2021
Description/PI's answer: For application 2 the deviation to the target dose was +14.7% instead of $\pm 5\%$ requested in the study plan.
Impact: The residues measured in this trial are higher than the ones measured in the other field samples. The higher dose rate may have caused the increase. The impact is none considering this a worst case.
Deviation No. 2 for the trial F/PR21/AP01: 30/11/2021
Description/PI's answer: The farmer cannot provide the pesticide history for 2019.
Impact: No impact.
Deviation No. 3 for the trial F/PR21/AP01: occurred from 08/09/2021 to 06/10/2021, Issued on 15/03/2022
Description/PI's answer: During storage of specimens in industrial freezer 71CE02, the data logger used to record temperatures did not work. Temperatures could not be recorded with a GLP validated system, however the industrial site where specimens were stored could provide records which showed that temperatures were always below -20°C. Specimens were stored in frozen conditions ($\leq -18^\circ\text{C}$). Temperatures will be excluded from the GLP compliance of the raw data.
Impact: No impact.
Deviation No. 4 for the trial F/PR21/AP01: occurred on 25/08/2021, issued on 18/03/2022
Description/PI's answer: The trialist Jeremy Rossignol did not sign the sheet "information sur les precautions à prendre" regarding the test item use. The technician left the company. However, all precautions have been taken by the technician during the application in order to guarantee his safety. Moreover, the technician had access to the Safety Data Sheet.
Impact: No impact.

GLP: Yes

Acceptability:

Table A 32: Summary of the study RAU-008-21 trials

Report No. Location	Commodity/ Variety	Date of (b) 1) Sowing or Transplanting 2) Flowering 3) Harvest	Application details			Dates of Treatment (s) or No. of Treat- ment and Last Date (c)	Growth Stage at Last Treatment or Date	Residues (mg/kg)							PHI (Days) (d)	Remarks
			g ai/ha	Water L/ha	g ai/ hL			M04	M14	M15	M16	M17	M18	SUM as M04*		
RAU-008-21 F/PR21/AP01 67170 Brumath France	Apple / Pink gold	1) year 2018 2) from 18/04 to 30/04/2021 3) 08/09/2021 14/09/2021 22/09/2021 29/09/2021	119.2	597	20	25/08/2021	85	0.0714	<0.01 (0.0039)	N.D.	N.D.	N.D.	<0.01 (0.0032)	0.0867	7	Analytical method vali- dated in RAU- 003-20 (see section B5 for full details)
								0.065	<0.01 (0.0034)	N.D.	N.D.	N.D.	<0.01 (0.0039)	0.0805	13	
			137.6	690		01/09/2021		0.0813	<0.01 (0.0035)	N.D.	N.D.	N.D.	<0.01 (0.0048)	0.0978	21	
								0.075	N.D.	N.D.	N.D.	N.D.	<0.01 (0.0053)	0.0915	28	
RAU-008-21 H/PR21/AP02 6795 Bordány Hun- gary	Apple / Jonagored	1) before 2010 2) from 12/04 to 26/04/2021 3) 26/08/2021 03/09/2021 09/09/2021 16/09/2021	119.2	896	13	13/08/2021	83	0.0178	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058	6	Mean recovery fruit: M04: 98.94% M14: 99.91% M15: 95.98% M16: 99.61% M17: 100.30% M18: 100.88%
								0.0127	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058	14	
			116.8	877		20/08/2021		0.0104	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058	20	
								<0.01 (0.0095)	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058	27	
RAU-008-21 P/PR21/AP03 89-240	Apple / Cortland	1) 14/04/1995 2) from 10/04 to 25/04/2021 3) 08/09/2021 15/09/2021	114.4	952	12	24/08/2021	81	0.0184	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058	7	M04: 6.85% M14: 9.83% M15: 4.23% M16: 9.34% M17: 5.10% M18: 8.89%

Miastowice Poland		22/09/2021 29/09/2021				01/09/2021		0.0177	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058	14	Maximum interval be- tween harvest and analysis was 246 d at - 18°C
			122.4	1020				0.0137	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058	21	
								<0.01 (0.0078)	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058	28	
RAU-008-21 P/PR21/AP04 11-010 Bark Poland	Apple / Antonowka	1) 15/09/2004 2) from 20/05 to 06/06/2021 3) 08/09/2021 15/09/2021 22/09/2021 28/09/2021	121.6	810	15	25/08/2021	79	0.028	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058	7	LOQ single analyte: 0.01 mg/kg LOD single analyte: 0.003 mg/kg
								0.0233	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058	14	
			124.8	830		01/09/2021		0.0281	N.D.	N.D.	N.D.	N.D.	<0.01 (0.0030)	< 0.058	21	
								0.0134	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058	27	

- (a) According to Codex Classification/Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
N.A.- Not Available N.D.= Not Detectable (lower than Limit of Detection)

* Residue of sum expressed as M04 (mg/kg) = residue of M04+ M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04

A 2.1.3.2 Plum

Table A 4: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, 2014)	-	-	-	-	-
Intended cGAP (number 7)	2	160 g as/Ha	7 days	BBCH 51-85	3

A 2.1.3.2.1 Study RAU-024-20

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference:	KCA 6.3.2/01
Report	<p>Determination of prothioconazole metabolites residues in raw agricultural commodity plum after two applications of SIP41061 (Prothioconazole 400 g/l SC) (Northern Europe, 4 trials, year 2020).</p> <p>Massardi E., 2021</p> <p>Report N. RAU-024-20</p> <p>Research Center BioSphereS by Biotechnologie BT</p>
Guideline(s):	<p>Yes</p> <p>Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (as revised in 1997) ENV/MC/CHEM(98)17.</p> <p>Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990.</p> <p>Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999).</p> <p>Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 13, Multi-site studies) OECD ENV/JM/MONO(2002)9.</p> <p>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 78/117/EEC and 91/414/EEC.</p> <p>Directives 2004/9/EC, of 11 February 2004, on the inspection and verification of good laboratory practice (GLP) and 2004/10/EC, of 11 February 2004, on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.</p>

EU Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000).
Italian legislation Decree Law N° 50, 2 March 2007, regarding implementation of the directives 2004/9/CE and 2004/10/CE.
EC guidance document 1607/VI/97 rev.2, 10/6/1999.
EC guidance document SANCO 7525/VI/95 rev. 10.3, 13 June 2017.
Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009).
Commission regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009.

Deviations:

Yes

- Deviation No. 1 for the Analytical Phase: 09/03/2021

Description: The column was replaced. As a consequence of the different diameter, the flow has been increased.

Reason: The column was no longer performing.

Impact: None, the columns are equivalent considering the scale up of method.

- Deviation No. 1 for the trial F/PR20/PL01: 11/08/2020

Description: The bottom of trees was harvested by the farmer on plots C and T, so the sample of fruits have been taken from the middle and top of the trees.

PI's answer: The application 2 was done on the whole plot (bottom, middle and top of the trees). The fruits harvested by error by the farmer were destroyed.

Impact: None.

- Deviation No. 1 for the trial P/PR20/PL04: 28/07/2020

Description: The storage temperature for the test item exceeded the higher limit of 26 °C set according to internal SOPs, during period from 28/07/2020 to 21/08/2020.

PI's answer: None.

Impact: None.

GLP:

Yes

Acceptability:

Table A 63: Summary of the study RAU-024-20 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treat- ment				Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			App. N.	g a.s./ ha	Water (l/ha)	g a.s./hl				M04	M14	M15	M16		
(a)	(a)	(b)					(c)							(d)	(e)
RAU-024-20 F/PR20/PL01 49730 Varennes sur Loire (Pays de la Loire) France	Plum / TC Sun	1) year 2005 2) from 20/02 to 15/03/2020 3) 14/08/2020	A1	158.7	793	20	04/08/2020	89	Fruit (flesh)	<0.01 (0.0067)	N.D.	N.D.	N.D.	3	The analytical method was validated in study RAU-003-21. Mean recovery: - M04: 104.06% - M14: 96.23% - M15: 100.21% - M16: 101.27% RSD - M04: 3.9% - M14: 2.73% - M15: 2.88% - M16: 5.22% Time interval between sampling and sample extraction: 236 days LOQ single analyte: 0.001 mg/kg LOD single analyte: 0.003 mg/kg
			A2	158.0	790		11/08/2020		Whole Fruit	<0.01 (0.0066)	N.D.	N.D.	N.D.		
RAU-024-20 H/PR20/PL02 5561 Békésszentandrá (Békés country) Hungary	Plum / Lepo- tica	1) 10/10/2004 2) from 10/04 to 20/04/2020 3) 17/07/2020	A1	163.6	767	21	07/07/2020	85	Fruit (flesh)	0.0119	N.D.	N.D.	N.D.	3	
			A2	155.7	730		14/07/2020		Whole fruit	0.0114	N.D.	N.D.	N.D.		
RAU-024-20 P/PR20/PL03 62-404 Samarzewo (Wielkopolskie) Poland	Plum / Jojo	1) 15/03/2010 2) from 25/04 to 15/05/2020 3) 03/09/2020	A1	165.0	1031	16	24/08/2020	85	Fruit (flesh)	<0.01 (0.0037)	N.D.	N.D.	N.D.	3	
			A2	152.3	952		31/08/2020		Whole fruit	<0.01 (0.0035)	N.D.	N.D.	N.D.	3	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment				Dates of treatment or no. of treat- ments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days) (d)	Details on trial (e)
			App. N.	g a.s./ ha	Water (l/ha)	g a.s./hl				M04	M14	M15	M16		
RAU-024-20 P/PR20/PL04 11-010 Bark (Warmin- sko Mazurskie) Poland	Plum / Walor	1) 10/09/2003 2) from 24/04 to 05/05/2020 3) 26/08/2020	A1	158.8	993	16	16/08/2020	85	Fruit (flesh)	0.0236	N.D.	N.D.	N.D.	3	
			A2	155.2	970		23/08/2020		Whole fruit	0.0223	N.D.	N.D.	N.D.	3	

Table A 124: Summary of the study RAU-024-20 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment				Dates of treatment or no. of treat- ments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI (days) (d)	Details on trial (e)
			App. N.	g a.s./ ha	Water (l/ha)	g a.s./hl				M17	M18	SUM as M04*		
RAU-024-20 F/PR20/PL01 49730 Varennes sur Loire (Pays de la Loire) France	Plum / TC Sun	1) year 2005 2) from 20/02 to 15/03/2020 3) 14/08/2020	A1	158.7	793	20	04/08/2020	89	Fruit (flesh)	<0.01 (0.0067)	N.D.	-	3	The analytical method was validated in study RAU-003-21. Mean recovery: - M17: 79.49% - M18: 101.11% RSD - M17: 6.17% - M18: 6.32%
			A2	158.0	790		11/08/2020		Whole Fruit	<0.01 (0.0066)	N.D.	<0.058		
RAU-024-20 H/PR20/PL02 5561 Békésszentandrás (Békés country) Hungary	Plum / Lepo- tica	1) 10/10/2004 2) from 10/04 to 20/04/2020 3) 17/07/2020	A1	163.6	767	21	07/07/2020	85	Fruit (flesh)	N.D.	N.D.	-	3	Time interval between sampling and sample extraction: 236 days LOQ single analyte: 0.001 mg/kg LOD single analyte: 0.003 mg/kg
			A2	155.7	730		14/07/2020		Whole fruit	N.D.	N.D.	<0.058		
RAU-024-20 P/PR20/PL03 62-404 Samarzewo (Wielkopolskie) Poland	Plum / Jojo	1) 15/03/2010 2) from 25/04 to 15/05/2020 3) 03/09/2020	A1	165.0	1031	16	24/08/2020	85	Fruit (flesh)	N.D.	N.D.	-	3	
			A2	152.3	952		31/08/2020		Whole fruit	N.D.	N.D.	<0.058	3	
RAU-024-20	Plum / Walor	1) 10/09/2003 2) from	A1	158.8	993	16	16/08/2020	85	Fruit (flesh)	N.D.	N.D.	-	3	

P/PR20/PL04 11-010 Bark (Warminsko Mazurskie) Poland		24/04 to 05/05/2020 3) 26/08/2020	A2	155.2	970		23/08/2020		Whole fruit	N.D.	N.D.	<0.058	3	
--	--	--	----	-------	-----	--	------------	--	----------------	------	------	--------	---	--

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

*Residue of sum expressed as M04 (mg/kg) = residue of M04+ M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04

A 2.1.3.2.2 Study RAU-010-21

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference: KCA 6.3.2/02

Report Determination of Prothioconazole metabolites residues in raw agricultural commodity plum after two applications of SIP41061 (Prothioconazole 400 g/L SC) – (Central Europe, 4 decline trials, year 2021).
Report N. RAU-010-21
Massardi E., 2021
Research Center BioSphereS by Biotechnologie BT

Guideline(s): Yes
OECD 509
SANTE/2019/12752

Deviations: Yes

Deviation No. 1 for the trial G/PR21/PL04: 15/09/2021

Description: There was no data logger included in the shipping box during the transport of the samples from the freezers of the test site to the laboratory and as a consequence the temperature could not be logged.

The period of transport was from 23 August 2021 13:30 pm to 31 August 2021 09:15 am. However, there is a confirmation by the shipping company of the freezer truck that the temperatures during the whole course of the transport were within the range indicated by the study plan.

For the given period of transportation, no exceedance of the temperature has occurred because during the whole transportation chain no automatic alert (alert if temperature is higher than -20 °C) of an exceedance was sent to the system of the shipping company.

If there is an exceedance of the temperature an automatic message is sent which did not happen for the given period.

Impact: None.

GLP: Yes

Acceptability:

Table A 7: Summary of the study RAU-010-21 trials

Report No. Location	Commodity/ Variety	Date of (b) 1) Sowing or Transplanting 2) Flowering 3) Harvest	Application Rate per Treatment			Dates of Treatment(s) or No. of Treatment and Last Date (c)	Growth Stage at Last Treatment or Date (BBCH)	Portion Analysed (a)	Residues of (mg/kg)							PHI (Days) (d)	Remarks:(e)
			g a.i./ha	Water L/ha	g a.i./hL				M04	M14	M15	M16	M17	M18	Sum as M04*		
RAU-010-21 H/PR21/PL01 5400 Mezőtúr Hungary	Plum / Cacanska Lepotica	1) 10/10/2002	154.4	482	32	23/07/2021	85	Flesh	<0.01 (0.0076)	N.D.	N.D.	N.D.	N.D.	N.D.	/	0	The analytical method was validated in study RAU-003-21 Mean recovery fruit: M04: 88.22 % M14: 78.47% M15: 80.61% M16: 79.51% M17: 69.59% M18: 85.81% RSD M04:13.29% M14:17.17% M15: 14.11% M16: 14.92% M17: 7.48% M18: 13.53% Max time interval between sampling and sample
		2) from 30/03 to 20/04/2021						Whole fruit	<0.01 (0.0071)	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058		
		3) 30/07/2021						Flesh	<0.01 (0.0083)	N.D.	N.D.	N.D.	N.D.	N.D.	/	3	
		02/08/2021						Whole fruit	<0.01 (0.0077)	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058		
		06/08/2021	155.2	484	32	30/07/2021		Flesh	<0.01 (0.0046)	N.D.	N.D.	N.D.	N.D.	N.D.	/	7	
		13/08/2021						Whole fruit	<0.01 (0.0043)	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058		
								Flesh	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	/	14	
								Whole fruit	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058		
RAU-010-21 H/PR21/PL02 5094 Tiszajenő Hungary	Plum / Stanley	1) 19/11/2006	153.2	478	32	16/08/2021	87	Flesh	0.0112	N.D.	N.D.	N.D.	N.D.	N.D.	/	0	
		2) from 02/04 to 30/04/2021						Whole fruit	0.0105	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058		
		3) 23/08/2021						Flesh	0.0162	N.D.	N.D.	N.D.	N.D.	N.D.	/	3	
		26/08/2021						Whole fruit	0.0152	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058		
		30/08/2021	157.6	493	32	23/08/2021		Flesh	0.019	N.D.	N.D.	N.D.	N.D.	N.D.	/	7	
		06/09/2021						Whole fruit	0.0177	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058		

								Flesh	<0.01 (0.0076)	N.D.	N.D.	N.D.	N.D.	N.D.	/	14	extraction: 136 days
								Whole fruit	<0.01 (0.0070)	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058		LOQ single analyte: 0.001 mg/kg LOD single analyte: 0.003 mg/kg
RAU-010-21 P/PR21/PL03 89-240 Miastowice Poland	Plum / Herman	1) 20/03/2006	162	1012		26/07/2021	85	Flesh	0.0183	N.D.	N.D.	N.D.	N.D.	N.D.	/	0	
		2) from 20/04 to 08/05/2021						Whole fruit	0.0176	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058		
		3) 02/08/2021	163.6	1022	16	02/08/2021		Flesh	0.044	N.D.	N.D.	N.D.	N.D.	N.D.	/	3	
		05/08/2021						Whole fruit	0.0426	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058		
		09/08/2021						Flesh	0.0199	N.D.	N.D.	N.D.	N.D.	N.D.	/	7	
		15/08/2021						Whole fruit	0.0192	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058		
								Flesh	0.0235	N.D.	N.D.	N.D.	N.D.	N.D.	/	13	
								Whole fruit	0.0226	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058		
RAU-010-21 G/PR21/PL04 97332 Volkach Germany	Plum / Katinka	1) year 2007	153.2	957		13/07/2021	81.85	Flesh	0.0425	N.D.	N.D.	N.D.	N.D.	N.D.	/	0	
		2) from 11/04 to 22/04/2021						Whole fruit	0.0394	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058		
		3) 20/07/2021	166	1037	16	20/07/2021		Flesh	0.063	N.D.	N.D.	N.D.	N.D.	N.D.	/	3	
		23/07/2021						Whole fruit	0.0596	N.D.	N.D.	N.D.	N.D.	N.D.	0.0731		
		27/07/2021						Flesh	0.0415	N.D.	N.D.	N.D.	N.D.	N.D.	/	7	
		03/08/2021						Whole fruit	0.0395	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058		
								Flesh	0.0286	N.D.	N.D.	N.D.	N.D.	N.D.	/	14	
								Whole fruit	0.0272	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058		

- (a) According to Codex Classification/Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

N.A.- Not Available N.D.= Not Detectable (lower than Limit of Detection)

*Residue of sum expressed as M04 (mg/kg) = residue of M04+ M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04

A 2.1.3.3 Apricot

Table A 8: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, year)	-	-	-	-	-
Intended cGAP (number 7)	2	160 g as/Ha	7 days	BBCH 51-85	3

A 2.1.3.3.1 Study SPK-20-45307

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference: KCA 6.3.3/01

Report Prothioconazole – Residue Study on Apricot and Peach in Northern Europe – 2020.
Terranegra A., 2021
Report N. SPK-20-45307
Staphyt Italia S.R.L.

Guideline(s): GLP Guidelines:
The Italian GLP guidelines indicated by “Decreto Legislativo N° 50 del 2/03/2007”.
The OECD Principles of Good Laboratory Practice (as Revised in 1997), OECD Series on Principles of GLP and Compliance Monitoring Number 1, ENV/MC/CHEM (98)17.
The national requirements are compatible with Good Laboratory Practice regulations specified by regulatory authorities throughout the European Community, the United States of America (EPA and FDA) and Japan (MHLW, MAFF and METI).
The Application of GLP Principles to Field Studies, OECD Series on Principles of GLP and Compliance Monitoring Number 6 (Revised 1999), ENV/JM/MONO(99)22.
Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies, OECD Series on Principles of GLP and Compliance Monitoring Number 13, ENV/JM/MONO(2002)9.
Field guidelines:
General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95 rev.5, 22 July 1997).
OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published on 7 September 2009).
Analytical guidelines:
EC - Guidance document on residual analytical methods SAN-TE/2020/12830 rev.1.

Guidance Documents on Pesticide Residue Analytical Methods (SAN-CO/825/00 rev.8.1, 16 Nov. 2010).

OECD (2007): Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17.

Deviations:

Deviation n° 1: 22/04/2021.

Description: The Internal code of delegate phase RAU-023-20 is not in compliance with SOP MNG005-03, however the internal code was leaved as RAU-023-20 even if, due to internal laboratory organisation, the analytical phase was conducted in 2021 instead of 2020.

Reason: The code has been taken before 2021.

Impact: None.

Deviation n° 2.

Description: Due to electricity blackout for around 2 hours, specimens storage temperature inside freezers reached -13.0°C and -17.8°C as maximum temperature.

Impact: None.

Deviation n° 3.

Description: Deviation to the test item target dose at Application 1 was - 6.3%.

Impact: None

Deviation n° 4.

Description: Internal code not in compliance with internal SOP.

Impact: None.

GLP:

Yes

Acceptability:

Table A 9: Summary of the study SPK-20-45307 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment				Dates of treat- ment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			App. N.	g a.s./ ha	Water (l/ha)	g a.s./hl				M04	M14	M15	M16		
Hungary Szolnok county 5008 Szandaszolos - Szolnok Trial number SPK-20-45307 HU01	Apricot Big red	1- 03/01/2009 2- From 13 to 26/04/2020 3- - 30/06/2020	A1	156	563	28	16/06/2020	81	Fruits	0.0461	N.D.	N.D.	N.D.	3	Mean recovery fruit Peach: - M04: 86.07% - M14: 80.43% - M15: 98.31% - M16: 97.38% RSD Peach - M04: 17.04% - M14: 10.24% - M15: 9.21% - M16: 8.60%
			A2	168	605		22/06/2020	85							
Hungary Fejér county 2475 Kápolnásnyék Trial number SPK-20-45307 HU02	Apricot Gönci magyar kajsza	1- 30/09/2008 2- From 31/03 to 09/04/2020 3- - 03/07/2020	A1	159	479	33	26/06/2020	85	Fruits	<0.01 (0.0082)	N.D.	N.D.	N.D.	3	Mean recovery fruit Apricot: - M04: 105.24% - M14: 100.19% - M15: 98.64% - M16: 98.62% RSD Apricot - M04: 3.38% - M14: 2.98% - M15: 3.55% - M16: 3.25%
			A2	161	484		03/07/2020	87							
Poland Łódzkie 96-116 Józefatów Trial number SPK-20-45307 PL03	Peach Royal glory	1- 02/04/2015 2- From 24/04 to 08/05/2020 3- -From 24 to 30/07/2020	A1	166	700	24	17/07/2020	81	Fruits	0.0469	N.D.	N.D.	N.D.	14	Time interval between sampling and sample extraction: 313 days apricot, 295 days peach
			A2	167	701		24/07/2020	85							
Poland Wielkopolska 62-095 Białezin Trial number SPK-20-45307 PL0	Peach Early orange	1- 17/03/2007 2- From 13 to 25/04/2020 3- From 10 to 14/07/2020	A1	169	1018	17	03/07/2020	85	Fruits	0.0767	N.D.	N.D.	N.D.	3	LOQ single analyte: 0.01 mg/kg LOD single analyte: 0.003 mg/kg
			A2	166	997		10/07/2020	87							

Table A 10: Summary of the study SPK-20-45307 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treat- ment				Dates of treatment or no. of treat- ments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)			PHI (days)	Details on trial
			App. N.	g a.s./ ha	Water (l/ha)	g a.s./hl				M17	M18	SUM as M04*		
Hungary Szolnok county 5008 Szandaszolos - Szolnok Trial number SPK-20-45307 HU01	Apricot Big red	1- 03/01/2009 2- From 13 to 26/04/2020 3- - 30/06/2020	A1	156	563	28	16/06/2020	81	Fruits	N.D.	N.D.	0.0604	3	Mean recovery fruit Peach - M17: 88.97% - M18: 93.82%
			A2	168	605		22/06/2020	85						RSD fruit Peach - M17: 14.68% - M18: 9.42%
Hungary Fejer county 2475 Kápolnásnyék Trial number SPK-20-45307 HU02	Apricot Gönci magyar kajsza	1- 30/09/2008 2- From 31/03 to 09/04/2020 3- - 03/07/2020	A1	159	479	33	26/06/2020	85	Fruits	N.D.	N.D.	0.1025	3	Mean recovery fruit Apri- cot: - M17: 103.72% - M18: 103.38% RSD Apricot - M17: 1.97% - M18: 3.07%
			A2	161	484		03/07/2020	87						
Poland Łódzkie 96-116 Józefatów Trial number SPK-20-45307 PL03	Peach Royal glory	1- 02/04/2015 2- From 24/04 to 08/05/2020 3- -From 24 to 30/07/2020	A1	166	700	24	17/07/2020	81	Fruits	N.D.	N.D.	0.0612	14	Time interval between sampling and sample extraction: 313 days apricot, 295 days peach
			A2	167	701		24/07/2020	85						LOQ single analyte: 0.01 mg/kg LOD single analyte: 0.003 mg/kg
Poland Wielkopolska	Peach Early	1- 17/03/2007	A1	169	1018	17	03/07/2020	85	Fruits	N.D.	N.D.	0.0910	3	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treat- ment				Dates of treatment or no. of treat- ments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)			PHI (days)	Details on trial
			App. N.	g a.s./ ha	Water (l/ha)	g a.s./hl				M17	M18	SUM as M04*		
62-095 Białęzin Trial number SPK-20-45307 PL0	orange	2- From 13 to 25/04/2020 3- From 10 to 14/07/2020	A2	166	997		10/07/2020	87						

(a) According to Codex Classification/Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

N.A.- Not Available N.D.= Not Detectable (lower than Limit of Detection)

*Residue of sum expressed as M04 (mg/kg) = residue of M04+ M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04

A 2.1.3.3.2 Study RAU-009-21

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference:	KCA 6.3.3/02
Report	<p>Determination of prothioconazole metabolites residues in raw agricultural commodity apricot and peach after two applications of SIP41061 (prothioconazole 400 G/L SC)</p> <p>Massardi E.</p> <p>Report N. RAU-009-21</p> <p>Research Center BioSphereS by Biotechnologie BT</p>
Guideline(s):	<p>Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (as revised in 1997) ENV/MC/CHEM(98)17</p> <p>Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990.</p> <p>Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999)</p> <p>Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 13, Multi-site studies) OECD ENV/JM/MONO(2002)9</p> <p>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 78/117/EEC and 91/414/EEC</p> <p>Directives 2004/9/EC, of 11 February 2004, on the inspection and verification of good laboratory practice (GLP) and 2004/10/EC, of 11 February 2004, on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances</p> <p>Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes SANTE/2020/12830, rev.1 (24/02/2021)</p> <p>Italian legislation Decree Law N° 50, 2 March 2007, regarding implementation of the directives 2004/9/CE and 2004/10/CE</p> <p>EC guidance document 1607/VI/97 rev.2, 10/6/1999</p> <p>EC guidance document SANTE/2019/12752</p> <p>Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009)</p> <p>Commission regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009</p>
Deviations:	NO

GLP: Yes

Acceptability:

Table A 10: Summary of the study RAU-009-21 trials

Report No. Location	Commodity/ Variety	Date of (b) 1) Sowing or Transplanting 2) Flowering 3) Harvest	Application Rate per Treatment			Dates of Treat- ment(s) or No. of Treatment and Last Date (c)	Growth Stage at Last Treatment or Date (BBCH)	Portion Analysed (a)	Residues of (mg/kg)							PHI (Days) (d)	Remarks:(e)
			g a.i./ha	Water L/ha	g a.i./hL				M04	M14	M15	M16	M17	M18	Sum as M04*		
RAU-009-21 H/PR21/PE01 6795 Bordány Hungary	Prunus persica / Gugli Peach Elmina	1) before 2009 2) from 03/04 to 25/04/2021 3) 10/09/2021 13/09/2021 17/09/2021 21/09/2021	166.8	730	23	03/09/2021	85	Flesh	0.1256	N.D.	N.D.	N.D.	N.D.	N.D.	/	0	Mean recovery fruit Apricot: M04: 104.41% M14: 101.19% M15: 99.02% M16: 98.70% M17: 96.43% M18: 102.05% RSD Apricot M04: 12.12% M14: 5.43% M15: 8.56% M16: 6.62% M17: 9.17% M18: 10.16%
								Whole fruit	0.1168	N.D.	N.D.	N.D.	N.D.	N.D.	0.1301		
								Flesh	0.073	N.D.	N.D.	N.D.	N.D.	N.D.	/	3	
								Whole fruit	0.0643	N.D.	N.D.	N.D.	N.D.	N.D.	0.0769		
			162.4	710	23	10/09/2021		Flesh	0.1153	N.D.	N.D.	N.D.	N.D.	N.D.	/	7	
								Whole fruit	0.1039	N.D.	N.D.	N.D.	N.D.	N.D.	0.1168		
								Flesh	0.0715	N.D.	N.D.	N.D.	N.D.	N.D.	/	11	
								Whole fruit	0.0668	N.D.	N.D.	N.D.	N.D.	N.D.	0.0801		
RAU-009-21 P/PR21/AR01 62-095 Białezyn Poland	Prunus armeni- niaca / Early Apricot Or- ange	1) 17/03/2007 2) from 20/04 to 05/05/2021 3) 06/07/2021 09/07/2021 13/07/2021 15/07/2021	156.4	977	16	29/06/2021	85	Flesh	0.0837	N.D.	N.D.	N.D.	N.D.	< 0.01 (0.0054)	/	0	
								Whole fruit	0.0796	N.D.	N.D.	N.D.	N.D.	< 0.01 (0.0051)	0.0954		
								Flesh	0.0863	N.D.	N.D.	N.D.	N.D.	N.D.	/	3	
								Whole fruit	0.0799	N.D.	N.D.	N.D.	N.D.	N.D.	0.0931		

Report No. Location	Commodity/ Variety	Date of (b) 1) Sowing or Transplanting 2) Flowering 3) Harvest	Application Rate per Treatment			Dates of Treat- ment(s) or No. of Treatment and Last Date (c)	Growth Stage at Last Treatment or Date (BBCH)	Portion Analysed (a)	Residues of (mg/kg)							PHI (Days) (d)	Remarks:(e)
			g a.i./ha	Water L/ha	g a.i./hL				M04	M14	M15	M16	M17	M18	Sum as M04*		
			154.8	967	16	06/07/2021		Flesh	0.0474	N.D.	N.D.	N.D.	N.D.	< 0.01 (0.0061)	/	7	M17: 5.05% M18: 7.33%
								Whole fruit	0.0438	N.D.	N.D.	N.D.	N.D.	< 0.01 (0.0056)	0.0598		Time interval between sampling and sample extraction: 103 days peach, 168 days apricot
								Flesh	0.027	N.D.	N.D.	N.D.	N.D.	N.D.	/		
								Whole fruit	0.0255	N.D.	N.D.	N.D.	N.D.	N.D.	<0.058	9	LOQ single analyte: 0.01 mg/kg LOD single analyte: 0.003 mg/kg

(a) According to Codex Classification/Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

N.A.- Not Available N.D.= Not Detectable (lower than Limit of Detection)

*Residue of sum expressed as M04 (mg/kg) = residue of M04+ M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04

A 2.1.3.4 Cherry

Table A 11: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, year)	-	-	-	-	-
Intended cGAP (number 7)	2	160 g as/Ha	7 days	BBCH 51-85	3

A 2.1.3.4.1 Study RAU-017-20

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference: KCA 6.3.4/01

Report
Determination of Prothioconazole metabolites residues in raw agricultural commodity cherry after two applications of SIP41061 (Prothioconazole 400 g/l sc) in open field condition.
(4 trials, Northern Europe, year 2020)
Massardi E., 2021
Report N. RAU-017-20
Research Center BioSphereS by Biotechnologie BT

Guideline(s): Yes
Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (as revised in 1997) ENV/MC/CHEM(98)17.
Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990.
Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999).
Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 13, Multi-site studies) OECD ENV/JM/MONO(2002)9.
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 78/117/EEC and 91/414/EEC.
Directives 2004/9/EC, of 11 February 2004, on the inspection and verification of good laboratory practice (GLP) and 2004/10/EC, of 11 February 2004, on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.
EU Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000).

Italian legislation Decree Law N° 50, 2 March 2007, regarding implementation of the directives 2004/9/CE and 2004/10/CE.

EC guidance document 1607/VI/97 rev.2, 10/6/1999.

EC guidance document SANCO 7525/VI/95 rev. 10.3, 13 June 2017 SANTE/2019/12752.

Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009).

Commission regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009.

Deviations:

Yes

Deviation No. 1 for the Analytical Phase: 12/04/2021

Description: The column was replaced. As a consequence of the different diameter, the flow has been increased.

Reason: The column was no longer performing.

Impact: None, the columns are equivalent considering the scale up of method.

Deviation No. 1 for the trial H/PR20/CH02: 02/06/2020

Description: At the A1 application the deviation to the target dose was -6.8 % (more than $\pm 5\%$ planned).

PI's answer: None.

Impact: None.

GLP:

Yes

Acceptability:

Table A 125: Summary of the study RAU-017-20 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treat- ment				Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			App. N.	g a.s./ ha	Water (l/ha)	g a.s./hl				M04	M14	M15	M16		
(a)	(a)	(b)					(c)							(d)	(e)
RAU-017-20 H/PR20/CH01 7400 Kaposvár (Southwestern) Hungary	Sweet cherry / Katalin	1) year 2002 2) from 08/04 to 23/04/2020 3) 29/06/2020	A1	162.0	685	24	19/06/2020	85	Whole Fruits	0.1506	N.D.	N.D.	N.D.	3	The analytical method was validated in study RAU-003-20. Mean recovery cherry: - M04: 94.39% - M14: 84.14% - M15: 84.40% - M16: 86.12% RSD - M04: 2.63% - M14: 2.31% - M15: 3.16% - M16: 2.68% Time interval between sampling and sample extraction: 265 days LOQ single analyte: 0.01 mg/kg LOD single analyte: 0.003 mg/kg
			A2	159.0	673		26/06/2020								
RAU-017-20 H/PR20/CH02 5065 Nagykörű (Central) Hungary	Sweet cherry / Vera	1) 05/03/2009 2) from 13/03 to 29/03/2020 3) 12/06/2020	A1	149.3	560	27	02/06/2020	85	Fruits	0.0780	N.D.	N.D.	N.D.	3	
			A2	152.8	573		09/06/2020								
RAU-017-20 P/PR20/CH03 14-260 Fijewo (North) Poland	Sour cherry / Łutówka	1) 18/09/2017 2) from 02/05 to 18/05/2020 3) 27/07/2020	A1	163.0	1018	16	17/07/2020	85	Fruits	0.2581	N.D.	N.D.	N.D.	3	
			A2	157.6	985		24/07/2020								

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treat- ment				Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial
			App. N.	g a.s./ ha	Water (l/ha)	g a.s./hl				M04	M14	M15	M16		
	(a)	(b)					(c)							(d)	(e)
RAU-017-20 P/PR20/CH04 62-404 Samarzewo (Centre) Poland	Sweet cherry / Staccato	1) 12/04/2011 2) from 19/04 to 03/05/2020 3) 10/07/2020	A1	162.8	1018	16	30/06/2020	85	Fruits	0.2493	N.D.	N.D.	N.D.	3	
			A2	161.9	1012		07/07/2020								

Table A 13: Summary of the study RAU-017-20 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety/ (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treat- ment				Dates of treatment or no. of treat- ments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI (days) (d)	Details on trial (e)
			App. N.	g a.s./ ha	Water (l/ha)	g a.s./hl				M17	M18	SUM as M04**		
RAU-017-20 H/PR20/CH01 7400 Kaposvár (Southwestern) Hungary	Sweet cherry / Katalin	1) year 2002 2) from 08/04 to 23/04/2020 3) 29/06/2020	A1	162.0	685	24	19/06/2020	85	Whole Fruits	N.D.	N.D.	0.1649	3	The analytical method was validated in study RAU-003-20. Mean recovery cherry: - M17: 73.86% - M18: 92.12% RSD - M17: 2.94% - M18: 3.77% Time interval between sampling and sample extraction: 265 days LOQ single analyte: 0.01 mg/kg LOD single analyte: 0.003 mg/kg
			A2	159.0	673		26/06/2020							
RAU-017-20 H/PR20/CH02 5065 Nagykőrű (Central) Hungary	Sweet cherry / Vera	1) 05/03/2009 2) from 13/03 to 29/03/2020 3) 12/06/2020	A1	149.3	560	27	02/06/2020	85	Fruits	N.D.	N.D.	0.0923	3	
			A2	152.8	573		09/06/2020							
RAU-017-20 P/PR20/CH03 14-260 Fijewo (North) Poland	Sour cherry / Łutówka	1) 18/09/2017 2) from 02/05 to 18/05/2020 3) 27/07/2020	A1	163.0	1018	16	17/07/2020	85	Fruits	N.D.	<0.01 (0.0043)	0.2736	3	
			A2	157.6	985		24/07/2020							
RAU-017-20 P/PR20/CH04 62-404 Samarzewo (Centre) Poland	Sweet cherry / Staccato	1) 12/04/2011 2) from 19/04 to 03/05/2020 3) 10/07/2020	A1	162.8	1018	16	30/06/2020	85	Fruits	N.D.	N.D.	0.2636	3	
			A2	161.9	1012		07/07/2020							

(a) According to Codex Classification/Guide

- (b) Only if relevant
- (c) Year must be indicated
- (d) Days after last application (Label pre-harvest interval, PHI, underline)
- (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
N.A.- Not Available N.D.= Not Detectable (lower than Limit of Detection)

*Residue of sum expressed as M04 (mg/kg) = residue of M04+ M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04

A 2.1.3.4.2 Study RAU-011-21

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference:	KCA 6.3.4/02
Report	<p>Determination of Prothioconazole metabolites residues in raw agricultural commodity cherry after two applications of SIP41061 (Prothioconazole 400 g/l sc) .-(Central Europe, 4 decline trials, year 2021) Massardi E., 2022 Report N. RAU-011-21 Research Center BioSphereS by Biotechnologie BT</p>
Guideline(s):	<p>Yes</p> <p>Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (as revised in 1997) ENV/MC/CHEM(98)17</p> <p>Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990.</p> <p>Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999)</p> <p>Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 13, Multi-site studies) OECD ENV/JM/MONO(2002)9</p> <p>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 78/117/EEC and 91/414/EEC</p> <p>Directives 2004/9/EC, of 11 February 2004, on the inspection and verification of good laboratory practice (GLP) and 2004/10/EC, of 11 February 2004, on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances</p> <p>Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes SANTE/2020/12830, rev.1 (24/02/2021)</p> <p>Italian legislation Decree Law N° 50, 2 March 2007, regarding implementation of the directives 2004/9/CE and 2004/10/CE</p> <p>EC guidance document 1607/VI/97 rev.2, 10/6/1999</p> <p>EC guidance document SANTE/2019/12752</p> <p>Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009)</p> <p>Commission regulation (EU) No 284/2013 of 1 March 2013 setting</p>

out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009

Deviations:

Yes

Deviation No. 1 for the trial H/PR21/CH01: 15/06/2021 issued on 17/06/2021

Description: The 0 DALA samples was collected less than 2 hours after the second application.

PI's answer: The mistake derived from inattention of the trialist. Time interval between last application end and specimen collection was 0.58 h regarding untreated specimen and 1.21 h regarding treated specimens

Impact: None, worse case sampling.

Deviation No. 1 for the trial H/PR21/CH02: 16/06/2021

Description: At the A2 application the deviation to the target dose was -6 % (more than $\pm 5\%$ spray tolerance planned).

PI's answer: None.

Impact: None.

Deviation No. 2 for the trial H/PR21/CH02: 16/06/2021 issued on 17/06/2021

Description: The 0 DALA samples were collected less than 2 hours after the second application.

PI's answer: The mistake derived from inattention of the trialist. Time interval between last application end and specimen collection was 0.46 h regarding untreated specimen and 1.14 h regarding treated specimens.

Impact: None, worse case sampling.

Deviation No. 1 for the trial P/PR21/CH03: 29/08/2021 issued on 21/09/2021

Description: No electricity at station Łajsy from 29-08-2021 10:00 am to 30-08-2021 to 9:00 am. At freezer 1116 max. temperature recorded it was -6.4°C inside retain samples P/PR21/CH03/37C, P/PR21/CH03/41C, at freezer 1112 max. temperature recorded it was -8.9°C inside retain samples P/PR21/CH03/38T, P/PR21/CH03/39T, P/PR21/CH03/40T, P/PR21/CH03/42T. Samples still frozen.

PI's answer: None.

Impact: None.

GLP:

Yes

Acceptability:

Table A 14: Summary of the study RAU-011-21 trials

Report No. Location	Commodity/ Variety	Date of (b) 1) Sowing or Transplanting 2) Flowering 3) Harvest	Application Rate per Treatment			Dates of Treatment(s) or No. of Treatment and Last Date (c)	Growth Stage at Last Treatment or Date (BBCH)	Portion Analysed (a)	Residues of (mg/kg)							PHI (Days) (d)	Remarks
			g a.i./ha	Water L/ha	g a.i./hL				M04	M14	M15	M16	M17	M18	Sum as M04*		
RAU-011-21 H/PR21/CH01 5065 Nagykörű Hungary	Prunus avium / Vera	1) 15/10/2004 2) from 06/04 to 19/04/2021 3) 15/06/2021 18/06/2021 23/06/2021 30/06/2021	155.2	755	20	09/06/2021	85	Whole Fruits	0.0556	N.D.	N.D.	N.D.	N.D.	N.D.	0.0699	0	The analytical method was validated in study RAU-003-20 Mean recovery: M04: 91.87% M14: 86.42% M15: 76.09% M16: 79.32% M17: 70.92% M18: 91.98%
									0.0848	N.D.	N.D.	N.D.	N.D.	N.D.	0.0991	3	
			157.2	786		15/06/2021			0.0708	N.D.	N.D.	N.D.	N.D.	N.D.	0.0851	8	
									0.0563	N.D.	N.D.	N.D.	N.D.	N.D.	0.0706	15	
RAU-011-21 H/PR21/CH02 5094 Tiszajenő Hungary	Prunus avium / Karmen	1) 10/10/2010 2) from 10/04 to 23/04/2021 3) 16/06/2021 19/06/2021 23/06/2021 30/06/2021	153.2	479	32	09/06/2021	85	Whole Fruits	0.1004	N.D.	N.D.	N.D.	N.D.	N.D.	0.1147	0	RSD M04: 3.72% M14: 7.53% M15: 16.59% M16: 17.30% M17: 4.47% M18: 1.93%
									0.0923	N.D.	N.D.	N.D.	N.D.	N.D.	0.1066	3	
			150.4	470		16/06/2021			0.0704	N.D.	N.D.	N.D.	N.D.	N.D.	0.0847	7	
									0.0518	N.D.	N.D.	N.D.	N.D.	N.D.	0.0661	14	
RAU-011-21 P/PR21/CH03 11-010 Bark Poland	Prunus cerasus / Łutówka	1) 20/09/2000 2) from 10/05 to 25/05/2021 3) 19/07/2021 22/07/2021 26/07/2021 02/08/2021	152.8	956	16	12/07/2021	85	Whole Fruits	0.078	N.D.	N.D.	N.D.	N.D.	<0.01 (0.0046)	0.0938	0	Time interval between sampling and sample extraction: 167 days LOQ single analyte: 0.01 mg/kg LOD single analyte:
									0.0949	N.D.	N.D.	N.D.	N.D.	<0.01 (0.0039)	0.11	3	
			154.8	967		19/07/2021			0.056	<0.01 (0.0042)	N.D.	N.D.	N.D.	<0.01 (0.0046)	0.0729	7	
									0.0374	<0.01 (0.0052)	N.D.	N.D.	N.D.	<0.01 (0.0052)	<0.058	14	
	Prunus	1) 05/04/2018	159.6	699	23	05/07/2021	85	Whole	0.3852	N.D.	N.D.	N.D.	N.D.	<0.01	0.3996	0	

RAU-011-21 P/PR21/CH04 96-116 Józefatów Poland	cerasus / Debreczyn	2) from 01/05 to 11/05/2021 3) 12/07/2021 15/07/2021 19/07/2021 26/07/2021					Fruits						(0.0031)			0.003 mg/kg
								0.3242	<0.01 (0.0034)	N.D.	N.D.	N.D.	<0.01 (0.0040)	0.3398	3	
			162.4	709		12/07/2021		0.2832	<0.01 (0.0043)	N.D.	N.D.	N.D.	<0.01 (0.0060)	0.3016	7	
								0.1127	<0.01 (0.0031)	N.D.	N.D.	N.D.	<0.01 (0.0042)	0.1282	14	

(a) According to Codex Classification/Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

N.A.- Not Available N.D.= Not Detectable (lower than Limit of Detection)

*Residue of sum expressed as M04 (mg/kg) = residue of M04+ M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04

A 2.1.3.5 Zucchini

Table A 15: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, year 2014)	-	-	-	-	-
Intended cGAP (number 5)	3	200 g as/Ha	10 days	BBCH 11-89	10

A 2.1.3.5.1 Study BIU-021-20

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference: KCA 6.3.5/01

Report

Determination of Prothioconazole residues in raw agricultural commodity zucchini after three applications of sip41099 (Prothioconazole 200 g/L – Azoxystrobin 250 g/L SC) in greenhouse condition (Southern Europe, 4 trials, year 2020).
Casalnuovo L., 2021
Report N. BIU-021-20
Research Center BioSphereS by Biotecnologie BT

Guideline(s):

Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (as revised in 1997) ENV/MC/CHEM (98)17.
Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990.
Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 13, Multi-site studies) OECD ENV/JM/MONO (2002)9.
Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999).
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 78/117/EEC.
Directives 2004/9/EC, of 11 February 2004, on the inspection and verification of good laboratory practice (GLP) and 2004/10/EC, of 11 February 2004, on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.
EU Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000).

Italian legislation Decree Law No.50, 2 March 2007, regarding implementation of the directives 2004/9/CE and 2004/10/CE.

Commission Regulation (EU) N. 284/2013 of 1st of March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) n.1107/2009.

Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009).

Deviations:

Deviation^o 1 to the Study Plan for trial I/PA20/ZU05 of 13/05/2020

Description: the deviation from the target rate was + 5.56 % instead of \pm 5.00 % as requested in the Study Plan.

Reason for deviation: unexpected change of instrumental pressure.

Impact: None.

Impact: None, the columns are equivalent.

GLP:

Yes

Table A 166: Summary of the study BIU-021-20 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment					Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial	
			Plot	Active ingredient	g a.s./ ha	Water (l/ha)	g a.s./hl				M04	M14	M15	M16			
BIU-021-20 I/PA20/ZU05 15053 Castelnuovo Scrivia (AL) Italy	Zucchini / Altea	1) 28/03/2020 2) N.A. 3) 08/06/2020	A1	T	Prothioconazole	126.67	633.33	20.00	13/05/2020	72-73	Fruits	0.0175	N.D.	N.D.	N.D.	3	Mean recovery: M04: 88.03% M14: 87.48% M15: 85.01% M16: 85.39% RSD M04: 11.66% M14: 13.94% M15: 14.57% M16: 8.73%
					Azoxystrobin	158.33		25.00									
			A2		Prothioconazole	117.33	586.67	20.00	22/05/2020		Fruits	N.D.	N.D.	N.D.	N.D.	7	
					Azoxystrobin	146.67		25.00									
			A3		Prothioconazole	118.67	593.33	20.00	01/06/2020		Fruits	N.D.	N.D.	N.D.	N.D.	7	
					Azoxystrobin	148.33		25.00									
BIU-021-20 I/PA20/ZU06 26041 Casalmaggiore (CR) Italy	Zucchini / Infinity	1) 03/09/2020 2) N.A. 3) 06/11/2020	A1	T	Prothioconazole	124.67	623.33	20.00	08/10/2020	85-87	Fruits	0.0342	N.D	N.D	N.D	3	Time interval between sampling and sample extraction: 351 days LOQ single ana- lyte: 0.001 mg/kg LOD single ana- lyte: 0.003 mg/kg
					Azoxystrobin	155.83		25.00									
			A2		Prothioconazole	121.33	606.67	20.00	19/10/2020		Fruits	0.0452	N.D	N.D	N.D	7	
					Azoxystrobin	151.67		25.00									
			A3		Prothioconazole	122.00	610.00	20.00	30/10/2020		Fruits		N.D	N.D	N.D	7	
					Azoxystrobin	152.50		25.00									

BIU-021-20 I/PA20/ZU07 47522 San Martino in Fiume - Cesena (FC) Italy	Zucchini / Rigas	1)19/06/2020 2) N.A. 3) 10/08/2020	A1	T	Prothioconazole	117.60	490.00	24.00	14/07/2020	85-87	Fruits	< 0.01 (0.0065)	N.D.	N.D.	N.D.	3	
					Azoxystrobin	147.00		30.0									
			A2		Prothioconazole	116.00	483.33	24.00	24/07/2020								
					Azoxystrobin	145.00		30.0									
			A3		Prothioconazole	122.40	510.00	24.00	03/08/2020								
					Azoxystrobin	153.00		30.0									
BIU-021-20 S/PA20ZU08 41720 Los Palacios y Villafranca (Andalucía) Spain	Zucchini / Lucía	1) 01/10/2020 2) N.A. 3) 30/11/2020	A1	T	Prothioconazole	114.60	429.00	26.71	04/11/2020	87	Fruits	0.0350	N.D	N.D	N.D	3	
					Azoxystrobin	143.30		33.40									
			A2		Prothioconazole	119.20	477.00	26.66	13/11/2020								
					Azoxystrobin	149.00		33.33									
			A3		Prothioconazole	117.60	441.00	26.22	23/11/2020								
					Azoxystrobin	147.00		33.33									

Table A 17: Summary of the study BIU-021-20 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment						Dates of treat- ment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI (days)	Details on trial
			App. N.	Active ingredient	g a.s./ ha	Water (l/ha)	g a.s./hl	M17				M18	Sum as M04			
	(a)	(b)						(c)							(d)	(e)
BIU-021-20 I/PA20/ZU05 15053	Zucchini / Altea	1) 28/03/2020 2) N.A. 3) 08/06/2020	A1	T	Prothioconazole	126.67	633.33	20.00	13/05/2020	72-74	Fruits	N.D	N.D	<0.058	3	Mean recovery: M17: 101.02%
					Azoxystrobin	158.33		25.00								

Castelnuovo Scrivia (AL) Italy			A2		Prothioconazole	117.33	586.67	20.00	22/05/2020							M18: 89.54% RSD M17: 7.78% M18: 14.54% Time interval between sampling and sample extraction: 351 days
					Azoxystrobin	146.67		25.00								
			A3		Prothioconazole	118.67	593.33	20.00	01/06/2020							
					Azoxystrobin	148.33		25.00								
BIU-021-20 I/PA20/ZU06 26041 Casalmaggiore (CR) Italy	Zucchini / Infinity	1) 03/09/2020 2) N.A. 3) 06/11/2020	A1	T	Prothioconazole	124.67	623.33	20.00	08/10/2020	85-87	Fruits	N.D	N.D	<0.058	3	LOQ single ana- lyte: 0.001 mg/kg LOD single ana- lyte: 0.003 mg/kg
					Azoxystrobin	155.83		25.00								
			A2		Prothioconazole	121.33	606.67	20.00	19/10/2020							
					Azoxystrobin	151.67		25.00	30/10/2020							
			A3		Prothioconazole	122.00	610.00	20.00	19/10/2020							
					Azoxystrobin	152.50		25.00								
BIU-021-20 I/PA20/ZU07 47522 San Martino in Fiume - Cesena (FC) Italy	Zucchini / Rigas	1)19/06/2020 2) N.A. 3) 10/08/2020	A1	T	Prothioconazole	117.60	490.00	24.00	14/07/2020	85-87	Fruits	N.D	N.D	<0.058	3	
					Azoxystrobin	147.00		30.0								
			A2		Prothioconazole	116.00	483.33	24.00	24/07/2020							
					Azoxystrobin	145.00		30.0								
			A3		Prothioconazole	122.40	510.00	24.00	03/08/2020							
					Azoxystrobin	153.00		30.0								
BIU-021-20 S/PA20ZU08 41720 Los Palacios y Villafranca (Andalucía) Spain	Zucchini / Lucía	1) 01/10/2020 2) N.A. 3) 30/11/2020	A1	T	Prothioconazole	114.60	429.00	26.71	04/11/2020	87	Fruits	N.D	N.D	<0.058	3	
					Azoxystrobin	143.30		33.40								
			A2		Prothioconazole	119.20	447.00	26.66	13/11/2020							
					Azoxystrobin	149.00		33.33								
			A3		Prothioconazole	117.60	441.00	26.22	23/11/2020		Fruits	N.D	N.D	<0.058	7	

					Azoxystrobin	147.00		33.33									
--	--	--	--	--	--------------	--------	--	-------	--	--	--	--	--	--	--	--	--

(a) According to Codex Classification/Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

N.A.- Not Available N.D.= Not Detectable (lower than Limit of Detection)

*Residue of sum expressed as M04 (mg/kg) = residue of M04+ M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04

A 2.1.3.5.2 Study BIU-017-21

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference: KCA 6.3.5/02

Report

Determination of Prothioconazole metabolites residues in raw agricultural commodity zucchini following three applications of sip41099 (Prothioconazole 400 g/L SC) in greenhouse condition (Southern Europe, 4 trials, year 2021).

Casalinuovo L., 2022

Report N. BIU-017-21

Research Center BioSphereS by Biotecnologie BT

Guideline(s):

Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (as revised in 1997) ENV/MC/CHEM (98)17

Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990.

Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999)

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 78/117/EEC

Directives 2004/9/EC, of 11 February 2004, on the inspection and verification of good laboratory practice (GLP) and 2004/10/EC, of 11 February 2004, on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances

Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes SANTE/2020/12830, rev.1 (24/02/2021)

Italian legislation Decree Law No.50, 2 March 2007, regarding implementation of the directives 2004/9/CE and 2004/10/CE.

Commission Regulation (EU) N. 284/2013 of 1st of March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) n.1107/2009

Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009)

EC Technical guidance document SANTE/2019/12752

Deviations:

Deviation n°1 of 17/07/2021 for trial I/PR21/ZU05

Description: Weather Data between application A1 and application A3 are missing.

Reason for deviation: Malfunction of the data logger TINYTAG tgu-4500 inside the greenhouse. Weather Data outside the greenhouse were collected from the nearest weather station.

Impact: None.

Deviation n°1 of 26/10/2021 for trial I/PR21/ZU07

Description: Weather Data between application A1 and application A2 are missing.

Reason for deviation: Malfunction of the data logger TINYTAG tgu-4500 inside the greenhouse. Weather Data outside the greenhouse were collected from the nearest weather station.

Impact: None.

GLP: Yes

Acceptability:

Table A 18: Summary of the study BIU-017-21 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment					Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)				PHI (days)	Details on trial	
			Plot	Active ingredient	g a.s./ ha	Water (l/ha)	g a.s./hl				M04	M14	M15	M16			
BIU-017-21 I/PR21/ZU05 15053 Castelnuovo Scrvia (AL) Italy	Zucchini / Altea	1) 30/04/2021 2) N.A. 3) 05/07/2021 08/07/2021 12/07/2021 15/07/2021	A1	T	Prothioconazole	123.00	615.00	20.00	14/06/2021	77	Fruits	0.0379	N.D.	N.D.	N.D.	0	Mean recovery Fruits: M04: 99.17% M14: 108.15% M15: 108.15% M16: 105.15% RSD M04: 3.48% M14: 4.86% M15: 2.24% M16: 4.92%
			A2			118.00	590.00		24/06/2021			< 0.01 (0.0089)	N.D.	N.D.	N.D.	3	
			A3			120.00	600.00		05/07/2021			< 0.01 (0.0042)	N.D.	N.D.	N.D.	7	
												< 0.01 (0.0032)	N.D.	N.D.	N.D.	10	
BIU-017-21 I/PR21/ZU06 48027 Solarolo (RA) Italy	Zucchini / Ismaila F1	1) 27/04/2021 2) 15/05/2021 3) 01/06/2021 04/06/2021 07/06/2021 10/06/2021	A1	T	Prothioconazole	118.40	493.33	118.40	12/05/2021	70-75	Fruits	0.0189	N.D.	N.D.	N.D.	0	Time interval between sampling and sample extraction: 185 days LOQ single ana- lyte: 0.001 mg/kg LOD single ana- lyte: 0.003 mg/kg
			A2			121.20	505.00	121.20	22/05/2021			< 0.01 (0.0059)	N.D.	N.D.	N.D.	3	
			A3			115.60	481.66	115.60	01/06/2021			< 0.01 (0.0052)	N.D.	N.D.	N.D.	6	
												N.D.	N.D.	N.D.	N.D.	9	

BIU-017-21 I/PR21/ZU07 42022 Boretto (RE) Italy	Zucchini / Chiara Genovese	1) 28/08/2021 2) N.A. 3) 25/10/2021	A1	T	Prothioconazole	122.67	613.33	20.00	1/10/2021	85-87	Fruits	0.0197	N.D.	N.D.	N.D.	3	
			A2			121.33	606.67		11/10/2021								
			A3			122.00	610.00		22/10/2021								
BIU-017-21 I/PR21/ZU08 47023 San Martino in Fiume (FC) Italy	Zucchini / Rigas	1) 25/04/2021 2)13/05/2021 3) 04/06/2021	A1	T	Prothioconazole	118.40	493.33	24.00	12/05/2021	77	Fruits	0.0245	N.D.	N.D.	N.D.	3	
			A2			122.00	508.33		22/05/2021								
			A3			119.60	498.33		01/06/2021								

Table A 19: Summary of the study BIU-017-21 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment					Dates of treatment or no. of treat- ments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)			PHI (days)	Details on trial	
			Plot		Active ingredi- ent	g a.s./ ha	Water (l/ha)				g a.s./hl	M17	M18			Sum as M04*
BIU-017-21 I/PR21/ZU0 5 15053 Castelnuovo Scrvia (AL) Italy	Zucchini / Altea	1) 30/04/2021 2) N.A. 3) 05/07/2021 08/07/2021 12/07/2021 15/07/2021	A1	T	Prothioconazole	123.00	615.00	20.00	14/06/2021	77	Fruits	N.D.	N.D.	<0.058	0	Mean recov- ery: M17: 101.0% M18: 106.3% RSD M17: 7.12% M18: 5.35% Time interval between samplin- g and sample extracti- on: 185 days LOQ single analyte: 0.001
			A2			118.00	590.00		24/06/2021			N.D.	N.D.	<0.058	3	
												N.D.	N.D.	<0.058	7	
			A3			120.00	600.00		05/07/2021			N.D.	N.D.	<0.058	10	
BIU-017-21 I/PR21/ZU0 6 48027 Solarolo (RA) Italy	Zucchini / Ismaila F1	1) 27/04/2021 2) 15/05/2021 3) 01/06/2021 04/06/2021 07/06/2021 10/06/2021	A1	T	Prothioconazole	118.40	493.33	118.40	12/05/2021	70-75	Fruits	N.D.	N.D.	<0.058	0	
			A2			121.20	505.00	121.20	22/05/2021			N.D.	N.D.	<0.058	3	
									N.D.			N.D.	<0.058	6		
			A3			115.60	481.66	115.60	01/06/2021			N.D.	N.D.	<0.058	9	

BIU-017-21 I/PR21/ZU0 7 42022 Boretto (RE) Italy	Zucchini / Chiara Genovese	1) 28/08/2021 2) N.A. 3) 25/10/2021	A1	T	Prothioconazole	122.67	613.33	20.00	1/10/2021	85-87	Fruits	N.D.	N.D.	<0.058	3	mg/kg LOD single analyte: 0.003 mg/kg
			A2			121.33	606.67		11/10/2021							
			A3			122.00	610.00		22/10/2021							
BIU-017-21 I/PR21/ZU0 8 47023 San Martino in Fiume (FC) Italy	Zucchini / Rigas	1) 25/04/2021 2)13/05/2021 3) 04/06/2021	A1	T	Prothioconazole	118.40	493.33	24.00	12/05/2021	77	Fruits	N.D.	N.D.	<0.058	3	
			A2			122.00	508.33		22/05/2021							
			A3			119.60	498.33		01/06/2021							

- (a) According to Codex Classification/Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
N.A.- Not Available N.D.= Not Detectable (lower than Limit of Detection)

*Residue of sum expressed as M04 (mg/kg) = residue of M04+ M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04

A 2.1.3.6 Carrot

Table A 20: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, year 2014)	-	-	-	-	-
Intended cGAP (number 8)	2	200 g as/Ha	21 days	BBCH 16-46	21

A 2.1.3.6.1 Study RAU-021-20

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference: KCA 6.3.6/01

Report
Determination of prothioconazole metabolites residues in raw agricultural commodity carrot after two applications of SIP41099 (Prothioconazole 200 g/L + azoxystrobin 250 g/L SC) in open field conditions - 4 trials, Northern Europe, year 2020
Report N. RAU-021-20
Massardi E., 2021
Research Center BioSphereS by Biotechnologie BT

Guideline(s):
Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (as revised in 1997) ENV/MC/CHEM (98)17
Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 13, Multi-site studies) OECD ENV/JM/MONO (2002)9.
Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999)
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 78/117/EEC
Directives 2004/9/EC, of 11 February 2004, on the inspection and verification of good laboratory practice (GLP) and 2004/10/EC, of 11 February 2004, on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances
Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes SANTE/2020/12830, rev.1 (24/02/2021)
Italian legislation Decree Law No.50, 2 March 2007, regarding implementation of the directives 2004/9/CE and 2004/10/CE.
Commission Regulation (EU) N. 284/2013 of 1st of March 2013 setting out

the data requirements for plant protection products, in accordance with Regulation (EC) n.1107/2009

Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009)

EC guidance document 1607/VI/97 rev.2, 10/6/1999

EC Technical guidance document SANTE/2019/12752

Deviations:

Deviation No. 1 for the Analytical Phase: 16/04/2021

Description: The column was replaced. As a consequence of the different diameter, the flow has been increased.

Reason: The column was no longer performing.

Impact: None, the columns are equivalent considering the scale up of method.

- Deviation No. 1 for the trial F/PA20/CA01: 04/06/2019 reported on 12/10/2020

Description: PROSARO (containing prothioconazole and tebuconazole) and AMISTAR (containing azoxystrobin) were applied by farmer on winter wheat the 04/06/2019.

PI's answer: First application of the trial was done the 31/08/2020.

Impact: None.

- Deviation No. 2 for the trial F/PA20/CA01: 06/05/2019 and 20/05/2019 reported on 27/10/2020

Description: METCOSTAR (containing metconazole) was applied on the trial site the 06/05/2019 and VOXAN (containing epoxiconazole) was applied on the trial site the 20/05/2019.

PI's answer: First application of the trial was done the 31/08/2020.

Impact: None.

- Deviation No. 1 for the trial H/PA20/CA03: 14/09/2020

Description: In spite of the requirements of the Study Plan, a maintenance treatment was done on the trial site with DAGONIS (containing fluxapyroxad and difenoconazole) on 14/09/2020.

PI's answer: None.

Impact: None.

- Deviation No. 2 for the trial H/PA20/CA03: 05/10/2020

Description: The crop stage at harvest was BBCH 49 instead of BBCH 46.

PI's answer: None.

Impact: None.

- Deviation No. 1 for the trial P/PA20/CA04: 09/09/2020

Description: At the first application the deviation to the target dose was + 5.6 % (more than $\pm 5\%$ planned in the Study Plan).

PI's answer: None.

Impact: None.

GLP:

Yes

Validity

Material and methods

The analytical method was fully validated in RAU-003-21. The analytical method was validated on plum specimens as representative commodities for water matrices at 0.01 mg/kg (LOQ spiking level) and 1.0 mg/kg (100xLOQ spiking level). In order to verify the analytical method on carrot samples, a reduced validation was carried out according to SANCO/3029/99, rev. 4 (11/07/2000).

REDUCED VALIDATION - QUANTIFIER ION					
Matrix	Fortification Level (mg/kg)	Accuracy and precision per level		Overall accuracy and precision	
		Mean Recovery (%) n=3	RSD (%) n=3	Mean Recovery (%) n=6	RSD (%) n=6
Carrot	M04				
	0.01	104.87	1.43	102.68	3.20
	1.00	100.48	3.18		
	M14				
	0.01	97.54	0.92	101.09	3.97
	1.00	104.64	1.24		
	M15				
	0.01	106.31	1.29	104.03	2.84
	1.00	101.75	2.02		
	M16				
	0.01	99.11	0.99	101.23	2.56
	1.00	103.35	1.49		
	M17				
	0.01	88.13	2.48	95.81	9.01
	1.00	103.50	2.00		
	M18				
	0.01	98.98	1.46	101.65	3.03
	1.00	104.32	0.47		

The maximum storage interval between sampling and sample extraction was 277 days.

Table A 21: Summary of the study RAU-021-20 trials

Report No. Location	Commodity/ Variety	Date of (b) 1) Sowing or Transplanting 2) Flowering 3) Harvest	Application Rate per Treatment					Dates of Treatment (s) or No. of Treatment and Last Date (c)	Growth Stage at Last Treatment or Date	Portion Analysed (a)	Residues (mg/kg)							PHI (Days) (d)	Remarks:(e)
			Active ingredient	App. N.	g ai/ha	Water L/ha	g ai/ hL				M04	M14	M15	M16	M17	M18	SUM as M04*		
RAU-021-20 F/PA20/CA01 62860 Inchy en Artois (Hauts de France) France	Carrot / Nerac F1	1) 29/04/2020 2) Not Availa- ble 3) 05/10/2020	Prothioconazole	A1	167.1	313	53	31/08/2020	44	Root	0.0240	N.D.	N.D.	N.D.	N.D.	N.D.	<0.058	21	None
			A2	161.8	303	14/09/2020													
RAU-021-20 H/PA20/CA02 6795 Bordány (Csongrad csanad) Hungary	Carrot / Napa	1) 26/02/2020 2) Not Availa- ble 3) 16/07/2020	Prothioconazole	A1	162.7	407	40	11/06/2020	46	Root	<0.01 (0.0089)	N.D.	N.D.	N.D.	N.D.	N.D.	<0.058	21	None
			A2	166.7	417	25/06/2020													
RAU-021-20 H/PA20/CA03 6080 Szabadszállás (Bács Kiskun) Hungary	Carrot / Ro- mance	1) 01/06/2020 2) Not Appli- cable 3) 05/10/2020	Prothioconazole	A1	165.3	517	32	31/08/2020	46	Root	0.0830	N.D.	N.D.	N.D.	N.D.	N.D.	0.0973	21	None
			A2	158.9	497	14/09/2020													
RAU-021-20 P/PA20/CA04	Carrot / Joba	1) 28/04/2020 2) Not Availa- ble 3) 13/10/2020	Prothio- conazole	A1	168.9	317	53	09/09/2020	45	Root	0.0107	N.D.	N.D.	N.D.	N.D.	N.D.	<0.058	21	None

99-335 Witonia (Łódzkie) Poland				A2	161.8	303	22/09/2020												
--	--	--	--	----	-------	-----	------------	--	--	--	--	--	--	--	--	--	--	--	--

(a) According to Codex Classification/Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

N.A.- Not Available N.D.= Not Detectable (lower than Limit of Detection)

*Residue of sum expressed as M04 (mg/kg) = residue of M04+ M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04

A 2.1.3.6.2 Study RAU-017-21

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference: KCA 6.3.6/02

Report Determination of Prothioconazole metabolites residues in raw agricultural commodity carrot after two applications of SIP41061 (Prothioconazole 400 g/L SC) – (Central Europe, 4 trials, year 2021).
Report N. RAU-017-21
BioTecnologie BT.
Massardi E., 2022
Research Center BioSphereS by Biotechnologie BT

Guideline(s): Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (as revised in 1997) ENV/MC/CHEM (98)17
Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 13, Multi-site studies) OECD ENV/JM/MONO (2002)9.
Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999)
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 78/117/EEC
Directives 2004/9/EC, of 11 February 2004, on the inspection and verification of good laboratory practice (GLP) and 2004/10/EC, of 11 February 2004, on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances
Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes SANTE/2020/12830, rev.1 (24/02/2021)
Italian legislation Decree Law No.50, 2 March 2007, regarding implementation of the directives 2004/9/CE and 2004/10/CE.
Commission Regulation (EU) N. 284/2013 of 1st of March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) n.1107/2009
Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009)
EC guidance document 1607/VI/97 rev.2, 10/6/1999
EC Technical guidance document SANTE/2019/12752

Deviations: No

GLP: Yes

Validity

Material and methods

The analytical method was fully validated in RAU-003-21. In addition, in order to verify the performance of the analytical method procedural recovery tests were carried out at 0.01 mg/kg (LOQ spiking levels) and 1.0 mg/kg (100xLOQ spiking levels) for all analytes.

PROCEDURAL RECOVERY - QUANTIFIER ION					
Matrix	Fortification Level (mg/kg)	Accuracy and precision per level		Overall accuracy and precision	
		Mean Recovery (%) n=2	RSD (%) n=2	Mean Recovery (%) n=4	RSD (%) n=4
Carrot	M04				
	0.01	67.38	1.09	75.40	12.38
	1.00	83.42	2.31		
	M14				
	0.01	75.56	4.81	80.67	7.76
	1.00	85.78	0.13		
	M15				
	0.01	82.09	6.46	85.05	5.40
	1.00	88.01	0.16		
	M16				
	0.01	83.82	0.59	85.95	2.91
	1.00	88.08	0.66		
	M17				
	0.01	77.34	1.25	80.70	4.90
	1.00	84.06	1.12		
	M18				
	0.01	79.05	4.00	81.05	3.84
	1.00	83.05	2.08		

The maximum storage interval between sampling and sample extraction was 152 days

Table A 22: Summary of the study RAU-017-21 trials

Report No. Location	Commodity/ Variety	Date of (b) 1) Sowing or Transplanting 2) Flowering 3) Harvest	Application Rate per Treatment					Dates of Treatment (s) or No. of Treatment and Last Date (c)	Growth Stage at Last Treatment or Date	Portion Analysed (a)	Residues (mg/kg)						PHI (Days) (d)	Remarks:(e)	
			Active ingredient	App. N.	g ai/ha	Water L/ha	g ai/ hL				M04	M14	M15	M16	M17	M18			SUM as M04*
RAU-017-21 F/PR21/CA01 08190 Sault Saint Rémy, France	Carrot / Miami F1	1) 03/05/2021 2) Not Applica- ble 3) 25/10/2021	Prothioconazole	A1	202.4	607	33	20/09/2021	48	Roots	0.0336	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058	21	None
				A2	201.6	604		04/10/2021											
RAU-017-21 F/PR21/CA02 62860 Inchy en Artois, France	Carrot / Norway F1	1) 18/05/2021 2) Not Applica- ble 3) 13/10/2021	Prothioconazole	A1	196.0	587	33	06/09/2021	45	Roots	0.0211	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058	22	None
				A2	206.8	620		21/09/2021											
RAU-017-21 P/PR21/CA03 21-311 Wiski, Poland	Carrot / Flakkee	1) 20/04/2021 2) Not Applica- ble 3) 20/10/2021	Prothioconazole	A1	202.0	607	33	16/09/2021	49	Roots	<0.01 (0.009 5)	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058	21	None
				A2	200.0	600		29/09/2021											
RAU-017-21 P/PR21/CA04 62-285 Popowo Kościelne, Poland	Carrot / Volca- no	1) 02/04/2021 2) Not Applica- ble 3) 12/08/2021	Prothioconazole	A1	202.0	607	33	07/07/2021	45	Roots	0.0287	N.D.	N.D.	N.D.	N.D.	N.D.	< 0.058	22	None
				A2	199.6	600		21/07/2021											

- (a) According to Codex Classification/Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

N.A.- Not Available N.D.= Not Detectable (lower than Limit of Detection)

*Residue of sum expressed as M04 (mg/kg) = residue of M04+ M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04

A 2.1.3.7 Oilseed Rape

Table A 23: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, year 2014)	2	120 g as/ha	14 days	-	28
Intended cGAP (number 3)	2	180 g as/ha	14 days	BBCH 30-71	50

A 2.1.3.7.1 Study RAU-015-20

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference: KCA 6.3.7/01

Report

Determination of prothioconazole metabolites residues in raw agricultural commodity oilseed rape after two applications of SIP41099 (Prothioconazole 200 g/L + azoxystrobin 250 g/L SC) in open field conditions - 4 trials, Northern Europe, year 2020
Report N. RAU-015-20
Massardi E., 2021
Research Center BioSphereS by Biotechnologie BT

Guideline(s):

Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (as revised in 1997) ENV/MC/CHEM (98)17.
Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990.
Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 13, Multi-site studies) OECD ENV/JM/MONO (2002)9.
Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999).
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 78/117/EEC Directives 2004/9/EC, of 11 February 2004, on the inspection and verification of good laboratory practice (GLP) and 2004/10/EC, of 11 February 2004, on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.
EU Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000).

Italian legislation Decree Law No.50, 2 March 2007, regarding implementation of the directives 2004/9/CE and 2004/10/CE.

Commission Regulation (EU) N. 284/2013 of 1st of March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) n.1107/2009.

Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009).

Deviations:

Deviation No. 1 for the Analytical Phase: 12/04/2021

Description: The column was replaced. As a consequence of the different diameter, the flow has been increased. The guard column has not been used.

Reason: The column was no longer performing.

Impact: None, the columns are equivalent considering the scale up of method.

• Deviation No. 1 for the trial F/PA20/OS01: 09/07/2020

Description: The sampling was carried out at 38 DALA instead of 50 DALA for advanced maturity.

PI's answer: Application 2 was done at BBCH 80 as planned in the Study Plan. It was not possible to carried out sampling at 50 DALA, otherwise seeds would have been on soil.

Impact: None, measured residues are in line with current EU MRL, no relevant differences were observed respect the other trial samples.

• Deviation No. 1 for the trial F/PA20/OS02: 08/10/2020

Description: CARAMBA STAR (containing metconazole) was applied by farmer on 09/04/2020 and PROSARO (containing prothioconazole and tebuconazole) was applied on 21/05/2019.

PI's answer: As it was a late request unanticipated, in accordance with the Sponsor the trial site pesticide historic was accepted.

Impact: None, measured residues are in line with current EU MRL of Prothioconazole.

• Deviation No. 2 for trials F/PA20/OS01 and F/PA20/OS02: 18/04/2019 and 16/05/2019, reported on 22/10/2020

Description: LIBRAX (containing metconazole) was applied on 16/05/2019 on the field in which was set up the trial F/PA20/OS01. CHEROKEE (containing cyproconazole and propiconazole) was applied on 18/04/2019 on the field in which was set up the trial F/PA20/OS02.

PI's answer: As it was a late request unanticipated, in accordance with the Sponsor the trials sites pesticide historic was accepted.

Impact: None, measured residues are in line with current EU MRL of Prothioconazole.

• Deviation No. 1 for the trial P/PA20/OS04: 21/07/2020

Description: For a mistake with planning data, the sampling was carried out at 60 DALA (21/07/2020) instead of 50 DALA (11/07/2020) as planned in the Study Plan.

PI's answer: Sampling collection form in the FTN raw data part with actual sampling should be read 60 DALA instead of 50 DALA.

Impact: None, best case trial, DALA is in line with 25% variability criteria for residue trials.

GLP: Yes

Acceptability:

Material and methods

The analytical method was fully validated in RAU-003-21. In addition, in order to verify the performance of the analytical method procedural recovery tests were carried out at 0.01 mg/kg (LOQ spiking levels) and 1.0 mg/kg (100xLOQ spiking levels) for all analytes.

PROCEDURAL RECOVERY - QUANTIFIER ION					
Matrix	Fortification Level (mg/kg)	Accuracy and precision per level		Overall accuracy and precision	
		Mean Recovery (%) n=2	RSD (%) n=2	Mean Recovery (%) n=4	RSD (%) n=4
Sugar beet roots	M04				
	0.01	110.81	4.10	99.26	13.70
	1.00	87.71	0.28		
	M14				
	0.01	107.65	2.62	97.78	11.79
	1.00	87.91	1.42		
	M15				
	0.01	108.70	0.46	98.41	12.11
	1.00	88.11	1.64		
	M16				
	0.01	109.23	3.61	99.36	11.71
	1.00	89.48	0.92		
	M17				
	0.01	111.44	1.47	101.10	11.84
	1.00	90.77	0.23		
	M18				
	0.01	108.88	6.06	98.65	12.88
	1.00	88.43	5.35		

The maximum storage interval between sampling and sample extraction was 105 days.

Table A 24: Summary of the study RAU-015-20 trials

Report No. Location	Commodity/ Variety	Date of (b) 1) Sowing or Transplanting 2) Flowering 3) Harvest	Application Rate per Treatment				Dates of Treatment (s) or No. of Treat- ment and Last Date (c)	Growth Stage at Last Treatment or Date	Portion Analysed (a)	Residues (mg/kg)							PHI (Days) (d)
			Active ingredient	App. N.	g ai/ha	Water L/ha	g ai/ hL			M04	M14	M15	M16	M17	M18	SUM as M04*	
RAU-015-20 F/PA20/OS01 08360 Saint Fergeux (Grand Est) France	Oilseed rape / Architect	1) 20/08/2019 2) from 10/04 to 05/05/2020 3) 09/07/2020	Prothioconazole	A1	162.1	253	64	18/05/2020	80	Seeds	0.0103	N.D.	N.D.	N.D.	N.D.	<0.01 (0.0068)	38
				A2	166.4	260		01/06/2020		Straw	0.1719	0.0562	0.0378	<0.01 (0.0065)	N.D.	0.0716	
RAU-015-20 F/PA20/OS02 49260 Vaudelnay (Pays de la Loire) France	Oilseed rape / Delice	1) 27/08/2019 2) from 10/03 to 31/03/2020 3) 21/07/2020	Prothioconazole	A1	162.7	407	40	18/05/2020	80	Seeds	0.0225	N.D.	N.D.	N.D.	N.D.	0.106	50
				A2	168.0	420		01/06/2020		Straw	0.2168	0.0290	0.0192	N.D.	N.D.	0.0955	
RAU-015-20 P/PA20/OS03 14-100 Kajkowo (Warminsko) Poland	Oilseed rape / DK expres- sion	1) 24/08/2019 2) from 28/04 to 05/06/2020 3) 29/07/2020	Prothioconazole	A1	164.7	309	53	26/05/2020	75	Seeds	N.D.	N.D.	N.D.	N.D.	N.D.	<0.058	50
				A2	163.6	307		09/06/2020		Straw	0.0254	0.0249	0.0129	N.D.	N.D.	<0.01 (0.0089)	

RAU-015-20 P/PA20/OS04 62-105 Niemczyn (Wielkopolska) Poland	Oilseed rape / Chrobry	1) 30/08/2020 2) from 02/05 to 19/05/2020 3) 21/07/2020	Prothioconazole	A1	154.7	290	53	08/05/2020	71	Seeds	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	<0.058	60
				A2	156.4	293		22/05/2020		Straw	0.0334	<0.01 (0.0064)	N.D.	N.D.	N.D.	0.0155	0.0628	

- (a) According to Codex Classification/Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
N.A.- Not Available N.D.= Not Detectable (lower than Limit of Detection)

*Residue of sum expressed as M04 (mg/kg) = residue of M04+ M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04

A 2.1.3.7.2 Study RAU-014-21

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference:	KCA 6.3.7/02
Report	<p>Determination of prothioconazole metabolites residues in raw agricultural commodity oilseed rape after two applications of SIP41061 (Prothioconazole 400 g/L SC) in open field conditions – Central Europe, 4 trials, year 2021</p> <p>Report N. RAU-014-21</p> <p>Massardi E., 2022</p> <p>Research Center BioSphereS by Biotechnologie BT</p>
Guideline(s):	<p>Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (as revised in 1997) ENV/MC/CHEM (98)17.</p> <p>Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990.</p> <p>Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 13, Multi-site studies) OECD ENV/JM/MONO (2002)9.</p> <p>Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999).</p> <p>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 78/117/EEC</p> <p>Directives 2004/9/EC, of 11 February 2004, on the inspection and verification of good laboratory practice (GLP) and 2004/10/EC, of 11 February 2004, on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.</p> <p>EU Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000).</p> <p>Italian legislation Decree Law No.50, 2 March 2007, regarding implementation of the directives 2004/9/CE and 2004/10/CE.</p> <p>Commission Regulation (EU) N. 284/2013 of 1st of March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) n.1107/2009.</p> <p>Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009).</p>
Deviations:	<p>Yes</p> <p>Deviation No. 1 for the trial F/PR21/OS01: 12/05/2021</p> <p>Description: Application 1 was done at BBCH 69 instead of BBCH > 69 in order to have a time interval of 64 days between application 1 and commercial harvest sampling.</p> <p>PI's answer: Application 1 was done in accordance with the Study Director.</p> <p>Impact: None.</p> <p>• Deviation No. 1 for the trial H/PR21/OS02: 05/05/2021</p> <p>Description: Application timing for A1 was 14 DBA2 and after BBCH 69. In</p>

order to keep the schedule for A2 and S1, and upon Study Director's email that 14DBA2 takes priority, A1 application was done at BBCH 65.

PI's answer: As harvest (S1) was planned for 08 July and A2 for 19 May, A1 application had to be done on 05 May.

Impact: None.

• Deviation No. 1 for trials P/PR21/OS03: occurred on 28/05/2021 issued on 01/06/2021

Description: First application done at BBCH 67 instead of BBCH>69, because days from the first application to the harvest would be less than 64 days.

PI's answer: None.

Impact: None.

• Deviation No. 1 for the trial P/PR21/OS04: occurred on 31/05/2021 issued on 09/06/2021

Description: First application done at BBCH 67 instead of BBCH>69, because days from the first application to the harvest would be less than 64 days.

PI's answer: None.

Impact: None.

• Deviation No. 2 for the trial P/PR21/OS04: occurred on 29/08/2021 issued on 21/09/2021

Description: No electric city at station Łajsy from 10:00 am of 29-08-2021 to 9:00 am of 30-08-2021. At freezer 1116 max. temperature recorded was -6.4°C inside retain samples P/PR21/OS04/29C and P/PR21/OS04/30C; at freezer 1240 max. temperature recorded was -9.0°C inside retain samples P/PR21/OS04/31T and P/PR21/OS04/32T. Samples still frozen.

PI's answer: None.

Impact: None.

GLP: Yes

Acceptability:

Material and methods

The analytical method was fully validated in RAU-003-21. In addition, in order to verify the performance of the analytical method procedural recovery tests were carried out at 0.01 mg/kg (LOQ spiking levels) and 1.0 mg/kg (100xLOQ spiking levels) for all analytes.

PROCEDURAL RECOVERY - QUANTIFIER ION					
Matrix	Fortification Level (mg/kg)	Accuracy and precision per level		Overall accuracy and precision	
		Mean Recovery (%) n=2	RSD (%) n=2	Mean Recovery (%) n=4	RSD (%) n=4
Oilseed rape seeds	M04				
	0.01	89.62	3.73	85.85	5.66
	1.00	82.08	2.03		
	M14				
	0.01	87.56	8.61	89.17	5.95
	1.00	90.78	4.58		
	M15				

	0.01	105.38	16.04	93.67	17.96
	1.00	81.97	4.78		
	M16				
	0.01	86.91	5.81	83.30	6.17
	1.00	79.68	1.58		
	M17				
	0.01	96.00	9.00	88.30	11.56
	1.00	80.59	0.49		
	M18				
	0.01	90.94	18.69	88.12	11.75
	1.00	85.30	1.18		

PROCEDURAL RECOVERY - QUANTIFIER ION					
Matrix	Fortification Level (mg/kg)	Accuracy and precision per level		Overall accuracy and precision	
		Mean Recovery (%) n=2	RSD (%) n=2	Mean Recovery (%) n=4	RSD (%) n=4
Oilseed rape straw	M04				
	0.01	76.75	5.23	86.77	13.70
	1.00	96.79	2.59		
	M14				
	0.01	100.91	1.73	102.75	3.25
	1.00	104.59	3.92		
	M15				
	0.01	96.73	17.37	98.77	10.27
	1.00	100.81	3.11		
	M16				
	0.01	104.64	5.06	102.58	3.92
	1.00	100.53	1.86		
	M17				
	0.01	106.85	5.39	106.95	3.37
	1.00	107.05	2.24		
	M18				
	0.01	104.75	15.80	104.36	9.19
	1.00	103.97	1.21		

The maximum storage interval between sampling and sample extraction was 224 days.

Table A 25: Summary of the study RAU-014-21 trials

Report No. Location	Commodi- ty/ Variety	Date of (b) 1) Sowing or Transplant- ing 2) Flowering 3) Harvest	Application Rate per Treatment					Dates of Treat- ment (s) or No. of Treat- ment and Last Date (c)	Growth Stage at Last Treat- ment or Date	Portion Ana- lysed (a)	Residues (mg/kg)							PHI (Days) (d)
			Active ingredi- ent	App . N.	g ai/ha	Wa- ter L/ha	g ai/ hL				M04	M14	M15	M16	M1 7	M18	SUM as M04*	
RAU-014-21 F/PR21/OS01 37110 Dame Marie les Bois France	Oilseed rape / Tempo	1) 01/09/2020 2) from 20/04 to 14/05/2021 3) 16/07/2021	Prothioconazole	A1	184. 4	513	36	12/05/2021	75-78	Seeds	<0.01 (0.0092)	N.D.	N.D.	N.D.	N.D.	N.D.	<0.05 8	50
				A2	182. 0	506		27/05/2021		Straw	0.0175	0.0404	0.0164	<0.01 (0.0059)	N.D.	0.0113	0.0907	
RAU-014-21 H/PR21/OS02 5081 Szajol Hungary	Oilseed rape / Shrek	1) 23/08/2020 2) from 09/05 to 19/05/2021 3) 08/07/2021	Prothioconazole	A1	188. 0	209	90	05/05/2021	69	Seeds	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	<0.05 8	50
				A2	188. 0	209		19/05/2021		Straw	0.0328	<0.01 (0.0051)	N.D.	N.D.	N.D.	<0.01 (0.0080)	<0.058	
RAU-014-21 P/PR21/OS03 96-127 Lipce Reymon- towskie Poland	Oilseed rape / Gemini	1) 28/08/2020 2) from 04/05 to 30/05/2021 3) 29/07/2021	Prothioconazole	A1	178. 8	298	60	28/05/2021	74	Seeds	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	<0.05 8	49
				A2	173. 2	289		10/06/2021		Straw	0.0247	0.0420	<0.01 (0.0092)	<0.01 (0.0050)	N.D.	0.0115	0.0920	

RAU-014-21 P/PR21/OS04 14-100 Samborowo Poland	Oilseed rape / Arabella	1) 28/08/2020 2) from 07/05 to 06/06/2021 3) 02/08/2021	Prothioconazole	A1	186. 0	310	60	31/05/2021	75	Seeds	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	<0.05 8	49
				A2	174. 8	292		14/06/2021		Straw	0.0169	0.0351	0.0100	<0.01 (0.0043)	N.D.	<0.01 (0.0090)	0.0753	

- (a) According to Codex Classification/Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
N.A.- Not Available N.D.= Not Detectable (lower than Limit of Detection)

*Residue of sum expressed as M04 (mg/kg) = residue of M04+ M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04

A 2.1.3.8 Sugar beet

Table A 26: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, year 2014)	-	-	-	-	-
Intended cGAP (number 4)	2	160 g as/ha	14 days	BBCH 39-49	28

A 2.1.3.8.1 Study RAU-020-20

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference: KCA 6.3.8/01

Report
Determination of prothioconazole metabolites residues in raw agricultural commodity sugar beet after two applications of SIP41099 (Prothioconazole 200 g/L + azoxystrobin 250 g/L SC) in open field conditions - 3 trials, Northern Europe, year 2020
Report N. RAU-020-20
Massardi E., 2021
Research Center BioSphereS by Biotechnologie BT

Guideline(s):
Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (as revised in 1997) ENV/MC/CHEM (98)17
Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 13, Multi-site studies) OECD ENV/JM/MONO (2002)9.
Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990.
Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999)
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 78/117/EEC
Directives 2004/9/EC, of 11 February 2004, on the inspection and verification of good laboratory practice (GLP) and 2004/10/EC, of 11 February 2004, on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances
EU Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000)
Italian legislation Decree Law No.50, 2 March 2007, regarding implementa-

tion of the directives 2004/9/CE and 2004/10/CE.
Commission Regulation (EU) N. 284/2013 of 1st of March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) n.1107/2009
Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009)

Deviations: Yes

Deviation No. 1 for the trial U/PA20/SB01: 18/06/2019 reported on 07/04/2021

Description: The field was treated with prothioconazole in June 2019. Study plan requested that field was not treated with triazoles in 2019 and 2020.

PI's answer: Agreed with Study Director in advance that field was considered okay to set up the trial.

Impact: None, residues measured in sugar beet root and leaves of this trial are in line with the results of the samples coming from the other NEU trials.

• Deviation No. 1 for the trial H/PA20/SB03: 08/10/2020

Description: Though the harvest was originally planned for 14th October and the trial area was clearly marked, the farmer harvested the field earlier and destroyed the trial area. Sampling at harvest cannot be done.

PI's answer: None.

Impact: The trial has been destroyed, so it was deleted from the study with an amendment. The trial will be rescheduled in another study.

GLP: Yes

Acceptability:

Material and methods

The analytical method was fully validated in RAU-003-21. In addition, in order to verify the performance of the analytical method procedural recovery tests were carried out at 0.01 mg/kg (LOQ spiking levels) and 1.0 mg/kg (100xLOQ spiking levels) for all analytes.

PROCEDURAL RECOVERY - QUANTIFIER ION					
Matrix	Fortification Level (mg/kg)	Accuracy and precision per level		Overall accuracy and precision	
		Mean Recovery (%) n=2	RSD (%) n=2	Mean Recovery (%) n=4	RSD (%) n=4
Sugar beet root	M04				
	0.01	101.17	5.69	94.87	8.48
	1.00	88.56	1.68		
	M14				
	0.01	91.56	5.97	90.36	3.82
	1.00	89.16	0.25		

	M15				
	0.01	96.06	1.32	92.25	4.83
	1.00	88.45	0.51		
	M16				
	0.01	97.65	2.87	91.55	7.90
	1.00	85.45	0.02		
	M17				
	0.01	107.59	0.72	92.26	19.24
	1.00	76.93	2.60		
	M18				
	0.01	96.69	5.95	92.87	6.00
	1.00	89.05	1.45		

PROCEDURAL RECOVERY - QUANTIFIER ION					
Matrix	Fortification Level (mg/kg)	Accuracy and precision per level		Overall accuracy and precision	
		Mean Recovery (%) n=2	RSD (%) n=2	Mean Recovery (%) n=4	RSD (%) n=4
Sugar beet leaves	M04				
	0.01	77.76	1.59	80.79	4.85
	1.00	83.82	3.33		
	M14				
	0.01	91.07	0.51	90.48	0.95
	1.00	89.88	0.87		
	M15				
	0.01	89.35	3.21	89.56	2.82
	1.00	89.78	3.65		
	M16				
	0.01	97.77	1.32	93.61	5.21
	1.00	89.45	0.84		
	M17				
	0.01	87.80	2.62	81.45	9.28
	1.00	75.10	2.87		
	M18				
	0.01	95.70	1.47	92.64	3.94
	1.00	89.58	0.84		

The maximum storage interval between sampling and sample extraction was 244 days.

Table A 277: Summary of the study RAU-020-20 trials

Report No. Location	Commodity/ Variety	Date of (b) 1) Sowing or Transplanting 2) Flowering 3) Harvest	Application Rate per Treatment					Dates of Treatment (s) or No. of Treat- ment and Last Date (c)	Growth Stage at Last Treatment or Date	Portion Analysed (a)	Residues (mg/kg)							PHI (Days) (d)
			Active ingredient	App. N.	g ai/ha	Water L/ha	g ai/ hL				M04	M14	M15	M16	M17	M18	SUM as M04*	
RAU-020-20 U/PA20/SB01 PE8 6TZ Fotheringhay (East Mid- lands) United King- dom	Sugar beet / KWS Sabatina	1) 04/04/2020 2) Not Availa- ble 3) 20/10/2020	Prothioconazole	A1	167.2	313	53	07/09/2020	48	Root	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	<0.058	29
A2				156.4	293	21/09/2020		Leaves		0.0500	N.D.	N.D.	N.D.	N.D.	N.D.	0.0201	0.0805	
RAU-020-20 P/PA20/SB02 99-335 Witonia (Todzkie) Poland	Sugar beet / Bravura	1) 28/03/2020 2) Not Availa- ble 3) 23/09/2020	Prothioconazole	A1	156.0	390	40	12/08/2020	48	Root	<0.01 (0.0044)	N.D.	N.D.	N.D.	N.D.	N.D.	<0.058	28
A2				162.6	407	26/08/2020		Leaves		0.0513	0.0108	N.D.	N.D.	N.D.	N.D.	0.0304	0.0991	
RAU-020-20 P/PA20/SB04 63-220 Slawoszew (Wielkopolskie) Poland	Sugar beet / Leandrus	1) 26/03/2020 2) Not Availa- ble 3) 23/09/2020	Prothioconazole	A1	163.6	307	53	12/08/2020	48	Root	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	<0.058	28
A2				158.4	297	26/08/2020		Leaves		0.0459	<0.01 (0.0070)	N.D.	N.D.	N.D.	<0.01 (0.0080)	0.0687		

- (a) According to Codex Classification/Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

N.A.- Not Available N.D.= Not Detectable (lower than Limit of Detection)

*Residue of sum expressed as M04 (mg/kg) = residue of M04+ M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04

A 2.1.3.8.2 Study RAU-015-21

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference:	KCA 6.3.8/02
Report	<p>Determination of prothioconazole metabolites residues in raw agricultural commodity sugar beet (roots) after two applications of SIP41061 (Prothioconazole 400 g/L SC) in open field conditions – Central Europe, 5 trials, year 2021</p> <p>Report N. RAU-015-21</p> <p>Massardi E., 2022</p> <p>Research Center BioSphereS by Biotechnologie BT</p>
Guideline(s):	<p>Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (as revised in 1997) ENV/MC/CHEM (98)17</p> <p>Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice and Compliance Monitoring (Monograph 13, Multi-site studies) OECD ENV/JM/MONO (2002)9.</p> <p>Guidelines on Producing Residue Data from Supervised Trials, FAO, Rome 1990.</p> <p>Compliance Monitoring Number 6, the Application of GLP Principles to Field Studies, Environment Monograph No. 50 (1999)</p> <p>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 78/117/EEC</p> <p>Directives 2004/9/EC, of 11 February 2004, on the inspection and verification of good laboratory practice (GLP) and 2004/10/EC, of 11 February 2004, on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances</p> <p>EU Guidance documents on residue analytical methods SANCO/825/00 rev. 8.1 (16/11/2010) and SANCO/3029/99, rev. 4 (11/07/2000)</p> <p>Italian legislation Decree Law No.50, 2 March 2007, regarding implementation of the directives 2004/9/CE and 2004/10/CE.</p> <p>Commission Regulation (EU) N. 284/2013 of 1st of March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) n.1107/2009</p> <p>Organization for Economic Co-operation and Development (OECD 509) Guideline for the Testing of Chemicals (Crop Field Trial, adopted 7 September 2009)</p>
Deviations:	<p>Yes</p> <p>Deviation No. 1 for the trial U/PR21/SB01: occurrence on 27/04/2020, issued on 04/02/2022</p> <p>Description: Prothioconazole (prothioconazole 110 g/L) was applied to the previous crop in field on 27/04/2020.</p>

PI's answer: Full crop protection is recoded in the field trial notebook and field phase report.

Impact: As the samples coming from this trial were not analysed there is no impact on this study.

• Deviation No. 1 for the trial H/PR21/SB04: 10/08/2021

Description: At the application the deviation to the target dose was +8.3 % (more than $\pm 5\%$ spray tolerance planned).

PI's answer: None.

Impact: None

GLP: Yes

Acceptability:

Material and methods

The analytical method was fully validated in RAU-003-21. In addition, in order to verify the performance of the analytical method procedural recovery tests were carried out at 0.01 mg/kg (LOQ spiking levels) and 1.0 mg/kg (100xLOQ spiking levels) for all analytes.

PROCEDURAL RECOVERY - QUANTIFIER ION					
Matrix	Fortification Level (mg/kg)	Accuracy and precision per level		Overall accuracy and precision	
		Mean Recovery (%) n=2	RSD (%) n=2	Mean Recovery (%) n=4	RSD (%) n=4
Sugar beet roots	M04				
	0.01	110.81	4.10	99.26	13.70
	1.00	87.71	0.28		
	M14				
	0.01	107.65	2.62	97.78	11.79
	1.00	87.91	1.42		
	M15				
	0.01	108.70	0.46	98.41	12.11
	1.00	88.11	1.64		
	M16				
	0.01	109.23	3.61	99.36	11.71
	1.00	89.48	0.92		
	M17				
	0.01	111.44	1.47	101.10	11.84
	1.00	90.77	0.23		
	M18				
	0.01	108.88	6.06	98.65	12.88
	1.00	88.43	5.35		

The maximum storage interval between sampling and sample extraction was 105 days.

Table A 288: Summary of the study RAU-015-21 trials

Report No. Location	Commodity/ Variety	Date of (b) 1) Sowing or Transplanting 2) Flowering 3) Harvest	Application Rate per Treatment					Dates of Treatment (s) or No. of Treat- ment and Last Date (c)	Growth Stage at Last Treatment or Date	Portion Analysed (a)	Residues (mg/kg)							PHI (Days) (d)	Remarks:(e)
			Active ingredient	App. N.	g ai/ha	Water L/ha	g ai/ hL				M04	M14	M15	M16	M17	M18	SUM as M04*		
RAU-015-21 H/PR21/SB05 7465 Szentgáloskér Hungary	Sugar beet / Barna	1) 15/04/2021 2) Not Appli- cable 3) 15/10/2021	Prothioconazole	A1	164.0	615	27	03/09/2021	39	Roots	N.D.	N.D.	N.D.	N.D.	N.D.	N.D.	<0.058	29	None
			A2	160.0	600	16/09/2021													

(a) According to Codex Classification/Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
N.A.- Not Available N.D.= Not Detectable (lower than Limit of Detection)

*Residue of sum expressed as M04 (mg/kg) = residue of M04+ M14 expressed as M04 + M15 expressed as M04 + M16 expressed as M04 + M17 expressed as M04 + M18 expressed as M04

A 2.1.3.9 Wheat

Table A 29: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, year 2014)	-	-	-	-	-
Intended cGAP (number 1)	2	200 g as/ha	14 days	BBCH 29-69	21

A 2.1.3.9.1 Study QG20005

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference: KCA 6.3.9

Report
Magnitude of Residues of Prothioconazole-desthio and Hydroxy- Prothioconazole-desthio Metabolites Following Two Applications of a 250 g/L EC Formulation to Wheat in Northern and Southern Europe, 2020 – Interim report
Report N. QG20005
Andrews G., 2022
Battelle UK

Guideline(s):
General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95 rev.5, 22 July 1997).
OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published on 7 September 2009).
SANTE/2020/12830, Rev.1, Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, 2. February 2021

Deviations: No

GLP: Yes

Acceptability:

Table A 30: Summary of the study Q20005 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Method of treatment	Application detail			Dates of treat- ment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residue mg/kg	PHI (days)	Details on trial
				kg a.s./ ha	Water (l/ha)	g a.s./hl				M04 (prothio- desthio)		
QG20005-01 17091 Schossow, Germany	Wheat/ Licamero	1) 20/04/2020 2) 14/06- 09/07/2020 3) n.av	Boom Spray	0.1928 0.2044	286 303	0.0674 0.0675	22/06/2020 07/07/2020	BBCH 69	Grain Straw	<0.005 0.0446	63 63	Method: Battelle No. QG/20/011 (study ongoing) LOQ = 0.005 mg/kg LOD = 0.0015 mg/kg Maximum storage period = 542 days Control samples <0.0015 mg/kg Overall Procedural Recover- ies Grain: Mean = 95%, RSD = 3.8% Straw: Mean = 99%, RSD = 8.7%
QG20005-02 04827 Machern OT, Germany	Wheat/ Licamero	1) 02/04/2020 2) 12/06- 26/06/2020 3) 26/06/2020 26/06/2020 03/07/2020 16/07/2020 31/07/2020 31/07/2020	Foliar Spray	0.2038 0.2099	302 311	0.0675 0.0675	12/06/2020 26/06/2020	BBCH 69	Immature Plant Immature Plant Immature Plant Immature Plant Grain Straw	0.0980 1.580 0.366 0.118 <0.005 0.175	0 0 7 20 35 35	
QG20005-03 France	Wheat/ n.av	1) n.av n.av	Foliar Spray	n.av n.av	n.av n.av	n.av n.av	n.av n.av	n.av	Grain Straw	<0.005 0.386	n.av n.av	
QG20005-04 96157 Ebrach, Germany	Wheat/ Licamero	1) 06/04/2020 2) 17/06- 03/07/2020 3) n.av	Foliar Spray	0.2006 0.2074	297 307	0.0675 0.0676	17/06/2020 01/07/2020	BBCH 69	Immature Plant Immature Plant Immature Plant Immature Plant Grain Straw	0.0946 0.444 0.0250 0.834 0.0309 0.938	0 0 7 21 35 35	
QG20005-05 3470 Kortenen, Belgium	Wheat/ Tybalt	1) 03/04/2020 2) 06/2020 3) 10/08/2020	Foliar Spray	0.208 0.208	206 206	0.101 0.101	12/06/2020 26/06/2020	BBCH 69	Grain Straw	<0.005 0.195	45 45	
QG20005-06 6599 AV Ven- Zelderheide, The Netherlands	Wheat/ Benning- ton	1) 25/11/2019 2) 06/2020 3) 09/06/2020 17/06/2020 29/06/2020	Foliar Spray	0.2091 0.2105	207 208	0.101 0.101	27/05/2020 09/06/2020	BBCH 69	Immature Plant Immature Plant Immature Plant Immature Plant Immature Plant	0.254 1.67 0.846 0.470 0.176	0 0 8 20 35	

		14/07/2020 21/07/2020							Grain Straw	<0.005 0.418	42 42	
QG20005-07 7215 AD Joppe, Netherlands	Wheat/ Tybalt	1) 11/04/2020 2) 06/2020 3) 04/08/2020	Foliar Spray	0.2052 0.2024	203 200	0.101 0.101	08/06/2020 22/06/2020	BBCH 69	Grain Straw	<0.005 0.340	43 43	
QG20005-08 46342 Velen, Ger- many	Wheat/ Kamerad B	1) 02/11/2019 2) 05/2020 3) 10/06/2020 17/06/2020 01/07/2020 15/07/2020 27/07/2020	Foliar Spray	0.2078 0.2064	205 204	0.101 0.101	27/05/2020 10/06/2020	BBCH 69	Immature Plant Immature Plant Immature Plant Immature Plant Immature Plant Grain Straw	0.366 0.546 0.0384 0.0330 0.0342 <0.005 0.191	0 0 7 21 35 47 47	

- (a) According to Codex Classification/Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
N.A.- Not Available N.D.= Not Detectable (lower than Limit of Detection)

A 2.1.3.10 Barley

Table A 31: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (Art. 12, EFSA, year 2014)	-	-	-	-	-
Intended cGAP (number 2)	2	200 g as/ha	14 days	BBCH 29-61	21

A 2.1.3.10.1 Study QG20006

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference: KCA 6.3.10

Report Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole- desthio Metabolites Following Two Applications of a 250 g/L EC Formulation to Barley in Northern and Southern Europe, 2020.
Interim report N. QG20006
Andrews G., 2022
Battelle UK

Guideline(s): General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95 rev.5, 22 July 1997).
OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published on 7 September 2009).
SANTE/2020/12830, Rev.1, Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, 2. February 2021

Deviations: No

GLP: Yes

Validity:

Table A 32: Summary of the study Q20006 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Method of treatment	Application detail			Dates of treat- ment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residue mg/kg	PHI (days)	Details on trial
				kg a.s./ ha	Water (l/ha)	g a.s./hl				M04 (prothio- desthio)		
QG20006-01 17091 Schossow, Mecklenburg-West Pomerania Germany	Barley Quench	1.20/04/2020 2.25/06-08/07/20 3.17/08/20	Foliar Spray	0.200 0.204	297 303	0.067 0.067	22/06/20 07/07/20	BBCH 69	Grain Straw	0.00696 0.20	41 41	Method: Battelle No. QG/20/011 (study ongoing) LOQ = 0.005 mg/kg LOD = 0.0015 mg/kg Maximum storage period = 568 days Control samples <0.0015 mg/kg Overall Procedural Recover- ies Grain: Mean = 97%, RSD = 2.4% Straw: Mean = 94%, RSD = 5.3%
QG20006-02 04668 Grimma OT Motterwitz, Saxony Germany	Barley Quench	1.20/03/2020 2.12/06-01/07/20 3.01/07/20	Foliar Spray	0.202 0.200	300 297	0.067 0.067	17/06/20 01/07/20	BBCH 69	Immature Plant Immature Plant Immature Plant Immature Plant Grain Straw	0.398 1.81 1.04 0.744 0.0835 0.68	0 0 6 21 35 35	
QG20006-03 Post code: 49350 47°17'28.73" N – 0°15'2.41" O France	Barley RG Planet	1.27/03/2020 2.08/06-16/06/20 3.17/07/20	Foliar Spray	0.200 0.200	249 239	0.08 0.083	03/06/20 16/06/20	BBCH 69	Grain Straw	0.0215 2.02	30 30	
QG20006-04 96157 Ebrach, Bavaria Germany	Barley Quench	1.06/04/2020 2.19/06-01/07/20 3.05/08/20	Foliar Spray	0.204 0.196	303 291	0.067 0.067	17/06/20 01/07/20	BBCH 69	Immature Plant Immature Plant Immature Plant Immature Plant Grain Straw	0.316 0.818 0.071 1.29 0.107 2.24	0 0 7 21 35 35	
QG20006-05 3470 Kortenaen, Belgium	Barley/ Irina	1) 03/04/2020 2) 06/2020 3) 04/08/2020	Foliar Spray	0.205 0.2108	203 208	0.101 0.101	12/06/2020 26/06/2020	BBCH 61	Grain Straw	0.0324 0.416	39 39	
QG20006-06 6599 AV Ven- Zelderheide, The Netherlands	Barley/ Irina	1) 03/04/2020 2) 06/2020	Foliar Spray	0.205 0.206	203 204	0.101 0.101	09/06/2020 24/06/2020	BBCH 69	Immature Plant Immature Plant Immature Plant Immature Plant Immature Plant Grain	0.37 1.52 0.672 0.30 0.204 0.0189	0 0 8 20 35 42	

									Straw	0.29	42	
QG20006-07 7215 AD Joppe, Netherlands	Barley/ Irina	1) 11/04/2020 2) 06/2020 3) 04/08/2020	Foliar Spray	0.208 0.2024	206 200	0.101 0.101	08/06/2020 22/06/2020	BBCH 69	Grain Straw	0.0233 0.646	43 43	
QG20006-08 46342 Velen, Ger- many	Barley/ KWS Keeper	1) 15/10/2019 2) 05/2020 3) 27/05/2020	Foliar Spray	0.2064 0.2051	204 203	0.101 0.101	12/05/2020 27/05/2020	BBCH 69	Immature Plant	0.34	0	
									Immature Plant	2.14	0	
									Immature Plant	0.236	6	
									Immature Plant	0.196	21	
									Grain	0.0117	36	
									Straw	0.161	36	

(a) According to Codex Classification/Guide

(b) Only if relevant

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

N.A.- Not Available N.D.= Not Detectable (lower than Limit of Detection)

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new study was submitted.

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

No new study was submitted.

A 2.1.5.1 Processing studies on a core set of representative processes

No new study was submitted.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new study was submitted.

A 2.1.7 Other/Special Studies

A study is underway to determine the magnitude of residues of prothioconazole-desthio in honey following two tunnel applications of an EC formulation containing prothioconazole to phacelia in northern and southern Europe during 2021. An interim report is presented to detail the prothioconazole-desthio residues determined from the field samples

A 2.1.7.1 Study QG21003

Comments of zRMS:	Study is accepted
-------------------	-------------------

Reference:	KCA 6.10/01
Report	INTERIM REPORT Magnitude of Residues of Prothioconazole-desthio and Hydroxyprothioconazole-desthio Metabolites in Honey Following Two Tunnel Applications of a Prothioconazole 250 g/L EC Formulation (FF-065) to Phacelia in Northern and Southern Europe, 2021; Andrews, G.; 2022; Report No QG21003
Guideline(s):	Yes General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95 rev.5, 22 July 1997). OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published on 7 September 2009). Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey, SANTE/11956/2016 rev. 9, 14 September 2018. SANTE/2020/12830, Rev.1, Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, 2. February 2021
Deviations:	Yes Deviation to Study Plan n.1 Description: Field sprayed with triazoles in June 2019, 2 years and 2 months before the trial started Impact: None expected and on review of analytical data to date none seen Deviation to Study Plan n.2 Description: Freezer SUK-CO2 went above -18°C on 4 occasions and reached a maximum temperature of -15.4 C due to samples being added. Affected specimen 013 Impact: None, samples remained frozen throughout
GLP:	No – study is an interim report
Acceptability:	

The objective of the study is to determine the magnitude of residues of prothioconazole-desthio and metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-

triazole moiety (expressed as prothioconazole-desthio only) in honey following two tunnel applications of an EC formulation containing 250 g/L prothioconazole to phacelia in northern and southern Europe, 2021.

The interim report details the prothioconazole-desthio residues determined from the field samples.

Materials and methods

Two tunnel applications at 0.200 kg prothioconazole/ha using an EC formulation containing 250 g/L prothioconazole were made to phacelia at four trial sites in northern and southern Europe during 2021. Final applications were made during flowering (BBCH 67-69), with sampling of honey performed at comb-closure or water content < 20%. Field specimens of honey were shipped from the test sites to the test laboratory under frozen conditions. Upon receipt, the field specimens were stored in a freezer except for the removal of a subsample for analysis.

Method of Analysis

Honey samples are analysed for prothioconazole-desthio according to a method currently being validated at Battelle UK Limited. Prior to analysis, the honey samples did not require homogenisation. All samples remained in the freezer until processing. The analytical procedure involves extraction *via* shaking with water followed by addition of acetonitrile and extraction with a QuEChERS salt kit. Clean up is *via* a d-SPE followed by dilution for final determination by liquid chromatography with tandem mass spectrometry (LC-MS/MS), monitoring two ion mass transitions, with an LOQ of 0.005 mg/kg. The following LC-MS/MS conditions were used for the analyses:

HPLC-MS/MS Conditions

Column: Kintex 5 µm XB-C18 100A, 150 x 4.6 mm
Guard column: C18 4 x 3.0 mm – Part no. AJ0-4287
Column oven temperature: 40 °C
Injection volume: 60 µL
Mobile phase: A: Water containing 0.1 % (v/v) formic acid
B: Methanol containing 0.1 % (v/v) formic acid

Time [min]	%A	%B
0.00	40	60
1.00	40	60
5.00	10	90
6.00	10	90
6.10	0	100
7.00	0	100
7.10	40	60
9.00	40	60

Flow diverted to waste from 0.0 to 4.0 and from 6.0 to 9.0 minutes.

Flow rate: 1000 µL/min
Retention time: Prothioconazole-desthio: ca. 5.4 min

Mass Spectrometer Conditions

MS system: API 5000
Ionisation type: Electrospray ionisation (ESI)
Ion source: Turbo Spray
Polarity: Positive
Scan type: MRM

Curtain gas (CUR): 30 (arbitrary units)
Temperature (TEM): 650 °C
Ionspray voltage (IS): 5500 V
Collision gas (CAD): Medium
Gas 1 (GS1): 50 (arbitrary units)
Gas 2 (GS2): 50 (arbitrary units)
Entrance potential (EP): 10 V
Dwell time: 250 msec

Source and detection parameters for MS/MS experiments:

Compound	Parent (m/z)	CE (V)	DP (V)	CXP (V)	Fragment ions (m/z)	
Prothioconazole-desthio	312.1	20	126	10	70.1	Quantification
		30		15	125.0	Confirmation

CE: Collision energy; DP: Declustering Potential; CXP: Collision cell exit potential

Honey will be analysed for hydroxy-prothioconazole-desthio metabolites according to a method currently being validated at Battelle UK Limited.

Results and discussions

Limits of Quantification and Detection

The limit of quantification (LOQ) was 0.005 mg/kg for all analytes and the limit of detection was defined as the lowest calibration standard (0.00125 mg/kg).

Linearity

Calibration curves containing prothioconazole-desthio from matrix-matched solutions were obtained in the range of 0.05 to 2.5 ng/mL for honey analyses. 8 calibration standards were injected covering the range from 30% of the LOQ to 20% above the highest fortification level. The correlation coefficient, *r*, was greater than 0.995, demonstrating satisfactory linearity.

Specificity

Chromatographic interferences at the retention time of prothioconazole-desthio were less than 30% of the limit of quantification in blank and control samples, demonstrating satisfactory selectivity.

Accuracy and Precision

Mean recovery per analytical batch and overall mean recovery were all within the range of 60-120% (LOQ) and 70-120% (10xLOQ). Residues in control samples and reagent blank were all <30 % of the LOQ. Procedural recoveries at the LOQ and 10x LOQ ranged from 101-103 %, demonstrating acceptable performance of the analytical method during the study.

Stability of analytes in standard solutions and sample extracts

Stability of analytes in standard solutions and in sample extracts is currently being determined within study QG20011 and study QG21009, respectively. Stability of frozen samples of prothioconazole-desthio and hydroxy-prothioconazole-desthio metabolites in honey is currently being determined within study QG21007. All extracts were analysed within proven extract stability durations.

Table A 33: Summary of the study Q21003 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of Sampling	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL				Prothioconazole- desthio		
(a)	(b)				(c)				(d)	(e)	
Southern EU											
QG21003-01 Villemur sur tarn, France, 2021	Honeybee – <i>Apis Mellifera buckfast L.</i> (Hymenoptera, Apidae)	20/10/21	199 201	296 299	67.4 67.4	29/09/21 12/10/21	BBCH 67	Honey	<0.005	8	Maximum of 6 months frozen storage between sampling and analysis.
QG21003-02 Los palacios y villafranca, Spain, 2021		27/05/21	202 197	300 293	67.3 67.4	11/05/21 21/05/21	BBCH 69		0.012	6	Method Battelle No. QG/21/009 (LOQ = 0.005 mg/kg)
Northern EU											
QG21003-03 Blaufelden, Germany, 2021	Honeybee – <i>Apis Mellifera buckfast L.</i> (Hymenoptera, Apidae)	12/10/21	197 203	292 302	67.4 67.3	21/09/21 01/10/21	BBCH 67		<0.005	11	Maximum of 6 months frozen storage between sampling and analysis.
QG21003-04 Bucknell, UK, 2021		08/09/21	214 216	212 214	101.1 101.0	17/08/21 31/08/21	BBCH 67-69		<0.005	8	Method Battelle No. QG/21/009 (LOQ = 0.005 mg/kg)

(a) According to CODEX Classification / Guide

(b) Date of honey sampling

(c) Year must be indicated

(d) Days after last application (Label pre-harvest interval, PHI, underline)

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Conclusion

A study is being performed to investigate the magnitude of residues of prothioconazole-desthio in honey following two tunnel applications of an EC formulation containing prothioconazole to phacelia in northern and southern Europe during 2021. The interim data demonstrate that the magnitude of residues of prothioconazole-desthio in honey resulting from applications at the proposed GAP for SIP 41061 are not expected to exceed the default EU MRL of 0.05 mg/kg. Full study details, supporting analytical method validation and storage stability data will be provided upon completion of the studies.

A 2.1.7.2 RAU-028-21

Comments of zRMS:	Study is accepted Data gap: stability of 1,2,4-T and TA in rape seed is not confirmed.
-------------------	---

Reference:	KCA 6.10/02
Report	Determination of Triazole Derivative Metabolites (TDMs) residues in various crop matrices Report N. RAU-028-21 Massardi E., 2022 BioSpheres by Biotechnologie BT
Guideline(s):	Yes 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 78/117/EEC and 91/414/EEC EU Guidance documents on residue analytical methods SANTE/2020/12830 rev.1. Commission regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009
Deviations:	<ul style="list-style-type: none"> Deviation No. 1 to the Study Plan: 17/03/2022 Description: The sample coded I/PA20/PS02/11C is taken from the study BIU-026-20 as matrix exempt of Triazole Derivatives Metabolites to be used as blank matrix in this study (according to preliminary non GLP analysis). The sample was already homogenized and is recoded as TR/PS/01. Reason: The untreated peas dry seeds samples of this study cannot be used as a blank matrix because they had a residue of Triazole Derivatives Metabolites near to the standard at the LOD level. Impact: None. Deviation No. 2 to the Study Plan: 21/03/2022 Description: The sample coded I/PA20/OR01/03C is taken from the study BIU-023-20 as matrix exempt of Triazole Derivatives Metabolites to be used as blank matrix in this study (according to preliminary non GLP analysis). The sample was already homogenized and is recoded TR/OS/01. Reason: The untreated oilseed rape seeds samples of this study cannot be used as a blank matrix because they had a residue of Triazole Derivatives Metabolites near to the standard at the LOD level.

Impact: None.

• **Deviation No. 3 to the Study Plan: 05/04/2022**

Description: The sample coded I/PR20/PL01/01C is taken from the study BIU-015-20 as matrix exempt of Triazole Derivatives Metabolites to be used as blank matrix in this study (according to preliminary non GLP analysis). The sample was already homogenized and is recoded as TR/PL/01.

Reason: The untreated plum samples of this study cannot be used as a blank matrix because they had a residue of Triazole Derivatives Metabolites near to the standard at the LOD level.

Impact: None.

• **Deviation No. 4 to the Study Plan: 19/04/2022**

Description: The samples coded I/PA20/PS02/07C and I/PA20/PS02/09C are taken from the study BIU-026-20 as matrices exempt of Triazole Derivatives Metabolites to be used as blank matrices in this study (according to preliminary non GLP analysis). The samples were already homogenized. The sample coded I/PA20/PS02/07C is recoded as TR/PG/01 and the sample coded I/PA20/PS02/09C is recoded as TR/PV/01.

Reason: The untreated peas green seeds and peas vines samples are taken from the same trial of the peas dry seeds sample, which was already certified as matrix exempt of TDMs (see Deviation No. 1 to the Study Plan RAU-028-21).

Impact: None.

• **Deviation No. 5 to the Study Plan: 01/06/2022**

Description: The matrices coded “Peach of 31/05/2022” and “Apricot of 31/05/2022” are acquired from the supermarket to be used as blank matrix in this study. The matrices were verified as matrix exempt of Triazole Derivatives Metabolites according to preliminary non GLP analysis. Both matrices were homogenized on June 01, 2022. The sample coded “Peach of 31/05/2022” is recoded as TR/PE/01 and the sample coded “Apricot of 31/05/2022” is recoded as TR/AR/01.

Reason: The untreated peach and apricot samples of this study cannot be used as blank matrices because they had a residue of Triazole Derivatives Metabolites near to the standard at the LOD level.

Impact: None.

• **Deviation No. 6 to the Study Plan: 13/06/2022**

Description: The sample coded I/PA20/OR01/01C is taken from the study BIU-023-20 as matrix exempt of Triazole Derivatives Metabolites to be used as blank matrix in this study (according to preliminary non GLP analysis). The sample was already homogenized and is recoded as TR/OW/01.

Reason: The untreated oilseed rape straw sample is taken from the same trial of the oilseed rape seeds sample, which was already certified as matrix exempt of TDMs (see Deviation No. 2 to the Study Plan RAU-028-21).

Impact: None.

GLP:

Yes

Acceptability:

Summary

The objective of the study was to evaluate the residue of Triazole derivative metabolites (1,2,4-T, TA, TAA and TLA) in different vegetable matrices coming from residue studies carried out during 2021 owned by Sipcam Oxon S.p.A. using analytical method validated under GLP compliance according to SANTE/2020/12830 rev 1.

The Analytical Phase was conducted to determine the residues of Triazole derivative metabolites (TDMs) 1,2,4-Triazole, Triazole-alanine, Triazole-acetic acid and Triazole-lactic acid in different vegetable matrices: apple, peach, apricot, plum, cherry, sugar beet (root), peas (green seeds, dry seeds and vines), beans (green seeds, dry seeds and vines), carrot, zucchini, melon (peel and pulp), almond, oilseed rape (seeds and straw) and rice (grain and straw), coming from residue trials owned by Sipcam Oxon S.p.A. conducted in 2021.

The analytical method used was validated during the GLP Study RAU-027-21. The method consists in extraction using methanol with 1% formic acid and, if necessary, a purification step by C18-sorbent (Discovery DSC-18). The extracted samples were finally analyzed with a HPLC system coupled with a Triple Quadrupole Mass analyzer with Differential Mobility Spectrometry (LC-DMS/MS/MS). The target limit of quantification (LOQ) was 0.04 mg/kg for each analyte in each matrix.

In order to demonstrate the validity of the analytical method, procedural recovery was done at 0.04 mg/kg (LOQ level) and at 1 mg/kg (25xLOQ level) for each matrix.

The mean recoveries and Relative Standard Deviations per level for each analyte in each matrix analyzed fulfil the acceptability criteria of SANTE/2020/12830, rev.1 (24/02/2021) guideline. For the detailed results, please see the final report.

The results obtained in the crops of interest in the present application are reported in the following tables.

Table A 34: Summary of the study RAU-028-21

Matrix	Original GLP Study	Sample code	Type	Commodity	Residues of (mg/kg)			
					1,2,4 - TRIAZOLE	TRIAZOLE ALANINE	TRIAZOLE ACETIC ACID	TRIAZOLE LACTIC ACID
Apple	RAU-008-21 (KCA 6.3.1/02)	F/PR21/AP01/01C	Control	Fruits	N.D.	N.D.	N.D.	N.D.
		F/PR21/AP01/02T	Treated	Fruits	N.D.	N.D.	N.D.	N.D.
		F/PR21/AP01/03T	Treated	Fruits	N.D.	N.D.	N.D.	N.D.
		F/PR21/AP01/04T	Treated	Fruits	N.D.	N.D.	N.D.	N.D.
		F/PR21/AP01/05C	Control	Fruits	N.D.	N.D.	N.D.	N.D.
		F/PR21/AP01/06T	Treated	Fruits	N.D.	N.D.	N.D.	N.D.
		H/PR21/AP02/07C	Control	Fruits	N.D.	N.D.	N.D.	N.D.
		H/PR21/AP02/08T	Treated	Fruits	N.D.	< 0.04 (0.0303)	N.D.	< 0.04 (0.0227)
		H/PR21/AP02/09T	Treated	Fruits	N.D.	< 0.04 (0.0265)	N.D.	< 0.04 (0.0229)
		H/PR21/AP02/10T	Treated	Fruits	N.D.	< 0.04 (0.0260)	N.D.	< 0.04 (0.0260)
		H/PR21/AP02/11C	Control	Fruits	N.D.	N.D.	N.D.	< 0.04 (0.0124)
		H/PR21/AP02/12T	Treated	Fruits	N.D.	< 0.04 (0.0226)	N.D.	< 0.04 (0.0232)
		P/PR21/AP03/13C	Control	Fruits	N.D.	< 0.04 (0.0205)	N.D.	N.D.
		P/PR21/AP03/14T	Treated	Fruits	N.D.	< 0.04 (0.0173)	N.D.	N.D.
		P/PR21/AP03/15T	Treated	Fruits	N.D.	< 0.04 (0.0140)	N.D.	N.D.
		P/PR21/AP03/16T	Treated	Fruits	N.D.	< 0.04 (0.0174)	N.D.	N.D.
		P/PR21/AP03/17C	Control	Fruits	N.D.	< 0.04 (0.0227)	N.D.	N.D.
		P/PR21/AP03/18T	Treated	Fruits	N.D.	< 0.04 (0.0137)	N.D.	N.D.
		P/PR21/AP04/19C	Control	Fruits	N.D.	N.D.	N.D.	N.D.
		P/PR21/AP04/20T	Treated	Fruits	N.D.	N.D.	N.D.	N.D.
		P/PR21/AP04/21T	Treated	Fruits	N.D.	N.D.	N.D.	N.D.
		P/PR21/AP04/22T	Treated	Fruits	N.D.	N.D.	N.D.	N.D.
		P/PR21/AP04/23C	Control	Fruits	N.D.	N.D.	N.D.	N.D.
		P/PR21/AP04/24T	Treated	Fruits	N.D.	N.D.	N.D.	N.D.

N.D.: Not Detectable, residues lower than the Limit of Detection. The LOD is 0.012 mg/kg for all analytes.

Matrix	Original Study	Sample code	Type	Commodity	Residues of (mg/kg)
--------	----------------	-------------	------	-----------	---------------------

					1,2,4 - TRIAZOLE	TRIAZOLE ALA- NINE	TRIAZOLE ACE- TIC ACID	TRIAZOLE LAC- TIC ACID
Plum	RAU-010-21	H/PR21/PL01/01C	Control	Flesh	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/PL01/02T	Treated	Flesh	<0.04 (N.D.)	< 0.04 (0.0222)	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/PL01/03T	Treated	Flesh	<0.04 (N.D.)	< 0.04 (0.0209)	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/PL01/04T	Treated	Flesh	<0.04 (N.D.)	< 0.04 (0.0299)	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/PL01/05C	Control	Flesh	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/PL01/06T	Treated	Flesh	<0.04 (N.D.)	< 0.04 (0.0207)	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/PL02/07C	Control	Flesh	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/PL02/08T	Treated	Flesh	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/PL02/09T	Treated	Flesh	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/PL02/10T	Treated	Flesh	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/PL02/11C	Control	Flesh	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/PL02/12T	Treated	Flesh	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR21/PL03/13C	Control	Flesh	<0.04 (N.D.)	0.1589	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR21/PL03/14T	Treated	Flesh	<0.04 (N.D.)	0.0460	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR21/PL03/15T	Treated	Flesh	<0.04 (N.D.)	0.0406	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR21/PL03/16T	Treated	Flesh	<0.04 (N.D.)	0.0424	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR21/PL03/17C	Control	Flesh	<0.04 (N.D.)	0.1149	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR21/PL03/18T	Treated	Flesh	<0.04 (N.D.)	0.0470	<0.04 (N.D.)	<0.04 (N.D.)
		G/PR21/PL04/19C	Control	Flesh	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		G/PR21/PL04/20T	Treated	Flesh	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		G/PR21/PL04/21T	Treated	Flesh	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		G/PR21/PL04/22T	Treated	Flesh	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		G/PR21/PL04/23C	Control	Flesh	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		G/PR21/PL04/24T	Treated	Flesh	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)

Matrix	Original GLP Study	Sample code	Type	Commodity	Residues of (mg/kg)
--------	-----------------------	-------------	------	-----------	------------------------

					1,2,4 - TRIAZOLE	TRIAZOLE ALANINE	TRIAZOLE ACETIC ACID	TRIAZOLE LACTIC ACID
Oilseed rape	RAU-014-21 (KCA 6.3.4/02)	F/PR21/OS01/01C	Control	Seeds	N.D.	0.7772	N.D.	< 0.04 (0.0249)
		F/PR21/OS01/02C	Control	Straw	N.D.	N.D.	N.D.	N.D.
		F/PR21/OS01/03T	Treated	Seeds	N.D.	0.2969	N.D.	< 0.04 (0.0126)
		F/PR21/OS01/04T	Treated	Straw	N.D.	N.D.	N.D.	N.D.
		H/PR21/OS02/05C	Control	Seeds	< 0.04 (0.0123)	6.3287	0.0866	0.1963
		H/PR21/OS02/06C	Control	Straw	N.D.	< 0.04 (0.0361)	0.3150	0.1077
		H/PR21/OS02/07T	Treated	Seeds	< 0.04 (0.0141)	6.2290	0.1038	0.2045
		H/PR21/OS02/08T	Treated	Straw	N.D.	N.D.	0.4661	0.2361
		P/PR21/OS03/09C	Control	Seeds	N.D.	0.0781	N.D.	N.D.
		P/PR21/OS03/10C	Control	Straw	N.D.	N.D.	N.D.	N.D.
		P/PR21/OS03/11T	Treated	Seeds	N.D.	0.1138	N.D.	N.D.
		P/PR21/OS03/12T	Treated	Straw	N.D.	N.D.	N.D.	< 0.04 (0.0184)
		P/PR21/OS04/13C	Control	Seeds	N.D.	0.7092	< 0.04 (0.0217)	< 0.04 (0.0389)
		P/PR21/OS04/14C	Control	Straw	N.D.	N.D.	< 0.04 (0.0284)	N.D.
		P/PR21/OS04/15T	Treated	Seeds	N.D.	0.4867	< 0.04 (0.0184)	< 0.04 (0.0249)
		P/PR21/OS04/16T	Treated	Straw	N.D.	N.D.	< 0.04 (0.0243)	N.D.

N.D.: Not Detectable, residues lower than the Limit of Detection. The LOD is 0.012 mg/kg for all analytes in all matrices, except for the oilseed rape straw in which the LOD is 0.018 mg/kg for all analytes.

Matrix	Original GLP Study	Sample code	Type	Commodity	Residues of (mg/kg)			
					1,2,4 - TRIAZOLE	TRIAZOLE ALANINE	TRIAZOLE ACETIC ACID	TRIAZOLE LACTIC ACID
Sugar beet	RAU-015-21 (KCA 6.3.5/02)	P/PR21/SB02/03C	Control	Root	N.D.	< 0.04 (0.0396)	N.D.	N.D.
		P/PR21/SB02/04T	Treated	Root	N.D.	< 0.04 (0.0130)	N.D.	N.D.
		P/PR21/SB03/05C	Control	Root	N.D.	< 0.04 (0.0186)	N.D.	N.D.
		P/PR21/SB03/06T	Treated	Root	N.D.	< 0.04 (0.0158)	N.D.	N.D.
		H/PR21/SB04/07C	Control	Root	N.D.	N.D.	N.D.	N.D.
		H/PR21/SB04/08T	Treated	Root	N.D.	N.D.	N.D.	N.D.
		H/PR21/SB05/09C	Control	Root	N.D.	< 0.04 (0.0336)	N.D.	N.D.
		H/PR21/SB05/10T	Treated	Root	N.D.	0.0553	N.D.	N.D.

N.D.: Not Detectable, residues lower than the Limit of Detection. The LOD is 0.012 mg/kg for all analytes in all matrices.

Matrix	Original Study	Sample code	Type	Commodity	Residues of (mg/kg)			
					1,2,4 - TRIAZOLE	TRIAZOLE ALA-NINE	TRIAZOLE ACE-TIC ACID	TRIAZOLE LAC-TIC ACID
Apricot	RAU-009-21	P/PR21/AR01/01C	Control	Flesh	<0.04 (N.D.)	0.0485	<0.04 (N.D.)	< 0.04 (0.0196)
		P/PR21/AR01/02T	Treated	Flesh	<0.04 (N.D.)	0.0765	<0.04 (N.D.)	< 0.04 (0.0253)
		P/PR21/AR01/03T	Treated	Flesh	<0.04 (N.D.)	0.0975	<0.04 (N.D.)	< 0.04 (0.0330)
		P/PR21/AR01/04T	Treated	Flesh	<0.04 (N.D.)	0.1562	<0.04 (N.D.)	< 0.04 (0.0342)
		P/PR21/AR01/05C	Control	Flesh	<0.04 (N.D.)	< 0.04 (0.0385)	<0.04 (N.D.)	< 0.04 (0.0172)
		P/PR21/AR01/06T	Treated	Flesh	<0.04 (N.D.)	0.1408	<0.04 (N.D.)	< 0.04 (0.0373)
Peach		H/PR21/PE01/01C	Control	Flesh	<0.04 (N.D.)	0.0884	< 0.04 (0.0175)	0.0729
		H/PR21/PE01/02T	Treated	Flesh	<0.04 (N.D.)	0.0939	<0.04 (N.D.)	< 0.04 (0.0378)
		H/PR21/PE01/03T	Treated	Flesh	<0.04 (N.D.)	0.0656	<0.04 (N.D.)	< 0.04 (0.0385)
		H/PR21/PE01/04T	Treated	Flesh	<0.04 (N.D.)	0.0999	< 0.04 (0.0130)	< 0.04 (0.0309)
		H/PR21/PE01/05C	Control	Flesh	<0.04 (N.D.)	0.0850	< 0.04 (0.0139)	0.0561
		H/PR21/PE01/06T	Treated	Flesh	<0.04 (N.D.)	0.0616	<0.04 (N.D.)	< 0.04 (0.0318)
Note. <0.04 (N.D.): Not Detectable, residues lower than the Limit of Detection. The LOD is 0.012 mg/kg for all analytes in all matrices								

Matrix	Original Study	Sample code	Type	Commodity	Residues of (mg/kg)			
					1,2,4 - TRIAZOLE	TRIAZOLE ALA-NINE	TRIAZOLE ACE-TIC ACID	TRIAZOLE LAC-TIC ACID
Cherry	RAU-011-21	H/PR21/CH01/01C	Control	Fruits	<0.04 (N.D.)	0.0636	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/CH01/02T	Treated	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/CH01/03T	Treated	Fruits	<0.04 (N.D.)	< 0.04 (0.0135)	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/CH01/04T	Treated	Fruits	<0.04 (N.D.)	< 0.04 (0.0194)	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/CH01/05C	Control	Fruits	<0.04 (N.D.)	0.0459	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/CH01/06T	Treated	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/CH02/07C	Control	Fruits	<0.04 (N.D.)	< 0.04 (0.0333)	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/CH02/08T	Treated	Fruits	<0.04 (N.D.)	0.0548	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/CH02/09T	Treated	Fruits	<0.04 (N.D.)	0.0514	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/CH02/10T	Treated	Fruits	<0.04 (N.D.)	0.0426	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/CH02/11C	Control	Fruits	<0.04 (N.D.)	< 0.04 (0.0170)	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR21/CH02/12T	Treated	Fruits	<0.04 (N.D.)	0.0543	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR21/CH03/13C	Control	Fruits	<0.04 (N.D.)	0.1223	<0.04 (N.D.)	0.0525
		P/PR21/CH03/14T	Treated	Fruits	<0.04 (N.D.)	0.0588	<0.04 (N.D.)	0.0454
		P/PR21/CH03/15T	Treated	Fruits	<0.04 (N.D.)	0.0771	<0.04 (N.D.)	0.0484
		P/PR21/CH03/16T	Treated	Fruits	<0.04 (N.D.)	0.0902	<0.04 (N.D.)	0.0464
		P/PR21/CH03/17C	Control	Fruits	<0.04 (N.D.)	0.1139	< 0.04 (0.0139)	0.0589
		P/PR21/CH03/18T	Treated	Fruits	<0.04 (N.D.)	0.0833	< 0.04 (0.0133)	0.0474
		P/PR21/CH04/19C	Control	Fruits	<0.04 (N.D.)	< 0.04 (0.0370)	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR21/CH04/20T	Treated	Fruits	<0.04 (N.D.)	0.0430	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR21/CH04/21T	Treated	Fruits	<0.04 (N.D.)	0.0471	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR21/CH04/22T	Treated	Fruits	<0.04 (N.D.)	< 0.04 (0.0361)	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR21/CH04/23C	Control	Fruits	<0.04 (N.D.)	< 0.04 (0.0320)	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR21/CH04/24T	Treated	Fruits	<0.04 (N.D.)	0.0506	<0.04 (N.D.)	<0.04 (N.D.)

Note. <0.04 (N.D.): Not Detectable, residues lower than the Limit of Detection. The LOD is 0.012 mg/kg for all analytes in all matrices

Matrix	Original Study	Sample code	Type	Commodity	Residues of (mg/kg)			
--------	----------------	-------------	------	-----------	---------------------	--	--	--

					1,2,4 - TRIAZOLE	TRIAZOLE ALA- NINE	TRIAZOLE ACE- TIC ACID	TRIAZOLE LAC- TIC ACID
Zucchini	BIU-017-21	I/PR21/ZU05/01C	Control	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PR21/ZU05/02T	Treated	Fruits	<0.04 (N.D.)	< 0.04 (0.0134)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PR21/ZU05/03T	Treated	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PR21/ZU05/04T	Treated	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PR21/ZU05/05C	Control	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PR21/ZU05/06T	Treated	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PR21/ZU06/07C	Control	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PR21/ZU06/08T	Treated	Fruits	<0.04 (N.D.)	< 0.04 (0.0226)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PR21/ZU06/09T	Treated	Fruits	<0.04 (N.D.)	< 0.04 (0.0128)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PR21/ZU06/10T	Treated	Fruits	<0.04 (N.D.)	< 0.04 (0.0140)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PR21/ZU06/11C	Control	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PR21/ZU06/12T	Treated	Fruits	<0.04 (N.D.)	< 0.04 (0.0135)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PR21/ZU07/13C	Control	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PR21/ZU07/14T	Treated	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PR21/ZU08/15C	Control	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PR21/ZU08/16T	Treated	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)

Matrix	Original Study	Sample code	Type	Commodity	Residues of (mg/kg)			
					1,2,4 - TRIAZOLE	TRIAZOLE ALA- NINE	TRIAZOLE ACE- TIC ACID	TRIAZOLE LAC- TIC ACID
Carrot	RAU-017-21	F/PR21/CA01/01C	Control	Root	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		F/PR21/CA01/02T	Treated	Root	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		F/PR21/CA02/03C	Control	Root	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		F/PR21/CA02/04T	Treated	Root	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR21/CA03/05C	Control	Root	<0.04 (N.D.)	< 0.04 (0.017)	<0.04 (N.D.)	<0.04 (N.D.)

Matrix	Original Study	Sample code	Type	Commodity	Residues of (mg/kg)			
					1,2,4 - TRIAZOLE	TRIAZOLE ALA-NINE	TRIAZOLE ACE-TIC ACID	TRIAZOLE LAC-TIC ACID
		P/PR21/CA03/06T	Treated	Root	<0.04 (N.D.)	< 0.04 (0.014)	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR21/CA04/07C	Control	Root	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR21/CA04/08T	Treated	Root	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)

A 2.1.7.1 Study RAU-024-22

Comments of zRMS:	Study is accepted. Data gap: stability of 1,2,4-T and TA in rape seed is not confirmed.
-------------------	--

Reference:	KCA 6.10/03
Report	Determination of Triazole Derivative Metabolites (TDMs) residues in various crop matrices Report N. RAU-024-22 Massardi E., 2022
Guideline(s):	Yes General recommendations for the design, preparation and realization of residue trials (SANCO 7029/VI/95 rev.5, 22 July 1997). OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published on 7 September 2009). Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey, SANTE/11956/2016 rev. 9, 14 September 2018. SANTE/2020/12830, Rev.1, Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, 2. February 2021
Deviations:	No
GLP:	Yes
Acceptability:	

The objective of the study was to evaluate the residue of Triazole derivative metabolites (1,2,4-T, TA, TAA and TLA) in different vegetable matrices coming from residue studies carried out during 2020 owned by Sipcam Oxon S.p.A. using analytical method validated under GLP compliance according to SANTE/2020/12830 rev 1 in study RAU-027-21 (please see dRR Part B, Section 5 for further details).

The method consists in extraction using methanol with 1% formic acid and, if necessary, a purification step by C18-sorbent (Discovery DSC-18). The extracted samples were finally analyzed with a HPLC system coupled with a Triple Quadrupole Mass analyzer with Differential Mobility Spectrometry (LC-DMS/MS/MS).

The target limit of quantification (LOQ) was 0.04 mg/kg for each analyte in each matrix.

Linearity, selectivity, accuracy (recovery), precision (repeatability), specificity, limit of quantification (LOQ), limit of detection and matrix effect was evaluated according to SANTE/2020/12830 rev 1. All parameters were in compliance with requirements reported in the guideline for each analyte. The stability of standard solutions was confirmed for 15 days in the Study RAU-027-21 above mentioned.

The acceptability ranges for mean recoveries and Relative Standard Deviations per level adopted in this Study are summarized in the following table:

Concentration level (mg/kg)	Range of mean recoveries (%)	Precision, RSD (%)
≤ 0.01	60 - 120	30
> 0.01 - ≤ 0.1	70 - 120	20
> 0.1 - ≤ 1.0	70 - 110	15
> 1	70 - 110	10

The mean recoveries and Relative Standard Deviations per level for each analyte in each matrix analyzed fulfil the acceptability criteria of SANTE/2020/12830, rev.1 (24/02/2021) guideline.

The residue values found in the crops of interest in the present application are reported in the following tables:

Table A 35: Summary of the study RAU-024-22

Matrix	Original Study	Sample code	Type	Commodity	Residues of (mg/kg)			
					1,2,4 - TRIAZOLE	TRIAZOLE ALA-NINE	TRIAZOLE ACE-TIC ACID	TRIAZOLE LAC-TIC ACID
Apple	SPK-20-45305	SPK-20-45305 FR01 1	Control	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		SPK-20-45305 FR01 3	Treated	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		SPK-20-45305 HU02 5	Control	Fruits	<0.04 (N.D.)	<0.04 (0.0170)	<0.04 (N.D.)	<0.04 (0.0183)
		SPK-20-45305 HU02 7	Treated	Fruits	<0.04 (N.D.)	<0.04 (0.0368)	<0.04 (N.D.)	<0.04 (0.0251)
		SPK-20-45305 PL03 9	Control	Fruits	<0.04 (N.D.)	<0.04 (0.0154)	<0.04 (N.D.)	<0.04 (N.D.)
		SPK-20-45305 PL03 11	Treated	Fruits	<0.04 (N.D.)	<0.04 (0.0145)	<0.04 (N.D.)	<0.04 (N.D.)
		SPK-20-45305 PL04 13	Control	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		SPK-20-45305 PL04 15	Treated	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)

Matrix	Original Study	Sample code	Type	Commodity	Residues of (mg/kg)			
					1,2,4 - TRIAZOLE	TRIAZOLE ALA-NINE	TRIAZOLE ACE-TIC ACID	TRIAZOLE LAC-TIC ACID
Plum	RAU-024-20	F/PR20/PL01/01C	Control	Flesh	<0.04 (N.D.)	<0.04 (0.0390)	<0.04 (N.D.)	<0.04 (N.D.)
		F/PR20/PL01/02T	Treated	Flesh	<0.04 (N.D.)	0.0787	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR20/PL02/03C	Control	Flesh	<0.04 (N.D.)	0.0588	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR20/PL02/04T	Treated	Flesh	<0.04 (N.D.)	<0.04 (0.0268)	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR20/PL03/05C	Control	Flesh	<0.04 (N.D.)	0.1220	<0.04 (N.D.)	<0.04 (0.0236)
		P/PR20/PL03/06T	Treated	Flesh	<0.04 (N.D.)	<0.04 (0.0179)	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR20/PL04/07C	Control	Flesh	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR20/PL04/08T	Treated	Flesh	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)

Matrix	Original Study	Sample code	Type	Commodity	Residues of (mg/kg)			
--------	----------------	-------------	------	-----------	---------------------	--	--	--

					1,2,4 - TRIAZOLE	TRIAZOLE ALA- NINE	TRIAZOLE ACE- TIC ACID	TRIAZOLE LAC- TIC ACID
Apricot	SPK-20-45307	SPK-20-45307 HU01 1	Control	Flesh	<0.04 (N.D.)	0.2913	<0.04 (N.D.)	0.0900
		SPK-20-45307 HU01 3	Treated	Flesh	<0.04 (N.D.)	0.2176	<0.04 (N.D.)	0.0850
		SPK-20-45307 HU02 5	Control	Flesh	<0.04 (N.D.)	0.1006	<0.04 (N.D.)	<0.04 (0.0343)
		SPK-20-45307 HU02 7	Treated	Flesh	<0.04 (N.D.)	0.0888	<0.04 (N.D.)	0.0421
Peach		SPK-20-45307 PL03 9	Control	Flesh	<0.04 (N.D.)	0.1161	<0.04 (N.D.)	<0.04 (0.0229)
		SPK-20-45307 PL03 11	Treated	Flesh	<0.04 (N.D.)	0.1195	<0.04 (N.D.)	<0.04 (0.0206)
		SPK-20-45307 PL04 13	Control	Flesh	<0.04 (N.D.)	0.0593	<0.04 (N.D.)	<0.04 (0.0231)
		SPK-20-45307 PL04 15	Treated	Flesh	<0.04 (N.D.)	0.0632	<0.04 (N.D.)	<0.04 (0.0251)

Matrix	Original Study	Sample code	Type	Commodity	Residues of (mg/kg)			
					1,2,4 - TRIAZOLE	TRIAZOLE ALA-NINE	TRIAZOLE ACE-TIC ACID	TRIAZOLE LAC-TIC ACID
Cherry	RAU-017-20	H/PR20/CH01/01C	Control	Fruits	<0.04 (N.D.)	1.1032	0.0947	0.1782
		H/PR20/CH01/02T	Treated	Fruits	<0.04 (N.D.)	1.1068	0.0952	0.1567
		H/PR20/CH02/03C	Control	Fruits	<0.04 (N.D.)	0.1202	<0.04 (N.D.)	<0.04 (N.D.)
		H/PR20/CH02/04T	Treated	Fruits	<0.04 (N.D.)	<0.04 (0.0368)	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR20/CH03/05C	Control	Fruits	<0.04 (N.D.)	0.0414	<0.04 (N.D.)	<0.04 (0.0186)
		P/PR20/CH03/06T	Treated	Fruits	<0.04 (N.D.)	<0.04 (0.0379)	<0.04 (N.D.)	<0.04 (0.0157)
		P/PR20/CH04/07C	Control	Fruits	<0.04 (N.D.)	0.0983	<0.04 (N.D.)	<0.04 (N.D.)
		P/PR20/CH04/08T	Treated	Fruits	<0.04 (N.D.)	0.0971	<0.04 (N.D.)	<0.04 (N.D.)

Matrix	Original Study	Sample code	Type	Commodity	Residues of (mg/kg)			
					1,2,4 - TRIAZOLE	TRIAZOLE ALA-NINE	TRIAZOLE ACETIC ACID	TRIAZOLE LACTIC ACID
Oilseed rape	RAU-015-20	F/PA20/OS01/01C	Control	Seeds	<0.04 (N.D.)	0.9686	<0.04 (0.0188)	0.0621

Matrix	Original Study	Sample code	Type	Commodity	Residues of (mg/kg)			
					1,2,4 - TRIAZOLE	TRIAZOLE ALA-NINE	TRIAZOLE ACETIC ACID	TRIAZOLE LACTIC ACID
		F/PA20/OS01/02C	Control	Straw	<0.06 (N.D.)	<0.06 (0.0243)	<0.06 (0.0243)	<0.06 (0.0317)
		F/PA20/OS01/03T	Treated	Seeds	<0.04 (N.D.)	0.8113	<0.04 (0.0161)	0.0607
		F/PA20/OS01/04T	Treated	Straw	<0.06 (N.D.)	<0.06 (N.D.)	<0.06 (0.0214)	<0.06 (0.0375)
		F/PA20/OS02/05C	Control	Seeds	<0.04 (N.D.)	0.1507	<0.04 (N.D.)	<0.04 (N.D.)
		F/PA20/OS02/06C	Control	Straw	<0.06 (N.D.)	<0.06 (N.D.)	<0.06 (N.D.)	<0.06 (N.D.)
		F/PA20/OS02/07T	Treated	Seeds	<0.04 (N.D.)	0.1825	<0.04 (N.D.)	<0.04 (0.0143)
		F/PA20/OS02/08T	Treated	Straw	<0.06 (N.D.)	<0.06 (N.D.)	<0.06 (N.D.)	<0.06 (N.D.)
		P/PA20/OS03/09C	Control	Seeds	<0.04 (N.D.)	0.0990	<0.04 (N.D.)	<0.04 (N.D.)
		P/PA20/OS03/10C	Control	Straw	<0.06 (N.D.)	<0.06 (N.D.)	<0.06 (N.D.)	<0.06 (N.D.)
		P/PA20/OS03/11T	Treated	Seeds	<0.04 (N.D.)	0.2773	<0.04 (0.0149)	<0.04 (0.0294)
		P/PA20/OS03/12T	Treated	Straw	<0.06 (N.D.)	<0.06 (0.0276)	<0.06 (N.D.)	<0.06 (N.D.)
		P/PA20/OS04/13C	Control	Seeds	<0.04 (N.D.)	0.4288	<0.04 (N.D.)	<0.04 (0.0292)
		P/PA20/OS04/14C	Control	Straw	<0.06 (N.D.)	<0.06 (N.D.)	<0.06 (N.D.)	<0.06 (N.D.)
		P/PA20/OS04/15T	Treated	Seeds	<0.04 (N.D.)	0.9243	<0.04 (0.0167)	0.0562
		P/PA20/OS04/16T	Treated	Straw	<0.06 (N.D.)	<0.06 (0.0213)	<0.06 (0.0217)	<0.06 (0.0311)

Note. <0.04 (N.D.): Not Detectable, residues lower than the Limit of Detection. The LOD is 0.012 mg/kg for all analytes in all matrices, except for the oilseed rape straw matrix in which the LOD is 0.018 mg/kg for all analytes.

Matrix	Original Study	Sample code	Type	Commodity	Residues of (mg/kg)			
					1,2,4 - TRIAZOLE	TRIAZOLE ALA-NINE	TRIAZOLE ACETIC ACID	TRIAZOLE LACTIC ACID
Sugarbeet	RAU-020-20	U/PA20/SB01/01C	Control	Root	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		U/PA20/SB01/03T	Treated	Root	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		P/PA20/SB02/05C	Control	Root	<0.04 (N.D.)	0.0552	<0.04 (N.D.)	<0.04 (N.D.)
		P/PA20/SB02/07T	Treated	Root	<0.04 (N.D.)	0.0814	<0.04 (N.D.)	<0.04 (N.D.)
		P/PA20/SB04/13C	Control	Root	<0.04 (N.D.)	<0.04 (0.0124)	<0.04 (N.D.)	<0.04 (N.D.)
		P/PA20/SB04/15T	Treated	Root	<0.04 (N.D.)	<0.04 (0.0286)	<0.04 (N.D.)	<0.04 (N.D.)

Note. <0.04 (N.D.): Not Detectable, residues lower than the Limit of Detection. The LOD is 0.012 mg/kg for all analytes in all matrices, except for the oilseed rape straw matrix in which the LOD is 0.018 mg/kg for all analytes.

Matrix	Original Study	Sample code	Type	Commodity	Residues of (mg/kg)			
					1,2,4 - TRIAZOLE	TRIAZOLE ALA-NINE	TRIAZOLE ACETIC ACID	TRIAZOLE LACTIC ACID
Zucchini	BIU-021-20	I/PA20/ZU05/01C	Control	Fruits	<0.04 (N.D.)	<0.04 (0.0149)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PA20/ZU05/02T	Treated	Fruits	<0.04 (N.D.)	<0.04 (0.0127)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PA20/ZU06/05C	Control	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)
		I/PA20/ZU06/06T	Treated	Fruits	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)	<0.04 (N.D.)

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Prothioconazole-desthio



European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Prothioconazole-desthio

LOQs (mg/kg) range from: to:	
Toxicological reference values	
ADI (mg/kg bw/day):	0.01
ARfD (mg/kg bw):	0.01
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 : ---						Exposure resulting from	
	Calculated exposure (% of ADI) MS Diet		Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NIEDI calculation (based on average food consumption)	19%	NL toddler	1.92	6%	Apples	3%	Sugar beet roots	3%	Milk: Cattle		
	13%	NL child	1.29	5%	Sugar beet roots	3%	Apples	1%	Milk: Cattle		
	12%	DE child	1.22	7%	Apples	1.0%	Milk: Cattle	0.8%	Wheat		
	7%	FR toddler 2 3 yr	0.72	2%	Apples	2%	Sugar beet roots	1%	Milk: Cattle		
	7%	DK child	0.72	1%	Apples	1%	Rye	0.9%	Cucumbers		
	7%	FR child 3 15 yr	0.70	2%	Sugar beet roots	1%	Milk: Cattle	1.0%	Apples		
	7%	DE women 14-50 yr	0.66	3%	Sugar beet roots	1%	Apples	0.6%	Milk: Cattle		
	7%	UK infant	0.66	2%	Milk: Cattle	0.9%	Apples	0.8%	Sugar beet roots		
	6%	DE general	0.64	2%	Sugar beet roots	1%	Apples	0.6%	Milk: Cattle		
	6%	UK toddler	0.62	2%	Sugar beet roots	1%	Milk: Cattle	1.0%	Apples		
	5%	RO general	0.52	1%	Wheat	0.8%	Apples	0.8%	Sugar beet roots		
	5%	NL general	0.48	2%	Sugar beet roots	0.8%	Apples	0.4%	Milk: Cattle		
	5%	GEMS/Food G15	0.47	0.9%	Wheat	0.6%	Apples	0.4%	Barley		
	5%	GEMS/Food G06	0.47	1%	Wheat	0.9%	Sugar beet roots	0.5%	Apples		
	5%	GEMS/Food G08	0.46	0.8%	Wheat	0.7%	Apples	0.4%	Barley		
	4%	SE general	0.45	0.6%	Wheat	0.6%	Milk: Cattle	0.6%	Apples		
	4%	FR infant	0.44	1.0%	Apples	0.8%	Milk: Cattle	0.8%	Sugar beet roots		
	4%	GEMS/Food G11	0.43	0.9%	Apples	0.7%	Wheat	0.4%	Carrots		
	4%	GEMS/Food G07	0.43	0.8%	Wheat	0.6%	Apples	0.4%	Potatoes		
	4%	ES child	0.37	0.9%	Wheat	0.7%	Apples	0.6%	Milk: Cattle		
	4%	GEMS/Food G10	0.37	0.8%	Wheat	0.4%	Apples	0.3%	Potatoes		
	3%	IE adult	0.33	0.5%	Wheat	0.4%	Apples	0.3%	Pears		
	3%	FI 3 yr	0.32	0.6%	Cucumbers	0.5%	Apples	0.5%	Carrots		
	3%	LT adult	0.29	1%	Apples	0.3%	Potatoes	0.2%	Cucumbers		
	3%	PT general	0.28	0.8%	Wheat	0.6%	Apples	0.5%	Potatoes		
	3%	IT toddler	0.27	1%	Wheat	0.5%	Apples	0.2%	Pears		
	2%	PL general	0.25	1%	Apples	0.3%	Potatoes	0.2%	Carrots		
	2%	FR adult	0.24	0.5%	Sugar beet roots	0.4%	Wheat	0.4%	Apples		
	2%	ES adult	0.24	0.5%	Wheat	0.4%	Apples	0.2%	Milk: Cattle		
	2%	FI 6 yr	0.24	0.4%	Cucumbers	0.4%	Potatoes	0.4%	Carrots		
	2%	DK adult	0.22	0.6%	Apples	0.3%	Carrots	0.3%	Milk: Cattle		
	2%	UK vegetarian	0.20	0.4%	Wheat	0.3%	Apples	0.3%	Sugar beet roots		
	2%	IT adult	0.20	0.8%	Wheat	0.5%	Apples	0.1%	Pears		
	2%	UK adult	0.17	0.3%	Wheat	0.3%	Sugar beet roots	0.2%	Apples		
	1%	FI adult	0.13	0.3%	Apples	0.2%	Cucumbers	0.2%	Carrots		
	0.9%	IE child	0.09	0.2%	Wheat	0.2%	Apples	0.2%	Milk: Cattle		


1, 2, 4 Triazole

 <p>European Food Safety Authority</p> <p>EFSA PRIMO revision 3.1: 2019/03/19</p>		1,2,4 Triazole				Input values					
		LOQs (mg/kg) range from: _____ to: _____									
		Toxicological reference values									
		ADI (mg/kg bw/day): 0.023		ARID (mg/kg bw): 0.1							
		Source of ADI: _____		Source of ARID: _____							
Year of evaluation: _____		Year of evaluation: _____									
Comments: _____											
Normal mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
				No of diets exceeding the ADI : _____							
TMDI/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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
	4%	NL toddler	0.98	2%	Apples	0.9%	Sugar beet roots	0.8%	Pears		
	3%	NL child	0.73	1%	Sugar beet roots	1%	Apples	0.2%	Pears		
	3%	DE child	0.69	2%	Apples	0.2%	Wheat	0.2%	Carrots		
	2%	DE women 14-50 yr	0.36	0.8%	Sugar beet roots	0.4%	Apples	0.1%	Wheat		
	2%	DK child	0.35	0.4%	Apples	0.3%	Cucumbers	0.2%	Rye		
	1%	DE general	0.34	0.7%	Sugar beet roots	0.4%	Apples	0.1%	Wheat		
	1%	FR toddler 2-3 yr	0.33	0.6%	Apples	0.5%	Sugar beet roots	0.1%	Wheat		
	1%	FR child 3-15 yr	0.32	0.6%	Sugar beet roots	0.3%	Apples	0.2%	Wheat		
	1%	UK toddler	0.28	0.6%	Sugar beet roots	0.3%	Apples	0.2%	Wheat		
	1%	GEMS/Food G06	0.24	0.3%	Wheat	0.3%	Sugar beet roots	0.2%	Apples		
	1%	NL general	0.24	0.5%	Sugar beet roots	0.3%	Apples	0.1%	Wheat		
	1.0%	UK infant	0.23	0.3%	Apples	0.2%	Sugar beet roots	0.2%	Carrots		
	0.9%	RO general	0.21	0.2%	Apples	0.2%	Sugar beet roots	0.2%	Wheat		
	0.9%	FR infant	0.21	0.3%	Apples	0.2%	Sugar beet roots	0.2%	Carrots		
	0.8%	GEMS/Food G15	0.19	0.2%	Wheat	0.2%	Apples	0.1%	Carrots		
	0.8%	GEMS/Food G08	0.19	0.2%	Apples	0.2%	Wheat	0.1%	Carrots		
	0.8%	GEMS/Food G07	0.18	0.2%	Wheat	0.2%	Apples	0.1%	Rapeseeds/canola seeds		
	0.8%	SE general	0.17	0.2%	Apples	0.1%	Carrots	0.1%	Wheat		
	0.8%	GEMS/Food G11	0.17	0.3%	Apples	0.2%	Wheat	0.1%	Carrots		
	0.7%	FI 3 yr	0.16	0.2%	Cucumbers	0.2%	Apples	0.1%	Carrots		
	0.7%	IT toddler	0.16	0.3%	Wheat	0.2%	Apples	0.1%	Peaches		
	0.6%	IE adult	0.15	0.1%	Apples	0.1%	Wheat	0.1%	Pears		
	0.6%	PT general	0.14	0.2%	Apples	0.2%	Wheat	0.1%	Carrots		
	0.6%	ES child	0.14	0.2%	Apples	0.2%	Wheat	0.1%	Pears		
	0.6%	GEMS/Food G10	0.14	0.2%	Wheat	0.1%	Apples	0.0%	Carrots		
	0.6%	LT adult	0.13	0.3%	Apples	0.1%	Cucumbers	0.0%	Rye		
0.6%	PL general	0.13	0.4%	Apples	0.1%	Carrots	0.0%	Pears			
0.5%	IT adult	0.12	0.2%	Wheat	0.1%	Apples	0.1%	Peaches			
0.5%	FR adult	0.12	0.1%	Sugar beet roots	0.1%	Apples	0.1%	Wheat			
0.5%	FI 6 yr	0.12	0.1%	Cucumbers	0.1%	Carrots	0.1%	Apples			
0.4%	DK adult	0.10	0.2%	Apples	0.1%	Carrots	0.1%	Pears			
0.4%	ES adult	0.10	0.1%	Apples	0.1%	Wheat	0.1%	Pears			
0.4%	UK vegetarian	0.09	0.1%	Apples	0.1%	Sugar beet roots	0.1%	Wheat			
0.3%	UK adult	0.07	0.1%	Sugar beet roots	0.1%	Wheat	0.1%	Apples			
0.3%	FI adult	0.07	0.1%	Apples	0.1%	Cucumbers	0.1%	Carrots			
0.2%	IE child	0.04	0.1%	Apples	0.1%	Wheat	0.0%	Carrots			


Triazole Alanina

 <p>European Food Safety Authority</p> <p>EFSA PRIMo revision 3.1, 2016/03/19</p>		Triazole Alanine				Input values					
		LOQs (mg/kg) range from:		to:		<div>Details - chronic risk assessment</div> <div>Supplementary results - chronic risk assessment</div>					
		Toxicological reference values									
		ADI (mg/kg bw/day):		0.3		ARID (mg/kg bw):		0.3		<div>Details - acute risk assessment/children</div> <div>Details - acute risk assessment/adults</div>	
Source of ADI:				Source of ARID:							
Year of evaluation:				Year of evaluation:							
Comments:											
Normal mode											
Chronic risk assessment: JMPR methodology (IED/TMDI)											
				No of diets exceeding the ADI :		---					
TMDI/IED 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	MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
	2%	DK child	4.58	0.8%	Rye	0.6%	Wheat	0.0%	Apples		
	1%	GEMS/Food G06	3.34	1%	Wheat	0.0%	Sugar beet roots	0.0%	Apples		
	1%	NL toddler	3.26	0.6%	Wheat	0.1%	Apples	0.1%	Rapeseeds/canola seeds		
	1.0%	IT toddler	3.00	1.0%	Wheat	0.0%	Apples	0.0%	Peaches		
	1.0%	DE child	2.88	0.6%	Wheat	0.2%	Apples	0.1%	Rye		
	0.9%	NL child	2.73	0.6%	Wheat	0.1%	Sugar beet roots	0.1%	Apples		
	0.8%	GEMS/Food G08	2.49	0.6%	Wheat	0.1%	Rye	0.1%	Barley		
	0.8%	GEMS/Food G15	2.45	0.7%	Wheat	0.1%	Barley	0.0%	Rye		
	0.8%	RO general	2.36	0.7%	Wheat	0.0%	Apples	0.0%	Sugar beet roots		
	0.8%	GEMS/Food G07	2.33	0.6%	Wheat	0.1%	Rapeseeds/canola seeds	0.0%	Barley		
	0.8%	FR child 3 15 yr	2.30	0.7%	Wheat	0.0%	Sugar beet roots	0.0%	Apples		
	0.7%	GEMS/Food G10	2.08	0.6%	Wheat	0.0%	Barley	0.0%	Rapeseeds/canola seeds		
	0.7%	ES child	2.03	0.6%	Wheat	0.0%	Apples	0.0%	Peaches		
	0.7%	UK toddler	1.95	0.6%	Wheat	0.0%	Sugar beet roots	0.0%	Apples		
	0.6%	IT adult	1.90	0.6%	Wheat	0.0%	Peaches	0.0%	Apples		
	0.6%	PT general	1.90	0.6%	Wheat	0.0%	Rye	0.0%	Apples		
	0.6%	GEMS/Food G11	1.88	0.5%	Wheat	0.1%	Barley	0.0%	Apples		
	0.5%	FR toddler 2 3 yr	1.65	0.4%	Wheat	0.0%	Apples	0.0%	Sugar beet roots		
	0.5%	SE general	1.64	0.5%	Wheat	0.0%	Rye	0.0%	Apples		
	0.5%	DE women 14-50 yr	1.54	0.3%	Wheat	0.1%	Rye	0.1%	Sugar beet roots		
	0.5%	DE general	1.52	0.3%	Wheat	0.1%	Rye	0.1%	Sugar beet roots		
	0.5%	UK infant	1.40	0.4%	Wheat	0.0%	Apples	0.0%	Sugar beet roots		
	0.4%	NL general	1.25	0.3%	Wheat	0.0%	Sugar beet roots	0.0%	Rapeseeds/canola seeds		
0.4%	IE adult	1.24	0.3%	Wheat	0.0%	Rye	0.0%	Oat			
0.4%	ES adult	1.21	0.3%	Wheat	0.0%	Barley	0.0%	Apples			
0.4%	FR adult	1.07	0.3%	Wheat	0.0%	Sugar beet roots	0.0%	Apples			
0.4%	FI 3 yr	1.07	0.2%	Wheat	0.1%	Rye	0.0%	Oat			
0.4%	LT adult	1.05	0.2%	Rye	0.2%	Wheat	0.0%	Apples			
0.3%	UK vegetarian	0.98	0.3%	Wheat	0.0%	Apples	0.0%	Sugar beet roots			
0.3%	FI 6 yr	0.86	0.1%	Wheat	0.1%	Rye	0.0%	Oat			
0.3%	DK adult	0.80	0.2%	Wheat	0.1%	Rye	0.0%	Apples			
0.3%	UK adult	0.80	0.2%	Wheat	0.0%	Sugar beet roots	0.0%	Apples			
0.2%	IE child	0.53	0.2%	Wheat	0.0%	Apples	0.0%	Carrots			
0.2%	FR infant	0.53	0.1%	Wheat	0.0%	Apples	0.0%	Sugar beet roots			
0.2%	FI adult	0.52	0.1%	Rye	0.0%	Wheat	0.0%	Oat			
0.0%	PL general	0.13	0.0%	Apples	0.0%	Carrots	0.0%	Pears			

Triazole Acetic Acid

 <p>European Food Safety Authority</p> <p>EFSA PRIMA revision 3.1: 20190219</p>		Triazole Acetic Acid				Input values					
		LOQs (mg/kg) range from: _____ to: _____				<div>Details - chronic risk assessment</div> <div>Supplementary results - chronic risk assessment</div>					
		Toxicological reference values									
		ADI (mg/kg bw/day): 1		ARID (mg/kg bw): 1		<div>Details - acute risk assessment/children</div> <div>Details - acute risk assessment/adults</div>					
Source of ADI: _____		Source of ARID: _____									
Year of evaluation: _____		Year of evaluation: _____									
Comments: _____											
Normal mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
No of diets exceeding the ADI: ---				Exposure resulting from							
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/IEDI calculation (based on average food consumption)	0.2%	DK child	2.15	0.1%	Rye	0.1%	Wheat	0.0%	Apples		
	0.2%	NL toddler	1.75	0.1%	Wheat	0.0%	Apples	0.0%	Sugar beet roots		
	0.2%	DE child	1.60	0.1%	Wheat	0.0%	Apples	0.0%	Rye		
	0.2%	GEMS/Food G06	1.54	0.1%	Wheat	0.0%	Sugar beet roots	0.0%	Apples		
	0.1%	NL child	1.49	0.1%	Wheat	0.0%	Sugar beet roots	0.0%	Apples		
	0.1%	IT toddler	1.35	0.1%	Wheat	0.0%	Apples	0.0%	Peaches		
	0.1%	FR child 3 15 yr	1.15	0.1%	Wheat	0.0%	Sugar beet roots	0.0%	Apples		
	0.1%	RO general	1.12	0.1%	Wheat	0.0%	Apples	0.0%	Sugar beet roots		
	0.1%	GEMS/Food G15	1.08	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
	0.1%	GEMS/Food G08	1.06	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
	0.1%	UK toddler	0.98	0.1%	Wheat	0.0%	Sugar beet roots	0.0%	Apples		
	0.1%	GEMS/Food G07	0.96	0.1%	Wheat	0.0%	Apples	0.0%	Barley		
	0.1%	ES child	0.94	0.1%	Wheat	0.0%	Apples	0.0%	Pears		
	0.1%	GEMS/Food G10	0.89	0.1%	Wheat	0.0%	Barley	0.0%	Apples		
	0.1%	FR toddler 2 3 yr	0.89	0.1%	Wheat	0.0%	Apples	0.0%	Sugar beet roots		
	0.1%	PT general	0.87	0.1%	Wheat	0.0%	Apples	0.0%	Carrots		
	0.1%	GEMS/Food G11	0.86	0.1%	Wheat	0.0%	Apples	0.0%	Barley		
	0.1%	IT adult	0.86	0.1%	Wheat	0.0%	Apples	0.0%	Peaches		
	0.1%	DE women 14-50 yr	0.85	0.0%	Wheat	0.0%	Sugar beet roots	0.0%	Apples		
	0.1%	DE general	0.81	0.0%	Wheat	0.0%	Sugar beet roots	0.0%	Rye		
	0.1%	SE general	0.80	0.1%	Wheat	0.0%	Rye	0.0%	Apples		
	0.1%	UK infant	0.71	0.0%	Wheat	0.0%	Apples	0.0%	Sugar beet roots		
	0.1%	NL general	0.61	0.0%	Wheat	0.0%	Sugar beet roots	0.0%	Apples		
	0.1%	IE adult	0.60	0.0%	Wheat	0.0%	Apples	0.0%	Rye		
	0.1%	ES adult	0.55	0.0%	Wheat	0.0%	Apples	0.0%	Barley		
	0.1%	LT adult	0.52	0.0%	Rye	0.0%	Wheat	0.0%	Apples		
	0.1%	FI 3 yr	0.52	0.0%	Wheat	0.0%	Rye	0.0%	Cucumbers		
	0.1%	FR adult	0.52	0.0%	Wheat	0.0%	Sugar beet roots	0.0%	Apples		
	0.0%	UK vegetarian	0.46	0.0%	Wheat	0.0%	Apples	0.0%	Sugar beet roots		
	0.0%	FI 6 yr	0.42	0.0%	Wheat	0.0%	Rye	0.0%	Cucumbers		
0.0%	DK adult	0.40	0.0%	Wheat	0.0%	Rye	0.0%	Apples			
0.0%	UK adult	0.38	0.0%	Wheat	0.0%	Sugar beet roots	0.0%	Apples			
0.0%	FR infant	0.35	0.0%	Wheat	0.0%	Apples	0.0%	Sugar beet roots			
0.0%	FI adult	0.26	0.0%	Rye	0.0%	Wheat	0.0%	Apples			
0.0%	IE child	0.24	0.0%	Wheat	0.0%	Apples	0.0%	Carrots			
0.0%	PL general	0.13	0.0%	Apples	0.0%	Carrots	0.0%	Pears			

Triazole Lactic acetic

 <p>European Food Safety Authority</p> <p>EFSA PRIMA revision 3.1 - 2018/02/19</p>		Triazole Lactic Acid				Input values					
		LOQs (mg/kg) range from: _____ to: _____				<div>Details - chronic risk assessment</div> <div>Supplementary results - chronic risk assessment</div> <div>Details - acute risk assessment/children</div> <div>Details - acute risk assessment/adults</div>					
		Toxicological reference values									
		ADI (mg/kg bw/day): 0.3		ARID (mg/kg bw): 0.3		Source of ADI: _____		Source of ARID: _____		Year of evaluation: _____	
Comments: _____											
Normal mode											
Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
				No of diets exceeding the ADI : _____		---				Exposure resulting from	
TMDI/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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
	0.3%	NL toddler	0.94	0.1%	Apples	0.1%	Sugar beet roots	0.1%	Pears		
	0.2%	NL child	0.69	0.1%	Sugar beet roots	0.1%	Apples	0.0%	Pears		
	0.2%	DE child	0.64	0.2%	Apples	0.0%	Carrots	0.0%	Pears		
	0.1%	DE women 14-50 yr	0.34	0.1%	Sugar beet roots	0.0%	Apples	0.0%	Carrots		
	0.1%	DE general	0.31	0.1%	Sugar beet roots	0.0%	Apples	0.0%	Carrots		
	0.1%	FR toddler 2 3 yr	0.30	0.0%	Apples	0.0%	Sugar beet roots	0.0%	Carrots		
	0.1%	FR child 3 15 yr	0.28	0.0%	Sugar beet roots	0.0%	Apples	0.0%	Carrots		
	0.1%	DK child	0.25	0.0%	Apples	0.0%	Cucumbers	0.0%	Carrots		
	0.1%	UK toddler	0.24	0.0%	Sugar beet roots	0.0%	Apples	0.0%	Carrots		
	0.1%	NL general	0.22	0.0%	Sugar beet roots	0.0%	Apples	0.0%	Rapeseeds/canola seeds		
	0.1%	UK infant	0.20	0.0%	Apples	0.0%	Sugar beet roots	0.0%	Carrots		
	0.1%	FR infant	0.20	0.0%	Apples	0.0%	Sugar beet roots	0.0%	Carrots		
	0.1%	GEMS/Food G06	0.17	0.0%	Sugar beet roots	0.0%	Apples	0.0%	Cucumbers		
	0.1%	RO general	0.16	0.0%	Apples	0.0%	Sugar beet roots	0.0%	Carrots		
	0.0%	FI 3 yr	0.14	0.0%	Cucumbers	0.0%	Apples	0.0%	Carrots		
	0.0%	GEMS/Food G08	0.14	0.0%	Apples	0.0%	Carrots	0.0%	Rapeseeds/canola seeds		
	0.0%	GEMS/Food G15	0.14	0.0%	Apples	0.0%	Carrots	0.0%	Plums		
	0.0%	SE general	0.14	0.0%	Apples	0.0%	Carrots	0.0%	Pears		
	0.0%	GEMS/Food G11	0.14	0.0%	Apples	0.0%	Carrots	0.0%	Beetroots		
	0.0%	PL general	0.13	0.0%	Apples	0.0%	Carrots	0.0%	Pears		
	0.0%	GEMS/Food G07	0.13	0.0%	Apples	0.0%	Rapeseeds/canola seeds	0.0%	Carrots		
	0.0%	IE adult	0.12	0.0%	Apples	0.0%	Pears	0.0%	Carrots		
	0.0%	LT adult	0.11	0.0%	Apples	0.0%	Cucumbers	0.0%	Carrots		
	0.0%	PT general	0.10	0.0%	Apples	0.0%	Carrots	0.0%	Peaches		
	0.0%	FI 6 yr	0.10	0.0%	Cucumbers	0.0%	Carrots	0.0%	Apples		
	0.0%	GEMS/Food G10	0.10	0.0%	Apples	0.0%	Carrots	0.0%	Rapeseeds/canola seeds		
	0.0%	ES child	0.10	0.0%	Apples	0.0%	Pears	0.0%	Peaches		
	0.0%	FR adult	0.10	0.0%	Sugar beet roots	0.0%	Apples	0.0%	Carrots		
	0.0%	IT toddler	0.09	0.0%	Apples	0.0%	Peaches	0.0%	Pears		
0.0%	DK adult	0.09	0.0%	Apples	0.0%	Carrots	0.0%	Pears			
0.0%	IT adult	0.08	0.0%	Apples	0.0%	Peaches	0.0%	Pears			
0.0%	ES adult	0.08	0.0%	Apples	0.0%	Pears	0.0%	Peaches			
0.0%	UK vegetarian	0.07	0.0%	Apples	0.0%	Sugar beet roots	0.0%	Carrots			
0.0%	FI adult	0.06	0.0%	Apples	0.0%	Cucumbers	0.0%	Carrots			
0.0%	UK adult	0.06	0.0%	Sugar beet roots	0.0%	Apples	0.0%	Carrots			
0.0%	IE child	0.02	0.0%	Apples	0.0%	Carrots	0.0%	Pears			

A 3.2 IEDI calculations

NR

A 3.3 IESTI calculations - Raw commodities

Prothioconazole-desthio

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

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

Show results for all crops																
Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):				IESTI new Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI new):				IESTI new Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI new):			
	---				---				---				---			
	IESTI				IESTI				IESTI new				IESTI new			
	Highest % of ARfD/ADI		MRL / input for RA Exposure (mg/kg) (µg/kg bw)		Highest % of ARfD/ADI		MRL / input for RA Exposure (mg/kg) (µg/kg bw)		Highest % of ARfD/ADI		MRL / input for RA Exposure (mg/kg) (µg/kg bw)		Highest % of ARfD/ADI		MRL / input for RA Exposure (mg/kg) (µg/kg bw)	
	80%	Pears	0 / 0.06	8.0	34%	Cherries (sweet)	0 / 0.34	3.4	20%	Cucumbers	0.05 / 0.05	2.0	8%	Cucumbers	0.05 / 0.05	0.83
	63%	Apples	0 / 0.06	6.3	20%	Swedes/rutabagas	0 / 0.06	2.0	10%	Courgettes	0.05 / 0.05	1.00	6%	Courgettes	0.05 / 0.05	0.60
42%	Cherries (sweet)	0 / 0.34	4.2	18%	Pears	0 / 0.06	1.8	1%	Gherkins	0.05 / 0.05	0.14	4%	Gherkins	0.05 / 0.05	0.40	
38%	Cucumbers	0.05 / 0.06	3.8	16%	Apples	0 / 0.06	1.6									
37%	Carrots	0 / 0.06	3.7	16%	Cucumbers	0.05 / 0.06	1.6									
35%	Apricots	0 / 0.1	3.5	14%	Courgettes	0.05 / 0.06	1.4									
33%	Beetroots	0 / 0.06	3.3	13%	Beetroots	0 / 0.06	1.3									
31%	Plums	0 / 0.07	3.1	13%	Plums	0 / 0.07	1.3									
30%	Swedes/rutabagas	0 / 0.06	3.0	11%	Carrots	0 / 0.06	1.1									
27%	Courgettes	0.05 / 0.06	2.7	11%	Apricots	0 / 0.1	1.1									
21%	Parsnips	0 / 0.06	2.1	9%	Quinces	0 / 0.06	0.88									
21%	Turnips	0 / 0.06	2.1	8%	Parsnips	0 / 0.06	0.82									
18%	Salsifies	0 / 0.06	1.8	6%	Turnips	0 / 0.06	0.65									
14%	Quinces	0 / 0.06	1.4	6%	Salsifies	0 / 0.06	0.62									
8%	Medlar	0 / 0.06	0.80	6%	Parsleyroots/Hamburg	0 / 0.06	0.60									
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)								

1, 2, 4 Triazole

Acute risk assessment /children					Acute risk assessment / adults / general population					
Details - acute risk assessment /children					Details - acute risk assessment/adults					
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.										
Show results for all crops										
Unprocessed commodities	Results for children				Results for adults					
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):					
	---				---					
	IESTI				IESTI					
	Highest % of ARfD/ADI		MRL / input for RA (mg/kg)		Highest % of ARfD/ADI		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)	
	Commodities		Exposure (µg/kg bw)		Commodities		Exposure (µg/kg bw)			
	6%	Pears	0 / 0.04	5.5	1%	Swedes/rutabagas	0 / 0.04	1.4		
	4%	Apples	0 / 0.04	4.3	1%	Pears	0 / 0.04	1.2		
	4%	Peaches	0 / 0.04	3.8	1%	Apples	0 / 0.04	1.1		
	3%	Cucumbers	0 / 0.04	2.6	1%	Cucumbers	0 / 0.04	1.1		
3%	Carrots	0 / 0.04	2.5	0.9%	Courgettes	0 / 0.04	0.93			
2%	Beetroots	0 / 0.04	2.3	0.9%	Beetroots	0 / 0.04	0.92			
2%	Swedes/rutabagas	0 / 0.04	2.1	0.8%	Carrots	0 / 0.04	0.79			
2%	Courgettes	0 / 0.04	1.9	0.7%	Peaches	0 / 0.04	0.75			
2%	Plums	0 / 0.04	1.7	0.7%	Plums	0 / 0.04	0.71			
1%	Parsnips	0 / 0.04	1.4	0.6%	Quinces	0 / 0.04	0.61			
1%	Turnips	0 / 0.04	1.4	0.6%	Parsnips	0 / 0.04	0.56			
1%	Apricots	0 / 0.04	1.4	0.4%	Turnips	0 / 0.04	0.45			
1%	Salsifies	0 / 0.04	1.2	0.4%	Apricots	0 / 0.04	0.44			
1.0%	Quinces	0 / 0.04	0.98	0.4%	Salsifies	0 / 0.04	0.43			
0.6%	Medlar	0 / 0.04	0.55	0.4%	Parsley roots/Hamburg roots	0 / 0.04	0.41			
Expand/collapse list										
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)										

Triazole Alanina

Acute risk assessment /children					Acute risk assessment / adults / general population					
Details - acute risk assessment /children					Details - acute risk assessment/adults					
	The acute risk assessment is based on the ARfD.									
	The calculation is based on the large portion of the most critical consumer group.									
	Show results for all crops									
Unprocessed commodities	Results for children				Results for adults					
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):					
	---				---					
	IESTI				IESTI					
	Highest % of ARfD/ADI		MRL / input for RA (mg/kg)		Highest % of ARfD/ADI		MRL / input for RA (mg/kg)		Exposure (µg/kg bw)	
	Commodities		Exposure (µg/kg bw)		Commodities		Exposure (µg/kg bw)			
	7%	Peaches	0 / 0.22	21	4%	Cherries (sweet)	0 / 1.11	11		
	5%	Cherries (sweet)	0 / 1.11	14	1%	Peaches	0 / 0.22	4.1		
	3%	Apricots	0 / 0.22	7.7	1%	Wheat	0 / 0.43	3.6		
	2%	Wheat	0 / 0.43	6.3	0.8%	Apricots	0 / 0.22	2.4		
2%	Pears	0 / 0.04	5.5	0.7%	Rye	0 / 0.43	2.1			
1%	Apples	0 / 0.04	4.3	0.5%	Swedes/rutabagas	0 / 0.04	1.4			
0.9%	Rye	0 / 0.43	2.7	0.4%	Pears	0 / 0.04	1.2			
0.8%	Carrots	0 / 0.04	2.5	0.4%	Apples	0 / 0.04	1.1			
0.8%	Beetroots	0 / 0.04	2.3	0.3%	Barley	0 / 0.21	1.0			
0.7%	Swedes/rutabagas	0 / 0.04	2.1	0.3%	Beetroots	0 / 0.04	0.92			
0.6%	Plums	0 / 0.04	1.7	0.3%	Carrots	0 / 0.04	0.79			
0.5%	Parsnips	0 / 0.04	1.4	0.2%	Plums	0 / 0.04	0.71			
0.5%	Turnips	0 / 0.04	1.4	0.2%	Quinces	0 / 0.04	0.61			
0.4%	Salsifies	0 / 0.04	1.2	0.2%	Parsnips	0 / 0.04	0.56			
0.4%	Barley	0 / 0.21	1.2	0.1%	Turnips	0 / 0.04	0.45			
Expand/collapse list										

Triazole Acetic Acid

Acute risk assessment /children				Acute risk assessment / adults / general population				
Details - acute risk assessment /children				Details - acute risk assessment/adults				
	The acute risk assessment is based on the ARfD.							
	The calculation is based on the large portion of the most critical consumer group.							
	Show results for all crops							
Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI		MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI		MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	Commodities				Commodities			
	0.6% Pears		0 / 0.04	5.5	0.2% Wheat		0 / 0.19	1.6
	0.4% Apples		0 / 0.04	4.3	0.1% Swedes/rutabagas		0 / 0.04	1.4
	0.4% Peaches		0 / 0.04	3.8	0.1% Pears		0 / 0.04	1.2
	0.3% Wheat		0 / 0.19	2.7	0.1% Apples		0 / 0.04	1.1
0.3% Cucumbers		0 / 0.04	2.6	0.1% Cucumbers		0 / 0.04	1.1	
0.3% Carrots		0 / 0.04	2.5	0.10% Cherries (sweet)		0 / 0.1	0.95	
0.2% Beetroots		0 / 0.04	2.3	0.09% Courgettes		0 / 0.04	0.93	
0.2% Swedes/rutabagas		0 / 0.04	2.1	0.09% Beetroots		0 / 0.04	0.92	
0.2% Courgettes		0 / 0.04	1.9	0.09% Rye		0 / 0.19	0.92	
0.2% Plums		0 / 0.04	1.7	0.08% Carrots		0 / 0.04	0.79	
0.1% Parsnips		0 / 0.04	1.4	0.07% Peaches		0 / 0.04	0.75	
0.1% Turnips		0 / 0.04	1.4	0.07% Plums		0 / 0.04	0.71	
0.1% Apricots		0 / 0.04	1.4	0.06% Quinces		0 / 0.04	0.61	
0.1% Salsifies		0 / 0.04	1.2	0.06% Parsnips		0 / 0.04	0.56	
0.1% Rye		0 / 0.19	1.2	0.04% Turnips		0 / 0.04	0.45	
Expand/collapse list								

Triazole Lactic acetic

	Show results for all crops									
Unprocessed commodities	Results for children				Results for adults					
	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):					
	---				---					
	IESTI				IESTI					
	Highest % of ARfD/ADI		Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI		Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	3%		Peaches	0 / 0.08	7.6	0.5%		Cherries (sweet)	0 / 0.16	1.6
	2%		Pears	0 / 0.04	5.5	0.5%		Peaches	0 / 0.08	1.5
1%		Apples	0 / 0.04	4.3	0.5%		Swedes/rutabagas	0 / 0.04	1.4	
0.9%		Apricots	0 / 0.08	2.8	0.4%		Pears	0 / 0.04	1.2	
0.9%		Cucumbers	0 / 0.04	2.6	0.4%		Apples	0 / 0.04	1.1	
0.8%		Carrots	0 / 0.04	2.5	0.4%		Cucumbers	0 / 0.04	1.1	
0.8%		Beetroots	0 / 0.04	2.3	0.3%		Courgettes	0 / 0.04	0.93	
0.7%		Swedes/rutabagas	0 / 0.04	2.1	0.3%		Beetroots	0 / 0.04	0.92	
0.6%		Cherries (sweet)	0 / 0.16	1.9	0.3%		Apricots	0 / 0.08	0.87	
0.6%		Courgettes	0 / 0.04	1.9	0.3%		Carrots	0 / 0.04	0.79	
0.6%		Plums	0 / 0.04	1.7	0.2%		Plums	0 / 0.04	0.71	
0.5%		Parsnips	0 / 0.04	1.4	0.2%		Quinces	0 / 0.04	0.61	
0.5%		Turnips	0 / 0.04	1.4	0.2%		Parsnips	0 / 0.04	0.56	
0.4%		Salsifies	0 / 0.04	1.2	0.1%		Turnips	0 / 0.04	0.45	
0.3%		Quinces	0 / 0.04	0.98	0.1%		Salsifies	0 / 0.04	0.43	
Expand/collapse list										
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)										

A 3.4 IESTI calculations - Processed commodities

Prothioconazole-desthio

Processed commodities	Results for children				Results for adults				Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI new):				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)
	64%	Sugar beets (root) / sugar	0 / 0.7	6.4	25%	Sugar beets (root) / sugar	0 / 0.7	2.5	11%	Courgettes / boiled	0.05 / 0.05	1.1	8%	Courgettes / boiled	0.05 / 0.05	0.80
	31%	Apples / juice	0 / 0.06	3.1	23%	Beetroots / boiled	0 / 0.06	2.3	5%	Gherkins / pickled	0.05 / 0.05	0.49	#NUM!	#NUM!	#NUM!	#NUM!
	29%	Turnips / boiled	0 / 0.06	2.9	19%	Apples / juice	0 / 0.06	1.9	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	29%	Parsnips / boiled	0 / 0.06	2.9	13%	Courgettes / boiled	0.05 / 0.06	1.3	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	26%	Beetroots / boiled	0 / 0.06	2.6	12%	Parsnips / boiled	0 / 0.06	1.2	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	21%	Carrots / juice	0 / 0.06	2.1	11%	Turnips / boiled	0 / 0.06	1.1	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	21%	Courgettes / boiled	0.05 / 0.06	2.1	5%	Salsifies / boiled	0 / 0.06	0.48	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	19%	Pears / juice	0 / 0.06	1.9	5%	Carrots / canned	0 / 0.06	0.47	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	15%	Salsifies / boiled	0 / 0.06	1.5	4%	Barley / beer	0 / 0.01	0.36	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	13%	Gherkins / pickled	0.05 / 0.06	1.3	2%	Head cabbages / canned	0 / 0.02	0.19	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	6%	Potatoes / dried (flakes)	0 / 0.05	0.59	1%	Beans / canned	0 / 0.02	0.14	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	5%	Plums / juice	0 / 0.06	0.55	1%	Maize / oil	0 / 0.25	0.13	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	2%	Wheat / milling (flour)	0 / 0.02	0.24	0.9%	Wheat / bread/pizza	0 / 0.02	0.09	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	2%	Maize / oil	0 / 0.25	0.23	0.8%	Potatoes / chips	0 / 0.01	0.08	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	2%	Oat / boiled	0 / 0.05	0.18	0.8%	Wheat / pasta	0 / 0.02	0.08	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
Expand/collapse list																
Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Prothioconazole-desthio is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.																

1, 2, 4 Triazole

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	4%	Sugar beets (root) / sugar	0 / 0.48	4.4	2%	Sugar beets (root) / sugar	0 / 0.48	1.8
	2%	Apples / juice	0 / 0.04	2.2	2%	Beetroots / boiled	0 / 0.04	1.6
	2%	Turnips / boiled	0 / 0.04	2.0	1%	Apples / juice	0 / 0.04	1.3
	2%	Parsnips / boiled	0 / 0.04	2.0	0.9%	Courgettes / boiled	0 / 0.04	0.91
	2%	Beetroots / boiled	0 / 0.04	1.8	0.9%	Parsnips / boiled	0 / 0.04	0.85
	1%	Carrots / juice	0 / 0.04	1.4	0.8%	Turnips / boiled	0 / 0.04	0.76
	1%	Courgettes / boiled	0 / 0.04	1.4	0.3%	Salsifies / boiled	0 / 0.04	0.33
	1%	Pears / juice	0 / 0.04	1.3	0.3%	Peaches / canned	0 / 0.04	0.33
	1%	Peaches / canned	0 / 0.04	1.0	0.3%	Carrots / canned	0 / 0.04	0.33
	1%	Salsifies / boiled	0 / 0.04	1.0	0.07%	Barley / beer	0 / 0	0.07
	0.9%	Gherkins / pickled	0 / 0.04	0.92	0.05%	Quinces / jam	0 / 0.04	0.05
	0.7%	Peaches / juice	0 / 0.04	0.66	0.04%	Wheat / bread/pizza	0 / 0.01	0.04
	0.4%	Plums / juice	0 / 0.04	0.38	0.04%	Wheat / pasta	0 / 0.01	0.04
	0.1%	Quinces / jam	0 / 0.04	0.12	0.03%	Wheat / bread (wholemeal)	0 / 0.01	0.03
	0.1%	Wheat / milling (flour)	0 / 0.01	0.12	0.02%	Oat / boiled	0 / 0.01	0.02

Triazole Alanina

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	2%	Peaches / canned	0 / 0.22	5.7	0.6%	Wheat / bread/pizza	0 / 0.43	1.9
	2%	Wheat / milling (flour)	0 / 0.43	5.2	0.6%	Peaches / canned	0 / 0.22	1.8
	1%	Sugar beets (root) / sugar	0 / 0.48	4.4	0.6%	Sugar beets (root) / sugar	0 / 0.48	1.8
	0.8%	Wheat / milling (wholemeal)-l	0 / 0.43	2.4	0.6%	Wheat / pasta	0 / 0.43	1.7
	0.7%	Apples / juice	0 / 0.04	2.2	0.5%	Beetroots / boiled	0 / 0.04	1.6
	0.7%	Turnips / boiled	0 / 0.04	2.0	0.5%	Wheat / bread (wholemeal)	0 / 0.43	1.5
	0.7%	Parsnips / boiled	0 / 0.04	2.0	0.5%	Barley / beer	0 / 0.04	1.5
	0.6%	Beetroots / boiled	0 / 0.04	1.8	0.4%	Apples / juice	0 / 0.04	1.3
	0.6%	Peaches / juice	0 / 0.1	1.7	0.3%	Parsnips / boiled	0 / 0.04	0.85
	0.5%	Rye / boiled	0 / 0.43	1.6	0.3%	Turnips / boiled	0 / 0.04	0.76
	0.5%	Rye / milling (wholemeal)-bal	0 / 0.43	1.5	0.1%	Salsifies / boiled	0 / 0.04	0.33
	0.5%	Carrots / juice	0 / 0.04	1.4	0.1%	Carrots / canned	0 / 0.04	0.33
	0.4%	Pears / juice	0 / 0.04	1.3	0.1%	Oat / boiled	0 / 0.21	0.32
	0.3%	Salsifies / boiled	0 / 0.04	1.0	0.02%	Quinces / jam	0 / 0.04	0.05
	0.3%	Oat / boiled	0 / 0.21	0.75	#NUM!	#NUM!	#NUM!	#NUM!
Expand/collapse list								

Triazole Acetic Acid

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	0.4%	Sugar beets (root) / sugar	0 / 0.48	4.4	0.2%	Sugar beets (root) / sugar	0 / 0.48	1.8
	0.2%	Wheat / milling (flour)	0 / 0.19	2.3	0.2%	Beetroots / boiled	0 / 0.04	1.6
	0.2%	Apples / juice	0 / 0.04	2.2	0.1%	Apples / juice	0 / 0.04	1.3
	0.2%	Turnips / boiled	0 / 0.04	2.0	0.09%	Courgettes / boiled	0 / 0.04	0.91
	0.2%	Parsnips / boiled	0 / 0.04	2.0	0.09%	Parsnips / boiled	0 / 0.04	0.85
	0.2%	Beetroots / boiled	0 / 0.04	1.8	0.08%	Wheat / bread/pizza	0 / 0.19	0.83
	0.1%	Carrots / juice	0 / 0.04	1.4	0.08%	Turnips / boiled	0 / 0.04	0.76
	0.1%	Courgettes / boiled	0 / 0.04	1.4	0.07%	Wheat / pasta	0 / 0.19	0.72
	0.1%	Pears / juice	0 / 0.04	1.3	0.07%	Wheat / bread (wholemeal)	0 / 0.19	0.66
	0.1%	Wheat / milling (wholemeal)-I	0 / 0.19	1.0	0.04%	Barley / beer	0 / 0.01	0.42
	0.1%	Peaches / canned	0 / 0.04	1.0	0.03%	Salsifies / boiled	0 / 0.04	0.33
	0.1%	Salsifies / boiled	0 / 0.04	1.0	0.03%	Peaches / canned	0 / 0.04	0.33
	0.1%	Gherkins / pickled	0 / 0.04	0.92	0.03%	Carrots / canned	0 / 0.04	0.33
	0.1%	Rye / boiled	0 / 0.19	0.69	0.01%	Oat / boiled	0 / 0.06	0.09
	0.1%	Peaches / juice	0 / 0.04	0.66	0.01%	Quinces / jam	0 / 0.04	0.05

Triazole Lactic acetic

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	1%	Sugar beets (root) / sugar	0 / 0.48	4.4	0.6%	Sugar beets (root) / sugar	0 / 0.48	1.8
	0.7%	Apples / juice	0 / 0.04	2.2	0.5%	Beetroots / boiled	0 / 0.04	1.6
	0.7%	Peaches / canned	0 / 0.08	2.1	0.4%	Apples / juice	0 / 0.04	1.3
	0.7%	Turnips / boiled	0 / 0.04	2.0	0.3%	Courgettes / boiled	0 / 0.04	0.91
	0.7%	Parsnips / boiled	0 / 0.04	2.0	0.3%	Parsnips / boiled	0 / 0.04	0.85
	0.6%	Beetroots / boiled	0 / 0.04	1.8	0.3%	Turnips / boiled	0 / 0.04	0.76
	0.5%	Carrots / juice	0 / 0.04	1.4	0.2%	Peaches / canned	0 / 0.08	0.65
	0.5%	Courgettes / boiled	0 / 0.04	1.4	0.1%	Salsifies / boiled	0 / 0.04	0.33
	0.4%	Pears / juice	0 / 0.04	1.3	0.1%	Carrots / canned	0 / 0.04	0.33
	0.3%	Salsifies / boiled	0 / 0.04	1.0	0.02%	Barley / beer	0 / 0	0.07
	0.3%	Gherkins / pickled	0 / 0.04	0.92	0.02%	Quinces / jam	0 / 0.04	0.05
	0.2%	Peaches / juice	0 / 0.04	0.66	0.01%	Oat / boiled	0 / 0.01	0.02
	0.1%	Plums / juice	0 / 0.04	0.38	#NUM!	#NUM!	#NUM!	#NUM!
	0.0%	Quinces / jam	0 / 0.04	0.12	#NUM!	#NUM!	#NUM!	#NUM!
	0.0%	Oat / boiled	0 / 0.01	0.04	#NUM!	#NUM!	#NUM!	#NUM!

Appendix 4 Additional information provided by the applicant

Dietary burden calculation

Animal burden calculation												prothioconazole								
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)	0.075		mg/kg bw/d	%	0.112		mg/kg bw/d	%	0.173		mg/kg bw/d	%	0.213		mg/kg bw/d	%				
Contributor 1	Barley	straw	30		Barley	straw	30		Barley	straw	60		Barley	straw	60					
Contributor 2	Potato	process wast	40		Potato	process wast	30		Potato	process wast	40		Beet, sugar	dried pulp	40					
Contributor 3	Swede	roots	30		Swede	roots	20				0				0					
Contributor 4			0		Barley	grain	20				0				0					
Median intake	0.0260		mg/kg bw/d		0.0314		mg/kg bw/d		0.0384		mg/kg bw/d		0.0407		mg/kg bw/d					
Maximum Intake	Swine								Intakes >0.004 mg/kg bw/d are highlighted											
	Breeding			260 kg 6 kg			Finishing										100 kg 3 kg			
(mg/kg bw/d)	0.016		mg/kg bw/d	%	0.016		mg/kg bw/d	%												
Contributor 1	Potato	process wast	20		Beet, sugar	dried pulp	20													
Contributor 2	Cabbage, heads	leaves	10		Swede	roots	40													
Contributor 3	Swede	roots	40		Barley	grain	40													
Contributor 4	Barley	grain	30																	
Median intake	0.014		mg/kg bw/d		0.015		mg/kg bw/d													
Maximum Intake	Poultry																			
	Broiler			1.7 kg 0.12 kg			Layer										1.9 kg 0.13 kg		Turkey	
(mg/kg bw/d)	0.014		mg/kg bw/d	%	0.038		mg/kg bw/d	%	0.009		mg/kg bw/d	%								
Contributor 1	Swede	roots	10		Barley	straw	5		Swede	roots	10									
Contributor 2	Potato	dried pulp	20		Swede	roots	10		Wheat	milled bypds	20									
Contributor 3	Barley	grain	70		Potato	dried pulp	15		Barley	grain	50									
Contributor 4					Barley	grain	70													
Median intake	0.013		mg/kg bw		0.017		mg/kg bw		0.008		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	3.14		2.92		5.2		5.00		0.71		0.54									
Median	1.08		0.82		1.15		0.96		0.60		0.49									
	Poultry				Intake >0.1 mg/kg DM in red characters															
	Broiler		Layer						Turkey											
Maximum	0.20		0.55						0.13											
Median	0.18		0.25						0.12											

Animal burden calculation										1,2,4 Triazole											
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				Dairy				Ram/Ewe				Lamb								
	500 kg 12 kg				650 kg 25 kg				75 kg 2.5 kg				40 kg 1.7 kg								
(mg/kg bw/d)	0.009	mg/kg bw/d	%	0.017	mg/kg bw/d	%	0.017	mg/kg bw/d	%	0.022	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	Beet, sugar	dried pulp	40						
Contributor 2	Swede	roots	40	Swede	roots	20	Swede	roots	30	Swede	roots	30	Swede	roots	30						
Contributor 3	Rape	forage	10	Rape	forage	10	Rape	forage	30	Rape	forage	30	Rape	forage	30						
Contributor 4	Oat	grain	25	Oat	grain	30			0			0			0						
Median intake	0.0095	mg/kg bw/d		0.0168	mg/kg bw/d				0.0087	mg/kg bw/d					0.0216	mg/kg bw/d					
Maximum Intake	Swine										Intakes >0.004 mg/kg bw/d are highlighted										
	Breeding				Finishing																
	260 kg 6 kg				100 kg 3 kg																
(mg/kg bw/d)	0.009	mg/kg bw/d	%	0.010	mg/kg bw/d	%															
Contributor 1	Beet, sugar	dried pulp	20	Beet, sugar	dried pulp	20															
Contributor 2	Swede	roots	40	Swede	roots	40															
Contributor 3	Rape	forage	20	Oat	grain	40															
Contributor 4	Oat	grain	20																		
Median intake	0.009	mg/kg bw/d		0.010	mg/kg bw/d																
Maximum Intake	Poultry																				
	Broiler				Layer				Turkey												
	1.7 kg 0.12 kg				1.9 kg 0.13 kg				7 kg 0.5 kg												
(mg/kg bw/d)	0.007	mg/kg bw/d	%	0.008	mg/kg bw/d	%	0.006	mg/kg bw/d	%												
Contributor 1	Swede	roots	10	Swede	roots	10	Swede	roots	10												
Contributor 2	Canola	meal	18	Rape	forage	10	Canola	meal	20												
Contributor 3	Oat	grain	70	Wheat	milled bypdt	20	Oat	grain	50												
Contributor 4				Oat	grain	60															
Median intake	0.007	mg/kg bw		0.008	mg/kg bw		0.006	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	0.39	0.44		0.5	0.51			0.37	0.35												
Median	0.39	0.44		0.26	0.51			0.37	0.35												
	Poultry																				
	Broiler	Layer			Turkey																
Maximum	0.10	0.11		0.09	Intake >0.1 mg/kg DM in red characters																
Median	0.10	0.11		0.09																	

Animal burden calculation										Triazole Alanine													
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)	0.032	mg/kg bw/d	%	0.051	mg/kg bw/d	%	0.055	mg/kg bw/d	%	0.083	mg/kg bw/d	%	0.083	mg/kg bw/d	%	0.083	mg/kg bw/d	%	0.083	mg/kg bw/d	%		
Contributor 1	Wheat	milled bypdt	30	Wheat	milled bypdt	30	Wheat	milled bypdt	40	Wheat	milled bypdt	50	Wheat	milled bypdt	50	Wheat	milled bypdt	50	Wheat	milled bypdt	50		
Contributor 2	Rye	grain	40	Rye	grain	40	Rye	grain	40	Rye	grain	40	Wheat	grain	50	Wheat	grain	50	Wheat	grain	50		
Contributor 3	Swede	roots	30	Swede	roots	20	Swede	roots	20	Swede	roots	0	Wheat	grain	50	Wheat	grain	50	Wheat	grain	50		
Contributor 4			0	Rape	forage	10						0	Wheat	grain	50	Wheat	grain	50	Wheat	grain	50		
Median intake	0.0322	mg/kg bw/d		0.0509	mg/kg bw/d		0.0548	mg/kg bw/d		0.0830	mg/kg bw/d		0.0830	mg/kg bw/d		0.0830	mg/kg bw/d		0.0830	mg/kg bw/d			
Maximum Intake	Swine										Intakes >0.004 mg/kg bw/d are highlighted												
	Breeding			260 kg 6 kg			Finishing			100 kg 3 kg													
(mg/kg bw/d)	0.045	mg/kg bw/d	%	0.059	mg/kg bw/d	%																	
Contributor 1	Wheat	milled bypdt	50	Wheat	milled bypdt	50																	
Contributor 2	Rye	grain	50	Rye	grain	50																	
Contributor 3			0			0																	
Contributor 4			0																				
Median intake	0.045	mg/kg bw/d		0.059	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)	0.075	mg/kg bw/d	%	0.073	mg/kg bw/d	%	0.073	mg/kg bw/d	%	0.073	mg/kg bw/d	%	0.073	mg/kg bw/d	%	0.073	mg/kg bw/d	%	0.073	mg/kg bw/d	%		
Contributor 1	Wheat	milled bypdt	20	Wheat	milled bypdt	20	Wheat	milled bypdt	20	Wheat	milled bypdt	20	Wheat	milled bypdt	20	Wheat	milled bypdt	20	Wheat	milled bypdt	20		
Contributor 2	Rye	grain	70	Wheat	grain	70	Wheat	grain	70	Rye	grain	60	Wheat	grain	60	Wheat	grain	60	Wheat	grain	60		
Contributor 3	Swede	roots	10	Swede	roots	10	Swede	roots	10	Swede	roots	10	Swede	roots	10	Swede	roots	10	Swede	roots	10		
Contributor 4						0																	
Median intake	0.075	mg/kg bw		0.073	mg/kg bw		0.073	mg/kg bw		0.073	mg/kg bw		0.073	mg/kg bw		0.073	mg/kg bw		0.073	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	1.34		1.32			1.6		1.95			1.96		1.96										
Median	1.34		1.32			1.65		1.95			1.96		1.96										
	Poultry					Intake >0.1 mg/kg DM in red characters																	
	Broiler		Layer		Turkey																		
Maximum	1.07		1.06		1.02																		
Median	1.07		1.06		1.02																		

Animal burden calculation										Triazole Acetic Acid														
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)	0.019	mg/kg bw/d	%	0.029	mg/kg bw/d	%	0.043	mg/kg bw/d	%	0.060	mg/kg bw/d	%											
Contributor 1	Wheat	milled bypdt	30	Wheat	milled bypdt	30	Rape	forage	40	Rape	forage	40												
Contributor 2	Barley	straw	30	Barley	straw	30	Wheat	milled bypdt	40	Wheat	milled bypdt	50												
Contributor 3	Swede	roots	40	Swede	roots	20	Swede	roots	20	Swede	roots	10												
Contributor 4			0	Rye	grain	20			0			0												
Median intake	0.0162	mg/kg bw/d		0.0243	mg/kg bw/d		0.0262	mg/kg bw/d		0.0389	mg/kg bw/d													
Maximum Intake	Swine										Intakes >0.004 mg/kg bw/d are highlighted													
	Breeding			260 kg 6 kg			Finishing			100 kg 3 kg														
	(mg/kg bw/d)	0.027	mg/kg bw/d	%	0.028	mg/kg bw/d	%																	
Contributor 1	Rape	forage	20	Wheat	milled bypdt	50																		
Contributor 2	Wheat	milled bypdt	50	Swede	roots	40																		
Contributor 3	Swede	roots	30	Rye	grain	10																		
Contributor 4			0																					
Median intake	0.022	mg/kg bw/d		0.028	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)	0.035	mg/kg bw/d	%	0.043	mg/kg bw/d	%	0.034	mg/kg bw/d	%														
Contributor 1	Wheat	milled bypdt	20	Rape	forage	10	Wheat	milled bypdt	20															
Contributor 2	Swede	roots	10	Wheat	milled bypdt	20	Swede	roots	10															
Contributor 3	Rye	grain	70	Swede	roots	10	Rye	grain	60															
Contributor 4				Wheat	grain	60																		
Median intake	0.035	mg/kg bw		0.033	mg/kg bw		0.034	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	0.80	0.77		1.3	1.41		1.18	0.93																
Median	0.68	0.63		0.79	0.91		0.93	0.93																
	Poultry																							
	Broiler	Layer		Turkey			Intake >0.1 mg/kg DM																	
Maximum	0.49	0.62		0.47			in red characters																	
Median	0.49	0.49		0.47																				

Animal burden calculation

Triazole lactic acid

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 (mg/kg bw/d)	Cattle						Sheep					
	Beef			Dairy			Ram/Ewe			Lamb		
	500 kg 12 kg			650 kg 25 kg			75 kg 2.5 kg			40 kg 1.7 kg		
	0.011	mg/kg bw/d	%	0.019	mg/kg bw/d	%	0.024	mg/kg bw/d	%	0.031	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	Rape	forage	10	Rape	forage	10	Rape	forage	40	Rape	forage	40
Contributor 3	Swede	roots	40	Swede	roots	20	Swede	roots	20	Swede	roots	20
Contributor 4	Barley	grain	25	Barley	grain	30			0			0
Median intake	0.0092	mg/kg bw/d		0.0163	mg/kg bw/d		0.0084	mg/kg bw/d		0.0216	mg/kg bw/d	

Maximum Intake (mg/kg bw/d)	Swine					
	Breeding			Finishing		
	260 kg 6 kg			100 kg 3 kg		
	0.011	mg/kg bw/d	%	0.010	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	Barley	grain	40
Contributor 4	Barley	grain	20			
Median intake	0.008	mg/kg bw/d		0.010	mg/kg bw/d	

Intakes >0.004 mg/kg bw/d are highlighted

Maximum Intake (mg/kg bw/d)	Poultry					
	Broiler		Layer		Turkey	
	1.7 kg 0.12 kg		1.9 kg 0.13 kg		7 kg 0.5 kg	
	0.005	mg/kg bw/d	0.009	mg/kg bw/d	0.005	mg/kg bw/d
Contributor 1	Swede	roots	10	Rape	forage	10
Contributor 2	Canola	meal	18	Swede	roots	10
Contributor 3	Barley	grain	70	Canola	meal	20
Contributor 4			Barley	grain	70	Barley
Median intake	0.005	mg/kg bw	0.005	mg/kg bw	0.005	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	0.44	0.48	0.7	0.72	0.48	0.33
Median	0.38	0.42	0.25	0.51	0.37	0.33
	Poultry			Intake >0.1 mg/kg DM in red characters		
	Broiler	Layer	Turkey			
Maximum	0.06	0.14	0.06			
Median	0.06	0.08	0.06			