

# REGISTRATION REPORT

## Part B

### Section 7

#### Metabolism and Residues

Detailed summary of the risk assessment

Product code: CA3642

Product name(s): Joust Pro

Chemical active substance:

prothioconazole, 150 g/L

azoxystrobin, 150 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

New Authorisation (Art.33)

Sponsor: Nufarm Crop Products UK Limited

Applicant: Nufarm Polska Sp. z o. o.

Submission date: 1/02/2023, updated: 23/06/2023; 23/10/2023;  
28/03/2024

MS Finalisation date: May 2024 (initial Core Assessment)

October 2024, December 2024 (final Core Assessment)

## Version history

When	What
February 2023	Applicant version. First submission.
June 2023	Update of Table 7.1-1 according to the request of the zRMS PL
October 2023	Update from the applicant following zRMS PL comments. Additional data are highlighted in grey.
December 2023	<p>Initial zRMS assessment</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are <del>struck through</del> and <del>shaded</del> for transparency.</p> <p>Following the evaluation and before sending the document for commenting, all colored highlighting was removed, from the parts updated by the Applicant, for better legibility.</p>
March 2024	Update from the applicant with finalised report S23-100807
May 2024	<p>Update to Initial zRMS assessment following the submitted residue study (S23-100807)</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are <del>struck through</del> and <del>shaded</del> for transparency.</p> <p>Following the evaluation and before sending the document for commenting, all colored highlighting was removed, from the parts updated by the Applicant, for better legibility.</p>
October 2024	<p>Final report (Core Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are <b>highlighted in yellow</b>. Not agreed or not relevant information are <del>struck through</del> and <del>shaded</del> for transparency.</p>
December 2024	<p>Final report (Core Assessment updated following the second commenting period)</p> <p>No additional information or assessments after the commenting period.</p>

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

### **7.1 Summary and zRMS Conclusion**

#### **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 CA3642 are presented in Table 7.1-1. They have been selected from the individual GAPs in the zone. A list of all intended uses within the zone is given in Part B, Section 0.

##### **Overall conclusion**

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for prothioconazole and azoxystrobin as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of prothioconazole residues, including the triazole derivative metabolites, and of azoxystrobin are unlikely to present a public health concern.

There are sufficient independent residue trials to support the proposed major uses of PPP on cereals and winter oilseed rape and these uses are accepted.

According to Article 51 of Regulation 1107/2009 the proposed minor uses of PPP on spring oilseed rape, sunflower, linseed, poppy, mustard, gold of pleasure seeds can be accepted.

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended uses.

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

##### **Data gaps**

Noticed data gaps are: none

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

Table A.1. Acceptability of chemical GRPs (and respective risk rank GRPs, 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 (Additionally: developmental stages of the pest or pest group)	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as		Timing / Growth stage of crop & season	Number Min - Max	Min. interval between applications (days) min	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1-14	Wheat (winter & spring)  Spelt  Einkorn wheat  Emmer Wheat  Tritordeum	Central Zone	CA3642	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia triticina</i> (PUCCRT) Yellow Rust <i>Puccinia striiformis</i> (PUC CST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acuformis</i> / <i>Pseudocercospora herpotrichoides</i> (PSDCHE) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Head blight of cereals <i>Fusarium</i> spp. (FUSASP) <i>Microdochium</i> spp. (MICDSP)	EC	250 g/L	foliar spray	BBCH 30 – 69 (spring)	1-2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210)  b) 720-840 (360+360 – 420+420)	100-400	35	A

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  (Additionally: developmental stages of the pest or pest group)	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as		Timing / Growth stage of crop & season	Number  Min - Max	Min. interval between applications (days) min	L product / ha  a) max. rate per appl. b) max. total rate per crop/season	g as/ha  a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
15-25	Durum Wheat	Central Zone	CA3642	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia triticina</i> (PUCCRT) Yellow/stripe Rust <i>Puccinia striiformis</i> (PUCCST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	EC	250 g/L	foliar spray	BBCH 30 – 69 (spring)	1-2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210)  b) 720-840 (360+360 – 420+420)	100- 400	35	A

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  (Additionally: developmental stages of the pest or pest group)	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	Method / Kind	Timing / Growth stage of crop & season	Number Min - Max	Min. interval between applications (days) min	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
26-38	Triticale (winter & spring)	Central Zone	CA3642	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia triticina</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUC CST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	EC	250 g/L	foliar spray	BBCH 30 – 69 (spring)	1-2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210)  b) 720-840 (360+360 – 420+420)	100-400	35	A

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  (Additionally: developmental stages of the pest or pest group)	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	Method / Kind	Timing / Growth stage of crop & season	Number Min - Max	Min. interval between applications (days) min	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
39-52	Rye (winter & spring)	Central Zone	CA3642	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Brown rust <i>Puccinia recondita</i> / <i>Puccinia recondita</i> f. sp. <i>Recondite</i> (PUCCRE/PUCCRR) Eyespot <i>Pseudocercospora herpotrichoides</i> (PSDCHE) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium</i> spp. (FUSASP) <i>Microdochium</i> spp. (MICDSP)	EC	250 g/L	foliar spray	BBCH 30 – 69 (spring)	1-2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210)  b) 720-840 (360+360 – 420+420)	100-400	35	A
53-65	Oat (winter & spring)	Central Zone	CA3642	F	Crown Rust <i>Puccinia coronate</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf spot of oat <i>Pyrenophora chaetomioides</i> (PYRNAV) Eyespot <i>Oculimacula acuformis</i> / <i>Pseudocercospora herpotrichoide</i> (PSDCHE)	EC	250 g/L	foliar spray	BBCH 30 – 61 (spring)	1-2	14-21	a) 1.0 b) 2.0	a) 300 (150+150)  b) 600 (300+300)	100-400	35	A

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  (Additionally: developmental stages of the pest or pest group)	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	Method / Kind	Timing / Growth stage of crop & season	Number Min - Max	Min. interval between applications (days) min	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
66-78	Barley (winter & spring)	Central Zone	CA3642	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> / <i>Pseudocercospora herpotrichoides</i> (PSDCHE) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	EC	250 g/L	foliar spray	BBCH 30 – 61 (spring)	1-2	14-21	a) 1.0 b) 2.0	a) 300 (150+150)  b) 600 (300+300)	100-400	35	A

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  (Additionally: developmental stages of the pest or pest group)	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion	
						Type	Conc. of as		Timing / Growth stage of crop & season	Number  Min - Max	Min. interval between applications (days) min	L product / ha  a) max. rate per appl. b) max. total rate per crop/season	g as/ha  a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			
79-90	Winter Oilseed Rape	Central Zone	CA3642	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Grey mould <i>Botryotinia cinerea</i> (BOTRCI)	EC	250 g/L	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180)  b) 300 - 360 (150+150- 180+180)	100- 400	56	A	

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  (Additionally: developmental stages of the pest or pest group)	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	Method / Kind	Timing / Growth stage of crop & season	Number - Min Max	Min. interval between applications (days) min	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
91-10-2	Spring Oilseed Rape	Central Zone	CA3642	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Grey mould <i>Botryotinia cinera</i> (BOTRCI)	EC	250 g/L	foliar spray	BBCH 20 – 69 (Spring)	1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150-180+180)  b) 300 - 360 (150+150-180+180)	100-400	56	A only for minor use according to Article 51
103	Sunflower	Central Zone	CA3642	F	Sclerotinia Stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Grey mould <i>Botryotinia cinera</i> (BOTRCI)Stalk rot of sunflower <i>Diaporthe helianthi</i> (DIAPHE) Black stem of Sunflower <i>Plenodomus lindquistii</i> (LEPTLI)	EC	250 g/L	foliar spray	BBCH 16– 64 (spring)	1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 240-360 (120+120 – 180+180)  b) 240-360 (120+120 – 180+180)	100-400	56	A only for minor use according to Article 51
104	Flax (for fiber production only)	Central Zone	CA3642	F	Powdery mildew flax <i>Erysiphe spp</i> (ERYSP)	EC	250 g/L	Foliar spray	BBCH 33 – 51	1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150-180+180)  b) 300 - 360 (150+150-180+180)	100-400	N/A	A



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  (Additionally: developmental stages of the pest or pest group)	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	Method / Kind	Timing / Growth stage of crop & season	Number Min - Max	Min. interval between applications (days) min	L product / ha  a) max. rate per appl. b) max. total rate per crop/season	g as/ha  a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
105-116	Linseeds, Poppy, Mustard and Gold of pleasure	Central Zone	CA3642	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	EC	250 g/L	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150-180+180)  b) 300 - 360 (150+150-180+180)	100-400	56	A minor use according to Article 51

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

\*\* Use also code numbers according to Annex I of Regulation (EU) No 396/2005

\*\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 “Conclusion”

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

## 7.1.2 Summary of the evaluation

The preparation CA3642 is composed of prothioconazole, an active substance belonging to the triazole chemical group and azoxystrobin.

The toxicological reference values of azoxystrobin, prothioconazole and the main metabolites of prothioconazole - prothioconazole-desthio and the triazole derivative metabolites (TDMs), are presented in the table hereafter.

**Table 7.1-2: Toxicological reference values for the dietary risk assessment of azoxystrobin, prothioconazole, prothioconazole-desthio and TDMs**

Reference value	Source	Year	Value	Study relied upon	Safety factor
<b>Prothioconazole-desthio</b>					
ADI	EFSA	2007	0.01 mg/kg bw/day	18-Month Mouse Carcinogenicity	100
ARfD	EFSA	2007	0.01 mg/kg bw	Developmental study in rabbits <del>rat</del>	100
<b>1,2,4-triazole (1,2,4-T)</b>					
ADI	EFSA Journal 2018; 16(7):5376	2018	0.023 mg/kg bw/day	Rat 12-month study	300
ARfD		2018	0.1 mg/kg bw	Rabbit developmental study	300
<b>Triazole alanine (TA)</b>					
ADI	EFSA Journal 2018; 16(7):5376	2018	0.3 mg/kg bw/day	Rabbit developmental study	100
ARfD		2018	0.3 mg/kg bw	Rabbit developmental study	100
<b>Triazole acetic acid (TAA)</b>					
ADI	EFSA Journal 2018; 16(7):5376	2018	1 mg/kg bw/day	Rat 2 generation and Rabbit developmental studies	100
ARfD		2018	1 mg/kg bw	Rat 2 generation and Rabbit developmental studies	100
<b>Triazole lactic acid (TLA)</b>					
ADI	EFSA Journal 2018; 16(7):5376	2018	0.3 mg/kg bw/day	Bridging from TA	
ARfD		2018	0.3 mg/kg bw	Bridging from TA	
<b>Azoxystrobin</b>					
ADI	EFSA Journal 2010; 8(4):1542	2010	0.2 mg/kg bw/day	2-year rat	100
ARfD		2010	Not necessary	-	-

### 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?
1-14	Wheat (winter & spring) Spelt Einkorn wheat Emmer Wheat Tritordeum	Yes	Yes	Yes	Yes	Yes	No	No
15-	Durum Wheat	Yes	Yes	Yes	Yes	Yes		No

Use- No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
25								
26- 38	Triticale (winter & spring)	Yes	Yes	Yes	Yes	Yes		No
39- 52	Rye (winter & spring)	Yes	Yes	Yes	Yes	Yes		No
53- 65	Oat (winter & spring)	Yes	Yes	Yes	Yes	Yes		No
66- 78	Barley (winter & spring)	Yes	Yes	Yes	Yes	Yes		No
79- 90	Winter Oilseed Rape	Yes	Yes	Yes	Yes	Yes		No
91- 102	Spring Oilseed Rape	Yes	Yes only for minor use according to Article 51	Yes	Yes	Yes		No
103	Sunflower	Yes	Yes only for minor use according to Article 51	Yes	Yes	Yes		No
104	Flax (for fiber production only)	Not applicable - Non food/feed use						No
105- 116	Linseeds, Poppy, Mustard and Gold of pleasure	Yes	Yes only for minor use according to Article 51	Yes	Yes	Yes		No

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

The effects of processing on the nature of active substance residues have been investigated. Data on effects of processing on the amount of residue have been submitted.

Regarding TDMs, studies show that they remained stable under the standard hydrolysis conditions. Studies on magnitude of residues in processed commodities in wheat, barley and oilseed rape after treatment with prothioconazole were presented in the Triazole Derivate Metabolites Addendum - Confirmatory data (B.7.5.2, UK, 2018). These data were not considered for the risk assessment (the most critical processing factors, considering data provided for all active substances belonging to the triazole group, were taken into account in the TDM EU risk assessment).

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

Regarding TDMs, in the framework of the confirmatory data, several field rotational crop trials have been conducted to investigate the magnitude of TDM residues in rotational crops after the use of triazole active substances. Residues of TA, TLA and TAA were found above 0.01 mg/kg in succeeding crops. These results were considered in the consumer risk assessment performed in the framework of the review of TDMs confirmatory data.

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

Regarding TDM arising from prothioconazole uses, as concluded by the UK, “further consideration is not required due to the fact that none of the TDMs were identified” in the available livestock metabolism studies conducted with prothioconazole.

### 7.1.2.2 Summary for azoxystrobin

**Table 7.1-4: Summary for azoxystrobin**

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1-14	Wheat (winter & spring) Spelt Einkorn wheat Emmer Wheat Triticordeum	Yes	Yes	Yes	Yes	Yes	No	No
15-25	Durum Wheat	Yes	Yes	Yes	Yes	Yes		No
26-38	Triticale (winter & spring)	Yes	Yes	Yes	Yes	Yes		No
39-52	Rye (winter & spring)	Yes	Yes	Yes	Yes	Yes		No
53-65	Oat (winter & spring)	Yes	Yes	Yes	Yes	Yes		No
66-78	Barley (winter & spring)	Yes	Yes	Yes	Yes	Yes		No
79-90	Winter Oilseed Rape	Yes	Yes	Yes	Yes	Yes		No
91-102	Spring Oilseed Rape	Yes	Yes only for minor use according to Article 51	Yes	Yes	Yes		No
103	Sunflower	Yes	Yes only for minor use according to Article 51	Yes	Yes	Yes		No
104	Flax (for fiber production only)	Not applicable - Non food/feed use					No	No
105-116	Linseeds, Poppy, Mustard and Gold of pleasure	Yes	Yes minor uses according to Article 51	Yes	Yes	Yes		No

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

There are sufficient independent residue trials to support the proposed major uses of PPP on cereals and winter oilseed rape.

Based on the SANTE/2019/12752, four residue trials on oilseed rape can be used for extrapolation to following minor **uses** ~~on minor crops~~: sunflower (in PL), spring oilseed rape, linseed, poppy, mustard and gold of pleasure seeds before and after forming of the edible part. So the proposed **minor** ~~uses on minor crops~~ (art. 51): spring oilseed rape and sunflower, linseed, poppy, mustard, gold of pleasure seeds are considered acceptable.

The effects of processing on the nature of azoxystrobin residues have been investigated. Data on effects of processing on the amount of residue have been submitted. These data were not considered for risk assessment.

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

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

### 7.1.2.3 Summary for CA3642

**Table 7.1-5: Information on CA3642 (KCA 6.8)**

Crop	PHI for CA3642 proposed by applicant	PHI sufficiently supported for		PHI for CA3642 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Prothioconazole	Azoxystrobin		
Barley (winter & spring)	35	Yes	Yes	35	-
Oat (winter & spring)	35	Yes	Yes	35	-
Wheat (winter & spring), Spelt, Einkorn wheat Emmer Wheat Tritordeum, Durum Wheat, Triticale (winter & spring)	35	Yes	Yes	35	-
Rye (winter & spring)	35	Yes	Yes	35	-
Oilseed rape (winter & spring)	56	Yes	Yes	56	-
Sunflower	56	Yes	Yes	56	-
Flax (for fibre production only)	Not applicable - Non-food/feed use				
Linseeds, Poppy, Mustard and Gold of pleasure	56	Yes	Yes	56	-

**Table 7.1-6: Waiting periods before planting succeeding crops**

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for CA3642
Crop group	Led by prothioconazole	Led by azoxystrobin	
All crops	Not needed	Not needed	Not needed

## Assessment

### 7.2 Prothioconazole

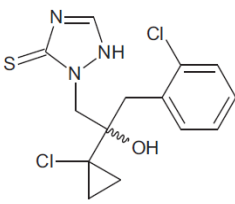
The applicant Nufarm has a letter of access from Bayer CropScience AG which authorizes the respective authorities to access the summaries of some studies on prothioconazole owned by Bayer Group in support of Nufarm application to obtain a registration under Art.33 of EU Regulation 1107/2009. These summaries are presented in the document provided by Bayer CropScience AG (Bayer doc. No. M-777951-01-1). It should be noted that the applicant Nufarm does not have access to the study reports owned by Bayer Group and therefore kindly asks the zRMS to refer to them.

The active substance prothioconazole belongs to the triazole chemical group. Triazole derivative metabolites (TDMs) are common metabolites of all triazole fungicides and have to be considered in the consumer risk assessment. The data on TDMs provided in the present application are from the “Triazole Derivate Metabolites addendum – confirmatory data prepared by the rapporteur Member State, the United Kingdom” (UK, 2018). As confirmatory data, they are out of data protection. Following this, EFSA issued the “Peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted” (EFSA, 2018). These conclusions were taken into account in the present assessment.

**According to SANTE/11509/2013– rev. 5.2 and since the active substance prothioconazole is not yet renewed, the “old data requirements” (Reg. (EU) No 544/2011) and the endpoints from the inclusion of prothioconazole (DAR) apply to the current assessment. Studies from the DAR are not protected anymore.**

General data on prothioconazole are summarized in the table below (last updated 2022/11/22).

**Table 0-1: 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 <sub>14</sub> H <sub>15</sub> Cl <sub>2</sub> N <sub>3</sub> O S
Molar mass	344.26 g/mol
Chemical group	Triazole
Mode of action (if available)	Steroid demethylation in the ergosterol biosynthesis pathway
Systemic	Yes
Company	Bayer CropScience*
Rapporteur Member State (RMS)	First approval: the United Kingdom Renewal (ongoing): Poland
Approval status	Approved
Restriction	No
Review Report	SANCO/3923 /07 - final 10 December 2007 – Updated 26 January 2021
Current MRL regulation	Regulation (EU) <del>2019/552</del> 2024/1318

Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal: Conclusion on the peer review	Yes (EFSA, 2007)
EFSA Journal: conclusion on article 12	Yes (EFSA, 2014 and EFSA, 2020)
Current MRL applications on intended uses	No

\* Notifier in the EU process to whom the a.s. belongs

## 7.2.1 Stability of Residues (KCA 6.1)

### 7.2.1.1 Stability of residues during storage of samples

#### Available data

~~Two~~ **Three** new stability study summaries have been submitted by the applicant in the framework of this application. **Two of** the relevant ~~two~~ studies have already been mentioned by EFSA during the Article 12 MRL review process (EFSA, 2014 and EFSA, 2020) and are currently under review in the EU approval renewal process for prothioconazole. ~~The other one~~ was finalised in 2023 on oilseed rape (grain and straw). In addition, a new study investigating the storage stability of prothioconazole-desthio, its hydroxies and the triazole derivative metabolites in bee products has been performed (Kalathoor, R., report S20-09716). All available results are summarized in the Tables below. The detailed assessments of these studies are presented in Appendix 2.

**Table 0-2: Summary of stability data achieved at  $\leq -18^{\circ}\text{C}$  (unless stated otherwise) – Prothioconazole, prothioconazole-desthio and prothioconazole-hydroxy-desthio**

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat grain	Dry commodities/ High starch content	PTZ: 6 months PTZ-desthio: 18 months	EFSA, 2007 Heinemann, O., 2001, Report MR-282/00 ( <i>Not protected</i> )
Wheat straw	No group	PTZ: 6 months PTZ-desthio: 18 months	
Wheat forage/green matter	High water content	PTZ: 6 months PTZ-desthio: 18 months	
Animal Products: No EU data			
New data			
Plant products			
Canola, seeds	High oil content	PTZ-desthio: 24 months PTZ-OH-desthio: 25 months	PTZ-desthio: Freitag, T., 2007, report MR-07/282 (EFSA, 2014) ( <i>Access from Bayer</i> )
Canola, whole plant	High water content	PTZ-desthio: 24 months	
Canola, pod	No group	PTZ-desthio: 24 months	
Orange fruit	High acid content	PTZ-OH-desthio: 25 months	PTZ-OH-desthio: Freitag, T., 2011, report MR-08/024 (EFSA, 2020) ( <i>Access from Bayer</i> )
Potato tuber	High starch content	PTZ-OH-desthio: 25 months	
Tomato fruit	High water content	PTZ-OH-desthio: 25 months	
Soybean	High oil content	PTZ-OH-desthio: 25 months	
Animal Products:			
Ruminant muscle, fat, liver, kidney and milk	No group	PTZ-desthio: 1 month Prothioconazole-3-OH-desthio (M14): 1 month Prothioconazole-4-OH-desthio (M15): 1 month	Animal feeding study, Report No.: MR-535/00 ( <i>Not protected</i> )

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Honey	No group	PTZ-desthio: 182 days PTZ-OH-desthio: 157 days, except for PTZ- $\alpha$ -OH-desthio (134 days)	Kalathoor, R., Report No: S20-09716 ( <i>Nufarm, protected</i> )

PTZ-OH-desthio ( $\alpha$ -OH, 3-OH, 4-OH, 5-OH and 6-OH): prothioconazole-hydroxy-desthio, which includes prothioconazole- $\alpha$ -hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio, respectively.

**Table 0-3: Summary of stability data achieved at  $\leq -18^{\circ}\text{C}$  (unless stated otherwise) – TDMs**

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration (months)				Reference
		1,2,4-Triazole	Triazole Alanine	Triazole Acetic Acid	Triazole Lactic Acid	
Data relied on in EU						
Plant products						
Apples, tomatoes, mustard leaves, wheat forage, radishes tops/roots, turnips roots, sugar beet roots, cabbages, lettuces	High water content	6	53	53	48 (Only lettuce tested)	EFSA, 2018
Barley, wheat	High starch content	12	26	26	48	
Rapeseeds, soyabeans	High oil content	12 (soya bean only; not stable in rape seed)	26 (soya bean only; not stable in rape seed)	53	48	
Peas, dry; Navy beans	High protein content	No data	15	25	48	
Oranges	High acid content	No data	No data	No data	48	
Barley, wheat	Cereal straw	12	53	40	No data	
Animal products						
Ruminant	Milk	18	No data	No data	No data	EFSA, 2018
Poultry	Eggs	12	No data	No data	No data	
Ruminant/poultry	Liver	12	No data	No data	No data	
	Muscle	12	No data	No data	No data	
	Fat	12	No data	No data	No data	
New data						
Plant products						
Oilseed rape, grain	High oil content	55 days	55 days	-	-	Winter, O., Report No: S22-08287 (Nufarm, protected)
Oilseed rape, straw	No group	55 days	55 days	55 days	55 days	
Animal products						
Honey	No group	182 days	182 days	182 days	182 days	Kalathoor, R., Report No: S20-09716 (Nufarm, protected)

### Summary of studies reported in the EU - Prothioconazole

*EFSA Journal 2014;12(5):3689*

“In the framework of the peer review, storage stability of prothioconazole-desthio residues was demonstrated at  $-18^{\circ}\text{C}$  for 18 months in high water content matrices (wheat green matter), dry commodities (cereal grain) and straw (EFSA, 2007b; United Kingdom, 2004, 2007). Furthermore, storage stability of prothioconazole-desthio residues was subsequently demonstrated for a period of 24 months at  $-18^{\circ}\text{C}$  in commodities with high water content (spinach, sugar beet, tomatoes), high oil content (canola seeds), dry



commodities (dried peas) and canola straw (EFSA, 2009, 2010a, 2010b, 2012; Netherlands, 2007”).

EFSA Journal 2020;18(2):5999

“Freezer storage stability of prothioconazole- $\alpha$ -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 oil content (soya beans, oilseed rape) and high acid content (oranges) commodities for a period of 24 months [*nominal period; actual period is 25 months according to RAR, UK, 2018*]. Samples were fortified with a mixture containing all five analytes at a level of 0.1 mg/kg each.

Since all these compounds are included in the residue definition for risk assessment, spiking with a mixture was considered acceptable. Results demonstrate stability of all compounds in all matrices for a maximum of 24 months (duration of study) [*nominal period; actual period is 25 months according to RAR, UK, 2018*] when stored at  $\leq 18^{\circ}\text{C}$ .

It is noted that according to EU guidelines (European Commission, 1997f), applicable for the current assessment, cereals are considered as dry matrix, for which the storage stability of hydroxylated metabolites of prothioconazole-desthio has not been investigated. However, it is noted that the applicant has generated data according to the OECD guidelines (OECD, 2007) in the framework of the renewal of the approval of prothioconazole. According to OECD guideline, cereals are considered as high starch matrix. EFSA accepted the storage stability data on potatoes (high starch matrix) to address the storage stability in cereals.”

**Summary of studies reported in the EU - TDMs**

EFSA Journal 2018;16(7):5376

“From the submitted storage stability data, it can be concluded that the residue trials analysing TA, TAA and TLA residues in high water-, high oil-, high protein- and high starch content commodities were supported by acceptable storage stability data on these compounds, except for TA (raspberries, peas, rapeseeds) and TAA (raspberries). The residue trials analysed 1,2,4-T residues in most of the crops within a time interval for which acceptable storage stability of this compound could not be demonstrated, except for stone fruit, stem vegetables, soya beans and oats grain. Storage stability data were not provided and are required for 1,2,4-T, TA and TAA in high acid-content commodities, for 1,2,4-triazole in high protein-content commodities and for TLA in cereal straw to cover the maximum storage time interval of all residue trials in primary and rotational crops (data gap). For products of animal origin, the available storage stability data demonstrated acceptable freezer storage stability of 1,2,4-T in milk for 18 months and in eggs, liver, muscle and fat for 12 months. Additional storage stability data analysing for the residues of TA and TAA in milk and eggs were also provided but were not considered as acceptable since the homogenised samples of milk and eggs were fortified with a mixture of TA and TAA and not with the individual compound, respectively”.

**Conclusion on stability of residues during storage**

For prothioconazole and its metabolite, the provided studies on magnitude of residues are sufficiently supported by available storage stability data. For hydroxylated metabolites of prothioconazole-desthio, it is noted that EFSA accepted the storage stability data on potatoes (high starch matrix) to address the storage stability in cereals.

Regarding TDMs, 1,2,4-T and TA were shown ~~not~~ to be stable in oilseed rape seeds **up to 55 days (Study S22-08287)**. ~~However, the first storage interval tested was 113 days, thus not allowing to determine when a significant degradation of 1,2,4 T and TA occurs. In the new residue trials performed and presented in this dossier, some seeds samples were stored for less than or around 30 days before analyses (trials 02, 06, 09 of study S20-01046 and trial 01 of study S21-00259). Residue levels of TA in seeds in those trials are comparable to those obtained in the other available trials on oilseed rape (see 7.2.3). Thus, it is considered that all TA results in seeds are reliable and can be used for risk assessment. 1,2,4 T is not present in plants in general, as confirmed in the available residue trials on cereals and oilseed rape.~~

Regarding TLA, since storage stability was demonstrated for up to 12 months in all crop categories no additional storage stability data for this compound is required.

Therefore, all residue trials submitted to support the intended uses are sufficiently supported by storage stability data available on TDMs.

**zRMS comments:**

Information given by the Applicant is acceptable and sufficient.

Studies on the storage stability of prothioconazole and its metabolite in crop and animal tissues under frozen conditions were assessed in the framework at the EU level.

Residues of prothioconazole-desthio are stable for 18 months under deep-freeze storage in high water content matrices (wheat green matter), dry commodities (cereal grain) and straw and for 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.

Additionally, the results of the study of Freitag (2011, report MR-08/024) demonstrate the stability of residues of prothioconazole- $\alpha$ -hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio upon deep frozen storage at – 18 °C for up to 24 months in all tested matrices of plant origin (rape oil seed, orange fruit, potato tuber, tomato fruit and soybean).

Additionally, new study on the storage stability of prothioconazole-desthio, its hydroxies and the triazole derivative metabolites in bee products (Kalathoor, R, Report No: S20-09716) were submitted in the framework of this application. It should be noted that this study was reviewed and accepted by zRMS-PL in RR, Part B7 for PPP of Joust (CA3301) in January 2023.

The study was conducted over a maximum storage period up to 6 months in accordance to OECD Guideline 506 covering the storage of treated samples analysed in EAS Study S21-00428.

The study is deemed sufficient for assessing the stability of

- prothioconazole-desthio in homogenates of matrices honey, nectar and pollen upon storage at -18 °C for over 6 months (182 days for honey, 183 days for pollen, 198 days for nectar);
- prothioconazole upon storage at -18 °C in homogenates of matrices nectar for more than 6 months (198 days);
- prothioconazole- $\alpha$ -hydroxy-desthio in homogenates of matrices honey, nectar and pollen upon storage at -18 °C for 4.5 months (134 days for honey and nectar, 136 days for pollen);
- prothioconazole-3, -4, -5 and -6-hydroxy-desthio in homogenates of matrices honey, nectar and pollen upon storage at -18 °C for 5 months (157 days);
- 1,2,4-triazole, triazole alanine, triazole lactic acid and triazole acetic acid in homogenates of matrices honey, nectar and pollen upon storage at -18 °C for 6 months (182 days for honey and pollen, 185 days for nectar).

More details of this study are provided in Appendix 2.

Regarding the lack of the storage stability of 1,2,4-T and TA in oilseed rape, new stability study was submitted by Applicant (Winter, O., Report No: S22-08287). 1,2,4-T and TA were shown to be stable in oilseed rape seeds up to 55 days.

More details of this study are provided in Appendix 2.

**Remark:**

It should be noted that in the study S20-01046 the maximum period between sampling and last extraction was 73 days for seed samples (oilseed rape). There are insufficient stability data for 1,2,4-T and TA in oilseed rape to support the residue data presented in this study.

It should be noted that the storage period in the residue trials as a minor uncertainty which is not expected to impact the risk assessment.

The Applicant was asked by zRMS for additional clarification.

Nufarm points out that in the study report now submitted, the stability of 1,2,4-T and TA in oilseed rape grain is proven for 55 days.

With this in mind valid storage stability data for 1,2,4-T and TA can be considered the results from S20-01046-03.

Further to the above, Nufarm has performed 3 additional residue trials on oilseed rape (study S22-00257).

The magnitude of 1,2,4-T and TA residues in above residue trials, and the respective storage periods before the analysis are presented in the table below:

Source	GAP	Storage (days) seed	Residues 1,2,4-T	Residues TA
S22-00257	2 x 175 g as/ha, BBCH 69	2 trials with max 27	2x<0.003	1.2, 1.5
		1 trial with max 43	<0.003	0.95

Nufarm notes that 1,2,4-T is not detected above the LoQ in any of the trials presented; this is further confirmed in the quote from 2018 RAR from the RMS UK: "no 1,2,4-triazole was detected in any matrix it is assumed that 1,2,4 triazole (M13) was rapidly transformed to the metabolites TA, THP and TAA". Therefore, storage stability data for 1,2,4-T are not deemed necessary.

Considering TA: taking into account the residue data available for TA from all trials: S20-01046, S21-00259 and the newly presented trial S22-00257, when comparing values of TA residues when storage exceeds 55 days, with the ones from trials stored up to 55 days, the values are comparable:

**Mann-Whitney U-Test ( $\alpha$ : 0.05)** (FAO mai

Data set	NEU S19-01269	NEU	Rank Set 1	Rank Set 2
1	1.20	0.43	5	1
2	1.20	1.10	5	3
3	1.40	1.40	7.5	7.5
4	2.10	2.30	10	11
5		0.95		2
6		1.20		5
7		1.50		9
8				
Mean	1.48	1.27		
STMR	1.30	1.20		
Number of values:			4	7
Sum Rank:			28	39
U <sub>1</sub> and U <sub>2</sub> values:			10.5	17.5
Critical value:			3	( $\alpha$ = 0.05)
n <sub>a</sub> = 4			n <sub>b</sub> = 7	
Result:			Populations similar	

Consequently all TA residue data presented in the dossier are valid.

After commenting period cMS CZ does not agree with conclusion regarding the study S20-01046 (TA metabolite): "Mann-Whitney test results are not reliable in this case due to very limited data set.:

To make the statistical test more robust, TA levels measured in control samples are also included in the dataset. This approach is considered valid as the selection of the values used for the assessment considered both control and treated samples (the highest value was retained - the residue findings for TDMs were at a similar level in the untreated and treated samples due to the persistence of TDMs in soil following the widespread use of triazole pesticides by farmers as fungicides on various field crops).

As a result, a total of 8 samples is compared with 14 samples and the populations are found to be similar. Therefore, our conclusion is unchanged and all TA residue data presented in the dossier are valid.

**Mann-Whitney U-Test ( $\alpha$ : 0.05)** (FAO mai

Data set	NEU S19-01269	NEU	Rank Set 1	Rank Set 2
1	1.40	0.43	16.5	3
2	0.80	0.28	6	1
3	1.20	1.40	14	16.5
4	0.39	0.97	2	9
5	1.20	0.84	14	7
6	0.74	1.10	5	11
7	2.10	2.30	19.5	22
8	2.10	2.20	19.5	21
9		1.50		18
10		1.10		11
11		1.10		11
12		1.20		14
13		0.95		8
14		0.48		4
25				
Mean	1.24	1.13		
STMR	1.20	1.10		
Number of values:			8	14
Sum Rank:			97	157
U <sub>1</sub> and U <sub>2</sub> values:			51.5	60.5
Critical value:			26	( $\alpha$ =0.05)
n <sub>a</sub> = 8			n <sub>b</sub> = 14	
Result:			Populations similar	

**Conclusion:**

Sufficient stability data are available to support the residue data presented in the present dossier. No further data are required.

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

In available studies on magnitude of residues, batch recoveries were carried out in parallel and stored in the same conditions as the analytical batches. Acceptable recoveries were achieved, indicating acceptable stability of residue in extracts.

**zRMS comments:**

Information given by the Applicant is acceptable and sufficient.  
No further data are required.

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

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

**Available data**

No new data submitted in the framework of this application.

**Table 0-4: Summary of plant metabolism studies – Prothioconazole**

Table 6-4. Summary of plant metabolism studies – Flutocanazole								
Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (g a.s./ha)	No	PHI	Remarks	
EU data								
Cereals/grass	Wheat	[U- <sup>14</sup> C-phenyl]-PTZ	G (Spring wheat)	220	2 BBCH 32–65	Forage: 6days Hay: 26 days Grain & Straw:48 days		EFSA, 2007; FAO, 2008a, 2008b Haas, M.; Bornatsch, W., 2000 Report No.: MR-198/99 (Not protected)
		[3,5- <sup>14</sup> C-triazole]-PTZ-desthio	G (Summer wheat)	250	2 BBCH 31–59)	Forage: 0, 14 days Grain& Straw:48 days		EFSA, 2007; FAO, 2008a, 2008b Vogeler, K.; Sakamoto, H. Brauner, A., 1993, Report No.: PF3906 (Not protected)
		[3,5- <sup>14</sup> C-triazole]-PTZ	F (Spring wheat)	180-290	2 BBCH 32–65	Forage, hay, grain, straw		FAO, 2008a, 2008b Duah, F., 2004 Report No.: 200733 (Not protected)

		[U- <sup>14</sup> C-phenyl]-PTZ	G (Spring wheat, seed treatment)	20 g a.s./100 kg seed (N) or 100 g a.s./100 kg seed (5N)	1	Forage:57days Hay: 110 days Grain &Straw: 153 days		EFSA, 2007; FAO, 2008a, 2008b Haas, M., 2001, Report No.: MR-467/99 ( <i>Not protected</i> )
<b>Pulses/Oilseeds</b>	Peanut	[U- <sup>14</sup> C-phenyl]-PTZ	G	300	3 (21d interval) BBCH 66-75	Hay & nuts without shells, 14 days		EFSA, 2007; FAO, 2008a, 2008b Haas, M., 2001, Report No.: MR-193/01 ( <i>Not protected</i> )
		[3,5- <sup>14</sup> C-triazole]-PTZ	G	300	3 (21d interval) BBCH 66-75	Hay & nuts without shells, 14 days		EFSA, 2014; FAO, 2008a, 2008b Haas, M.; 2003, Report No.: MR-194/02 ( <i>Not protected</i> )

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

EFSA Journal 2014;12(5):3689

*Wheat (cereals/grass)*

“In the foliar treated wheat samples, the TRR levels accounted for 0.08 and 5 mg eq/kg in grain, 10 and 8 mg eq/kg in forage, 8.9 and 11.2 mg eq/kg in hay and 27 and 7.9 mg eq/kg in straw, respectively for the phenyl and the triazole labelling forms of prothioconazole. The level of metabolites identification accounted for 73 % and 66 % of the TRR in forage, 65 % and 75 % of the TRR in hay, 66 % and 61 % of the TRR in straw and 34 % and 94 % TRR in grain, respectively for the phenyl and triazole labellings. In all the wheat matrices, prothioconazole was extensively metabolized.

Prothioconazole-desthio was the major compound of the total residues in all wheat plant parts for the phenyl labelling form: 35.4 % of the TRR (3.70 mg eq/kg) in forage, 18.5 % of the TRR (1.64 mg eq/kg) in hay, 22.3 % of the TRR (5.95 mg eq/kg) in straw and 16 % of the TRR (0.014 mg eq/kg) in grain. The hydroxylated derivative metabolites of prothioconazole-desthio (M14, M15, M17) and their glucoside conjugates were also identified in forage (13.4 % of the TRR, 1.42 mg eq/kg), hay (19.5 % of the TRR, 1.74 mg eq/kg), grain (9.5 % of the TRR, 0.007 mg eq/kg) and straw (14.8 % of the TRR, 3.93 mg eq/kg). The parent compound and other minor metabolites were identified in all matrices and accounted each for less than 10 % TRR.

For the triazole labelling form, a similar metabolic pattern as for the phenyl labelling was observed in all wheat plant parts with the parent prothioconazole being also extensively metabolised (< 10 % TRR). Besides, cleavage of the triazole moiety of the prothioconazole-desthio occurred in all wheat matrices resulting in the formation of the following ‘triazole derivative metabolites’ (TDMs): triazole alanine and triazole acetic acid mainly recovered in grain at proportions of 71 % and 19 % of the TRR, respectively. It is noted that these compounds are common, unspecific metabolites of triazole fungicides.

In wheat after foliar application using [3,5-<sup>14</sup>C-triazole]-prothioconazole-desthio, the highest total residues levels were identified in straw (28.67 mg eq/kg), in forage (10.87 mg eq/kg) and to a minor extent in grain (2.85 mg eq/kg). Prothioconazole-desthio constituted the major compound of the total radioactive residues in forage (up to 86.8 % TRR, 8.94 mg eq/kg in green material) and in straw (71.9 % TRR, 20.61 mg eq/kg) whilst the triazole alanine and triazole acetic acid metabolites were significantly translocated to wheat grains, where they both represented 92.1 % of the TRR (2.63 mg eq/kg).

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 application. 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."

#### *Peanuts (pulses/oilseeds)*

"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".

#### EFSA Journal 2020;18(2):5999

"Based on metabolism study results, the MRL review derived the following tentative conversion factors to account for hydroxy metabolites of prothioconazole-desthio: 2 in cereal grains, pulses and oilseeds, leafy vegetables and tuber vegetables and 3 in cereal straw (EFSA, 2014)."

"The above studies do not investigate the possible impact of plant metabolism on the isomer ratio of prothioconazole. EFSA (2020) proposed that this matter is further considered in the framework of the renewal of the approval process of prothioconazole."

#### **Summary of plant metabolism studies reported in the EU - TDMs**

##### EFSA Journal 2018;16(7):5376

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

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

Similar metabolic patterns were depicted both in primary and in rotational crops. Pesticide residues monitoring data (DE survey, 2014–2015) on unprocessed food commodities (mainly fruits and vegetables)

showed residue levels above the limit of quantification (LOQ) for each of the TDMs, i.e. 0.035–0.064 mg/kg for 1,2,4-T, 1.2–1.4 mg/kg for TA, 0.39–0.45 mg/kg for TAA and 0.78–2.4 mg/kg for TLA. These results confirmed the occurrence of each of the TDMs in primary and rotational crops from the compiled metabolism data in plants”.

### Conclusion on metabolism in primary crops

For the intended uses on cereals and oilseed rape, the metabolism of prothioconazole is considered sufficiently addressed.

Prothioconazole is extensively metabolised, and the metabolic pathway was similar in all crops investigated. Prothioconazole-desthio was the predominant compound of the total residues with further hydroxylation (with the formation of several closely related metabolites) and glucosidation steps, whilst cleavage of the triazole bound of prothioconazole-desthio molecule resulted in the formation of TDMs.

#### **zRMS comments:**

Information given by the Applicant is acceptable and sufficient.

In the framework of the peer review under Directive 91/414/EEC and the Art.12 MRL review (EFSA, 2007, 2014), the metabolism of prothioconazole was investigated by foliar applications on root (sugar beet), pulses/oilseeds (peanut) and cereal/grass (wheat) crop groups and by seed treatment on cereal (wheat) (EFSA, 2007). In addition, the metabolism of prothioconazole-desthio labelled in the triazole moiety was investigated after foliar applications on cereals (EFSA, 2007).

Prothioconazole is extensively metabolised and the metabolic pathway was similar in all crops investigated. Prothioconazole-desthio was the predominant compound of the total residues with further hydroxylation (with the formation of several closely related metabolites) and glucosidation steps, whilst cleavage of the triazole bound of prothioconazole-desthio molecule resulted in the formation of TDMs.

In EFSA Journal 2018;16(7):5376 it is stated that *Primary crops metabolism data are reported for a total of 16 approved triazole compounds, and 2 triazole active substances that are not approved at EU level (bitteranol, flusilazole), on fruit crops, cereals (straw and grain), pulses and oilseeds and root crops.(...) Based on the metabolism data in primary and rotational crops that were compiled from the assessment of the 18 triazole active substances the triazole active substances were shown to degrade into the common metabolites 1,2,4-T, TA, TLA and TAA, known as TDMs.*

#### The residue definitions

Taking into account conclusions EFSA regarding residue definitions presented in EFSA Journal 2020;18(2):5999, EFSA Journal 2014;12(5):3689 and EFSA Journal 2018;16(7):5376, based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and degradation products, the residue definitions for plant products were proposed as ‘**prothioconazole-desthio (sum of isomers)**’ for enforcement and, as follows, for the risk assessment:

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

These residue definitions are applicable to primary crops, rotational crops and processed products and for both foliar and seed treatments.

Since all compounds included in the residue definitions are a mixture of enantiomers and since there are no enantiospecific analytical methods, the residue definitions are expressed as “sum of isomers”.

Although the residue definition for risk assessment includes consideration of all metabolites containing a common moiety, it is not possible to develop a common moiety method to meet the residue definition for risk assessment. For this reason, all the analytes have to be determined separately. 6 analytes, representing the major portion of the TRR (Total Radioactive Residue) for prothioconazole in the plant metabolism studies, should be determined in residue trials. These are: prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio (including all their acid-hydrolysable conjugates).

No further data are required.

## 7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

All crops under consideration can be grown in a crop rotation.

According to soil degradation studies, investigated in the framework of the EU pesticides peer review, prothioconazole itself is of very low persistence in soil (DT<sub>90</sub> field of 5.5 days (median)), whereas prothioconazole-desthio is of low persistence with DT<sub>90</sub> field of 140 days (median) (EFSA, 2007).

### Available data

No new data submitted in the framework of this application.

**Table 0-5: Summary of metabolism studies in rotational crops - Prothioconazole**

Crop group	Crop	Label position	Application and sampling details				Reference
			Method, F or G *	Rate (g a.s./ha)	Sowing intervals (DAT)	Harvest Timing	
EU data							
Leafy vegetables	Swiss chard	[U- <sup>14</sup> C-phenyl]-PTZ	G	1 x 580	28, 146, and 269	80, 188 and 348 days after treatment	EFSA, 2007 Phenyl-label: Haas, M., 2001, Report MR-159/00 ( <i>Not protected</i> )
		[3,5- <sup>14</sup> C-triazole]-PTZ	G	4 x 204	30, 125 and 366		
Root and tuber vegetables	Turnip	[U- <sup>14</sup> C-phenyl]-PTZ	G	1 x 580	28, 146, and 269	Turnip top and root, 94, 201 and 349 days after treatment	EFSA, 2014 Triazole label: Duah, F. K.; Kraai, M. J.; 2004, Report No. 200623 ( <i>Not protected</i> )
		[3,5- <sup>14</sup> C-triazole]-PTZ	G	4 x 204	30, 125 and 366		
Cereals	Wheat	[U- <sup>14</sup> C-phenyl]-PTZ	G	1 x 580	28, 146, and 269	Green material, 73, 178, and 327 days after treatment  Hay, 111, 231, and 377 days after treatment  Straw and grain, 145, 269, and 412 days after treatment	
		[3,5- <sup>14</sup> C-triazole]-PTZ	G	4 x 204	30, 125 and 366		

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

### Summary of rotational crop metabolism studies reported in the EU - Prothioconazole

*EFSA Journal 2014;12(5):3689*

“In wheat grain, the total radioactive residues were recovered at a trace level at all DATs ( $\leq 0.007$  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 M02<sub>30</sub>. 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.

No rotational crop studies with prothioconazole radiolabelled on the triazole ring were assessed in the framework of the peer review but such studies were reported and assessed by the JMPR (FAO, 2008a, 2008b). These indicated a cleavage of the triazole linkage with the formation of the major metabolites found in all rotational crop matrices as triazole alanine, triazole lactic acid and triazole acetic acid. Both the parent prothioconazole and prothioconazole-desthio were identified as minor metabolites.

Considering the application rates of prothioconazole reported in the authorized European GAPs, it can be concluded that prothioconazole residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crops and no risk mitigation measures need to be proposed.”

For prothioconazole radiolabelled on the triazole ring, it is proposed to refer to the unprotected study Duah, F. K.; Kraai, M. J.; 2004 (Report No. 200623), also presented in the draft RAR (UK, 2018).

#### *Draft Renewal Assessment Report of Prothioconazole (UK, 2018)*

“The nature and accumulation of [triazole-3,5-<sup>14</sup>C] prothioconazole residues was studied in confined rotational crops (cereals, leafy vegetables, and root crops) in the US.

The major residues found in all rotational crop matrices were triazolyl alanine (TA), triazolyl hydroxy propionic acid (THP) [also called Triazole lactic acid (TLA)], and triazolyl acetic acid (TAA).

TA (M31) represented 44 - 51 % of the TRR (0.120 - 0.252 mg/kg) in wheat forage, 33 - 36 % (0.719 - 0.846 mg/kg) in wheat hay, 15 - 28 % (0.197 - 0.407 mg/kg) in wheat straw, 58 - 68 % (2.264 - 3.940 mg/kg) in wheat grain, 49 - 56 % (0.023 - 0.096 mg/kg) in Swiss chard, 74 - 92 % (0.077 - 0.377 mg/kg) in turnip tops, and 81 - 93 % (0.048 - 0.411 mg/kg) in turnip roots.

THP (M30) represented 32 - 35 % (0.087 - 0.184 mg/kg) of the TRR in wheat forage, 24 - 39 % (0.562 - 0.871 mg/kg) in wheat hay, 28 - 33 % (0.382 - 0.498 mg/kg) in wheat straw, <1 - 1 % (0.023 - 0.047 mg/kg) in wheat grain, 30 - 32 % (0.038 - 0.060 mg/kg) in Swiss chard, 7 % (0.035 mg/kg) in turnip tops at 125 DAT, and 1 - 5 % (0.003 - 0.005 mg/kg) in turnip roots at 30 DAT and 125 DAT.

TAA represented 1 - 6 % (0.006 - 0.034 mg/kg) of the TRR in wheat forage, 10 - 22 % (0.222 - 0.578 mg/kg) in wheat hay, 17 - 26 % (0.233 - 0.437 mg/kg) in wheat straw, 23 - 29 % (0.958 - 1.485 mg/kg) in wheat grain, 1 - <18 % (0.001 - <0.008 mg/kg) in Swiss chard, <7 % (0.009 mg/kg or less) in turnip tops, and <5 % (<0.005 mg/kg) in turnip roots.

The minor residues found in the rotational crops were prothioconazole-desthio (M04), <1 - 4 % of the TRR (0.001 - 0.020 mg/kg) in all matrices except wheat grain; prothioconazole-triazolyl-ethanol-glucoside (M46), <1 - 5 % of the TRR (0.001 - 0.063 mg/kg) in all matrices except wheat grain and Swiss chard; prothioconazole-triazolyl-ethanol (M45), <1 - 7 % of the TRR (0.002 - 0.030 mg/kg) in all matrices except wheat grain; and prothioconazole- $\alpha$ -hydroxy-desthio (M18), <1 - 2 % of the TRR (0.002 - 0.026 mg/kg) in all matrices except wheat grain and Swiss chard. No prothioconazole was detected in any matrix at any DAT interval.

The major metabolites found in all crops were prothioconazole-desthio (M04), TA (M31), THP (M30) and TAA (M29). As no 1,2,4-triazole was detected in any matrix it is assumed that 1,2,4 triazole (M13) was rapidly transformed to the metabolites TA, THP and TAA.”

#### **Summary of rotational crop metabolism studies reported in the EU - TDMs**

##### *Triazole Derivate Metabolites, addendum – confirmatory data (UK, 2018)*

“For the rotational crops, metabolism data are available on leafy crops, root crops and cereal grain and

straw for a total of 12<sup>1</sup> approved triazole active substances and one non approved triazole active substance (flusilazole).

The rotational crop metabolism studies for the triazole active substances demonstrate that triazole alanine (TA), triazole acetic acid (TAA) and/or triazole lactic acid (TLA) were often found to represent a significant portion of the total radioactive residue in the rotational crops; in addition, 1,2,4-triazole (T) was detected but usually at much lower levels. Therefore, a number of field rotational crop trials have been conducted to investigate the magnitude of triazole derivative metabolite (TDM) residues in rotational crops after the use of triazole active substances”.

EFSA Journal 2020;18(2):5999

“During the peer review of TDMs in light of confirmatory data, the metabolism of various triazole compounds in rotational and primary crops was investigated. It was concluded that for TDMs similar metabolic patterns were depicted both in primary and rotational crops (EFSA, 2018)”. See also 7.2.2.1.

### Conclusion on metabolism in rotational crops

The metabolism of prothioconazole and TDMs in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not necessary.

Since the intended cGAPs are covered by the authorized European GAPs (EFSA RO, 2014), it can be concluded that prothioconazole residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crops and no risk mitigation measures need to be proposed.

Regarding TDMs, in the framework of the confirmatory data, a number of field rotational crop trials have been conducted to investigate the magnitude of TDM residues in rotational crops after the use of triazole active substances.

#### **zRMS comments:**

Information given by the Applicant is acceptable and sufficient.

In EFSA Journal 2020;18(2):5999 it is stated that *The metabolism of prothioconazole in rotational crops was investigated in the framework of the EU pesticides peer review in Swiss chards, turnips and spring wheat following the treatment of bare soil with prothioconazole at an application rate of 580 g/ha using the compound labelled in the phenyl ring. The main compounds identified were prothioconazole-desthio and its hydroxylated derivative metabolites, either free or conjugated.*

*The MRL review concluded that metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not necessary (EFSA, 2014).*

*The metabolism of prothioconazole labelled in triazole ring was assessed by the JMPR (FAO, 2009a) as reported in the MRL review. The studies indicate the cleavage of triazole linkage to form major metabolites TA, TLA and TAA (EFSA, 2014). During the peer review of TDMs in light of confirmatory data, the metabolism of various triazole compounds in rotational and primary crops was investigated.*

*It was concluded that for TDMs similar metabolic patterns were depicted both in primary and rotational crops (EFSA, 2018b).*

No further data are required.

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

#### Available data

No new data submitted in the framework of this application.

#### Summary of studies reported in the EU – **Prothioconazole and TDMs**

EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole

“As prothioconazole residues in treated commodities at harvest are at or near the LOQ and given the low degree of ADI exhaustion in consumer risk assessment, the effect of processing on the nature and level of residues were not investigated.”

EFSA Journal 2020;18(2):5999

<sup>1</sup> Epoxiconazole, penconazole, tebuconazole, fenbuconazole, flutriafol, paclobutrazole, metconazole, fluquiconazole, difenoconazole, tetraconazole, propiconazole, ipconazole.

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

#### **Conclusion on nature of residues in processed commodities**

No prothioconazole residue above the trigger value of 0.1 mg/kg is expected in raw agricultural commodities from the intended uses. Therefore, studies investigating the nature and magnitude of prothioconazole residues in processed commodities are not required (Reg. (EU) No 544/2011).

Regarding TDMs, studies show that they remained stable under the standard hydrolysis conditions.

#### **zRMS comments:**

The effect on the nature of prothioconazole and prothioconazole-desthio has not been investigated in the framework of the EU pesticides peer review.

The TDMs are stable under hydrolysis studies simulating baking/brewing/boiling, pasteurisation and sterilisation (EFSA, 2018).

As residues of prothioconazole exceeding 0.1 mg/kg are not expected in the treated crops, there is no need to investigate the effect of industrial and/or household processing.

No further data are required.

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

**Table 0-6: Summary of the nature of residues in commodities of plant origin**

Endpoints	
Plant groups covered	Cereals (Wheat) Pulses and oilseeds (Peanut)
Rotational crops covered	Cereals (Wheat) Leafy crops (Swiss chards) Root and tuber vegetables (Turnips)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not required for prothioconazole. TDMs are stable under standard hydrolysis conditions.
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable.
Plant residue definition for monitoring	RD-Monit.: Prothioconazole: Prothioconazole-desthio (sum of isomers) (Reg. (EU) <del>2019/552</del> 2024/1318 and EFSA, 2020)
Plant residue definition for risk assessment	RD-RA1) 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)  RD-RA2) TDMs (EFSA, 2018), with separate assessment of: - Triazole alanine (TA) and triazole lactic acid (TLA) - Triazole acetic acid (TAA) - 1,2,4-triazole (1,2,4-T)
Conversion factor from enforcement to RA	Tentative conversion factors* (based on metabolism study results) to account for hydroxy metabolites of prothioconazole-desthio: - 2 in cereal grains, pulses and oilseeds, leafy vegetables and tuber vegetables (EFSA, 2014) - 2.3 in wheat straw (EFSA, 2020) - 3 in other cereal straw (EFSA, 2014)

\*only applicable from RD-Monit. to RD-RA1 ; it is not possible to derive a CF from RD-Monit to RD-RA2.

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

### Available data

No new data submitted in the framework of this application.

**Table 0-7: Summary of animal metabolism studies - Prothioconazole**

Table 6-1: Summary of animal metabolism studies - Prothioconazole								
Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data and New data								
Lactating ruminants	Goat	[U- <sup>14</sup> C-phenyl] prothioconazole	1	10 (250 mg a.s./kg feed)	3	Milk	twice daily	EFSA, 2007 Report No.: MR-092/01 ( <i>Not protected</i> )
						Urine and faeces	Daily and at sacrifice	
						Tissues	at sacrifice	
				[U- <sup>14</sup> C-phenyl] prothioconazole-desthio	1	10 (195	3	Milk

				mg a.s./kg feed)		Urine and faeces	Daily and at sacrifice	MR-091/01 and MEF- 06/469 ( <i>Not protected</i> )
						Tissues	at sacrifice	
						Milk	twice daily	EFSA, 2014 Report MR- 448/02 ( <i>Not protected</i> )
		[3,5- <sup>14</sup> C-triazole] prothioconazole	1	10	3	Urine and faeces	Daily and at sacrifice	
						Tissues	at sacrifice	
<b>Laying poultry</b>	Hens	[U- <sup>14</sup> C-phenyl] prothioconazole	6	10	3	Eggs	Once daily	EFSA, 2007 Report No.: MR-309/01 ( <i>Not protected</i> )
						Excreta	At regular intervals	
						Tissues	at sacrifice (5 h after last administration)	
		[3,5- <sup>14</sup> C-triazole] prothioconazole	6	10	3	Eggs	Once daily	EFSA, 2014 Report No.: MEF-005/03 ( <i>Not protected</i> )
						Excreta	At regular intervals	
						Tissues	at sacrifice (5 h after last administration)	

### Summary of livestock metabolism studies - Prothioconazole

*EFSA Journal 2014;12(5):3689*

“The nature of prothioconazole residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (United Kingdom, 2004, 2007). Reported metabolism studies include two studies in lactating goats using respectively [U-<sup>14</sup>C-phenyl]-labelled prothioconazole and prothioconazole-desthio and one study in laying hens using [U-<sup>14</sup>C-phenyl]-labelled prothioconazole. Besides, two additional studies were assessed by the JMPR (FAO, 2008a, 2008b) on lactating goats and laying hens, using both [3,5-<sup>14</sup>C-triazole]-labelled prothioconazole.

#### *Lactating goats*

In each study, 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 ring labelling 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.

The total radioactive residues accounted respectively for 0.037 - 0.15 mg eq/kg in milk, 0.088 - 0.117 mg eq/kg in muscle and 0.169 - 0.174 mg eq/kg in fat. The extractabilities of the radioactive residues in all matrices ranged from 77 % (fat) to 98 % of the TRR (kidney). Identified radioactivity accounted for 57 % to 78 % of the TRR. 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-<sup>14</sup>C-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. The extractabilities of the residues in all matrices ranged from 82 % (liver) to 97 % of TRR (kidney). The rate of identification amounted to 70 % to 89 % of the TRR. 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. Metabolite M32<sup>2</sup> both under its free and glucuronide conjugated form was the predominant compound of the total residues in muscle (32 % TRR – 0.085 mg eq/kg), fat (27 % TRR – 0.063 mg eq/kg) and kidney (23 % TRR - 4.299 mg eq/kg). 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/M28<sup>3</sup>/M34<sup>4</sup>/M35<sup>5</sup>) 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.

Following prothioconazole administration to rats, metabolite 1,2,4-triazole was recovered in urine at minor amounts (2.3 % AR), whilst it was not recovered in goats. Therefore, meanwhile a harmonized approach on how to consider TDMs in the risk assessment, the general metabolic pathways in rodents and ruminants can be considered as comparable, mainly involving various types of hydroxylation affecting the chlorophenyl ring and leading to the formation of metabolites both under their free and glucuronide or sulphate conjugated forms. The metabolic pathway of prothioconazole-desthio depicted in ruminants can therefore be extrapolated to pigs.

#### *Laying hens*

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 ring labelling, 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 ring labelling. The extractability of the total radioactive residues ranged from 77 % TRR in eggs to 98 % TRR in fat.

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 M01<sup>6</sup> (20 % - 29 % TRR, 0.083 - 0.088 mg eq/kg) in fat as well as M06<sup>7</sup> 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 M45<sup>8</sup> (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)

<sup>2</sup> M32: 3-chloro-4-[(2RS)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propyl]cyclohexa-3,5-diene-1,2-diol.

<sup>3</sup> M28: 3-chloro-2-[2-(1-chlorocyclopropyl)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propyl]-6-methoxyphenol

<sup>4</sup> M34: 3-chloro-4-[2-(1-chlorocyclopropyl)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propyl]benzene-1,2-diol

<sup>5</sup> M35: 4-chloro-5-[(2RS)-2-(1-chlorocyclopropyl)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propyl]benzene-1,2-diol

<sup>6</sup> M01 or prothioconazole-S-methyl: (2RS)-2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-[5-(methylsulfanyl)-2,5-dihydro-1H-1,2,4-triazol-1-yl]propan-2-ol

<sup>7</sup> M06 or prothioconazole-S-glucuronide: 1-[(2RS)-2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-4,5-dihydro-1H-1,2,4-triazol-5-yl 1-thio-β-D-glucopyranosiduronic acid

<sup>8</sup> M45: (1RS)-1-(1-chlorocyclopropyl)-2-(1H-1,2,4-triazol-1-yl)ethanol

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.

#### *Overall assessment*

It is noted that in poultry no study was performed with prothioconazole-desthio and that the fate of the triazole moiety in livestock was only investigated for prothioconazole. However, the available studies indicate similar metabolic patterns for the different compounds and moieties investigated. Additional studies addressing these requirements are therefore not expected to provide different results. It is also noted that no livestock metabolism study was performed with administration of all the metabolites included in the residue definition set for risk assessment in plants. Nevertheless, EFSA assumes that the administration of prothioconazole-desthio only in the livestock metabolism studies is acceptable since no different metabolic route of degradation would be expected if all the metabolites containing the moiety of the residue definition for risk assessment in plants were considered. Therefore, no additional metabolism data are deemed necessary.

Based on the overall metabolic picture of prothioconazole and prothioconazole-desthio in animals, the residue definition for enforcement in animal products is proposed as prothioconazole-desthio (sum of isomers) for all livestock matrices. It is noted that although only the glucuronide conjugates of prothioconazole-desthio were detected in milk, the actual residue levels are expected at a trace level at the calculated dietary burden (< 0.01 mg/kg) and EFSA considers that analysing the conjugates of prothioconazole-desthio would have a negligible impact on the residue levels enforced in milk. In case the livestock dietary burden is further increased in the future due to additional uses on feed items, the residue definition for enforcement might have to be revised by including the glucuronide conjugates of prothioconazole-desthio for all livestock matrices.

For risk assessment, since all the metabolites are structurally related to prothioconazole-desthio and consist mainly in hydroxylated derivatives, EFSA assumes as a worst case that the toxicological end points allocated to prothioconazole-desthio should also be applied to these metabolites. The residue is therefore 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)."

#### **Summary of livestock metabolism studies - TDMs**

EFSA Journal 2018;16(7):5376

"Compiled metabolism data respectively for ruminants (11<sup>9</sup>) and for poultry (6<sup>10</sup>) from approved triazole active substances were available.

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

Since TA is a major component in feed items, the potential transfer of this compound in poultry and ruminant matrices was further investigated in a metabolism study conducted with <sup>14</sup>C-TA. TA remains the major compound of the total residues in all poultry matrices (84–97.2% TRR) and in ruminant tissues (56–76% TRR) while TA and 1,2,4-T accounted for 8% and 86% TRR, respectively, in milk. TLA and TAA were detected in very low levels in all matrices (< 1% TRR). The potential transfer of TAA, TLA and 1,2,4-T present in feed items to the animal matrices was not further investigated. Although there are indications from the ruminant metabolism study conducted with the <sup>14</sup>C-TA, that there is no accumulation of TAA and TLA (4.2% and < 1% of the total administered dose in urine, respectively), these metabolites were however

<sup>9</sup> Epoxiconazole, metconazole, triticonazole, prothioconazole, prothioconazole-desthio, tebuconazole, fenbuconazole, tetraconazole, propiconazole, difenoconazole, fluquinconazole.

<sup>10</sup> Metconazole, prothioconazole, tebuconazole, fenbuconazole, propiconazole, difenoconazole.

detected in the ruminant matrices from the feeding study conducted with TA.”

### Conclusion on metabolism in livestock

The available studies indicate similar metabolic patterns for the different compounds and moieties investigated. Although no livestock metabolism study was performed with administration of all the metabolites included in the residue definition set for risk assessment in plants, EFSA assumed that the administration of prothioconazole-desthio only in the livestock metabolism studies is acceptable since no different metabolic route of degradation would be expected if all the metabolites containing the moiety of the residue definition for risk assessment in plants were considered. Therefore, no additional metabolism data are deemed necessary.

According to SANTE/11509/2013 – rev. 5.2 and since the active substance prothioconazole is not yet renewed, the “old data requirements” (Reg. (EU) No 544/2011) and the endpoints from the inclusion of prothioconazole (DAR) apply to the current assessment. Therefore, no residue data on fish are required.

#### zRMS comments:

Information given by the Applicant is acceptable and sufficient.

In EFSA Journal 2014;12(5):3689 it is stated that *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).*

According to the EFSA Journal 2018;16(7):5376: *Ruminant and poultry metabolism studies labelled on the triazole ring are available.*

*(...) Based on the metabolism studies conducted, respectively, with triazole pesticide active substances and TA and considering the results of the livestock feeding studies carried out with TA and TAA, respectively, the experts agreed on the following residue definitions:*

- *Residue definition for enforcement: triazole parent compound only*
- *Residue definition for risk assessment:*
  1. *Triazole parent compound and any other relevant metabolite exclusively linked to the parent compound;*
  2. *TA and TLA, since these compounds share the same toxicity;*
  3. *TAA;*
  4. *1,2,4-triazole.*

No further data are required.

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

**Table 0-8: Summary on the nature of residues in commodities of animal origin**

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	1-2 days in milk
	Not observed in eggs
Animal residue definition for monitoring	Prothioconazole-desthio (sum of isomers) (EFSA, 2014 and Reg. (EU) <del>2019/552</del> 2024/1318)
Animal residue definition for risk assessment	RD-RA1) 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)  RD-RA2) TDMs (EFSA, 2018), with separate assessment of: <ul style="list-style-type: none"><li>- Triazole alanine (TA) and triazole lactic acid (TLA)</li><li>- Triazole acetic acid (TAA)</li></ul>



	- 1,2,4-triazole (1,2,4-T)
Conversion factor	EFSA, 2014*: - Ruminant liver: 2 - Ruminant kidney: 9 - not necessary for milk, ruminant muscle and ruminant fat
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes, Log P <sub>ow</sub> for prothioconazole-desthio = 3.04

\*Only applicable from RD-Monit. to RD-RA1; it is not possible to derive a CF from RD-Monit to RD-RA2.

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

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

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 Tables below. The detailed assessment of these studies is presented in Appendix 2.

It should be noted that:

- Only trials performed in the northern residue zone are presented.
- The selection of supporting data was made based on the BBCH growth stage at last application as according to SANTE/2019/12752 “In some cases (e.g., cereals, oilseeds), the crop growth stage at application is more important to consider for the selection of GAP-compliant trials while PHI (if specified in the GAP) may be of secondary relevance”.

#### (a) Prothioconazole

The residue levels according to the residue definition for monitoring (E = prothioconazole-desthio: sum of isomers) and for risk assessment n°1 (RA1 = sum of prothioconazole-desthio and its hydroxy metabolites) are presented in the Table 0-10.

In the framework of the active substance first inclusion, trials measuring levels of prothioconazole-desthio only in barley, wheat and oilseed rape were assessed in the DAR (UK, 2007). A summary is presented in the table below. These EU data were not considered as new trials measuring all compounds relevant to the RD-RA1 were performed and provided by the applicant in the present dossier.

**Table 0-9: Summary of EU data - Prothioconazole**

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = prothioconazole-desthio (sum of isomers) RA1 = sum of prothioconazole-desthio and its hydroxy metabolites
Barley <u>Grain</u>	DAR (UK, 2007) EFSA, 2007	N-EU (9)	GAP on which EU a.s. assessment is based: 2 x 200 g a.s./ha, BBCH 30-61 E: 9 x <0.01 RA1: no data on prothioconazole-hydroxy-desthio
Barley <u>Straw</u>	DAR (UK, 2007) EFSA, 2007	N-EU (9)	GAP on which EU a.s. assessment is based: 2 x 200 g a.s./ha, BBCH 30-61 E: 0.05, 0.08, 2x 0.10, 2x 0.13, 2x 0.14, 0.30 RA1: no data on prothioconazole-hydroxy-desthio
Wheat <u>Grain</u>	DAR (UK, 2007) EFSA, 2007	N-EU (11)	GAP on which EU a.s. assessment is based: 3 x 200 g a.s./ha, BBCH 26-69 E: 11 x <0.01 RA1: no data on prothioconazole-hydroxy-desthio
Wheat <u>Straw</u>	DAR (UK, 2007) EFSA, 2007	N-EU (11)	GAP on which EU a.s. assessment is based: 3 x 200 g a.s./ha, BBCH 26-69 E: 11 x <0.01 RA1: no data on prothioconazole-hydroxy-desthio
Oilseed rape <u>Seeds</u>	DAR (UK, 2007) EFSA, 2007	N-EU (8)	GAP on which EU a.s. assessment is based: 2 x 175 g a.s./ha, start BBCH 53, 14-28d int. E: 5 x < 0.01, 1 x 0.01, 2 x 0.02 RA1: no data on prothioconazole-hydroxy-desthio

**Table 0-10: Summary of new data supporting the intended uses of CA3642 and conformity to existing MRL – Prothioconazole**

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = prothioconazole-desthio (sum of isomers) RA1 = sum of prothioconazole-desthio and its hydroxy metabolites	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg) (Rounded)	Current EU MRL (mg/kg) *	MRL compliance
Barley → Oat <u>Grain</u>	New trials <i>Study 10-2204</i>	N-EU (2)	Trials GAP: 2 x 150 g a.s./ha, BBCH 61, PHI 34-35d E: 2x <0.01 RA1: 2x <0.06	N/A				
	New trials <i>Studies 13-2137 &amp; 13-2158</i>	N-EU (4)	Trials GAP: 2 x 125-135 g a.s./ha, BBCH 61, PHI 35-68d E: 3x <0.01, 0.011 RA1: 3x <0.06, 0.061					
	New trials <i>Study 17-2076</i>	N-EU (2)	Trials GAP: 2 x 140 g a.s./ha, BBCH 61, PHI 43-56d E: 2x <0.01 RA1: 2x <0.06					
	<b>Overall supporting data for cGAP Barley grain</b>	N-EU (8) <i>New trials</i>	<b>Intended cGAP: 2 x 150 g a.s./ha, BBCH 30-61</b> E: 7x <0.01, 0.011 RA1: 7x <0.06, 0.061	E: 0.01* RA: 0.06*	E: 0.011 RA: 0.061	0.013 (0.015)	Barley 0.2; Oat 0.05	Yes Yes
Barley → Oat <u>Straw</u>	New trials <i>Study 10-2204</i>	N-EU (2)	Trials GAP: 2 x 150 g a.s./ha, BBCH 61, PHI 34-35d E: 0.11, 0.54 RA1: 0.41, 1.2	N/A				
	New trials <i>Studies 13-2137 &amp; 13-2158</i>	N-EU (4)	Trials GAP: 2 x 125 g a.s./ha, BBCH 61, PHI 35-68d E: 0.039, 0.044, 0.087, 0.81 RA1: 0.10, 0.18, 0.43, 2.2					
	New trials <i>Study 17-2076</i>	N-EU (2)	Trials GAP: 2 x 140 g a.s./ha, BBCH 61, PHI 43-56d E: <0.01, 0.14 RA1: <0.06, 0.34					
	<b>Overall supporting data for cGAP Barley straw</b>	N-EU (8) <i>New trials</i>	<b>Intended cGAP: 2 x 150 g a.s./ha, BBCH 30-61</b> E: <0.01, 0.039, 0.044, 0.087, 0.11, 0.14, 0.54, 0.81 RA1: <0.06, 0.10, 0.18, 0.34, 0.41, 0.43, 1.2, 2.2	E: 0.099 RA: 0.375	E: 0.81 RA: 2.2	-	-	N/A

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = prothioconazole-desthio (sum of isomers) RA1 = sum of prothioconazole-desthio and its hydroxy metabolites	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg) (Rounded)	Current EU MRL (mg/kg) *	MRL compliance
Wheat → Triticale, Rye Grain	New trials <i>Study 17-2015</i>	N-EU (4)	Trials GAP: 2 x 200 g a.s./ha, BBCH 69, PHI 26-61d E: 4x <0.01 RA1: 4x <0.06	N/A				
	New trials <i>Study 16-2046</i>	N-EU (4)	Trials GAP: 2 x 200 g a.s./ha, BBCH 65-69, PHI 50-62d E: 4x <0.01 RA1: 4x <0.06					
	New trials <i>Study S19-01268</i>	N-EU (4)	Trials GAP: 2 x 200 g a.s./ha, BBCH 71-73, PHI 35d E: 2x <0.003, <0.01, 0.01 RA1: 4x <0.06					
	<b>Overall supporting data for cGAP</b> <i>Wheat grain</i>	N-EU (12) <i>New trials</i>	<b>Intended cGAP: 2 x 210 g a.s./ha, BBCH 30-69</b> E: 2x <0.003, 9x <0.01, 0.01 RA1: 12x <0.06	E: 0.01* RA: 0.06*	E: 0.01 RA: 0.06*	0.02	Wheat, Triticale, Spelt 0.1; Rye 0.05	Yes Yes
Wheat → Triticale, Rye Straw	New trials <i>Study 17-2015</i>	N-EU (4)	Trials GAP: 2 x 200 g a.s./ha, BBCH 69, PHI 26-61d E: 0.041, 0.089, 0.15, 0.18 RA1: 0.28, 0.30, 0.64, 1.01	N/A				
	New trials <i>Study 16-2046</i>	N-EU (4)	Trials GAP: 2 x 200 g a.s./ha, BBCH 65-69, PHI 50-62d E: 0.040, 0.046, 0.083, 0.094 RA1: 0.11, 0.12, 0.38, 0.60					
	New trials <i>Study S19-01268</i>	N-EU (4)	Trials GAP: 2 x 200 g a.s./ha, BBCH 71-73, PHI 35d E: 0.15, 0.28, 0.42, 0.98 RA1: 0.39, 1.4, 1.19, 2.93					
	<b>Overall supporting data for cGAP</b> <i>Wheat straw</i>	N-EU (12) <i>New trials</i>	<b>Intended cGAP: 2 x 210 g a.s./ha, BBCH 30-69</b> E: 0.040, 0.041, 0.046, 0.083, 0.089, 0.094, 0.15, 0.15, 0.18, 0.28, 0.42, 0.98 RA1: 0.11, 0.12, 0.28, 0.30, 0.38, 0.39, 0.60, 0.64, 1.01, 1.4, 1.19, 2.93	E: 0.12 RA: 0.495	E: 0.98 RA: 2.93	-	-	N/A
Oilseed rape → Sunflower, Linseed, Poppy,	New trials <i>Study S19-01269</i>	N-EU (4)	Trials GAP: 2 x 175 g a.s./ha, BBCH 69, PHI 56-39d E: 2x <0.01, 0.01, 0.03 <sup>a</sup> RA1: 2x <0.06, 0.06, 0.08 <sup>a</sup>	N/A				

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = prothioconazole-desthio (sum of isomers) RA1 = sum of prothioconazole-desthio and its hydroxy metabolites	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg) (Rounded)	Current EU MRL (mg/kg) *	MRL compliance
Mustard, Gold of pleasure <u>Seeds</u>	New trials <i>Study S20-01046</i>	N-EU (3)	Trials GAP: 2 x 175 g a.s./ha, BBCH 69-76, PHI 56-59d E: <0.003, 0.01, 0.02 RA1: <0.06, 0.06, 0.07					
	New trials <i>Study S21-00259</i>	N-EU (1)	Trials GAP: 2 x 175 g a.s./ha, BBCH 69, PHI 56d E: <0.003 RA1: <0.03					
	New trials <i>Study S22-00257</i>	N-EU (3)	Trials GAP: 2 x 175 g a.s./ha, BBCH 69, PHI 56d E: 3x <0.01 RA1: 0.03, <0.04, 0.06					
	<b>Overall supporting data for cGAP OSR seeds</b>	N-EU (8) 11 <i>New trials</i>	<b>Intended cGAP: 1 x 180 g a.s./ha, BBCH 69</b> E: 2x <0.003, 2x 5x<0.01, 2x 0.01, 0.02, 0.03 <sup>a</sup> RA1: <0.03, 0.03, 0.04, 3x <0.06, 2x 3x0.06, 0.07, 0.08 <sup>a</sup>	E: 0.01 RA: 0.06	E: 0.03 RA: 0.08	<del>0.048 (0.05)</del> <del>Rber</del> <del>0.04/Rmax</del> <del>0.04</del>  <del>0.050 (0.05)</del> <del>Rber</del> <del>0.02/Rmax</del> <del>0.03</del>	Rapeseed 0.15. Linseed, Poppy, Mustard 0.09. Gold of pleasure 0.04	Yes Yes Yes, according to HR, Rber/Rmax
	<b>Overall supporting data for gold of pleasure</b>	Merged N-EU + S-EU (16)  (19)	<b>Intended cGAP: 1 x 180 g a.s./ha, BBCH 69</b> NEU: <del>E: 2x &lt;0.003, 2x &lt;0.01, 2x 0.01, 0.02, 0.03<sup>a</sup></del> <del>RA1: &lt;0.03, 3x &lt;0.06, 2x 0.06, 0.07, 0.08<sup>a</sup></del>  E: 2x <0.003, 2x 5x<0.01, 2x 0.01, 0.02, 0.03 <sup>a</sup> RA1: <0.03, 0.03, 0.04, 3x <0.06, 2x 3x0.06, 0.07, 0.08 <sup>a</sup>  SEU: E: 3x <0.003, 2x <0.01, 2x 0.01, 0.02 RA1: 0.03, 5x <0.06, 0.06, 0.08	E: 0.01 RA: 0.06	E: 0.03 RA: 0.08	0.04 (0.04)	Gold of pleasure 0.04	Yes

\* Source of EU MRL: Reg. (EU) ~~2019/552~~ 2024/1318

<sup>a</sup> Oilseed rape: positive control for PTZ-desthio in seeds which leads to a higher residue level (highest value found in control seeds). As a worst case approach the value from the control sample was used for MRL compliance and risk assessment: results of the calculation show that no MRL exceedance and no unacceptable risk for consumers (see 7.2.8) is expected. The applicant will launch new trials in 2022 to address this.

**(b) Triazole derivative metabolites (TDMs)**

Triazole derivative metabolites (TDMs) are common metabolites of all triazole fungicides and have to be considered in the consumer risk assessment. The data on TDMs provided in the present application are from the “Triazole Derivate Metabolites addendum – confirmatory data prepared by the rapporteur Member State, the United Kingdom” (UK, 2018). As confirmatory data, they are out of data protection. Only trials performed with prothioconazole were considered and presented hereafter. Detailed results tables are reported in Appendix 2.

In most trials, TDMs were at a similar level in the control and treated samples. As triazoles are a common ingredient of numerous pesticides which were widely used as fungicides in various field crops and that TDMs show a great persistence in the soils, the contamination of control samples is most likely origin in former usage of pesticides containing triazoles on the sampling sites or nearby. The highest level between control and treated samples were therefore selected for the assessment.

The residue levels according to the residue definition for risk assessment n°2 (TDMs) are presented in Table 0-11.

**Table 0-11: Summary of EU reported and new data supporting the intended uses of CA3642 and conformity to existing MRL – TDMs**

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) RA2  <b>TDMs</b>	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Barley → Oat <u>Grain</u>	Confirmatory data TDMs – Prothioconazole (UK, 2018)	N-EU (8) Except TLA (4)	Trials GAP: 2 x 150-200 g a.s./ha, BBCH 61, PHI 34-63d <b>1,2,4-T</b> : 7x <0.01, 0.011 TAA: 0.033, 0.057, 0.057, 0.067, 0.157, 0.172, 0.217, 0.32 TA: 0.043, 0.184, 0.190, 0.226, 0.230, 0.250, 0.405, 0.440 TLA: 3x <0.01, 0.012	N/A				
		N-EU (2)	Trials GAP: seed treatment 27 g a.s./ha + foliar 2 x 200 g a.s./ha, BBCH 61, PHI 49-55 <b>1,2,4-T</b> : 2x <0.01 TAA: 0.022, 0.050 TA: 0.169, 0.382 TLA: 2x <0.01					
		New trials <i>Study 17-2076</i>	Trials GAP: 2 x 140 g a.s./ha, BBCH 61, PHI 43-56d <b>1,2,4-T</b> : 2x <0.01 TAA: 0.024, 0.078 TA: 0.052, 0.13 TLA: 2x <0.01					
	<b>Overall supporting data for cGAP Barley grain</b>	N-EU <i>All data</i> <b>1,2,4-T</b> (10+2) TAA (10+2) TA (10+2) TLA (6+2)	<b>Intended cGAP: 2 x 150 g a.s./ha, BBCH 30-61</b> <b>1,2,4-T</b> : 9x <0.01, 0.011; 2x <0.01 TAA: 0.022, 0.024, 0.033, 0.050, 0.057, 0.057, 0.067, 0.078, 0.157, 0.172, 0.217, 0.32 TA: 0.043, 0.052, 0.13, 0.184, 0.190, 0.226, 0.230, 0.250, 0.405, 0.440; 0.169, 0.382 TLA: 3x <0.01, 2x <0.01 <sup>a</sup> , 0.012; 2x <0.01	<b>1,2,4-T</b> : 0.01* TAA: 0.062 TA: 0.21 TLA: 0.01*	<b>1,2,4-T</b> : 0.011 TAA: 0.32 TA: 0.44 TLA: 0.012	-	-	N/A
Barley → Oat <u>Straw</u>	Confirmatory data TDMs – Prothioconazole (UK, 2018)	N-EU (4) Except TLA (0)	Trials GAP: 2 x 150-200 g a.s./ha, BBCH 61, PHI 34-62d <b>1,2,4-T</b> : 4x <0.05 TAA: 2x <0.05, 0.134, 0.136 TA: 4x <0.05 TLA: straw not analysed	N/A				

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) RA2  <u>TDMs</u>	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
		N-EU (2)	Trials GAP: seed treatment 27 + foliar 2 x 200 g a.s./ha, BBCH 61, PHI 49-55 <b>1,2,4</b> -T: 2x <0.01 TAA: <0.01, 0.013 TA: 0.015, 0.017 TLA: 0.085, 0.157					
	New trials <i>Study 17-2076</i>	N-EU (2)	Trials GAP: 2 x 140 g a.s./ha, BBCH 61, PHI 43-56d <b>1,2,4</b> -T: 2x <0.01 TAA: 0.010, 0.026 TA: <0.01, 0.030 TLA: 0.013, 0.028					
	<b>Overall supporting data for cGAP <i>Barley straw</i></b>	N-EU <i>All data</i> <b>1,2,4</b> -T(6+2) TAA (6+2) TA (6+2) TLA (2+2)	<b>Intended cGAP: 2 x 150 g a.s./ha, BBCH 30-61</b> <b>1,2,4</b> -T: 2x <0.01, 4x <0.05; 2x <0.01 TAA: 2x <0.05, 0.010, 0.026, 0.134, 0.136; <0.01, 0.013 TA: <0.01, 0.030, 4x <0.05; 0.015, 0.017 TLA: 0.013, 0.028; 0.085, 0.157	<b>1,2,4</b> -T: 0.01* TAA: 0.038 TA: 0.04 TLA: 0.057	<b>1,2,4</b> -T: 0.05* TAA: 0.136 TA: 0.05 TLA: 0.157	-	-	N/A
Wheat → Triticale, Rye <u>Grain</u>	Confirmatory data TDMs – Prothioconazole (UK, 2018)	N-EU (4) Except TLA (0)	GAP on which EU a.s. assessment is based: 3 x 187.5 g a.s./ha, BBCH 69, PHI 34-47d <b>1,2,4</b> -T: 4x <0.01 TAA: 0.138, 0.230, 0.243, 0.517 TA: 0.332, 0.586, 0.684, 1.069 TLA: not analysed	N/A				
		N-EU (2)	Trials GAP: seed treatment 30 + foliar 3 x 200 g a.s./ha, BBCH 69, PHI 43-49d <b>1,2,4</b> -T: 2x <0.01 TAA: 0.193, 0.377 TA: 0.486, 0.952 TLA: 2x <0.01					
	New trials <i>Study 17-2015</i>	N-EU (4)	Trials GAP: 2 x 200 g a.s./ha, BBCH 69, PHI 26-61d <b>1,2,4</b> -T: 4x <0.01 TAA: 0.085, 0.087, 0.092, 0.23 TA: 0.21, 0.37, 0.53, 0.65 TLA: 4x <0.01					

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) RA2  <u>TDMs</u>	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	New trials <i>Study 16-2046</i>	N-EU (4)	Trials GAP: 2 x 200 g a.s./ha, BBCH 65-69, PHI 50-62d <b>1,2,4-T</b> : 4x <0.01 TAA: 0.11, 0.13, 0.22, 0.26 TA: 0.23, 0.36, 0.77, 0.88 TLA: 4x <0.01					
	New trials <i>Study S19-01268</i>	N-EU (4)	Trials GAP: 2 x 200 g a.s./ha, BBCH 71-73, PHI 35d <b>1,2,4-T</b> : 2x <0.003, 2x <0.01 TAA: 0.16, 0.23, 0.35, 0.48 TA: 0.49, 0.71, 0.74, 1.10 TLA: 3x <0.01, 0.01					
	<b>Overall supporting data for cGAP Wheat grain</b>	N-EU <i>All data</i> <b>1,2,4-T</b> (16+2) TAA (16+2) TA (16+2) TLA (12+2)	<b>Intended cGAP: 2 x 210 g a.s./ha, BBCH 30-69</b> <b>1,2,4-T</b> : 2x <0.003, 14x <0.01; 2x <0.01 TAA: 0.085, 0.087, 0.092, 0.11, 0.13, 0.138, 0.16, 0.23, 0.22, 2x 0.230, 0.243, 0.26, 0.35, 0.48, 0.517; 0.193, 0.377 TA: 0.21, 0.23, 0.332, 0.36, 0.37, 0.49, 0.53, 0.586, 0.65, 0.684, 0.71, 0.74, 0.77, 0.88, 1.069, 1.10; 0.486, 0.952 TLA: 11x <0.01, 0.01; 2x <0.01	<b>1,2,4-T</b> : 0.01* TAA: 0.225 TA: 0.62 TLA: 0.01*	<b>1,2,4-T</b> : 0.01* TAA: 0.517 TA: 1.10 TLA: 0.01	-	-	N/A
Wheat → Triticale, Rye <u>Straw</u>	Confirmatory data TDMs – Prothioconazole (UK, 2018)	N-EU (4) Except TLA (0)	GAP on which EU a.s. assessment is based: 3 x 187.5 g a.s./ha, BBCH 69, PHI 34-47d <b>1,2,4-T</b> : 4x <0.05 TAA: 0.05, 0.067, 0.078, 0.307 TA: 3x <0.05, 0.079 TLA: not analysed	N/A				
		N-EU (2)	Trials GAP: seed treatment 30 + foliar 3 x 200 g a.s./ha, BBCH 69, PHI 43-49d <b>1,2,4-T</b> : 2x <0.01 TAA: 0.020, 0.047 TA: 0.019, 0.028 TLA: 0.048, 0.160					
	New trials <i>Study 17-2015</i>	N-EU (4)	Trials GAP: 2 x 200 g a.s./ha, BBCH 69, PHI 26-61d <b>1,2,4-T</b> : 4x <0.01 TAA: 0.010, 0.014, 0.048, 0.26 TA: <0.01, 0.010, 0.016, 0.10 TLA: <0.01, 0.033, 0.065, 0.11					



Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) RA2  <u>TDMs</u>	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	New trials <i>Study 16-2046</i>	N-EU (4)	Trials GAP: 2 x 200 g a.s./ha, BBCH 65-69, PHI 50-62d <b>1,2,4-T</b> : 4x <0.01 TAA: 0.018, 0.031, 0.036, 0.097 TA: 2x 0.011, 0.019, 0.063 TLA: 0.015, 0.019, 0.021, 0.14					
	New trials <i>Study S19-01268</i>	N-EU (4)	Trials GAP: 2 x 200 g a.s./ha, BBCH 71-73, PHI 35d <b>1,2,4-T</b> : 4x <0.003 TAA: 0.04, 0.05, 0.06, 0.12 TA: <0.01, 2x 0.01, 0.02 TLA: <0.01, 0.11, 0.18, 0.21					
	<b>Overall supporting data for cGAP</b> <i>Wheat straw</i>	N-EU <i>All data</i> <b>1,2,4-T</b> (16+2) TAA (16+2) TA (16+2) TLA (12+2)	<b>Intended cGAP: 2 x 210 g a.s./ha, BBCH 30-69</b> <b>1,2,4-T</b> : 4x <0.003, 4x <0.01, 4x <0.01, 4x <0.05; 2x <0.01 TAA: 0.010, 0.014, 0.018, 0.031, 0.036, 0.04, 0.048, 2x 0.05, 0.06, 0.067, 0.078, 0.097, 0.12, 0.26, 0.307; 0.020, 0.047 TA: 2x <0.01, 3x 0.01, 2x 0.011, 0.016, 0.019, 0.02, 3x <0.05, 0.063, 0.079, 0.10; 0.019, 0.028 TLA: 2x <0.01, 0.015, 0.019, 0.021, 0.033, 0.065, 2x 0.11, 0.14, 0.18, 0.21; 0.048, 0.160	<b>1,2,4-T</b> : 0.01* TAA: 0.049 TA: 0.019 TLA: 0.057	<b>1,2,4-T</b> : 0.05* TAA: 0.307 TA: 0.1 TLA: 0.21	-	-	N/A
Oilseed rape → Sunflower, Linseed, Poppy, Mustard, Gold of pleasure <u>Seeds</u>	Confirmatory data TDMs – Prothioconazole (UK, 2018)	N-EU (4)	Trials GAP: 2 x 150 g a.s./ha, BBCH 69-79, PHI 49-56d <b>1,2,4-T</b> : 4x <0.01 TAA: 4x <0.01 TA: 0.12, 0.16, 0.34, 0.70 TLA: 2x <0.01, 0.01, 0.03	N/A				
	New trials <i>Study S19-01269</i>	N-EU (4)	Trials GAP: 2 x 175 g a.s./ha, BBCH 69, PHI 56-39d <b>1,2,4-T</b> : 4x <0.003 TAA: 3x 0.01, 0.03, TA: 2x 1.2, 1.4, 2.1 TLA: 0.04, 0.05, 0.09, 0.16					
	New trials <i>Study S20-01046</i>	N-EU (3)	Trials GAP: 2 x 175 g a.s./ha, BBCH 69-76, PHI 56-59d <b>1,2,4-T</b> : 3x <0.003 TAA: <0.01, 2x 0.01 TA: 0.43, 1.1, 1.4 TLA: 0.03, 0.04, 0.05					

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) RA2  <u>TDMs</u>	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	New trials <i>Study S21-00259</i>	N-EU (1)	Trials GAP: 2 x 175 g a.s./ha, BBCH 69, PHI 56d <b>1,2,4-T</b> : <0.003 TAA: 0.01 TA: 2.3 TLA: 0.10					
	New trials <i>Study S22-00257</i>	N-EU (3)	Trials GAP: 2 x 175 g a.s./ha, BBCH 69, PHI 56d <b>1,2,4-T</b> : 3x <0.003 TAA: 3x 0.01 TA: 0.95, 1.2, 1.5 TLA: 0.04, 0.06, 0.07					
	<b>Overall supporting data for cGAP</b> <i>OSR seeds</i>	N-EU <i>New trials</i> <b>1,2,4-T</b> (11) TAA (11) TA (11) TLA (11)	<b>Intended cGAP: 1 x 180 g a.s./ha, BBCH 69</b> <b>1,2,4-T</b> : 8x <0.003 TAA: 2x <0.01, 8x 0.01, 0.03 TA: 0.43, 0.95, 1.1, 3x 1.2, 2x 1.4, 1.5, 2.1, 2.3 TLA: 0.03, 3x 0.04, 2x 0.05, 0.06, 0.07, 0.09, 0.10, 0.16	<b>1,2,4-T</b> : 0.003* TAA: 0.01 TA: 1.2 TLA: 0.05	<b>1,2,4-T</b> : 0.003* TAA: 0.03 TA: 2.3 TLA: 0.16	-	-	N/A

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

#### **Barley, Oat**

Barley and Oat are major crops in northern regions.

According to SANTE/2019/12752, extrapolation to oat is possible with a minimum of 8 trials on barley, which is the case here.

According to the available data, the intended uses on barley and oat are considered sufficiently supported in the Northern residue zone.

The data submitted show that no exceedance of the MRL will occur for all intended crops when CA3642 is applied according to the proposed GAP.

#### **Wheat, Rye, Triticale and Spelt, Einkorn wheat, Emmer Wheat, Triticale**

Wheat and rye are major crops in northern regions. Triticale, spelt, *Einkorn wheat*, *Emmer Wheat* and *Triticale* are ~~minor~~ major crops.

According to SANTE/2019/12752, extrapolation to rye, triticale, spelt, *Einkorn wheat*, *Emmer Wheat*, and *Triticale* is possible with a minimum of 8 trials on wheat, which is the case here.

According to the available data, the intended uses on wheat, ~~oat~~, **rye**, triticale and spelt, *Einkorn wheat*, *Emmer Wheat*, and *Triticale* are considered sufficiently supported in the Northern residue zone. The intended application rate of 210 g a.s./ha is slightly higher than most of the trials' application rate (200 g a.s./ha) but is included within the acceptable tolerance margin of 25%.

The data submitted show that no exceedance of the MRL will occur for all intended crops when CA3642 is applied according to the proposed GAP.

#### **Oilseed rape, Sunflower, Linseed, Poppy, Mustard and Gold of pleasure**

Oilseed rape and sunflower are major crops in northern regions. Linseed, poppy, mustard and gold of pleasure are minor crops.

According to SANTE/2019/12752, extrapolation to sunflower, linseed, poppy, mustard and gold of pleasure is possible.

According to the available data, the intended uses on oilseed rape, sunflower, linseed, poppy, mustard and gold of pleasure are considered sufficiently supported in the Northern climatic zone.

All trials were performed with 2 applications, which can be considered as a worst-case situation and therefore cover the intended GAP as the BBCH remains the same. The intended application rate of 180 g a.s./ha is slightly higher than most of the trials' application rate (175 g a.s./ha) but is included within the acceptable tolerance margin of 25%.

Although the calculated OECD MRL (~~0.048 mg/kg, rounded at~~ 0.05 mg/kg) is slightly above the in-force MRL of gold of pleasure (0.04 mg/kg), the highest residue level, Rber and Rmax were below this MRL. In addition, GAP compliant trials from the DAR confirm an MRL exceedance is not expected for gold of pleasure. And MRL was set considering a pooled NEU and SEU dataset.

Therefore, the data submitted show that no exceedance of the MRL will occur for all intended crops when CA3642 is applied according to the proposed GAP.

#### **zRMS comments:**

Residue Definitions (EFSA 2020; Reg EU ~~2019/552~~ 2024/1318):

Monitoring (Mo): Prothioconazole-desthio (sum of isomers)

Risk Assessment (RA):

- 1) 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)
- 2) TDMs (EFSA, 2018), with separate assessment of:
  - Triazole alanine (TA) and triazole lactic acid (TLA)
  - Triazole acetic acid (TAA)
  - 1,2,4-triazole (1,2,4-T)

#### **Wheat, rye, triticale and spelt, einkorn wheat, emmer wheat, tritordeum**

Wheat and rye are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on wheat can be used for extrapolation to rye, triticale and spelt before and after forming of the edible part. So the uses are also considered acceptable on rye, triticale and spelt, einkorn wheat, emmer wheat, tritordeum.

Sufficient trials on wheat conducted according to the residue definition for monitoring only (trials measuring levels of prothioconazole-desthio only) were previously presented and evaluated (DAR, 2007). There are no data on prothioconazole-hydroxy-desthio in the DAR (2007).

Three magnitude of residue studies were submitted in the framework of this application: studies 17-2015, S19-01268, 16-2046. It should be noted that the above-mentioned studies are currently being reviewed as part of the EU approval process for prothioconazole.

Summary is presented below.

**Table 1: Comparison of intended and critical EU GAPs for wheat, rye**

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP NEU + SEU (DAR, UK, 2007)	3	200	14-21	BBCH 26-69	35
Intended cGAP NEU	2	210	14-21	BBCH 30-69	35

### Summary

#### **1. Study 17-2015**

Four N-EU trials were conducted in accordance with the following GAP: 2 x 200 g a.s. /ha, application interval - 21 days, 2nd application at BBCH 69, outdoor.

Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in wheat grain at harvest were <0.01 mg/kg.

Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest were <0.06 mg/kg.

Residues of 1,2,4-triazole and triazole lactic acid, in wheat grain at harvest were <0.01 mg/kg.

Residues of triazole alanine, in wheat grain at harvest ranged between 0.21 and 0.65 mg/kg.

Residues of triazole acetic acid, in wheat grain at harvest ranged between 0.085 and 0.14 mg/kg.

#### **2. Study S19-01268**

Four N-EU trials were conducted in accordance with the following GAP: 2 x 200 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 71-73, outdoor.

Residues of prothioconazole-desthio, in wheat grain at harvest were between <0.003 and 0.01 mg/kg.

Residues of hydroxy- derivatives of prothioconazole-desthio, in wheat grain at harvest were <0.01 mg/kg.

Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest were <0.06 mg/kg.

Residues of 1,2,4-triazole and triazole lactic acid, in wheat grain at harvest were between <0.003 and 0.01 mg/kg.

Residues of triazole alanine, in wheat grain at harvest ranged between 0.49 and 1.1 mg/kg.

Residues of triazole acetic acid, in wheat grain at harvest ranged between 0.16 and 0.48 mg/kg.

#### **3. Study 16-2046**

Four N-EU trials were conducted in accordance with the following GAP: 2 x 200 g a.s. /ha, application interval - 20-24 days, 2nd application at BBCH 65-69, outdoor.

Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in wheat grain at harvest were <0.01 mg/kg.

Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest was <0.06 mg/kg.

Residues of 1,2,4-triazole and triazole lactic acid, in wheat grain at harvest were < 0.01 mg/kg.

Residues of triazole alanine, in wheat grain at harvest ranged between 0.11 and 0.26 mg/kg.

Residues of triazole acetic acid, in wheat grain at harvest ranged between 0.23 and 0.88 mg/kg.

Storage periods of residue samples covered by available storage stability studies.

Available results show that the in force MRL of prothioconazole on wheat of 0.1 mg/kg and on rye of 0.05 (Reg. (EU) ~~2019/552~~ 2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed uses.

The trials are supported by valid storage stability data and validated analytical methods.

**The proposed uses on wheat, rye, triticale, spelt, einkorn wheat, emmer wheat and Tritordeum are considered acceptable.**

### **Barley, oat**

Barley and oat are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on barley can be used for extrapolation to oat before and after forming of the edible part. So the uses are also considered acceptable on barley and oat.

Sufficient trials on barley conducted according to the residue definition for monitoring only (trials measuring levels of prothioconazole-desthio only) were previously presented and evaluated (DAR, 2007). There are no data on prothioconazole-hydroxy-desthio in the DAR (2007).

Four magnitude of residue studies were submitted in the framework of this application: study 13-2158, 13-2137, 10-2204 and 17-2076. It should be noted that the above-mentioned studies are currently being reviewed as part of the EU approval process for prothioconazole.

Summary is presented below.

**Table 2: Comparison of intended and critical EU GAPs for barley and oat**

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP NEU + SEU (DAR, UK, 2007)	2	200	14-21	BBCH 30-61	35
Intended cGAP	2	150	14-21	BBCH 30-61	35

### **Summary**

#### **1. Study 10-2204**

Two N-EU trials were conducted in accordance with the following GAP: 2 x 150 g a.s. /ha; application interval – 14 days, 2nd application at BBCH 61, outdoor.

The residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio in barley grain at harvest were <0.01 mg/kg.

In grain at harvest, the total residue was always <0.06 mg/kg.

#### **2. Studies 13-2137 and 13-2158**

Four N-EU trials were conducted in accordance with the following GAP: 2 x 125 g a.s. /ha; application interval – 6-20 days, 2nd application at BBCH 61, outdoor.

The residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio in barley grain at harvest were <0.01 mg/kg.

In grain at harvest, the total residue was always <0.06 mg/kg except for trial 13-2137-02, where the total residue reached 0.061 mg/kg.

#### **3. Studies 17-2076**

Two N-EU trials were conducted in accordance with the following GAP: 2 x 140 g a.s. /ha; application interval – 6-20 days, 2nd application at BBCH 61, outdoor.

Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in barley grain at harvest were <0.01 mg/kg. In grain at harvest, the total residue was always <0.06 mg/kg.

Residues of 1,2,4-triazole and of triazole lactic acid in barley grain at harvest were < 0.01 mg/kg.

Residues of triazole alanine in barley grain at harvest ranged between 0.052 and 0.13 mg/kg.

Residues of triazole acetic acid in barley grain at harvest ranged between 0.024 and 0.078 mg/kg.

Storage periods of residue samples covered by available storage stability studies.

Available results show that the in force MRL of prothioconazole on barley of 0.2 mg/kg and on oat of 0.05 (Reg. (EU) 2019/552, 2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed uses.

The trials are supported by valid storage stability data and validated analytical methods.

**The proposed uses on barley and oat are considered acceptable.**

**Oilseed rape, sunflower, linseed, poppy, mustard, gold of pleasure seeds**

Oilseed rape and sunflower are the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Linseed, poppy, mustard, gold of pleasure seeds are the minor crops in N-EU.

Based on the SANTE/2019/12752, 4 residue trials on oilseed rape can be used for extrapolation to following minor crops: linseed, poppy, mustard and gold of pleasure seeds before and after forming of the edible part.

Sufficient trials on oilseed rape conducted according to the residue definition for monitoring only (trials measuring levels of prothioconazole-desthio only) were previously presented and evaluated (DAR, 2007). There are no data on prothioconazole-hydroxy-desthio in the DAR (2007).

Three new magnitude of residue studies were submitted in the framework of this application: studies S19-01269, S20-01046, S21-00259. Summary is presented below.

**Table 3: Comparison of intended and critical EU GAPs for oilseed rape**

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP NEU + SEU (DAR, UK, 2007)	2	175	14-28	Start BBCH 53	56
Intended cGAP NEU	2	180	14	BBCH 69	56

**Summary**

**1. Study S19-01269**

Six N-EU trials were conducted in accordance with the following GAP: 2 x 175 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 69, outdoor.

Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in oilseed rape grain at harvest were between <0.003 and 0.03 mg/kg.

Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest ranged between <0.06 and 0.08 mg/kg.

Residues of 1,2,4-triazole in oilseed rape grain at harvest were < 0.003 mg/kg.

Residues of triazole alanine in oilseed rape grain at harvest ranged 1.2 – 2.1 mg/kg.

Residues of triazole acetic acid in oilseed rape grain at harvest ranged between <0.01 and 0.1 mg/kg.

Residues of triazole lactic acid in oilseed rape grain at harvest were between 0.02 and 0.12 mg/kg.

**2. Study S20-01046**

Four N-EU trials were conducted in accordance with the following GAP: 2 x 175 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 69, outdoor.

Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio in oilseed rape grain at harvest were between <0.003 and 0.02 mg/kg.

Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest ranged between <0.06 and 0.07 mg/kg.

Residues of 1,2,4-triazole in oilseed rape grain at harvest were < 0.003 mg/kg.

Residues of triazole alanine in oilseed rape grain at harvest ranged between 0.43 and 1.4 mg/kg.

Residues of triazole acetic acid in oilseed rape grain at harvest ranged between <0.01 and 0.01 mg/kg.

Residues of triazole lactic acid in oilseed rape grain at harvest were between 0.03 and 0.04 mg/kg.

**3. Study S21-00259**

One N-EU trial was conducted in accordance with the following GAP: 2 x 175 g a.s. /ha, application interval – 14 days, 2nd application at BBCH 69, outdoor.

Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in oilseed rape grain at harvest were between <0.003 and <0.01 mg/kg.

Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest was <0.03 mg/kg.

Residues of 1,2,4-triazole in oilseed rape grain at harvest were < 0.003 mg/kg.

Residues of triazole lactic acid in oilseed rape grain at harvest were 0.1 mg/kg.

Residues of triazole alanine in oilseed rape grain at harvest were 2.3 mg/kg.

Residues of triazole acetic acid in oilseed rape grain at harvest were 0.01 mg/kg.

#### 4. Study S22-00257

Three N-EU trials were conducted in accordance with the following GAP: 2 x 175 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 69, outdoor.

Residues of prothioconazole-desthio, PTZ-alpha-hydroxy-desthio and PTZ-4-hydroxy-desthio were below LOQ (0.01 mg/kg) in treated oilseed rape grain samples of all trials.

Residues of PTZ-3-hydroxy-desthio were between < 0.01 mg/kg and 0.02 mg/kg.

No residues of PTZ-5-hydroxy-desthio and PTZ-6-hydroxy-desthio were found in treated oilseed rape grain samples of all trials.

1,2,4-T: 3x <0.003 mg/kg

TAA: 3x 0.01 mg/kg

TA: 0.95, 1.2, 1.5 mg/kg

TLA: 0.04, 0.06, 0.07 mg/kg.

0400000	OILSEEDS AND OIL FRUITS	MRLs of prothioconazole-desthio (sum of isomers) (F) Reg. (EU) 2019/552
0401000	Oilseeds	
0401010	Linseeds	0.09
0401030	Poppy seeds	0.09
0401050	Sunflower seeds	0.2
0401060	Rapeseeds/canola seeds	0.15
0401080	Mustard seeds	0.09
0401130	Gold of pleasure seeds	0.04

Available results show that the in force MRL of prothioconazole on oilseed rape of 0.15 mg/kg, on sunflower of 0.2 mg/kg, on linseeds, poppy seeds and mustard seeds of 0.09 mg/kg and on gold of pleasure seeds of 0.04 mg/kg (Reg. (EU) ~~2019/552~~ 2024/1318) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed uses.

The trials are supported by valid storage stability data and validated analytical methods.

**The proposed uses on oilseed rape and uses on minor crops uses (art. 51): sunflower, linseed, poppy, mustard, gold of pleasure seeds are considered acceptable.**

## 7.2.4 Magnitude of residues in livestock

The proposed uses include crops relevant as feed items.

### 7.2.4.1 Dietary burden calculation

#### Prothioconazole

In the framework of the review of the existing MRLs for prothioconazole (EFSA, 2014) and its confirmatory data (EFSA, 2020), the median and maximum dietary burdens were calculated for different groups of livestock.

The input values used in the EU calculation were compared to the residue levels found in the trials supporting the intended uses of CA3642 (see Table 0-12). The EU inputs sufficiently cover the intended uses of CA3642. It is therefore proposed to refer to EFSA Reasoned Opinion (EFSA, 2020).

**Table 0-12: Comparison of EU input values for risk assessment with results from trials supporting the intended uses of CA3642 – Prothioconazole**

Feed Commodity	EU inputs (EFSA, 2020)		Data from trials supporting the intended uses of CA3642		EU data cover ? (Y/N)
Barley grain	0.07	STMR <sub>Monit</sub> x CF (2)	0.02	STMR <sub>Monit</sub> (0.01) x CF (2)	Y
Oat grain	0.02	STMR <sub>Monit</sub> x CF (2)	0.02	STMR <sub>Monit</sub> (0.01) x CF (2)	Y
Wheat grain	0.04	STMR <sub>Monit</sub> x CF (2)	0.02	STMR <sub>Monit</sub> (0.01) x CF (2)	Y
Rye grain	0.02	STMR <sub>Monit</sub> x CF (2)	0.02	STMR <sub>Monit</sub> (0.01) x CF (2)	Y
Barley straw	1.96 7.50	STMR <sub>Monit</sub> x CF (3) HR <sub>Monit</sub> x CF (3)	0.30 2.43	STMR <sub>Monit</sub> (0.099) x CF (3) HR <sub>Monit</sub> (0.81) x CF (3)	Y
Oat straw	1.26 7.50	STMR <sub>Monit</sub> x CF (3) HR <sub>Monit</sub> x CF (3)	0.30 2.43	STMR <sub>Monit</sub> (0.099) x CF (3) HR <sub>Monit</sub> (0.81) x CF (3)	Y Y
Wheat straw	2.69 5.52	STMR <sub>RA</sub> HR <sub>Monit</sub> x CF (2.3)	0.495 2.25	STMR <sub>RA</sub> HR <sub>Monit</sub> (0.98) x CF (2.3)	Y Y
Rye straw	2.25 5.52	STMR <sub>Monit</sub> x CF (3) HR <sub>Monit</sub> x CF (2.3)	0.65 3.68	STMR <sub>RA</sub> HR <sub>Monit</sub> (1.6) x CF (2.3)	Y Y
Rapeseed, seeds	0.08	STMR <sub>RA</sub>	0.06	STMR <sub>RA</sub>	Y
Linseed, seeds	0.06	STMR <sub>Monit</sub> x CF (2)	0.02	STMR <sub>Monit</sub> Rapeseed (0.01) x CF (2)	Y

**Table 0-13: Input values for the dietary burden calculation – Prothioconazole (considering the uses evaluated in Art. 12 procedure and the uses under consideration) (EFSA, 2020)**

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition in plant commodities: 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)				
Rape seed meal	0.16	STMR x PF (2) <sup>(a)</sup> (EFSA, 2020)	0.16	STMR x PF(2) <sup>(a)</sup> (EFSA, 2020)
Sunflower seed meal	0.04	STMR x CF (2) x PF (2) <sup>(a)</sup> (EFSA, 2015a,b) <sup>(a)</sup>	0.04	STMR x CF (2) x PF (2) <sup>(a)</sup> (EFSA, 2015a,b) <sup>(a)</sup>
Head cabbage	0.02	STMR x CF (EFSA, 2014)	0.12	HR x CF (EFSA, 2014)
Maize silage	0.01	STMR (EFSA, 2014)	0.01	HR (EFSA, 2014)
Maize grain	0.02	STMR (FAO, 2014) x CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) x CF (2) (EFSA, 2014)
Maize, milled by-products <sup>(b)</sup> Maize, hominy meal <sup>(b)</sup> Maize gluten feed/ gluten meal <sup>(b)</sup> Distiller's grain <sup>(b)</sup>	0.02	STMR (FAO, 2014) x CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2014) x CF (2) (EFSA, 2014)
Barley grain	0.07	STMR (FAO, 2009b) x CF (2) (EFSA, 2014)	0.07	STMR (FAO, 2009b) x CF (2) (EFSA, 2014)
Brewer's grain	0.23	STMR barley grain (FAO, 2009b) x CF (2) (EFSA, 2014) x PF (3.3) <sup>(a)</sup>	0.23	STMR barley grain (FAO, 2009b) x CF (2) (EFSA, 2014) x PF (3.3) <sup>(a)</sup>
Oat grain	0.02	STMR (FAO, 2009a) x CF (2) (EFSA, 2014)	0.02	STMR (FAO, 2009a) x CF (2) (EFSA, 2014)
Wheat grain	0.04	STMR (FAO, 2009b) x CF (2) (EFSA, 2014)	0.04	STMR (FAO, 2009b) x CF (2) (EFSA, 2014)
Wheat gluten meal <sup>(b)</sup>	0.04	STMR wheat grain (FAO, 2009b) x CF (2) x PF (1.8) <sup>(a)</sup>	0.04	STMR wheat grain (FAO, 2010) x CF (2) x PF (1.8) <sup>(a)</sup>
Wheat milled	0.28	STMR wheat grain (FAO,	0.28	STMR wheat grain (FAO, 2010)



(d): The STMR and HR values derived by the JMPR (FAO, 2009a,b) are lower than the values derived for cereals straws for the authorised EU uses reported in the MRL review.

Relevant groups	Dietary burden expressed in				Most critical diet	Most critical commodity	Trigger exceeded (Y/N) 0.1 mg/kg DM			
	mg/kg bw per day		mg/kg DM							
	Median	Maximum	Median	Maximum						
		Risk assessment residue definition in plant commodities: sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-								

Relevant groups	Dietary burden expressed in				Most critical diet	Most critical commodity	Trigger exceeded (Y/N) 0.1 mg/kg DM	
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
		triazole moiety, expressed as prothioconazole-desthio (sum of isomers)						
Cattle (all diets)	0.036	0.109	1.15	3.10	Dairy cattle	Barley	Straw	Y
Cattle (dairy only)	0.036	0.109	0.84	2.85	Dairy cattle	Barley	Straw	Y
Sheep (all diets)	0.075	0.236	1.77	5.5	Lamb	Barley	Straw	Y
Sheep (ewe only)	0.059	0.185	1.77	5.55	Ram/ewe	Barley	Straw	Y
Swine (all diets)	0.015	0.018	0.49	0.64	Swine (finishing)	Swede	Roots	Y
Poultry (all diets)	0.035	0.059	0.52	0.86	Poultry layer	Wheat	Straw	Y
Poultry (layer only)	0.035	0.059	0.52	0.86	Poultry layer	Wheat	Straw	Y

For prothioconazole residues, the results of the dietary burden calculation demonstrate that the exposure of all livestock species exceeds the trigger value of 0.1 mg/kg DM.

### TDMs

In the framework of the Peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data (EFSA, 2018), the median and maximum dietary burdens were calculated by the UK (2018) for different groups of livestock considering available data on TDMs.

The input values used in the EU dietary burden calculation (B.7.4, UK, 2018) were compared to the residue levels found in the trials supporting the intended uses of CA3642. Except TA in oilseed rape seed for which the STMR from trials is 1.3 mg/kg instead of 1.039 mg/kg presented in EU confirmatory data, all EU inputs cover the residue levels found in the provided trials. A comparison table is presented below.

**Table 0-15: Comparison of EU input values for risk assessment with results from trials supporting the intended uses of CA3642 – TDMs**

EU inputs (B.7.4, UK, 2018)								
1,2,4-T		TA		TAA		TLA		
STMR	HR	STMR	HR	STMR	HR	STMR	HR	
Cereals grains	0.05	*	0.621	*	0.79	*	0.022	*
Cereal straws/stover	0.05	0.05	0.12	0.65	0.24	0.78	0.37	1.1
Oilseeds grains	0.05	*	1.039	*	0.12	*	0.065	*
Trials supporting the intended uses of CA3301 (see 7.2.3)								
1,2,4-T		TA		TAA		TLA		
STMR	HR	STMR	HR	STMR	HR	STMR	HR	
Barley grains	0.01	*	0.21	*	0.062	*	0.01	*
Barley straw	0.01	0.05	0.04	0.05	0.038	0.136	0.057	0.157
Wheat grains	0.01	*	0.62	*	0.225	*	0.01	*
Wheat straw	0.01	0.05	0.019	0.1	0.049	0.307	0.057	0.21
OSR seeds	0.003	*	1.3	*	0.01	*	0.05	*
Comparison								
1,2,4-T		TA		TAA		TLA		
STMR	HR	STMR	HR	STMR	HR	STMR	HR	

Barley grains	ok	*	ok	*	ok	*	ok	*
Barley straw	ok	ok	ok	ok	ok	ok	ok	ok
Wheat grains	ok	*	ok	*	ok	*	ok	*
Wheat straw	ok	ok	ok	ok	ok	ok	ok	ok
OSR seeds	ok	*	not covered	*	ok	*	ok	*

\* Only STMR values are used for seeds/grains in the consumer risk assessment. HR value was therefore not taken into account for these commodities.

**1,2,4-T** : 1,2,4-triazole ; TA: Triazole alanine ; TAA: Triazole acetic acid ; TLA: Triazole lactic acid

The EU input value for TA in oilseed rape seeds does not cover the level found in the new provided trials. A new calculation was therefore performed for TA only, using the input values used in the EU assessment from TDM confirmatory data (B.7.4, UK,2018) and the highest value found for TA in oilseed rape seed. The detailed values are presented in Appendix A 4.1.

For **1,2,4-T**, TAA and TLA, it is proposed to refer to EU calculation (UK, 2018).

The results of the dietary burden are presented in the table below. The exposure of all livestock species exceeds the trigger value of 0.1 mg/kg DM and 0.004 mg/kg bw for all four triazole compounds (**1,2,4-T**, TA, TAA and TLA).

**Table 0-16: Results of the maximum dietary burden calculation – TDMs (B.7.4, UK, 2018 and new value for oilseed rape seeds)**

Relevant groups	Maximum Dietary burden expressed in										Trigger exceeded (Y/N)
	mg/kg bw per day					mg/kg DM					
	1,2,4-T <sup>(1)</sup>	TA <sup>(1)</sup>	TA <sup>(2)</sup>	TAA <sup>(1)</sup>	TLA <sup>(1)</sup>	1,2,4-T <sup>(1)</sup>	TA <sup>(1)</sup>	TA <sup>(2)</sup>	TAA <sup>(1)</sup>	TLA <sup>(1)</sup>	
Cattle (all diets)	0.109	0.405	0.413	0.140	0.177	3.75	13.63	13.89	4.29	4.61	Y
Cattle (dairy only)	0.109	0.405	0.413	0.140	0.177	2.83	10.52	10.73	3.63	4.61	Y
Sheep (all diets)	0.121	0.454	0.463	0.170	0.187	3.63	13.63	13.90	4.37	5.61	Y
Sheep (ewe only)	0.121	0.454	0.463	0.146	0.187	3.63	13.63	13.90	4.37	5.61	Y
Swine (all diets)	0.047	0.178	0.181	0.109	0.055	2.04	7.71	7.84	3.76	2.37	Y
Poultry (all diets)	0.038	0.165	0.167	0.140	0.052	0.54	2.34	2.36	2.05	0.77	Y
Poultry (layer only)	0.032	0.149	0.150	0.140	0.052	0.46	2.18	2.19	2.05	0.77	Y

(1) Results from TDM confirmatory data (UK, 2018)

(2) For TA, results calculated in the present dossier by using the same input values than UK 2018, except for oilseed rape seeds where an STMR of 1.3 mg/kg was used (instead of 1.039 initially). This value was also extrapolated to cotton, soybean, canola, safflower and sunflower seeds, as made by the UK.

In a second part, it is proposed to calculate the dietary burden considering the intended uses of CA3642 only and compare it to the EU calculation.

A processing factor of 1 was applied when residues in raw agricultural commodities were below the LOQ. Otherwise, default processing factors were used.

**Table 0-17: Input values for the dietary burden calculation – TDMs (considering the uses under consideration)**

Feed Commodity	<u>Median</u> dietary burden - Input value (mg/kg)					<u>Maximum</u> dietary burden - Input value (mg/kg)				
	1,2,4-T	TA	TAA	TLA	Comment	1,2,4-T	TA	TAA	TLA	Comment
Barley straw	0.01*	0.04	0.038	0.057	STMR (§ 7.2.3)	0.05*	0.05	0.136	0.157	HR (§ 7.2.3)
Oat straw	0.01*	0.04	0.038	0.057	STMR barley	0.05*	0.05	0.136	0.157	HR barley
Rye straw	0.01*	0.019	0.049	0.06	STMR wheat	0.05*	0.1	0.307	0.21	HR wheat
Triticale straw	0.01*	0.019	0.049	0.06	STMR wheat	0.05*	0.1	0.307	0.21	HR wheat
Wheat straw	0.01*	0.019	0.049	0.06	STMR (§ 7.2.3)	0.05*	0.1	0.307	0.21	HR wheat
Barley grain	0.01*	0.21	0.062	0.01*	STMR (§ 7.2.3)					Same as median
Oat grain	0.01*	0.21	0.062	0.01*	STMR barley					Same as median
Rye grain	0.01*	0.62	0.225	0.01*	STMR wheat					Same as median
Triticale grain	0.01*	0.62	0.225	0.01*	STMR wheat					Same as median
Wheat grain	0.01*	0.62	0.225	0.01*	STMR (§ 7.2.3)					Same as median
Brewer's grain dried	0.01*	0.69	0.20	0.010	STMR barley x PF					Same as median
Canola (Rape seed) meal	0.003*	2.60	0.02	0.10	STMR (§ 7.2.3) x PF					Same as median
Distiller's grain dried	0.01*	2.05	0.74	0.010	STMR wheat x PF					Same as median
Flaxseed/Linseed meal	0.003*	2.60	0.02	0.10	STMR rapeseed x PF					Same as median
Rape meal	0.003*	2.60	0.02	0.10	STMR (§ 7.2.3) x PF					Same as median
Wheat gluten meal	0.01*	1.12	0.41	0.01	STMR wheat x PF					Same as median
Wheat milled by-pdts	0.01*	4.34	1.58	0.01	STMR wheat x PF					Same as median

**Table 0-18: Results of the maximum 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) 0.004 mg/kg bw
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Cattle (all diets)	0.000	0.001	0.01	0.03	Dairy cattle	Barley	straw	No
Cattle (dairy only)	0.000	0.001	0.01	0.03	Dairy cattle	Barley	straw	No
Sheep (all diets)	0.001	0.002	0.02	0.04	Lamb	Barley	straw	No
Sheep (ewe only)	0.001	0.001	0.02	0.04	Ram/Ewe	Barley	straw	No
Swine (all diets)	0.000	0.000	0.01	0.01	Swine (finishing)	Barley	grain	No
Poultry (all diets)	0.001	0.001	0.01	0.02	Poultry layer	Wheat	straw	No
Poultry (layer only)	0.001	0.001	0.01	0.02	Poultry layer	Wheat	straw	No

**Table 0-19: Results of the maximum dietary burden calculation – Triazole alanine**

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No) 0.004 mg/kg bw
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Cattle (all diets)	0.068	0.069	1.77	1.78	Dairy cattle	Wheat	milled bypds	Yes
Cattle (dairy only)	0.068	0.069	1.77	1.78	Dairy cattle	Wheat	milled bypds	Yes
Sheep (all diets)	0.120	0.120	2.81	2.81	Lamb	Wheat	milled bypds	Yes
Sheep (ewe only)	0.075	0.076	2.26	2.28	Ram/Ewe	Wheat	milled bypds	Yes
Swine (all diets)	0.085	0.085	2.82	2.82	Swine (finishing)	Wheat	milled bypds	Yes
Poultry (all diets)	0.104	0.104	1.48	1.49	Poultry broiler	Wheat	milled bypds	Yes
Poultry (layer only)	0.101	0.102	1.48	1.49	Poultry layer	Wheat	milled bypds	Yes

**Table 0-20: Results of the maximum dietary burden calculation – Triazole acetic acid**

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No) 0.004 mg/kg bw
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Cattle (all diets)	0.025	0.027	0.65	0.71	Dairy cattle	Wheat	milled bypds	Yes
Cattle (dairy only)	0.025	0.027	0.65	0.71	Dairy cattle	Wheat	milled bypds	Yes
Sheep (all diets)	0.043	0.045	1.02	1.06	Lamb	Wheat	milled bypds	Yes
Sheep (ewe only)	0.028	0.030	0.83	0.91	Ram/Ewe	Wheat	milled bypds	Yes
Swine (all diets)	0.031	0.031	1.02	1.02	Swine (finishing)	Wheat	milled bypds	Yes
Poultry (all diets)	0.038	0.039	0.54	0.57	Poultry layer	Wheat	milled bypds	Yes
Poultry (layer only)	0.037	0.039	0.54	0.57	Poultry layer	Wheat	milled bypds	Yes

**Table 0-21: Results of the maximum dietary burden calculation – Triazole lactic acid**

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No) 0.004 mg/kg bw
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Cattle (all diets)	0.002	0.003	0.05	0.08	Dairy cattle	Barley	straw	No
Cattle (dairy only)	0.002	0.003	0.04	0.07	Dairy cattle	Barley	straw	No
Sheep (all diets)	0.002	0.005	0.06	0.13	Lamb	Barley	straw	Yes
Sheep (ewe only)	0.002	0.004	0.06	0.13	Ram/Ewe	Barley	straw	Yes
Swine (all diets)	0.001	0.001	0.03	0.03	Swine (finishing)	Canola	meal	No
Poultry (all diets)	0.002	0.003	0.03	0.04	Poultry layer	Wheat	straw	No
Poultry (layer only)	0.002	0.003	0.03	0.04	Poultry layer	Wheat	straw	No

For 1,2,4-triazole (1,2,4-T), in contrast to EU calculation, the results of the dietary burden calculation when considering CA3642 uses only demonstrate that the exposure of all livestock species does not exceed the trigger value of 0.1 mg/kg DM or 0.004 mg/kg bw.

For triazole alanine (TA) and triazole acetic acid (TAA), the results of the dietary burden calculation demonstrate that the exposure of all livestock species exceeds the trigger value of 0.1 mg/kg DM or 0.004 mg/kg bw.

For triazole lactic acid (TLA), the results of the dietary burden calculation demonstrate that the exposure slightly exceeds the trigger value of 0.1 mg/kg DM or 0.004 mg/kg bw for sheep only.

The results of the dietary burden for all TDMs, considering the intended uses of CA3642, are however covered by the dietary burdens calculated by the UK (2018) for the different groups of livestock.

**zRMS comments:**

Information given by the Applicant is acceptable and sufficient.

Prothioconazole

The median and maximum dietary burdens for livestock were estimated for prothioconazole and were calculated using the animal model calculator developed by EFSA (Animal model 2017). The summary submitted by the Applicant reflects the conclusions of the EFSA Reasoned Opinion (EFSA, 2020).

The calculated dietary burdens for prothioconazole were found to exceed the trigger value of 0.1 mg/kg DM (or 0.004 mg/kg bw/d, respectively) for all livestock groups. Further investigation of residues is therefore required.

#### TDMs

Livestock dietary burden calculation has been performed respectively for each TDM compound in the addendum – confirmatory data on TDMs performed by UK in 2018 (UK, 2018) using results from residue trials and from rotational crops. Additionally Applicant presented Livestock dietary burden calculation with using the input values used in the EU assessment from TDM confirmatory data (UK, 2018) and the highest value found for TA in oilseed rape seed.

The calculated dietary burdens for 1,2,4-triazole (1,2,4-T) were not found to exceed the trigger value of 0.1 mg/kg DM for all livestock groups.

The calculated dietary burdens for triazole alanine (TA) and triazole acetic acid (TAA) were found to exceed the trigger value of 0.1 mg/kg DM for all livestock groups.

The calculated dietary burdens for triazole lactic acid (TLA) were found to exceed the trigger value of 0.1 mg/kg DM for sheep only.

The feeding studies are required for TA, TAA and TLA.

It should be noted that the results of dietary burdens for TDMs taking into account the intended uses of CA3642 are covered by the dietary burdens calculated by the UK (2018) for the different groups of livestock.

#### Remark on residue behaviour in fish (B.7.2.2.5 and B.7.2.4)

According to the new Working Documents on the nature and magnitude of pesticide residues in fish (SANTE/10254/2021, SANTE/10252/2021) as well as on the dietary burden calculator for pesticide residues in fish (SANTE/10250/2021), data on residue behaviour in fish are required when the pesticide use may lead to residues >0.1 mg/kg in the total diet (dry weight basis) and when the active substances and/or metabolites are fat soluble, i.e. have a log Po/w  $\geq 3$ .

For prothioconazole-desthio the log Po/w is 3.04 and EFSA concluded that prothioconazole-desthio is fat soluble due to higher residue levels found in fat than in fat free muscle. Rape seed meal and cereal grains are used as a fish feeding stuff. However, residues of prothioconazole-desthio ranged from below the LOQ to 0.03 mg/kg in cereals grain and rape seeds. Residues above the trigger value of 0.1 mg/kg are therefore not expected. Further data are not required.

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

#### **Available data**

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

#### **Summary of livestock feeding studies – Prothioconazole**

*EFSA Journal 2014;12(5):3689 (Study Report No.: MR-535/00, not protected)*

“During the peer review under Directive 91/414/EEC, the magnitude of prothioconazole residues in ruminants was investigated in a feeding study with lactating cows (EFSA, 2007b; FAO, 2008a, 2008b; United Kingdom, 2004, 2007). 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. However, conversion factors reported above should in principle be covered by a new feeding study to estimate prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment.

Furthermore, in the framework of the reported feeding study, the storage stability of prothioconazole-

desthio, M14 [prothioconazole-3-hydroxy-desthio] and M15 [prothioconazole-4-hydroxy-desthio] 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.

[...]

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.”

Results of the ruminant livestock feeding study for prothioconazole residues are summarised in Table 0-22.



**Table 0-22: Overview of the values derived from livestock feeding studies - Prothioconazole**

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) <sup>(c)</sup>	Highest residue (mg/kg) <sup>(d)</sup>	Calculated MRL (mg/kg)	In-force MRL (mg/kg) Reg. (EU) 2019/552 2024/1318	CF for RA <sup>(e)</sup>
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) <sup>(a)</sup>	No	Result for enforcement		Result for RA <sup>(b)</sup>						
					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	0.015	0.017	0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01*	0.01	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*	0.02	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*	0.5	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*	0.5	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	0.036	0.109	0.15	42	<0.005 <sup>(f)</sup>	N/A	n.a.	n.a.	<0.005	<0.005	0.005*	0.01*	1.0
			0.91	42	<0.005 <sup>(f)</sup>	N/A	n.a.	n.a.					
			3.64	39	<0.005 <sup>(f)</sup>	N/A	n.a.	n.a.					
Ruminant muscle	0.036	0.109	0.15	3	<0.01	<0.01	n.a.	n.a.	<0.01	<0.01	0.01*	0.01	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*	0.02	1.0

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) <sup>(c)</sup>	Highest residue (mg/kg) <sup>(d)</sup>	Calculated MRL (mg/kg)	In-force MRL (mg/kg) Reg. (EU) <div>2019/552</div> <div>2024/1318</div>	CF for RA <sup>(e)</sup>
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d) <sup>(a)</sup>	No	Result for enforcement		Result for RA <sup>(b)</sup>						
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)					
Ruminant liver			0.91	3	<0.01	0.01	n.a.	n.a.	0.01	0.042	0.05	0.5	2.0
			3.64	3	0.02	0.04	n.a.	n.a.					
			0.15	3	0.02	0.03	n.a.	n.a.					
			0.91	3	0.14	0.18	n.a.	n.a.					
			3.64	3	0.68	1.20	n.a.	n.a.					
			0.15	3	<0.01	<0.01	n.a.	n.a.					
Ruminant kidney			0.91	3	0.03	0.03	n.a.	n.a.	<0.01	0.012	0.02	0.5	9.0
			3.64	3	0.13	0.24	n.a.	n.a.					

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

n.a.: Not analysed.

(a): Based on a 560 kg animal consuming 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, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 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.

## Summary of livestock feeding studies – **TDMs**

*EFSA Journal 2018;16(7):5376*

“Poultry and ruminants feeding studies were conducted respectively with TA and TAA and analysed for the magnitude of TA, TAA, 1,2,4-T and TLA residues.

The poultry feeding study conducted with TA showed that TA remained predominant in all matrices and a slight metabolism to 1,2,4-T in whole eggs, liver and muscle at the highest dosing level was noted. When the animals were fed with TAA, this compound was detected in eggs, fat and liver with residues of TA in liver only at all dosing levels.

From the ruminant feeding study conducted with TA, TA remained predominant in all tissues but with a significant metabolism of TA into 1,2,4-T in milk and to a minor extent into 1,2,4-T and TAA in tissues. TLA was identified in fat only but its detection was rather attributed to a contamination as the respective levels were independent from the dosing levels.

When ruminants were fed with TAA, this metabolite was only detected at the highest dose level in whole milk and in all tissues whilst TA was identified in liver, muscle and kidney at all the dosing levels. 1,2,4-T and TLA compounds were never detected (< 0.01 mg/kg).

Animal tissues, milk and eggs samples were analysed within 30 days of sampling.

Since livestock feeding studies were not conducted to address the potential transfer of 1,2,4-T and TLA in products of animal origin, the experts agreed that transfer factors for TA derived from the feeding studies conducted with TA should be applied to 1,2,4-T, assuming that the absorption and excretion behaviour of TA and 1,2,4-T are similar. Similarly transfer factors for TAA derived from the feeding studies conducted with TAA should be applied to TLA assuming that the absorption and excretion behaviour of TAA and TLA are comparable and because of the similarity of the functional groups. From the available toxicological studies, the absorption and excretion of TA, 1,2,4-T and TAA were shown to be similar and the experts agreed to estimate the 1,2,4-T residue levels in animal matrices by applying transfer factors for TA derived from the feeding study conducted with TA. A feeding study conducted with 1,2,4-T is therefore not required as no further metabolism of this compound in animal matrices is expected.

In contrast and since a similar absorption and excretion behaviour of TLA compared to the other TDMs could not be demonstrated, livestock feeding studies conducted with TLA or metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies should be provided (data gap).

Meanwhile and provisionally, transfer factors for TAA derived from the feeding study conducted with TAA were applied to estimate the residue levels of TLA in animal commodities. The magnitude of residues of each TDM in animal matrices were therefore estimated by using the approach of a separate dietary burden calculation for each TDM and the application of transfer factors respectively to 1,2,4-T and to TLA for which feeding studies are not available.

Furthermore, the residues of the TDMs (mainly 1,2,4-T and to a minor extent, TA) arising from the metabolism of triazole pesticide active substances in livestock should also be considered to derive the total residue levels of the individual TDMs in animal matrices. In the framework of these confirmatory data assessments and since feeding studies conducted with the triazole compounds were not available, the residue levels of 1,2,4-T and TA were estimated from the metabolism studies conducted with the triazole compounds when these were available. For any future assessment of triazole pesticide active substances, livestock feeding studies or, alternatively metabolism studies should be conducted with the triazole compounds to carry out a complete livestock exposure assessment.”

## Conclusion on feeding studies

For prothioconazole residues, the requested uses do not modify the theoretical maximum daily intake for animals. Regarding available feeding data, there is no risk for animal MRL to be exceeded.

Finally, as concluded by EFSA, although the maximum dietary burden for poultry exceeds the threshold of 0.1 mg/kg DM, no appropriate feeding study is available and none is required, since based on the metabolism study, no residues above the LOQ are expected in poultry matrices at the calculated dietary burden.

Regarding TDMs, the requested uses do not modify the theoretical maximum daily intake for animals and are covered by UK calculation made in the framework of the confirmatory data on TDM (UK, 2018 and EFSA, 2018). The intended uses are considered sufficiently supported considering current available data and the European assessment on T, TA, TLA and TAA.

**zRMS comments:**

Information given by the Applicant is acceptable and sufficient.

The livestock feeding studies was investigated during the peer review of prothioconazole. The intended uses do not modify the theoretical maximum daily intake for animals for prothioconazole and TDMs. The residues in animal commodities will not exceed MRLs (Reg. (EU) ~~2019/552~~ 2024/1318).

No further data are required to support the intended uses of CA3642/Joust Pro.

**Remark:**

It should be noted that EFSA recommended providing a ruminant feeding study to estimate the potential exposure to all the prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment.

Additionally, regarding TDMs EFSA identified livestock exposure assessment as a data gap.

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

### 7.2.5.1 Available data for all crops under consideration

No prothioconazole residue above the trigger value of 0.1 mg/kg is expected in raw agricultural commodities from the intended uses. Therefore, studies investigating the nature and magnitude of prothioconazole residues in processed commodities are not required (Reg. (EU) No 544/2011).

Regarding TDMs, the trigger value of 0.1 mg/kg is exceeded for TAA and TA in barley and wheat grains, and for TAA, TA and TLA in oilseed rape seeds.

In the framework of the peer review for TDM confirmatory data, a number of studies have been undertaken to assess the magnitude of residues in processed commodities. Processing factors were calculated, except when the residues were below the limit of quantification (LOQ) in the raw agricultural commodity.

Studies investigating the processing of wheat (1 trial) and barley (2 trials) treated with product containing prothioconazole only were presented in the confirmatory data (UK, 2018).

Studies investigating the processing of oilseed rape treated with product containing prothioconazole only (2 trials), and treated with prothioconazole and tebuconazole (1 trial) are presented in the confirmatory data (UK, 2018). For detailed summaries, please refer to Triazole Derivate Metabolites, addendum – confirmatory data (B.7.5.2, UK, 2018).

**Table 0-23: Overview of the available processing studies - TDMs**

Processed commodity	Individual Processing factors (Median)				Comments	Reference
	1,2,4-T	TA	TAA	TLA		
EU confirmatory data (B.7.5.2, UK, 2018)						
Wheat, aspirated grain fractions	NC	0.20	0.39	NA		UK, 2018
Wheat, Bran	NC	3.7	2.1	NA		
Wheat, Flour	NC	0.30	0.89	NA		
Wheat, Germ	NC	4.9	1.3	NC		
Wheat, Middlings	NC	0.66	0.80	NC		
Wheat, Shorts	NC	1.7	1.2	NC		

Processed commodity	Individual Processing factors (Median)				Comments	Reference
	1,2,4-T	TA	TAA	TLA		
Barley, Brewer's malt	NC, NC	0.78, 0.77 (0.775)	1.0, 1.1 (1.05)	>1.1, >1.5 (>1.3)		
Barley, Brewer's grain	NC, NC	<0.04, <0.03 (<0.035)	<0.05, <0.04 (<0.045)	NC, NC		
Barley, Brewer's yeast	NC, NC	0.24, 0.14 (0.19)	0.23, 0.23 (0.23)	NC, NC		
Barley, Beer	NC, NC	0.15, 0.13 (0.14)	0.29, 0.13 (0.21)	NC, NC		
Rapeseed, meal	NC, NC, NC, NC	2.9, 0.52, 0.81, 1.9 (1.35)	>1.2, >2, >2, NC (>2)	NA, >1, >3, >2 (>2)		
Rapeseed, press cake	NC, NC, NC	0.61, 0.78, 1.3 (0.78)	NC, NC, >1	>2, >2, NC (>2)		
Rapeseed, refined oil	NC, NC, NC, NC	<0.02, <0.03, <0.04, <0.03 (<0.03)	NC, NC, NC, NC	NA, NC, NC, NC		

NA not analysed

NC Not calculated since the residues were below the limit of quantification both in the raw agricultural commodity and in the processed fraction, no processing factor could be derived.

## 7.2.5.2 Conclusion on processing studies

No prothioconazole residue above the trigger value of 0.1 mg/kg is expected in raw agricultural commodities from the intended uses. Therefore, studies investigating the nature and magnitude of prothioconazole residues in processed commodities are not required.

Regarding TDMs, available studies show that TDM do not concentrate in processed wheat grains, barley grains and oilseed rape seeds, in general, except TA and TAA in wheat bran; TA in wheat germ and shorts; TA, TAA and TLA in rapeseed meal; and TLA in rapeseed press cake.

### zRMS comments:

Information given by the Applicant is acceptable and sufficient.

As residues of prothioconazole exceeding 0.1 mg/kg are not expected in the treated crops, there is no need to investigate the magnitude of prothioconazole residues in processed commodities.

Regarding TDMs, processing studies on wheat and oilseed rape grain have been evaluated in confirmatory data for Triazole Derivate Metabolites (UK, 2018).

Calculated processing factors show concentration of:

- TA and TAA in wheat bran,
- TA in wheat germ and shorts,
- TA, TAA and TLA in rapeseed meal,
- and TLA in rapeseed press cake.

No further data are required.

## 7.2.6 Magnitude of residues in representative succeeding crops

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

#### Available data

No new data submitted in the framework of this application.

#### Summary of field rotational crop studies reported in the EU - Prothioconazole

EFSA Journal 2014;12(5):3689

“Based on the confined rotational crop study, considering that the application rate of prothioconazole within the EU ranges between 0.009 – 0.600 kg a.s./ha and due to the fact that prothioconazole was applied to a bare soil in the metabolism study (interception of prothioconazole by the plants is expected in practice), it can be concluded that prothioconazole residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crops (see also 7.2.2.2). Therefore, no risk mitigation measures (plant back restrictions) need to be proposed”.

#### Summary of field rotational crop studies reported in the EU - TDMs

During the peer review of TDMs in light of confirmatory data (UK, 2018 and EFSA, 2018), a number of field rotational crop trials have been conducted to investigate the magnitude TDM residues in rotational crops after the use of triazole active substances.

Field rotational crop studies with prothioconazole conducted at different sites within Europe were evaluated in the framework of the peer review for TDM confirmatory data. For detailed summaries, please refer to Triazole Derivate Metabolites, addendum – confirmatory data (Appendix D, UK, 2018).

#### Confirmatory data on Triazole Derivative Metabolites (B.7.6.2.6; UK, 2018)

“Supervised field trials to investigate the residues in rotational crops after the use of FS and EC formulations containing 100 g/L and 250 g/L of prothioconazole were conducted at four test sites in Germany, the Netherlands, southern France and Spain. At each test site three ranges of plant-back intervals (20-35 days, 60-200 days and 270-365 days) and three crop groups (root crops represented by turnip and carrot, leafy crops represented by lettuce, cereals represented by barley) were investigated.

In the trials simulating a crop failure (emergency rotation) the EC formulation was applied once to bare soil at the rate of 630 g a.s./ha of prothioconazole. The rotational crops were sown or planted 21-34 days after the application. In the trials simulating a normal rotation the FS formulation was used to treat wheat seed at the rate of 15 g as/dt. The seed was sown at a nominal rate of 200 kg seed/ha and the wheat plants received 3 spray treatments at the rate of 200 g a.s./ha with the EC formulation. The treatments were conducted at the growth stages BBCH 32, BBCH 39 and BBCH 65-69, respectively, with intervals of 7-30 days between subsequent treatments. At harvest the wheat straw was ploughed in and the plot was left bare until rotational crops were sown or planted. The plant-back intervals were variable depending on the crop and ranged between 56 and 200 days for the short crop rotation and between 277 and 345 days for the annual crop rotation.

A summary of the median (STMR) and highest residues (HR) of 1,2,4-T, TA, TAA and TLA measured in the rotational crops for emergency rotation and normal rotation is given below”.

**Table 0-24: STMRs and HRs for the triazole derived metabolites in carrot / turnip, lettuce and barley grown as succeeding crops following the use of FS and EC formulations containing 100 g/L and 250 g/L of prothioconazole (UK, 2018)**

Commodity	No of Trials	STMR (mg/kg)				HR (mg/kg)			
		T	TA	TAA	TLA	T	TA	TAA	TLA
Carrot or turnip leaf – bare soil	4	0.01	0.032	0.01	0.057	0.01	0.176	0.01	0.132
Carrot or turnip leaf – normal rotation	7	0.01	0.01	0.01	0.019	0.01	0.039	0.01	0.046
Carrot or turnip root – bare soil	4	0.01	0.076	0.01	0.021	0.01	0.195	0.01	0.131
Carrot or turnip root – normal rotation	7	0.01	0.023	0.01	0.010	0.01	0.041	0.01	0.01
Lettuce – bare soil	4	0.01	0.047	0.022	0.079	0.01	0.091	0.03	0.01
Lettuce – normal rotation	8	0.01	0.011	0.023	0.02	0.01	0.012	0.036	0.048
Barley plant – bare soil	4	0.01	0.068	0.01	0.078	0.01	0.082	0.01	0.165
Barley plant – normal rotation	8	0.01	0.037	0.01	0.032	0.01	0.057	0.01	0.208
Barley straw – bare soil	4	0.01	0.053	0.063	0.113	0.01	0.129	0.288	0.192
Barley straw – normal rotation	8	0.01	0.011	0.019	0.042	0.01	0.023	0.057	0.068
Barley grain – bare soil	4	0.01	0.412	0.144	0.02	0.01	0.455	0.293	0.037
Barley grain – normal rotation	8	0.01	0.075	0.067	0.01	0.01	0.184	0.132	0.031

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. Separate STMRs and HRs were calculated based on the trials involving soil application and based on the trials with application to a preceding crop, respectively. The worst case STMR and the worst-case HR were then determined by selecting the greater STMR and the greater HR from the two datasets.

### Conclusion on rotational crops studies

For prothioconazole, residues in rotated crops at harvest were <0.01 mg/kg in food and less than primary

crop residues in feed, therefore further investigation into the magnitude of residues in rotational crops is not required.

Regarding TDMs, no residue of T above 0.01 mg/kg was found in succeeding crops. TA and TLA residues above 0.01 mg/kg were found in all tested succeeding crops. TAA was found in lettuce, barley straw and grain. These results were considered in the consumer risk assessment performed in the framework of the review of TDMs confirmatory data (UK, 2018).

**zRMS comments:**

Information given by the Applicant is acceptable and sufficient.

No residues are expected in rotational crops for the intended uses of CA3642 (Joust Pro), so additional field rotational crop studies are not considered required.

Regarding TDMs, rotational crop studies were considered by the UK in the assessment of confirmatory data on TDMs (the UK, 2018).

## **7.2.7 Other / special studies (KCA 6.10, 6.10.1)**

### **7.2.7.1 Effect on the residue level in pollen and bee products**

Prothioconazole is currently authorized based on the old data requirements, for which no residue study on honey was required in the DAR 2004. Consequently, the assessment of the present application is based on the same data requirements as for the active substance 2004 re-approval since prothioconazole is not renewed yet. This will avoid any distortion of competition in favour of the previous Art.33 dossiers for which no data on honey was required. Therefore, in the present application, information on honey is considered as informative only.

According to SANTE/11956/2016 rev. 9, rapeseed and some other oilseeds are considered as melliferous crops. As prothioconazole is proposed to be applied during the flowering stage (BBCH 60-69) and since the active substance is systemic, effects on the residue level in pollen and bee products have been investigated.

#### **Summary of new residue studies on bee products**

Five residue trials located in Northern and Southern Europe were conducted with winter oilseed rape as a melliferous source. Prothioconazole 250 g/L EC (CA3301) was applied twice, at a nominal application rate of 175 g a.s./ha for each application. This can be considered as a worst-case situation in term of application rate as only one application of 180 g a.s./ha is intended on rapeseed and other oilseeds for CA3642.

The first application was conducted before flowering and 14 days before the second application which was conducted at BBCH 61-63. As all trials were performed with 2 applications, they can be considered as a worst-case situation and therefore cover the intended GAP as the application rate and BBCH remains the same.

Forager bees (for nectar sampling) and pollen from pollen traps were collected. Honey was sampled from combs.

No residues (not detected, i.e., <0.003 mg/kg) of prothioconazole-desthio, alpha-OH, 3-OH, 4-OH 5-OH, 6-OH and 1,2,4-triazole were found in honey samples of all trials. The data submitted show that no exceedance of the MRL (0.05\* mg/kg) will occur in honey when CA3642 is applied according to the GAP on oilseed rape.

Residues of the metabolite triazole alanine (TA) were found in the untreated and treated honey samples of trial -02 and trial -04. The values found ranged from 0.0131 mg/kg to 0.0298 mg/kg. Residues of triazole acetic acid (TAA) were also detected in untreated and treated honey samples of trial -04 with values from 0.0330 mg/kg to 0.0646 mg/kg. Residues of the metabolite triazole lactic acid (TLA) were not quantified in treated honey samples of all trials, but was quantified (0.0179 - 0.0194 mg/kg) in untreated honey samples of trial -04.



The detailed assessment of these studies is presented in Appendix 2.

## Conclusion

No exceedance of the MRL (0.05\* mg/kg) will occur in honey when CA3642 is applied according to the GAP on oilseed rape.

### zRMS comments:

Information given by the Applicant is acceptable and sufficient.

The Applicant submitted an additional study to determine residues of prothioconazole in nectar, pollen and honey collected from honey bees from winter oilseed rape plants after two applications of CA3301 (175 g prothioconazole/ha) under semi-field conditions.

#### Residues in honey

No residues of prothioconazole-desthio, alpha-OH, 3-OH, 4-OH 5-OH, 6-OH and 1,2,4-triazole were found in treated honey samples of all trials.

Residues of triazole alanine (TA) ranged from 0.0131 mg/kg to 0.0298 mg/kg. The highest residues of triazole acetic acid (TAA) was 0.0330 mg/kg in one sample. Residues of triazole lactic acid (TLA) were not detectable in treated honey samples of all trials except trial -04 with values below LOQ.

This study complies with the requirements of SANTE /11956/2016 rev. 9, so the study is acceptable.

More details of the residue study in nectar, pollen and plants of oilseed rape is provided in Appendix 2.

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

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

### 7.2.8.1 Input values for the consumer risk assessment

#### Prothioconazole

TMDI calculation was performed using the in-force MRLs. The following conversion factors for enforcement to risk assessment were used:

- Oilseeds: 2 (derived from residue trials) (EFSA, 2014)
- Wheat: 2 (derived from residue trials) (EFSA, 2014)
- Root and tuber vegetables (except sugar beet): 2.7 (EFSA, 2020)
- Potatoes: 1 (derived from metabolism study) (EFSA, 2014)
- Maize: 1 (derived from metabolism study) (EFSA, 2014)
- Cranberries and Sweet corn: no conversion factor was available as the MRLs for these crops originate from CXLs which are derived according to a different residue definition
- A conversion factor of 2 for crops where no data according to the risk assessment residue definition are available and for which a risk management decision is pending: pulses, flowering brassica, Brussels sprouts, head cabbages, shallots, onions, leeks, rye, barley, oats (EFSA, 2020)
- All other crops: tentative conversion factor of 2 derived for all plant commodities (EFSA, 2014)
- Ruminant and pig liver: 2 (EFSA, 2014)
- Ruminant and pig kidney: 9 (EFSA, 2014)

**Table 0-25: Input values for the consumer risk assessment - Prothioconazole**

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<b>Risk assessment residue definition 1:</b> 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)				
Barley	0.4	EU MRL 0.2 x CF (2)	0.06*	STMR <sub>RA</sub> (see 7.2.3)
Wheat	0.2	EU MRL 0.1 x CF (2)	0.06*	STMR <sub>RA</sub> (see 7.2.3)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Oat, Rye	0.1	EU MRL 0.05 x CF (2)	0.06*	Extrapolation from barley and wheat
Rapeseed	0.30	EU MRL 0.15 x CF (2)	0.06	STMR <sub>RA</sub> (see 7.2.3)
Linseed, Poppy, Mustard	0.18	EU MRL 0.09 x CF (2)	0.06	Extrapolation from rapeseed
Gold of pleasure	0.08	EU MRL 0.04 x CF (2)	0.06	Extrapolation from rapeseed
Swine: Muscle/meat	0.01	EU MRL	0.01*	HR <sub>Enf</sub> (see 7.2.4.2)
Swine: Fat tissue	0.02	EU MRL	0.01*	HR <sub>Enf</sub> (see 7.2.4.2)
Swine: Liver	1.0	EU MRL 0.5 x PF (2)	0.02*	HR <sub>Enf</sub> x PF (2) (see 7.2.4.2)
Swine: Kidney	4.5	EU MRL 0.5 x PF (9)	0.09*	HR <sub>Enf</sub> x PF (9) (see 7.2.4.2)
Bovine, Sheep, Goat, Equine muscle/meat	0.01	EU MRL	0.01*	HR <sub>Enf</sub> (see 7.2.4.2)
Bovine, Sheep, Goat, Equine fat	0.02	EU MRL	0.01*	HR <sub>Enf</sub> (see 7.2.4.2)
Bovine, Sheep, Goat, Equine liver	1	EU MRL 0.5 x PF (2)	0.084	HR <sub>Enf</sub> x PF (2) (see 7.2.4.2)
Bovine, Sheep, Goat, Equine kidney	4.5	EU MRL 0.5 x PF (9)	0.108	HR <sub>Enf</sub> x PF (9) (see 7.2.4.2)
Poultry, muscle, fat	0.01*	EU MRL	0.01*(1)	See 7.2.4.2
Poultry, liver, kidney	0.1	EU MRL	0.01*(1)	See 7.2.4.2
Milk	0.01*	EU MRL	0.005*	HR <sub>Enf</sub> (see 7.2.4.2)
Eggs	0.01*	EU MRL	0.01*	EU MRL
Honey	0.05*	EU MRL	0.003*	HR <sub>Enf</sub> (see 7.2.7.1)
All other commodities	EU MRLs	EU MRLs (Reg. (EU) 2019/552) x CF (EFSA, 2014)	Acute risk assessment performed only for intended uses	

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

(1) Based on the metabolism study, no residues above the LOQ are expected in poultry matrices at the calculated dietary burden (EFSA, 2014)

## TDMs

In the framework of the Peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data (EFSA, 2018), the chronic risk assessment was calculated by the UK (2018) considering available data on TDMs.

The input values used in the EU calculation were compared to the residue levels found in the trials supporting the intended uses of CA3642 (see Table 0-15). Except TA in oilseed rape seed for which the STMR from trials is 1.2 mg/kg instead of 1.039 mg/kg presented in EU confirmatory data, all EU inputs cover the residue levels found in the provided trials.

A new calculation was therefore performed for the chronic risk assessment for TA only, using STMR values presented in the table below.

For T, TAA and TLA, it is proposed to refer to the results from the EU chronic risk calculation (UK, 2018).

A summary of the STMR input values used in the consumer intake assessments performed by the UK and in the present dossier is presented in the table below.

**Table 0-26: Input values for the chronic risk assessment – TDMs (UK, 2018 and uses under consideration)**

Crop group	Residue (mg/kg)			
	1,2,4-T <sup>(1)</sup>	TA	TAA <sup>(1)</sup>	TLA <sup>(1)</sup>
<b>Plants</b>				
	<b>STMR</b>	<b>STMR</b>	<b>STMR</b>	<b>STMR</b>
Citrus fruit	0.05	0.32	0.05	0.04
Pome fruit	0.01	0.039	0.03	0.03
Stone fruit	0.01	0.32	0.02	0.038
Berries	0.01	0.06	0.05	0.04
Banana	0.05	0.05	0.05	n.a
Root & tuber vegetables	0.01	0.184	0.01	0.021
Bulb vegetables	0.01	0.06	0.01	0.01
Fruiting vegetables	0.01	0.21	0.01	0.03
Brassica vegetables	0.039	0.17	0.01	0.01
Leafy vegetables	0.015	0.047	0.023	0.08
Legume vegetables	0.01	0.09	0.01	0.01
Stem vegetables	0.01	0.09	0.02	0.01
Pulses	0.05	0.17	0.05	0.01
<b>Oilseeds</b>	0.05	1.039 <sup>(1)</sup> / 1.2 <sup>(2)</sup>	0.12	0.065
<b>Oilfruits</b>	0.05	1.039 <sup>(1)</sup> / 1.2 <sup>(2)</sup>	0.12	0.065
<b>Cereals</b>	0.05	0.621	0.79	0.022
Sugar plants	0.05	0.05	0.05	0.01
<b>Animals</b>				
Ruminant meat	0.27	0.46	0.04	0.04
Ruminant fat	0.18	0.22	0.05	0.07
Ruminant liver	0.31	1.01	0.05	0.04
Ruminant kidney	0.32	0.49	0.15	0.09
Ruminant milk	0.3	0.04	0.04	0.04
Sheep meat	0.29	0.51	0.04	0.04
Sheep fat	0.19	0.23	0.06	0.07
Sheep liver	0.34	1.13	0.05	0.04
Sheep kidney	0.34	0.55	0.18	0.09
Sheep milk	0.32	0.04	0.04	0.04
Swine meat	0.13	0.21	0.04	0.04
Swine fat	0.1	0.09	0.04	0.07
Swine liver	0.13	0.5	0.04	0.04
Swine kidney	0.14	0.22	0.11	0.05
Poultry meat	0.04	0.11	0.04	0.04
Poultry fat	0.04	0.1	0.04	0.04
Poultry liver/kidney	0.04	0.27	0.05	0.04
Poultry Eggs	0.04	0.06	0.04	0.04
Honey	-	0.033 <sup>(3)</sup>	-	-

n.a not analysed

- (1) Input values from TDM confirmatory data (UK, 2018)
- (2) For TA, results calculated in the present dossier by using the same input values than UK 2018, except for oilseed rape seeds where an STMR of 1.2 mg/kg was used (instead of 1.039 initially). This value was extrapolated to the whole group of oilseeds and oilfruits, as made by the UK.
- (3) Results from honey trials was considered in the new chronic risk assessment for TA. The HR value was used as input since no STMR can be calculated based on 2 trials per zone.

As none of the TDMs were found to concentrate in fat then the residue levels for meat can be taken as the residue levels found in muscle.

For pulses, oilseeds, cereals and milk for the acute risk assessment the STMR has been used given these commodities are bulked and the uses of the triazole pesticides are pre-harvest uses.

The acute consumer risk assessment was performed considering the trials supporting CA3642 uses only.

**Table 0-27: Input values for the acute risk assessment – TDMs (uses under consideration)**

Commodity	Source	Acute risk assessment - Input value (mg/kg)			
		1,2,4-T	TA	TAA	TLA
Barley	STMR (see 7.2.3)	0.01*	0.21	0.062	0.01*

Commodity	Source	Acute risk assessment - Input value (mg/kg)			
		1,2,4-T	TA	TAA	TLA
Oat	Extrapolation from barley	0.01*	0.21	0.062	0.01*
Wheat	STMR (see 7.2.3)	0.01*	0.62	0.225	0.01*
Rye	Extrapolation from wheat	0.01*	0.62	0.225	0.01*
Rapeseed	STMR (see 7.2.3)	0.003*	<del>1.3</del> 1.2	0.01	0.05
Linseed, Poppy, Mustard	Extrapolation from rapeseed	0.003*	<del>1.3</del> 1.2	0.01	0.05
Gold of pleasure	Extrapolation from rapeseed	0.003*	<del>1.3</del> 1.2	0.01	0.05
Ruminant/Equine meat	HR (UK, 2018)	0.31	0.62	0.04	0.04
Ruminant/Equine fat	HR (UK, 2018)	0.24	0.34	0.08	0.1
Ruminant/Equine liver	HR (UK, 2018)	0.36	1.36	0.05	0.04
Ruminant/Equine kidney	HR (UK, 2018)	0.34	0.58	0.22	0.13
Ruminant/Equine milk	HR (UK, 2018)	0.35	0.04	0.04	0.04
Sheep/Goat meat	HR (UK, 2018)	0.33	0.68	0.04	0.04
Sheep/Goat fat	HR (UK, 2018)	0.26	0.38	0.08	0.11
Sheep/Goat liver	HR (UK, 2018)	0.39	1.80	0.05	0.04
Sheep/Goat kidney	HR (UK, 2018)	0.37	0.65	0.25	0.13
Sheep/Goat milk	HR (UK, 2018)	0.37	0.04	0.04	0.04
Swine meat	HR (UK, 2018)	0.17	0.27	0.04	0.04
Swine fat	HR (UK, 2018)	0.13	0.14	0.05	0.08
Swine liver	HR (UK, 2018)	0.17	0.61	0.05	0.04
Swine kidney	HR (UK, 2018)	0.20	0.27	0.14	0.08
Poultry meat	HR (UK, 2018)	0.04	0.12	0.04	0.04
Poultry fat	HR (UK, 2018)	0.04	0.11	0.04	0.04
Poultry liver/kidney	HR (UK, 2018)	0.04	0.31	0.05	0.04
Poultry Eggs	HR (UK, 2018)	0.04	0.06	0.04	0.04
Honey	HR (see 7.2.7.1)	0.003*	0.033	0.065	0.019

## 7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in A 2.2.

**Table 0-28: Consumer risk assessment**

Prothioconazole-desthio	
TMDI (% ADI) according to EFSA PRIMo	41% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Not triggered
IESTI (% ARfD) according to EFSA PRIMo*	<p>9% Wheat 7% Bovine: Liver 6% Milk: Cattle</p> <p><b>Highest IESTI:</b> Unprocessed commodities: for children: 9% ARfD (wheat) for adults: 5% ARfD (wheat) Processed commodities: for children: 7% ARfD (wheat/milling (flour)) for adults: 4% ARfD (barley/beer)</p>
<b>1,2,4-triazole (1,2,4-T)</b>	

TMDI/IEDI (% ADI) according to EFSA PRIMo	93% (based on NL toddler) (UK, 2018)
IESTI (% ARfD) according to EFSA PRIMo*	<del>43% Milk: Cattle</del> <del>9% Milk: Goat</del> <del>3% Bovine: Liver</del> <b>Highest IESTI:</b> Unprocessed commodities: for children: 43% ARfD (Milk: Cattle) for adults: 13% ARfD (Milk: Cattle) Processed commodities: for children: 0.1% ARfD (wheat/milling (flour)) for adults: 0.1% ARfD (barley/beer)
<b>Triazole alanine (TA)</b>	
TMDI/IEDI (% ADI) according to EFSA PRIMo	6% (based on NL toddler) (UK, 2018) 6% (based on NL toddler) (present assessment)
IESTI (% ARfD) according to EFSA PRIMo*	<del>4% Bovine: liver</del> <del>3% Wheat</del> <del>2% Milk: Cattle</del> <b>Highest IESTI:</b> Unprocessed commodities: for children: 4% ARfD (Bovine: Liver) for adults: 2% ARfD (Bovine: Liver) Processed commodities: for children: 2% ARfD (wheat/milling (flour)) for adults: 0.9% ARfD (wheat/bead/pizza)
<b>Triazole acetic acid (TAA)</b>	
TMDI/IEDI (% ADI) according to EFSA PRIMo	1% (based on NL toddler) (UK, 2018)
IESTI (% ARfD) according to EFSA PRIMo*	<del>0.5% Milk: Cattle</del> <del>0.3% Wheat</del> <del>0.1% Rye</del> <b>Highest IESTI:</b> Unprocessed commodities: for children: 0.5% ARfD (Milk: Cattle) for adults: 0.2% ARfD (Wheat) Processed commodities: for children: 0.3% ARfD (wheat/milling (flour)) for adults: 0.1% ARfD (wheat/bead/pizza)
<b>Triazole lactic acid (TLA)</b>	
TMDI/IEDI (% ADI) according to EFSA PRIMo	1% (based on NL toddler) (UK, 2018)
IESTI (% ARfD) according to EFSA PRIMo*	<del>2% Milk: Cattle</del> <del>0.3% Milk: Goat</del> <del>0.2% Poultry: Muscle/meat</del> <b>Highest IESTI:</b> Unprocessed commodities: for children: 2% ARfD (Milk: Cattle) for adults: 0.5% ARfD (Milk: Cattle) Processed commodities: for children: 0.0% ARfD (wheat/milling (flour)) for adults: 0.0% ARfD (Barley/beer)

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

The proposed uses of prothioconazole in the formulation CA3642 do not represent unacceptable acute and chronic risks for the consumer.

<p><b>Evaluator comment:</b>  Calculations presented by the Applicant are acceptable and sufficient.  <u>Prothioconazole</u>  The calculation of the TMDI using EFSA model (version 3.1) and MRLs values according to the Regulation (EU) <del>2019/552</del> <b>2024/1318</b> and appropriate conversion factors for enforcement to risk assessment led to a utilisation of the ADI of 41% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is wheat with 8% of the ADI. The intended uses will not result in a consumer chronic exposure</p>
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exceeding the ADI for prothioconazole-desthio.

An acute consumer risk assessment was performed based on the highest residue values (HR) of barley, oat, wheat, rye, triticale, oilseed rape, mustard, linseed, poppy, gold of pleasure and animals commodities. The highest International Estimated Short-Term Intake (IESTI) is at 9% and 5% of the ARfD for the consumption of wheat by children and by adults respectively.

#### TDMs

The dietary risk assessment was calculated using PRIMo rev 3.1 for each TDM. Toxicological reference values and input values from EFSA conclusion on confirmatory data on TDMs (EFSA, 2018) and for TA only, STMR value for oilseed rape were taken into account.

The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of prothioconazole residues and TDMs are unlikely to present a public health concern.

The intended uses of CA3642 / Joust Pro are accepted.

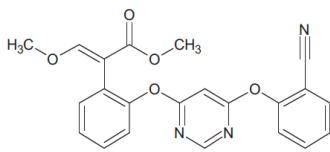
### 7.3 Azoxystrobin

According to SANTE/11509/2013– rev. 5.2 and since the active substance azoxystrobin is not yet renewed (AIR4), the “old data requirements” (Reg. (EU) No 544/2011) and the endpoints from the previous monograph of azoxystrobin (DAR, 2009) apply to the current assessment. Studies from the DAR are not protected anymore.

For your information, the applicant Nufarm has a letter of co-ownership by the Azoxystrobin Task Force which authorizes Nufarm to access to the studies submitted during the AIR4 renewal of azoxystrobin (process currently ongoing).

General data on azoxystrobin are summarized in the table below (last updated 2022/11/22).

**Table 7.3-1: General information on azoxystrobin**

Active substance (ISO Common Name)	Azoxystrobin
IUPAC	Methyl ( <i>E</i> )-2-{2[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate
Chemical structure	
Molecular formula	C <sub>22</sub> H <sub>17</sub> N <sub>3</sub> O <sub>5</sub>
Molar mass	403.4
Chemical group	Strobilurin
Mode of action (if available)	Inhibition of electron transport, consequently inhibiting fungal respiration.
Systemic	Yes
Companies	Adama (formerly Mahkteshim Agan)* Syngenta*
Rapporteur Member State (RMS)	Austria (Initially United Kingdom)
Approval status	Approved Regulation (EU) 2011/703 Regulation (EU) 2019/291 (extension of approval)
Restriction	Use as fungicide only
Review Report	SANCO/11027/2011 Rev 3 (17 June 2011)
Current MRL regulation	<del>Reg. (EU) 2022/476</del> <del>Reg. (EU) 2022/4363 (not yet applicable)</del> <del>COMMISSION REGULATION (EU) 2023/129 of 18 January 2023 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, prosulfocarb, sedaxane and valifenalate in or on certain products (not yet applicable)</del> COMMISSION REGULATION (EU) 2024/1078 of 15 April 2024 amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, flonicamid, isofetamid, mefentrifluconazole, metazachlor, pyrimethanil and quartz sand in or on certain products
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal: Conclusion on the peer review	Yes (EFSA, 2010)
EFSA Journal: conclusion on article 12	Yes (EFSA, 2013)

Current MRL applications on intended uses	EFSA-Q-2021-00039 (Greece) Rapeseeds and linseeds Status: Reasoned opinion available (EFSA Journal 2022;20(1):7051) – New MRL of 0.7 mg/kg for rapeseed (not yet voted or adopted)
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\* Notifier in the EU process to whom the a.s. belongs

### 7.3.1 Stability of Residues (KCA 6.1)

#### 7.3.1.1 Stability of residues during storage of samples

##### Available data

No new data submitted in the framework of this application.

**Table 7.3-2: Summary of stability data achieved at  $\leq -18^{\circ}\text{C}$  (unless stated otherwise)**

Table 7.3-2. Summary of stability data achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)			
Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products – Azoxystrobin and R230310 (z-isomer), separately			
Cereal grain	Dry/High starch content	2 years	EFSA, 2010, 2013 UK, 2009a
Cereal straw	No group	2 years	
Oilseed rape	High lipid content	2 years	
Soybean meal		2 years	
Pecans, nutmeat		2 years	
Peanut, nutmeat		2 years	
Peanut, oil		2 years	
Grapes	High acid content	2 years	
Orange		2 years	
Apples	High water content	2 years	
Banana		2 years	
Peach		2 years	
Tomatoes		2 years	
Cucumber		2 years	
Lettuce		2 years	
Carrot root		2 years	
Animal Products – Azoxystrobin and R230310 (z-isomer), separately			
Ruminant, Poultry	Muscle, fat, liver, kidney	10 months	EFSA, 2010, 2013 UK, 2009a
Ruminant	Milk	10 months	
Poultry	Eggs	10 months	
Honey	No group	81 days	AIR4 M-CA S6, Dec. 2021 (access from Task Force) Appeltauer, A., 2022 (Report No S21-01128)

##### Conclusion on stability of residues during storage

The storage stability of azoxystrobin and its Z-isomer R230310 was evaluated under the peer review of Directive 91/414/EEC (United Kingdom, 2009). Both compounds were shown to be stable up to 2 years in cereals and oilseeds commodities, and up to 10 months in livestock commodities.

For azoxystrobin, the provided studies on magnitude of residues are sufficiently supported by available



storage stability data.

To support the magnitude of residues in honey studies, which are considered as additional data<sup>11</sup>, the storage stability of azoxystrobin and its isomer in honey is currently being assessed in the framework of azoxystrobin AIR4 renewal. The report is now available, and results show that azoxystrobin and its isomer are stable up to 81 days in honey.

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

In available studies on magnitude of residues, batch recoveries were carried out in parallel and stored in the same conditions as the analytical batches. Acceptable recoveries were achieved, indicating acceptable stability of residue in extracts.

#### zRMS comments:

In EFSA Journal 2013;11(12):3497 it is stated that *The potential degradation of residues during storage of the residue trials samples was also assessed. In the framework of the peer review, storage stability of azoxystrobin was demonstrated for a period of 24 months at -18°C in commodities with high water content (banana, peach, tomato, cucumber, lettuce, carrot), high acid content (grape, apple, orange), high oil content (soybean meal, oilseed rape, pecans, peanut), dry commodities (cereal grain) as well as cereal straw (United Kingdom, 2009a).*

*(...) The storage stability of azoxystrobin residues in animal products was evaluated under the peer review of Directive 91/414/EEC (United Kingdom, 2009a). Studies demonstrated storage stability of azoxystrobin in milk, muscle, fat, liver and kidney, eggs for up to 10 months when stored deep frozen.*

Additionally the Applicant submitted the study on storage stability of azoxystrobin in honey (Appeltauer, 2022; Report S21-01128, access from Task Force). It should be noted that this study was reviewed and accepted by zRMS-PL in RR, Part B7 for PPP of Orondis Evo in June 2023.

Azoxystrobin and R230310 have been shown to be stable in honey for at least 81 days when stored frozen at -18°C.

The residue data are valid with regard to storage stability.

No additional data are required.

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

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

#### Available data

No new data submitted in the framework of this application.

**Table 7.3-3: Summary of plant metabolism studies**

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G <sup>(a)</sup>	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Grapes	<sup>14</sup> C-pyrimidinyl <sup>14</sup> C-cyanophenyl <sup>14</sup> C-phenylacrylate (b)	Foliar, F	0.25+ 1+ 1+ 0.25	4	21	-	EFSA, 2010, 2013 UK, 2009a
Pulses and oilseeds	Peanuts		Foliar, F	0.85+ 0.85+ 0.3	3	10	-	
Cereals	Winter		Foliar, F	0.5	2	Forage: 13	Forage: 13	

<sup>11</sup> Azoxystrobin is currently authorized based on the old data requirements, for which no residue study on honey was required in the DAR 2009. Consequently, the assessment of the present application is based on the same data requirements as for the active substance 2009 re-approval since azoxystrobin is not AIR4 renewed yet. This will avoid any distortion of competition in favour of the previous Art.33 dossiers for which no data on honey was required. Therefore, in the present application, information on honey is considered as informative only.

	wheat					Grain & straw: 61-62	Grain & straw: 61-62	
		<sup>14</sup> C-pyrimidinyl	Foliar, F	n.r.	1	28	Application at BBCH 71	

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

(b): A study with each label was performed for each crop, separately

n.r.: not reported

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

*EFSA Journal 2013;11(12):3497*

“The metabolism pattern was similar in all plant groups, parent azoxystrobin being the major compound, accounting for 17-43 % TRR in cereal grain and straw, 35-65 % TRR in grapes, and 14-48 % TRR in peanut hulls and hay. Azoxystrobin was not detected in peanut nuts, where radioactivity was found to be mainly incorporated in fatty acids (up to 49 % TRR), but no individual metabolite was present in peanut kernels at a level greater than 1 %. In the other crops, the major metabolites identified were M28, resulting from the cleavage of the ester link between the phenylacrylate and pyrimidyl ring, and metabolite M09 (Z-isomer of azoxystrobin), both mostly below 10 % TRR. Other metabolites were identified but they were all present in very small amounts (EFSA, 2010).

Consequently, the residue for enforcement and risk assessment in all plant commodities following foliar application is defined as azoxystrobin only.”

### Conclusion on metabolism in primary crops

The metabolism of azoxystrobin in plants is considered sufficiently addressed. The metabolism pattern was similar in all plant groups, with parent azoxystrobin being the major compound.

#### **zRMS comments:**

According to the OECD 501 a metabolism in crops study should be submitted for each type of crop group for which use is proposed. In order to extrapolate metabolism of a pesticide to all crop groupings, metabolism studies on a minimum of three representative crops (from the five different crop categories) should be conducted. If the results of these three studies indicate a comparable metabolic route, then additional studies will not be needed.

In EFSA Journal 2022;20(1):7051 it is stated that *The metabolism of azoxystrobin following foliar applications was investigated in crops belonging to the groups of fruit crops (grapes), cereals/grass (wheat) and pulses/oilseeds (peanuts). The metabolism pattern was similar in all plant groups with the parent azoxystrobin being the major compound, accounting for 17–43% total radioactive residue (TRR) in cereal grain and straw, 35–65% TRR in grapes and 14–48% TRR in peanut hulls and hay.*

*Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies and the capabilities of enforcement analytical methods, the residue definition for enforcement and risk assessment in all plant commodities following foliar application was proposed as ‘azoxystrobin’ (EFSA, 2010, 2013). The same residue definition is applicable to rotational crops and processed products. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition.*

For the intended uses, the metabolic behaviour in primary crops is sufficiently addressed.  
No additional data are required.

### 7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

All crops under consideration can be grown in a crop rotation.

According to the soil degradation studies evaluated in the framework of the EU peer review, DT<sub>50</sub> values of azoxystrobin range around 262 days. Thus, DT<sub>90</sub> value is expected to be higher than the trigger value of 100 days (EFSA, 2010).

#### **Available data**

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G <sup>(a)</sup>	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	<sup>14</sup> C-pyrimidinyl	Application on bare soil, G	2.2	30 200 365	At maturity	-	EFSA, 2010, 2013 UK, 2009a
Root and tuber vegetables	Radish	<sup>14</sup> C-cyanophenyl						
		<sup>14</sup> C-phenylacrylate <sup>(b)</sup>						
Cereals	Wheat							

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

(b): A study with each label was performed for each crop, separately

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

EFSA Journal 2013;11(12):3497

“The metabolism of azoxystrobin in rotational crops – radish, lettuce, and wheat – has been evaluated (United Kingdom, 2009a). The TRR in soil declined on average from 0.74–1.0 mg/kg at treatment to 0.79, 0.67 and 0.24 mg/kg at 30, 200, and 365 days after treatment, respectively. The metabolism of azoxystrobin in rotational crops was complex with a large number of conjugated metabolites formed. The residues declined significantly at longer plant back intervals. Radioactive residues in the 365-day crops were generally in concentrations below 0.01 mg/kg. As in the primary crops, parent azoxystrobin represented the major residue detected in all rotational crops (up to 17–44% TRR); with very low residue levels in the tested crops (< 0.01–0.08 mg/kg at 30 days and < 0.01–0.01 mg/kg at 200 days). In wheat forage and wheat straw at 30 days, TRRs were 0.15–0.34 and 1.4–1.9 mg/kg, respectively, which declined significantly at the longer plant back intervals of 200 days (0.02–0.05 and 0.06– 0.12 mg/kg, respectively) and 365 days (< 0.01 mg/kg). Azoxystrobin residues in wheat grain were < 0.01 mg/kg even in wheat planted 30 days after the treatment. Compounds G219, M4220, N121, N222, O223 and O324, which are the principal metabolites in rotated crops, are glucose conjugates and were also found in the primary crops in both free and conjugated forms. These metabolites are not more toxicologically significant than parent (United Kingdom, 2009a).

The peer-review concluded that the metabolism of azoxystrobin in succeeding crops is almost similar for all the analysed crops and also similar to that observed in the primary crops. The relevant residue in rotational crops should therefore be defined as parent azoxystrobin”.

### Conclusion on metabolism in rotational crops

The metabolism of azoxystrobin in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not necessary.

Since the intended cGAPs are covered by the authorized European GAPs (EFSA RO, 2013), it can be concluded that azoxystrobin residue levels in food and feed rotational commodities are expected to be covered by the residue levels in primary crops.

#### **zRMS comments:**

In accordance with the soil degradation studies evaluated in the framework of the peer review, the DT<sub>50</sub> value of azoxystrobin is 262 days (EFSA, 2010). DT<sub>90</sub> value is expected to be higher than the trigger value of 100 days (EFSA, 2010), and therefore, studies investigating the nature of residues in rotational crops are required.

In EFSA Journal 2016;14(5):4459 it is stated that *The nature and magnitude of azoxystrobin residues in rotational crops were investigated during the peer review. On the basis of studies conducted in lettuce, radish and wheat at a maximum dose rate of 2,200 g/ha, it was concluded that the metabolism of azoxystrobin is similar to that of the primary crops and that residues above 0.05 mg/kg are not expected in the rotational crops (EFSA, 2013).*

The peer-review concluded that the metabolism of azoxystrobin in succeeding crops is almost similar for all the analysed crops and also similar to that observed in the primary crops. The relevant residue in rotational crops should therefore be defined as parent azoxystrobin.

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

#### Available data

No new data submitted in the framework of this application.

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

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
<b>EU data</b>		
<b>Pasteurisation</b> (20 minutes, 90°C, pH 4)	Azoxystrobin (99.7-102.1%)	United Kingdom, 2009a EFSA, 2013
<b>Baking, boiling, brewing</b> (60 minutes, 100°C, pH 5)	Azoxystrobin (95.5-96.8%)	United Kingdom, 2009a EFSA, 2013
<b>Sterilisation</b> (20 minutes, 120°C, pH 6)	Azoxystrobin (95.9-98.6%)	United Kingdom, 2009a EFSA, 2013

#### Summary of studies reported in the EU

*EFSA Journal 2013;11(12):3497*

“The effect of processing on the nature of azoxystrobin was investigated in the framework of the EU peer review. Studies were conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). From these studies, it was concluded that processing by pasteurization, baking/brewing/boiling and sterilization is not expected to have a significant impact on the composition of residues in matrices of plant origin (United Kingdom, 2009a). The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops”.

#### Conclusion on nature of residues in processed commodities

No significant degradation of azoxystrobin was observed following standard incubations at different pH and temperatures. The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops.

#### zRMS comments:

Standard hydrolysis studies simulating the effect on the nature of azoxystrobin residues under processing conditions representative of pasteurisation, boiling and sterilisation were assessed in the peer review and it was concluded that the compound is hydrolytically stable (EFSA, 2010). Thus, for processed commodities, the same residue definition as for raw agricultural commodities is applicable.

Studies to assess the magnitude of azoxystrobin residues during processing have been assessed in the framework of the peer review and the Article 12 MRL review and processing factors were derived for several crops (EFSA, 2010, 2013).

No further data are required to support the proposed uses.

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

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

<b>Endpoints</b>	
Plant groups covered	Cereals (Wheat) Fruit crops (Grapes) Pulses and oilseeds (Peanut)
Rotational crops covered	Cereals (Wheat) Root and tuber vegetables (Radish) Leafy crops (Lettuce)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes

Processed commodities	Azoxystrobin (no significant degradation observed under standard hydrolysis conditions)
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Azoxystrobin (EFSA, 2010, EFSA, 2013 and Reg. (EU) <del>2019/552</del> <del>Reg. (EU) 2023/129</del> Reg. (EU) 2024/1078)
Plant residue definition for risk assessment	Azoxystrobin (EFSA, 2010, EFSA, 2013)
Conversion factor from enforcement to RA	None (EFSA, 2010, EFSA, 2013)

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

#### Available data

No new data submitted in the framework of this application.

**Table 7.3-7: Summary of animal metabolism studies**

Table 7.5-1: Summary of animal metabolism studies								
Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	<sup>14</sup> C-pyrimidinyl- or <sup>14</sup> C-cyanophenyl- or <sup>14</sup> C-phenylacrylate	n.r.	23.2-32.7	7	Milk	Twice daily	EFSA, 2010, 2013 UK, 2009a
						Urine and faeces	Daily	
						Tissues	After sacrifice	
		<sup>14</sup> C-cyanophenyl	1	25	7	Milk	Twice daily	
						Urine and faeces	Daily	
						Tissues	After sacrifice	
Laying poultry	Hens	<sup>14</sup> C-pyrimidinyl- or <sup>14</sup> C-cyanophenyl- or <sup>14</sup> C-phenylacrylate	n.r.	11	10	Eggs	Daily	
						Excreta	Daily	
						Tissues	After sacrifice	
			10	12.5	10	Eggs	n.r.	
						Excreta	Daily	
						Tissues	After sacrifice	

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

*EFSA Journal 2013;11(12):3497*

The nature of azoxystrobin residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (United Kingdom, 2009a).

Lactating goats were dosed with approximately 25 mg/kg in the diet of azoxystrobin, corresponding to approximately 1.2 times the exposure of meat ruminant. Laying hens were dosed with 11 - 12.5 mg/kg in the diet of azoxystrobin, corresponding to approximately 7 - 8 times the exposure of poultry. All studies showed that azoxystrobin was rapidly excreted in both lactating goats and laying hens. The transfer in

tissues was limited, the TRRs in muscle, fat, milk and egg white being <0.02 mg/kg. Thus, characterisation of residues was only performed in goat liver and kidney, and in poultry liver and egg yolk, where the TRRs were in the range of 0.05 to 1.19 mg/kg. In these matrices, the metabolism was shown to be very extensive, more than 20 compounds being identified/characterised, each accounting mostly for less than 5 % of the TRR. Some metabolites (M28, M2025, L426...) were however observed in higher proportions in some matrices, depending on the <sup>14</sup>C-label. The parent compound was less than 2 % of the TRR, except in egg yolk (12 % TRR for the cyanophenyl label). The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs.

As none of these compounds were considered as a sufficient marker for the residue in animal matrices, the residue for enforcement was then defined by default as azoxystrobin only. Validated analytical methods for enforcement of the proposed residue definition are available (see also section 1.2). However, no conclusion could be drawn on the toxicological profile of metabolites L127, L4 and L928 (EFSA, 2010). Additional data on the toxicological relevance of metabolites L1, L4 and L9 are therefore required. Meanwhile, it is proposed, on a tentative basis, to also define the residue for risk assessment as azoxystrobin only.

The conclusions reached by EFSA reflect the views of the RMS and are also in line with those of the JMPR (FAO, 2008). In the framework of the peer review, the proposed residue was not considered to be fat soluble based on the fact that the log Po/w of azoxystrobin is lower than 3".

EFSA Journal 2020;18(8):6231 - Evaluation of confirmatory data following the Article 12

"The previously derived residue definition for monitoring is still applicable (see Appendix B.2.1). The RMS proposed to confirm the residue definition for risk assessment in animal commodities which was tentatively set as azoxystrobin, pending information on the toxicological profile of metabolites L1, L4 and L9. This is discussed in Section 5".

"Regarding the toxicological assessment of livestock metabolites L1, L4 and L9, the submitted data allowed to conclude that the genotoxic potential of these three compounds can be ruled out. However, data addressing the general toxicity of these compounds were not provided. Based on calculations to demonstrate that the expected dietary exposure of consumers to these metabolites was lower than the TTC, the RMS concluded that further data addressing the general toxicity of these compounds were not needed and thus proposed to confirm the residue definition for risk assessment in animal commodities as azoxystrobin alone. EFSA highlighted that the TTC approach cannot be applied in this context. EFSA concludes that the data gap identified in the framework of the MRL review was only partially addressed. Further risk management considerations should be given to decide whether the argument of the low exposure calculated for metabolites L1, L4, L9 and K1 (conjugate of L1) is acceptable to waive the need to submit data on the general toxicity of L1, L4 and L9. Meanwhile, the residue definition for risk assessment in animal commodities is still deemed tentative".

### **Conclusion on metabolism in livestock**

The metabolism of azoxystrobin in animals is considered sufficiently addressed. All studies showed that azoxystrobin was rapidly excreted in both lactating goats and laying hens. The metabolism pattern was similar in ruminants and rodents and can therefore be extrapolated to pigs. The residue definition for livestock was set as azoxystrobin only for the monitoring (default) and also for the risk assessment (tentative).

According to SANTE/11509/2013– rev. 5.2 and since the active substance azoxystrobin is not yet renewed (AIR4), the "old data requirements" (Reg. (EU) No 544/2011) and the endpoints from the previous monograph of azoxystrobin (DAR, 2009) apply to the current assessment. Therefore, no residue data on fish are required.

#### **zRMS comments:**

Information given by the Applicant is sufficient.

In EFSA Journal 2010; 8(4):1542 it is stated that *Azoxystrobin was rapidly excreted in the metabolism studies performed on goats (2N dose) and poultry (8N dose). The transfer in tissues was limited, the TRRs in muscle, fat, milk and egg white being <0.02 mg/kg. Thus, characterisation of residues was only performed in goat liver and kidney, and in poultry liver and egg yolk, where the TRRs were in the range of 0.05 to 1.19 mg/kg. In these matrices,*

*the metabolism was shown to be very extensive, more than 20 compounds being identified/characterised, each accounting mostly for less than 5% of the TRR. Some metabolites (M28, M20, L4...) were however observed in higher proportions in some matrices, depending on the <sup>14</sup>C-label. The parent compound was less than 2% of the TRR, except in egg yolk (12% TRR for the cyanophenyl label). None of these compounds were considered as a sufficient marker for the residue in animal matrices, and **the residue for monitoring and risk assessment was then defined by default as azoxystrobin only**. However, the definition for risk assessment has to be considered provisional, pending additional information on the toxicological relevance of metabolites L1, L4 and L9.*

The data on *the toxicological relevance of metabolites L1, L4 and L9* provided in the present application are from the EFSA Journal 2020;18(8):6231 – “Evaluation of confirmatory data following the Article 12 and modification of the existing MRLs for azoxystrobin”. As confirmatory data, they are out of data protection.

According to the EFSA Journal 2020;18(8):6231 – “Evaluation of confirmatory data following the Article 12 and modification of the existing MRLs for azoxystrobin” *In the framework of the MRL review, EFSA identified data gaps related to the toxicological relevance of metabolites L1, L4 and L9, which were identified in ruminant liver and kidney (data gap number 35). In order to address this data gap, the applicant provided, in the framework of the current assessment, information that allowed to conclude that the genotoxic potential of these three compounds can be ruled out (see Section 1). However, the applicant did not provide data on the general toxicity of these metabolites. Instead, calculations were provided to demonstrate that the expected dietary exposure of consumers to these metabolites (from the intake of liver and kidney) is low and would therefore not be of toxicological concern. (...) Regarding the toxicological assessment of livestock metabolites L1, L4 and L9, the submitted data allowed to conclude that the genotoxic potential of these three compounds can be ruled out. (...) general toxicity of these metabolites was not addressed.*  
As confirmatory data, they are out of data protection.

#### Metabolism studies, methods of analysis and residue definitions in livestock (EFSA, 2020):

Livestock (available studies)	Animal	Dose (mg/kg diet)	Duration (days)	Comment/Source
Laying hen		11	10	Studies performed on goat using <sup>14</sup> C-pyrimidinyl <sup>14</sup> C-cyanophenyl and <sup>14</sup> C-phenylacrylate radiolabels
		12.5	10	
Lactating ruminants		23.2-32.7	7	Study performed on goat using <sup>14</sup> C-pyrimidinyl <sup>14</sup> C-cyanophenyl and <sup>14</sup> C-phenylacrylate radiolabels
		25	7	

Time needed to in milk and eggs (days)	Milk: not relevant	TRR in milk is ranging between 0.004–0.01 mg eq/L
	Eggs: 6–8	Observed in egg yolk (United Kingdom, 2009)
Metabolism in rat and ruminant similar	Yes	The general metabolic pathways in rodents and ruminants were found to be comparable
Can a general residue definition be proposed for animals?	Yes	–
Animal residue definition for monitoring (RD-Mo)	Azoxystrobin	
Animal residue definition for risk assessment (RD-RA)	Azoxystrobin (tentative, EFSA, 2010, 2013) [genotoxicity of metabolites L1, L4 and L9 can be ruled out but general toxicity of these metabolites was not addressed]	
Fat soluble residues	No	Log P <sub>o/w</sub> < 3
	GC-NPD (United Kingdom, 2009): Milk: LOQ 0.001 mg/kg. Eggs, Muscle, Fat, Liver/kidney: 0.01 mg/kg ILV available but confirmatory method missing.  HPLC-MS/MS (validated method in FAO, 2008): LOQ: 0.01 mg/kg in all tissues, milk and eggs	

TRR: total radioactive residue; P<sub>o/w</sub>: partition coefficient between n-octanol and water; GC-NPD: gas chromatography with nitrogen phosphorus detector; HPLC-MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

The log P<sub>o/w</sub> value for azoxystrobin is 2.5 (at 20°C) which is consistent with no accumulation potential in fish tissues. As the log P<sub>o/w</sub> of all components of the plant Residue Definition for Risk Assessment does not exceed 3, **metabolism studies in fish are not required.**

No further data are required to support the proposed uses.

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

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

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	In milk and eggs, a plateau level was never reached and no residues at or above 0.01 mg/kg was found in any of the samples (EFSA, 2013)
Animal residue definition for monitoring	Azoxystrobin (EFSA, 2010, EFSA, 2013, 2020 and Reg. (EU) 2019/552 Reg. (EU) 2023/129 Reg. (EU) 2024/1078)
Animal residue definition for risk assessment	Azoxystrobin – tentative (EFSA, 2010, EFSA, 2013) [genotoxicity of metabolites L1, L4 and L9 can be ruled out but general toxicity of these metabolites was not addressed] (EFSA, 2020)
Conversion factor	None (EFSA, 2010, EFSA, 2013, 2020)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No (log P <sub>OW</sub> = 2.5 at 20°C without pH dependence)

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

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. Additional new study was finalised in March 2024: “Determination of residues of Azoxystrobin after a single application of CA2702 in Oilseed rape (outdoor) at 4 sites in Northern Europe 2023” (KCA 6.3.3/07 – Study S23-100807). Data are added in the following table.

It should be noted that:

- Only trials performed in the northern residue zone are presented.
- The selection of supporting data was made based on the BBCH growth stage at last application as according to SANTE/2019/12752 “In some cases (e.g. cereals, oilseeds), the crop growth stage at application is more important to consider for the selection of GAP-compliant trials while PHI (if specified in the GAP) may be of secondary relevance”.



**Table 7.3-9: Summary of EU reported and new data supporting the intended uses of CA3642 and conformity to existing MRL**

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = RA = Azoxystrobin	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (Rounded) (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Barley → Oat Grain	EFSA, 2010	N-EU (8)	GAP on which EU a.s. assessment is based: 2 x 250 g a.s./ha, BBCH 59, PHI 35d E=RA: <0.01, 0.01, 0.02, 2x 0.04, 0.08, 0.20, 0.43	N/A				
	New trials <i>ChR-10-8230</i> **see remark below	NEU (4)	Trials GAP: 2 x 260 g a.s./ha, BBCH 57-59, PHI 34-40d E=RA: 0.042, 0.058, 0.10, 0.13					
	New trials <i>JCB-11-10126</i>	NEU (4)	Trials GAP: 2 x 250 g a.s./ha, BBCH 59, PHI 45-71d E=RA: <0.01, 0.011, 0.015, 0.016					
	Overall supporting data for cGAP	NEU (16)	<b>Intended cGAP: 2 x 150 g a.s./ha, BBCH 30-61, PHI 35d</b> E=RA: <0.01, <0.01, 0.01, 0.011, 0.015, 0.016, 0.02, 0.04, 0.04, 0.042, 0.058, 0.08, 0.10, 0.13, 0.20, 0.43 <sup>outlier</sup>	0.04	0.43	0.509 (0.5)	1.5	Yes
Barley → Oat Straw	EFSA, 2010	N-EU (8)	GAP on which EU a.s. assessment is based: 2 x 250 g a.s./ha, BBCH 59, PHI 35d E=RA: 0.11, 0.39, 0.48, 0.91, 1.3, 1.5, 2.7, 5.1	N/A				
	New trials <i>ChR-10-8230</i> **see remark below	NEU (4)	Trials GAP: 2 x 260 g a.s./ha, BBCH 57-59, PHI 34-40d E=RA: 1.72, 2.54, 3.18 <sup>(a)</sup> , 3.64					
	New trials <i>JCB-11-10126</i>	NEU (4)	Trials GAP: 2 x 250 g a.s./ha, BBCH 59, PHI 45-71d E=RA: 0.23, 0.29, 0.93, 1.5					
	Overall supporting data for cGAP	NEU (16)	<b>Intended cGAP: 2 x 150 g a.s./ha, BBCH 30-61, PHI 35d</b> E=RA: 0.11, 0.23, 0.29, 0.39, 0.48, 0.91, 0.93, 1.3, 1.5, 1.5, 1.72, 2.54, 2.7, 3.18 <sup>(a)</sup> , 3.64, 5.1	1.4	5.1	-	-	-
Wheat → Triticale, Rye Grain	EFSA, 2010	N-EU (9)	GAP on which EU a.s. assessment is based: 2 x 250 g a.s./ha, BBCH 69, PHI 35d E=RA: 3x <0.01, 0.01, 2x 0.04, 0.07, 0.09, 0.23	N/A				

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = RA = Azoxystrobin	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (Rounded) (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	New trials <i>ChR-10-8231</i> **see remark below	N-EU (4)	Trials GAP: Trials GAP: 2 x 260 g a.s./ha, BBCH 69, PHI 40-46d E=RA: <0.01, <0.01, 0.01, 0.013					
	New trials <i>JCB-11-10125</i>	N-EU (4)	Trials GAP: Trials GAP: 2 x 250 g a.s./ha, BBCH 69, PHI 36-66d E=RA: <0.01, <0.01, 0.022, 0.028					
	Overall supporting data for cGAP	N-EU (17)	<b>Intended cGAP: 2 x 210 g a.s./ha, BBCH 37-59, PHI 35d</b> E=RA: 7x <0.01, 2x 0.01, 0.013, 0.022, 0.028, 2x 0.04, 0.07, 0.09, 0.23	0.01	0.23	0.257 (0.3)	0.5	Yes
Wheat → Triticale, Rye <u>Straw</u>	EFSA, 2010	N-EU (9)	GAP on which EU a.s. assessment is based: 2 x 250 g a.s./ha, BBCH 69, PHI 35d E=RA: 0.34, 0.58, 0.65, 0.75, 0.82, 1.5, 2x 1.6, 2.0	N/A				
	New trials <i>ChR-10-8231</i> **see remark below	N-EU (4)	Trials GAP: Trials GAP: 2 x 260 g a.s./ha, BBCH 69, PHI 40-46d E=RA: 1.50, 2.02, 2.02, 2.29					
	New trials <i>JCB-11-10125</i>	N-EU (4)	Trials GAP: Trials GAP: 2 x 250 g a.s./ha, BBCH 69, PHI 36-66d E=RA: 0.41, 1.2, 1.7, 10.1					
	Overall supporting data for cGAP	N-EU (17)	<b>Intended cGAP: 2 x 210 g a.s./ha, BBCH 37-59, PHI 35d</b> E=RA: 0.34, 0.41, 0.58, 0.65, 0.75, 0.82, 1.2, 2x 1.5, 2x 1.6, 1.7, 2.0, 2x 2.02, 2.29, 10.1	1.5	10.1	-	-	-
Oilseed rape seeds → Sunflower, Linseed, mustard, poppy, gold of pleasure seeds	New trials <i>GBU-11-10127</i>	N-EU (4)	Trials GAP: 1 x 250 g a.s./ha, BBCH 69, PHI 60-66d E=RA: 4x <0.01	N/A				
	New trials <i>ChR-10-8214</i> **see remark below	N-EU (4)	Trials GAP: 1 x 250 g a.s./ha, BBCH 69, PHI 48-52d E=RA: <0.001, <0.01, 0.032, 0.13					
	New trials (S23-100807)	N-EU (4)	Trials GAP: 1 x 250 g a.s./ha, BBCH 69, PHI 49-60d E=RA: 4x <0.01	-				

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = RA = Azoxystrobin	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (Rounded) (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	Overall supporting data for cGAP	N-EU (8)	<b>Intended cGAP: 1 x 180 g a.s./ha, BBCH 69, PHI 56d</b> E=RA: <0.001, <del>5</del> 9x <0.01, 0.032, 0.13	0.010	0.13	<del>0.197</del> 0.161 (0.2)	Rapeseed: <del>0.5</del> 0.7 <sup>b</sup> , Mustard, Poppy, Gold of pleasure: 0.5 Linseed: 0.4	Yes

\* Source of EU MRL: ~~Reg. (EU) 2022/476. MRLs from Reg. (EU) 2022/1363 and PLAN/2022/1665 are not yet applicable. Please note there is no MRL change for the intended crops, except for rapeseed in PLAN/2022/1665 for which the MRL is proposed to be raised at 0.7 mg/kg. Reg. (EU) 2023/129~~ Reg. (EU) 2024/1078

\*\* According to the SANTE/2019/12752 trials from study **ChR-10-8214**, ChR-10-8230 and ChR-10-8231 are not considered independent. More details - see zRMS comments below and Appendix 2.

(a) Trial ChR-10-8233 PL02 at PBI 2 months (rotational crops) and trial ChR-10-8230 PL04 (primary crops) were performed in similar conditions (location, variety, date, and similar application rate on the primary crop barley). The residue level measured in barley straw is higher in rotational crops (3.18 mg/kg) compared to primary crop (1.93 mg/kg) and was therefore considered.

(b) ~~Commission Regulation (EU) 2023/129 of 18 January 2023 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, prosulfocarb, sedaxane and valifenalate in or on certain products: MRL for oilseed rape seeds is raised to 0.7 mg/kg. Not yet applicable.~~

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

#### **Barley, Oat**

Barley and Oat are major crops in northern regions.

According to SANTE/2019/12752, extrapolation to oat is possible with a minimum of 8 trials on barley, which is the case here.

The last application in the provided trials was performed slightly earlier (BBCH 59) compared to the intended GAP (BBCH 61). However, sufficient trials at the intended PHI of 35 days are available. In addition, all trials are overdosed (2 x 250-260 g a.s./ha instead of 2 x 150 g a.s./ha) and can be considered as a worst-case situation. They show that no MRL exceedance will occur. Therefore, no MRL exceedance will occur when CA3642 is applied according to the proposed GAP.

According to the available data, the intended uses on barley and oat are considered sufficiently supported in the Northern residue zone.

#### **Wheat, Rye, Triticale and Spelt, Einkorn wheat, Emmer Wheat, Triticale**

Wheat and rye are major crops in northern regions. Triticale, spelt, *Einkorn wheat*, *Emmer Wheat* and *Triticale* are ~~minor~~ **major** crops.

According to SANTE/2019/12752, extrapolation to rye, triticale, spelt, *Einkorn wheat*, *Emmer Wheat*, and *Triticale* is possible with a minimum of 8 trials on wheat, which is the case here.

All trials are slightly overdosed (2 x 250-260 g a.s./ha instead of 2 x 210 g a.s./ha) ~~and the last application was performed later (BBCH 69) compared to the intended GAP (BBCH 59)~~. Consequently, these trials can be considered as a worst-case situation. They show that no MRL exceedance will occur. Therefore, no MRL exceedance will occur when CA3642 is applied according to the proposed GAP.

According to the available data, the intended uses on wheat, ~~oat~~, **rye**, triticale and spelt, *Einkorn wheat*, *Emmer Wheat*, and *Triticale* are considered sufficiently supported in the Northern residue zone.

#### **Oilseed rape, Sunflower, Linseed, Poppy, Mustard and Gold of pleasure**

Oilseed rape and Sunflower are a major crop in northern regions. Linseed, poppy, mustard, and gold of pleasure are minor crops.

According to SANTE/2019/12752, extrapolation to sunflower, linseed, poppy, mustard, and gold of pleasure is possible.

All trials are overdosed (1 x 250 g a.s./ha instead of 1 x 180 g a.s./ha) and consequently they can be considered as a worst-case situation. They show that no MRL exceedance will occur. Therefore, no MRL exceedance will occur when CA3642 is applied according to the proposed GAP.

According to the available data, the intended uses on oilseed rape, sunflower, linseed, poppy, mustard, and gold of pleasure are considered sufficiently supported in the Northern residue zone.

#### **zRMS comments:**

Residue Definitions (EFSA 2010, 2013; Reg. (EU) 2024/1078):

Monitoring (Mo): Azoxystrobin

Risk Assessment (RA): Azoxystrobin

#### **Wheat, rye, triticale and spelt, einkorn wheat, emmer wheat, tritordeum**

Wheat and rye are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on wheat can be used for extrapolation to rye, triticale and spelt before and after forming of the edible part. So the uses are also considered acceptable on rye, triticale and spelt, einkorn wheat, emmer wheat, tritordeum.

Sufficient trials on wheat (9 trials) conducted according to the residue definition for monitoring and for risk assessment were previously presented and evaluated (EFSA, 2010). All trials are slightly overdosed (2 x 250 g a.s./ha instead of 2 x 210 g a.s./ha). Consequently, these trials can be considered as a worst-case situation.

Residues of azoxystrobin were: 3x <0.01, 0.01, 2x 0.04, 0.07, 0.09, 0.23 mg/kg.

Two additional magnitude of residue studies were submitted in the framework of this application: studies ChR-10-8231 and JCB-11-10125.

Summary is presented below.

### **1. Study ChR-10-8231**

Four N-EU trials were conducted in accordance with the following GAP: 2 x 260 g a.s. /ha, application interval - 21 days, 2nd application at BBCH 69, PHI 40 - 46d, outdoor.

Residues of azoxystrobin in wheat grain at harvest were  $2x < 0.01$ , 0.01, 0.013 mg/kg.

#### **Remark:**

According to the SANTE/2019/12752 four trials from study ChR-10-8231 are not considered independent. More details - see Appendix 2, point A 2.2.3.2.1.

### **2. Study JCB-11-10125**

Four N-EU trials were conducted in accordance with the following GAP: 2 x 250 g a.s. /ha, application interval - 14 days, BBCH 69, PHI 36 - 66d, outdoor.

Residues of azoxystrobin in wheat grain at harvest were  $2x < 0.01$ , 0.022, 0.028 mg/kg.

Storage periods of residue samples covered by available storage stability studies.

So overall, the data residue trials presented for wheat is complete even if the ChR-10-8231 trials are considered as not independent.

Available results show that the in force MRL of azoxystrobin on wheat and rye of 0.5 mg/kg (Reg. (EU) 2024/1078) will not be exceeded. The current EU MRL for azoxystrobin is sufficient to support the proposed uses.

The trials are supported by valid storage stability data and validated analytical methods.

**The proposed uses on wheat, rye, triticale, spelt, einkorn wheat, emmer wheat and Triticordeum are considered acceptable.**

#### **Barley, oat**

Barley and oat are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on barley can be used for extrapolation to oat before and after forming of the edible part. So the uses are also considered acceptable on barley and oat.

Sufficient trials on barley (8 trials) conducted according to the residue definition for monitoring and for risk assessment were previously presented and evaluated (EFSA, 2010). All trials are slightly overdosed (2 x 250 g a.s./ha instead of 2 x 150 g a.s./ha). Consequently, these trials can be considered as a worst-case situation.

Residues of azoxystrobin were:  $< 0.01$ , 0.01, 0.02,  $2x$  0.04, 0.08, 0.20, 0.43 mg/kg.

Two additional magnitude of residue studies were submitted in the framework of this application: studies ChR-10-8230 and JCB-11-10126.

Summary is presented below.

### **1. Study ChR-10-8230**

Four N-EU trials were conducted in accordance with the following GAP: 2 x 260 g a.s. /ha, application interval - 14 days, 2nd application at BBCH 59, outdoor.

Residues of azoxystrobin in barley grain at harvest were 0.042, 0.058, 0.10, 0.13 mg/kg.

#### **Remark:**

According to the SANTE/2019/12752 four trials from study ChR-10-8230 are not considered independent. More details- see Appendix 2, point A 2.2.3.1.1.

### **2. Study JCB-11-10126**

Four N-EU trials were conducted in accordance with the following GAP: 2 x 250 g a.s. /ha, application interval - 14 days, BBCH 59, outdoor.

Residues of azoxystrobin in barley grain at harvest were  $< 0.01$ , 0.011, 0.015, 0.016 mg/kg.

Storage periods of residue samples covered by available storage stability studies.

So overall, the data residue trials presented for barley is complete even if the ChR-10-8230 trials are considered as not independent.

Available results show that the in force MRL of azoxystrobin on barley and oat of 1.5 mg/kg (Reg. (EU) 2024/1078) will not be exceeded. The current EU MRL for azoxystrobin is sufficient to support the proposed uses.

The trials are supported by valid storage stability data and validated analytical methods.  
**The proposed uses on barley and oat are considered acceptable.**

**Oilseeds**

**Major crop: winter oilseed rape**

**Minor ~~crops~~ uses (article 51): sunflower (PL), spring oilseed rape, linseed, poppy, mustard, gold of pleasure seeds**

Oilseed rape and sunflower are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required.

Linseed, poppy, mustard, gold of pleasure seeds are the minor crops in N-EU and a minimum of four trials are required.

Eight new residue trials (GBU-11-10127 and ChR-10-8214) were conducted on oilseed rape in N-EU according to the residue definition for monitoring and for risk assessment. All trials are overdosed (1 x 250 g a.s./ha instead of 1 x 180 g a.s./ha) and consequently they can be considered as a worst-case situation.

**Summary**

**1. Study GBU-11-10127**

Four N-EU trials were conducted in accordance with the following GAP: 1 x 250 g a.s. /ha, application at BBCH 69, outdoor.

Residues of azoxystrobin in oilseed rape grain were below 0.01 mg/kg.

**2. Study ChR-10-8214**

Four N-EU trials were conducted in accordance with the following GAP: 1 x 250 g a.s. /ha, application at BBCH 69, outdoor.

Residues of azoxystrobin in oilseed rape grain ranged from <0.001 mg/kg to 0.13 mg/kg (2x<0.001, 0.032, 0.13 mg/kg).

**Remark:**

According to the SANTE/2019/12752, four trials from study ChR-10-8214 are not considered independent. More details - see Appendix 2, point A 2.2.3.3.2.

For oilseed rape, the dossier includes 4 trials from GBU-11-10127 and the 4 trials from ChR-10-8214, which are not considered independent. According to the SANTE/2019/12752, a minimum of eight independent trials are required to support the proposed use on major crop - winter oilseed rape.

Taking into account, Nufarm provided (March 2024) four additional independent residue trials on OSR (study S23-100807) to support registration of CA3642 / Joust Pro.

**3. Study S23-100807**

Four N-EU trials were conducted in accordance with the following GAP: 1 x 250 g a.s. /ha or 1 x 750 g a.s./ha, application at BBCH 69, outdoor.

Residues of azoxystrobin in oilseed rape grain were <0.01 mg/kg.

Available results show that the in force MRL of azoxystrobin on oilseed rape of 0.7 mg/kg (Reg. (EU) 2024/1078) will not be exceeded. The current EU MRLs for azoxystrobin are sufficient to support the proposed minor uses. Storage periods of residue samples covered by available storage stability studies.

**The proposed use on winter oilseed rape (major crop) is considered acceptable.**

**Minor uses ~~crops~~ (article 51): sunflower (in PL), spring oilseed rape, linseed, poppy, mustard and gold of pleasure seeds**

No new residue studies on minor crops have been submitted by the applicant in the framework of this application. Based on the SANTE/2019/12752, four residue trials on oilseed rape can be used for extrapolation to following minor uses ~~crops~~: sunflower (in PL), spring oilseed rape, linseed, poppy, mustard and gold of pleasure seeds before and after forming of the edible part.

Nine independent trials conducted on oilseed rape are available. Residues of azoxystrobin in oilseed rape grain ranged from <0.001 mg/kg to 0.13 mg/kg.

0400000	OILSEEDS AND OIL FRUITS	MRLs of Azoxystrobin Reg. (EU) 2024/1078
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0401000	Oilseeds	
0401010	Linseeds	0.4
0401030	Poppy seeds	0.5
0401050	Sunflower seeds	0.5
0401060	Rapeseeds/canola seeds	0.7
0401080	Mustard seeds	0.5
0401130	Gold of pleasure seeds	0.5

Available results show that the in force MRL of azoxystrobin on oilseed rape of 0.7 mg/kg, on sunflower, poppy seeds, gold of pleasure seeds and mustard seeds of 0.5 mg/kg, on linseeds of 0.4 mg/kg (Reg. (EU) 2024/1078) will not be exceeded. The current EU MRLs for azoxystrobin are sufficient to support the proposed minor uses. The trials are supported by valid storage stability data and validated analytical methods.

The proposed **minor** uses ~~on minor crops~~ (art. 51): spring oilseed rape and sunflower, linseed, poppy, mustard, gold of pleasure seeds are considered acceptable.

## 7.3.4 Magnitude of residues in livestock

### 7.3.4.1 Dietary burden calculation

In the framework of the review of the existing MRLs for azoxystrobin (EFSA, 2013) and its confirmatory data (EFSA, 2020), the median and maximum dietary burdens were calculated for different groups of livestock.

The input values used in the EU calculation were compared to the residue levels found in the trials supporting the intended uses of CA3642 (Table 7.3-10). The EU inputs sufficiently cover the intended uses of CA3642. It is therefore proposed to refer to EFSA Reasoned Opinion (EFSA, 2020).

**Table 7.3-10: Comparison of EU input values for risk assessment with results from trials supporting the intended uses of CA3642 – Azoxystrobin**

Feed Commodity	EU inputs (EFSA, 2020)		Data from trials supporting the intended uses of CA3642		EU data cover? (Y/N)
Barley, Oat grain	0.1	STMR (EFSA, 2013)	0.04	STMR (§ 7.3.3)	Y
Wheat, Rye grain	0.08	STMR (EFSA, 2013)	0.01	STMR (§ 7.3.3)	Y
Barley, Oat straw	2.3	STMR (EFSA, 2013)	1.4	STMR (§ 7.3.3)	Y
	5.5	HR (EFSA, 2013)	5.1	HR (§ 7.3.3)	
Wheat, Rye, Triticale straw	3.85	STMR (EFSA, 2013)	1.5	STMR (§ 7.3.3)	Y
	10.1	HR (EFSA, 2013)	10.1	HR (§ 7.3.3)	
Rapeseed, seeds	0.055	STMR (EFSA, 2013)	0.01	STMR (§ 7.3.3)	Y
Linseed, seeds	0.02	STMR (EFSA, 2016b)	0.01	STMR (§ 7.3.3)	Y

**Table 7.3-11: Results of the dietary burden calculation (EFSA, 2020)**

Relevant groups	Dietary burden expressed in				Most critical commodity <sup>(b)</sup>	Trigger exceeded (Y/N) 0.1 mg/kg DM	
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Risk assessment residue definition: Azoxystrobin							
Cattle (all diets)	0.46	0.59	12.0	15.4	Dairy cattle	Citrus, dried pulp	Y
Cattle (dairy only)	0.46	0.59	12.0	15.4	Dairy cattle	Citrus, dried pulp	Y
Sheep (all diets)	0.10	0.23	2.5	5.79	Lamb	Rye, straw	Y
Sheep (ewe only)	0.10	0.19	2.85	5.49	Ram/Ewe	Rye, straw	Y

Relevant groups	Dietary burden expressed in				Most critical commodity <sup>(b)</sup>		Trigger exceeded (Y/N) 0.1 mg/kg DM
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Swine (all diets)	0.20	0.25	8.76	10.6	Swine (breeding)	Citrus, dried pulp	Y
Poultry (all diets)	0.05	0.10	0.66	1.42	Poultry layer	Wheat, straw	Y
Poultry (layer only)	0.05	0.10	0.66	1.42	Poultry layer	Wheat, straw	Y

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

For azoxystrobin, the results of the dietary burden calculation demonstrate that the exposure of all livestock species exceeds the trigger value of 0.1 mg/kg DM.

#### **zRMS comments:**

Azoxystrobin is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens has been calculated for different groups of livestock using the EFSA Animal model 2017. The calculated dietary burden for azoxystrobin was found to exceed the trigger value of 0.1 mg/kg DM (or 0.004 mg/kg bw/d, respectively) for all groups of livestock. Therefore, further investigation of residues is required.

#### **Remark on residue behaviour in fish (B.7.3.2.5 and B.7.3.4)**

In accordance with SANCO/10254/2021, an assessment of metabolism in fish is required when pesticide use may lead to significant residues of an active substance or a major metabolite in total diet (i.e.  $\geq 0.1$  mg/kg feed on a dry matter basis) which also have the potential to accumulate (i.e.  $\log P_{o/w} > 3$ ). Azoxystrobin is the only analyte considered relevant to the consumer from exposure to plants and the  $\log P_{o/w}$  value for azoxystrobin is 2.5 (at 20°C) which is consistent with no accumulation potential in fish tissues. As the  $\log P_{o/w}$  of all components of the plant Residue Definition for Risk Assessment does not exceed 3, metabolism studies in fish are not required.

### **7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)**

#### **Available data**

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

#### **Summary of livestock feeding studies**

*EFSA Journal 2013;11(12):3497*

“During the peer review under Directive 91/414/EEC, the magnitude of azoxystrobin residues in livestock was investigated in feeding studies with lactating cows and laying hens (United Kingdom, 2009a).

Four groups of lactating cows, each consisting of three animals, were dosed for 30 consecutive days with azoxystrobin at levels of 5, 25, 75 and 250 mg/kg in the diet (equivalent to 0.18, 0.91, 2.73 and 9.09 mg/kg bw). Three groups of laying hens, each consisting of twelve animals were dosed for 28 consecutive days with azoxystrobin at levels of 6, 18, and 60 mg/kg in the diet (equivalent to 0.39, 1.2 and 3.9 mg/kg bw). The samples were analyzed for parent azoxystrobin. Results of both livestock feeding studies are summarized in Table 3-8. In milk and eggs, a plateau level was never reached and no residues at or above 0.01 mg/kg was found in any of the samples.

The storage stability of azoxystrobin residues in animal products was evaluated under the peer review of Directive 91/414/EEC (United Kingdom, 2009a). Studies demonstrated storage stability of azoxystrobin in milk, muscle, fat, liver and kidney, eggs for up to 10 months when stored deep frozen. According to the RMS, all samples reported in the PROFile were stored in compliance with the above reported storage conditions.

Consequently, the available data are considered sufficient for deriving MRLs in ruminants, pigs and poultry. These MRLs were derived in compliance with the latest recommendations on this matter (FAO, 2009) and are summarized in Table 3-7. Significant residues in tissues of ruminants, pigs and poultry, eggs



and milk, are not expected and MRLs for these commodities can be established at the LOQ. Considering that the residue definition for risk assessment is tentative, these MRLs are also considered tentative”.

EFSA Journal 2020;18(8):6231

In the framework of the MRL review, EFSA identified data gaps related to the toxicological relevance of metabolites L1, L4 and L9, which were identified in ruminant liver and kidney.

“Regarding the toxicological assessment of livestock metabolites L1, L4 and L9, the submitted data allowed to conclude that the genotoxic potential of these three compounds can be ruled out. However, data addressing the general toxicity of these compounds were not provided. Based on calculations to demonstrate that the expected dietary exposure of consumers to these metabolites was lower than the TTC, the RMS concluded that further data addressing the general toxicity of these compounds were not needed and thus proposed to confirm the residue definition for risk assessment in animal commodities as azoxystrobin alone. EFSA highlighted that the TTC approach cannot be applied in this context. EFSA concludes that the data gap identified in the framework of the MRL review was only partially addressed. Further risk management considerations should be given to decide whether the argument of the low exposure calculated for metabolites L1, L4, L9 and K1 (conjugate of L1) is acceptable to waive the need to submit data on the general toxicity of L1, L4 and L9. Meanwhile, the residue definition for risk assessment in animal commodities is still deemed tentative”.

The MRLs for animal commodities calculated during the Evaluation of confirmatory data following the Article 12 MRL review are presented in the table hereafter.

**Table 7.3-12: Overview of the values derived from livestock feeding studies (EFSA, 2020)**

Animal commodity	Residues at the closest feeding level (mg/kg)		Estimated value at 1N level		MRL proposal (mg/kg)
	Mean	Highest	STMR <sub>Mo</sub> (mg/kg)	HR <sub>Mo</sub> (mg/kg)	
<b>Cattle (all diets)</b>					
Closest feeding level:	0.91	mg/kg bw	1.5 N rate <sup>(c)</sup>		
Muscle	<0.01	<0.01	<0.01	<0.01	<b>0.01*</b>
Fat	<0.01	<0.01	<0.01	<0.01	<b>0.01*</b>
Liver	0.01	0.01	<0.01	<0.01	<b>0.01*</b> <sup>(f)</sup>
Kidney	<0.01	<0.01	<0.01	<0.01	<b>0.01*</b> <sup>(f)</sup>
<b>Cattle (dairy only)</b>					
Closest feeding level:	0.91	mg/kg bw	1.5 N rate <sup>(c)</sup>		
Milk <sup>(d)</sup>	<0.01	n.a.	<0.01	<0.01	<b>0.01*</b>
<b>Sheep (all diets) <sup>(e)</sup></b>					
Closest feeding level:	0.18	mg/kg bw	0.8 N rate <sup>(c)</sup>		
Muscle	<0.01	<0.01	<0.01	<0.01	<b>0.01*</b>
Fat	<0.01	<0.01	<0.01	<0.01	<b>0.01*</b>
Liver	<0.01	<0.01	<0.01	<0.01	<b>0.01*</b> <sup>(f)</sup>
Kidney	<0.01	<0.01	<0.01	<0.01	<b>0.01*</b> <sup>(f)</sup>
<b>Sheep (dairy only)</b>					
Closest feeding level <sup>(a)</sup> :	0.18	mg/kg bw	0.9 N rate <sup>(c)</sup>		
Milk <sup>(d)</sup>	<0.01	n.a.	<0.01	<0.01	<b>0.01*</b>
<b>Swine</b>					
Closest feeding level:	0.18	mg/kg bw	0.7 N rate <sup>(c)</sup>		
Muscle	<0.01	<0.01	<0.01	<0.01	<b>0.01*</b>
Fat	<0.01	<0.01	<0.01	<0.01	<b>0.01*</b>
Liver	<0.01	<0.01	<0.01	<0.01	<b>0.01*</b> <sup>(f)</sup>
Kidney	<0.01	<0.01	<0.01	<0.01	<b>0.01*</b> <sup>(f)</sup>
<b>Poultry (all diets)</b>					
Closest feeding level <sup>(a)</sup> :	0.39	mg/kg bw	4 N rate <sup>(c)</sup>		
Muscle	<0.01	<0.01	<0.01	<0.01	<b>0.01*</b>
Fat	<0.01	<0.01	<0.01	<0.01	<b>0.01*</b>
Liver	<0.01	<0.01	<0.01	<0.01	<b>0.01*</b>
<b>Poultry (layer only)</b>					
Closest feeding level:	0.39	mg/kg bw	4 N rate <sup>(c)</sup>		
Eggs	<0.01	<0.01	<0.01	<0.01	<b>0.01*</b>

n.a.: not applicable.

\*: Indicates that the MRL is proposed at the limit of quantification.

(a): Median residues recalculated at the 1N rate for the median dietary burden.

(b): Highest residues recalculated at the 1N rate for the maximum dietary burden.

(c): Closest feeding level and N dose rate related to the maximum dietary burden.

(d): For milk, mean was derived from samplings performed from day 1 to day 30 (daily mean of four cows).

(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

(f): Noting that the general toxicity of metabolites L1, L4 and L9 (found in liver and kidney) was not addressed.

### Conclusion on feeding studies

The requested uses do not modify the theoretical maximum daily intake for animals. Regarding available feeding data, there is no risk for animal MRL to be exceeded.

#### zRMS comments:

Data presented by Applicant in point 7.3.4.2 have been accepted and are sufficient to support the proposed uses.

The requested uses and the new mode of calculation do not modify the theoretical maximum daily intake for animals and regarding available feeding data, there is no risk for animal MRL to be exceeded (Reg. (EU) 2024/1078). No additional data are required.

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

### 7.3.5.1 Available data for all crops under consideration

Azoxystrobin residue above the trigger value of 0.1 mg/kg is expected in raw agricultural commodities from the intended uses. Therefore, investigation on the magnitude of residues in processed commodities is required.

New processing studies have been submitted by the applicant in the framework of this application. These studies are summarized in the table below. Only processing factors relevant for risk assessment were presented.

The detailed results are presented in Appendix 2.

**Table 7.3-13: Overview of the available processing studies**

Table 7.5-15: Overview of the available processing studies					
Processed commodity	Number of studies	Median PF * (Individual values)	Median CF **	Comments	Reference
Enforcement residue definition: Azoxystrobin					
EU data - Processing factors recommended (sufficiently supported by data)					
Barley, brewing malt	4	0.19	1	Processing factor for malt, beer and pot are actually lower than the value reported as residues were below the LOQ in the processed commodities (worst case assumption)	United Kingdom, 2009a
Barley, beer	4	0.23	1		
Barley, pot/pearl	4	0.25	1		
Barley, bran	4	3.25	1		
Wheat/rye, whole-meal flour	4	0.68	1	Processing factor for cooked beans is lower than 0.29 as residues were below the LOQ in the processed commodities (worst case assumption)	United Kingdom, 2009a
Wheat/rye, whole-meal bread	4	0.51	1		
Wheat/rye, white flour	4	0.45	1		
Wheat/rye, bran	4	1.67	1		
New data					

Barley, beer	4	0.03	1	Residues were below the LOQ in the processed commodities (worst case assumption)	Roussel, C-H., 2011 Report No.: ChR-10-8230
Barley, pot	4	0.14	1	-	
Wheat, whole-meal flour	4	0.82	1	-	Roussel, C-H., 2011 Report No.: ChR-10-8231
Wheat, whole-meal bread	4	0.56	1	-	
Wheat, white flour	4	0.26	1	Residues were below the LOQ in the processed commodities (worst case assumption)	
Wheat, bran	4	2.80	1	-	
Rapeseed, cake	1	0.86	1	-	Roussel, C-H., 2011 Report No.: ChR-10-8214
Rapeseed, raw oil	4	0.37	1		
Rapeseed, refined oil	4	0.36	1		
Rapeseed, cake	1	0.03	1		North, L., 2024 Report No.: S23-100807
Rapeseed, crude oil	1	0.04	1		
Rapeseed, refined oil	1	0.04	1		
Rapeseed, meal	2	0.265 (0.03; 0.5)	1		
Rapeseed, extracted oil	1	0.02	1		

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

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

### 7.3.5.2 Conclusion on processing studies

According to the available processing studies, azoxystrobin residues tends to be diluted in all relevant processed commodities from barley, wheat and oilseed rape, except for cereals bran in which a concentration of azoxystrobin residues is observed.

#### zRMS comments:

Data presented by Applicant in point 7.3.5 have been accepted and are sufficient to support the proposed uses. Processing studies are normally required if the supervised residue trials reveal that the total residues in commodities exceed the trigger value of 0.1 mg/kg, or if the total Theoretical Maximum Daily Intake (TMDI) is more than 10% of the ADI.

Based on these data requirements, processing studies are required for wheat, barley and oilseed rape.

Summary of processing studies reported in the EU:

#### United Kingdom, 2009

*“Adequate mass balance and follow-up processing studies are available for determining transfer factors for azoxystrobin residues in processed wheat commodities. These transfer factors can be used in consumer assessments to estimate dietary exposures to azoxystrobin in the following processed wheat commodities: wheat grain into flour, wheat germ, and bread. As a result of the low incurred residues seen in the processing studies the calculated processing factors are unreliable and careful judgement should be exercised if they are used quantitatively.”*

#### EFSA, 2013

*“Robust processing factors for enforcement and risk assessment were derived for peeled bananas, white wine, must, grape juice, grape pomace (wet and dry), brewing malt, beer, barley pot, barley bran, whole-meal and white flour, bread, wheat bran, fresh beans with pods cooked and canned. The processing factors reported for the other processed commodities should be considered as indicative as a minimum of 3 processing studies is normally required.”*

Four new processing studies for cereals and oilseed rape have been submitted by the Applicant in the framework of this application.  
The studies demonstrate that azoxystrobin residues concentrate in cereals bran whereas a reduction is observed in other processed commodities of wheat, barley and oilseed rape.  
More details of these studies are provided in Appendix 2.  
No additional data are required.

### 7.3.6 Magnitude of residues in representative succeeding crops

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

##### Summary of field rotational crop studies reported in the EU

Several rotational crop field trials were evaluated in the framework of the peer review (United Kingdom, 2009a, 2009b).

*EFSA Journal 2013;11(12):3497-48*

“Azoxystrobin was applied on wheat, cucumber or lettuce at 2 x 0.896 kg a.s./ha, 7-8 x 0.224 kg a.s./ha and 6 x 0.373 kg a.s./ha respectively. After harvest of these crops, rotational crops (mustard, lettuce, radish, turnip, beetroot and wheat) were sown at one, two or three different plant-back intervals (29 to 60 days following application of the active substance) and magnitude of residues was investigated in the different commodities thereof. Considering that all trials were overdosed, a correction factor was applied to the highest residue found in each commodity. At harvest, azoxystrobin residues were expected to be below the LOQ (0.01 mg/kg) in all mature plant parts except in wheat forage and wheat straw. The highest residues were expected to be 0.05 mg/kg and 0.04 mg/kg, respectively.”

##### Summary of new study on field rotational crop studies

In addition, new studies for residues in succeeding crops have been submitted by the applicant in the framework of this application. The detailed results are presented in Appendix 2.

Two foliar applications of 260 g azoxystrobin/ha were applied on barley (initial crop) at BBCH 39 and 59. Twenty days after application barley crop was destroyed and the succeeding crops radish, lettuce and barley were planted at three different plant back intervals (PBI) of 30 days, 2 months and 10 months. The succeeding crops were then sampled at normal harvest stage. At all tested PBI, azoxystrobin residues were found to be below the LOQ (0.01 mg/kg) in radish root and leaves, lettuce and barley grain, straw and green material.

##### Conclusion on rotational crops studies

According to available field rotational crop studies, no azoxystrobin residues above 0.01 mg/kg is expected in succeeding crops when CA3642 is applied according to the proposed GAP. Therefore, further investigation into the magnitude of residues in rotational crops is not required. No mitigation measure is necessary.

##### zRMS comments:

Data presented by Applicant in point 7.3.6 have been accepted and are sufficient to support the proposed uses. EFSA concluded in EFSA Journal 2022;20(1):7051 that *The possible transfer of azoxystrobin residues to crops that are grown in crop rotation has been assessed in the EU pesticides peer review and the MRL review (EFSA, 2010, 2013). In the context of the MRL review, it was concluded that no residues above the LOQ (0.01 mg/kg) are expected in crop parts intended for human consumption and that residues are very low in commodities intended for feed purposes (0.05 mg/kg in wheat forage and 0.04 mg/kg in wheat straw) (EFSA, 2013).* Since the maximum annual application rate for the crops under consideration (i.e. 0.5 kg a.s./ha) is lower than the maximum seasonal application rate assessed during the MRL review (i.e. 1 kg a.s./ha), the previous conclusion remains valid, provided that the active substance is applied according to the proposed GAP.

Additionally new rotational crop studies for radish, lettuce and barley planted at three different plant back intervals (PBI) of 30 days, 2 months and 10 months have been submitted by the Applicant in the framework of this application.  
The studies demonstrate that no azoxystrobin residues above 0.01 mg/kg is expected in succeeding crops when

CA3642 is applied according to the proposed GAP.  
More details of this study are provided in Appendix 2.  
No additional data are required.

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

#### 7.3.7.1 Effect on the residue level in pollen and bee products

Azoxystrobin is currently authorized based on the old data requirements, for which no residue study on honey was required in the DAR 2009. Consequently, the assessment of the present application is based on the same data requirements as for the active substance 2009 re-approval since azoxystrobin is not AIR4 renewed yet. This will avoid any distortion of competition in favour of the previous Art.33 dossiers for which no data on honey was required. Therefore, in the present application, information on honey is considered as informative only.

According to SANTE/11956/2016 rev. 9, rapeseed and some other oilseeds are considered as melliferous crops. As azoxystrobin is proposed to be applied during the flowering stage (BBCH 60-69) and since the active substance is systemic, effects on the residue level in pollen and bee products should be investigated.

The applicant Nufarm has a letter of co-ownership by the Azoxystrobin Task Force which authorizes Nufarm to access to the studies submitted during the AIR4 renewal of azoxystrobin (process currently ongoing).

For the residue studies on bee products, the applicant kindly asks the zRMS to refer to the studies submitted for the AIR4 renewal of azoxystrobin. It should be noted that during the AIR4 renewal process, one study was still ongoing. As the report is now available, the study was summarized in the present dossier.

#### **Summary of residue studies on bee products reported in the EU (AIR4)**

##### Summary from Azoxystrobin AIR 4 MCA Section 6 CA 6.10.1:

Bocksch 2008, T011298-06-REG

“Three semi-field trials are available that determine the magnitude of azoxystrobin residues in honey following application of azoxystrobin to oilseed rape (1 x 250 g a.s./ha, BBCH 63; honey sampled at maturity). Residues of azoxystrobin in samples of treated honey ranged from < 0.01 mg/kg to 0.01 mg/kg”.

Lebrun 2019, 349-2018

“A fourth semi-field trial is also available, in which residues of azoxystrobin were determined in nectar following the application of azoxystrobin to oilseed rape at BBCH 60 and BBCH 65 (2 x 250 g a.s./ha). Residues of azoxystrobin in samples of treated nectar ranged from < 0.005 mg/kg to 0.046 mg/kg. In accordance with SANTE/11956/2016 rev. 9, residues in nectar can be used as a surrogate for residues in honey.

Based on the available data, residues of azoxystrobin in honey are not expected to exceed the established MRL.

The available semi-field trials are considered a ‘worst-case’ situation because oilseed rape is a crop with a high melliferous capacity (SANTE/11956/2016 rev. 9).”

“A new study with four semi-field trials is currently being conducted, with 2 applications during flowering made to oilseed rape. This guideline compliant study will be available by December 2022 and will permit a robust assessment of residues of azoxystrobin in honey”.

As the report is now available, the study was included in the present dossier. A summary is presented hereafter and details in Appendix 2.

#### **Summary of new residue study (results not reported in AIR4 MCA S6)**

Four residue trials, located in Germany, Austria and Spain were conducted in 2021 with winter oilseed rape as a melliferous source. Azoxystrobin was applied twice, at a nominal application rate of 250 g a.s./ha for each application. The applications were conducted during flowering between BBCH 62-65 and separated by a 5–7-day interval. Honey was sampled and azoxystrobin residues were measured.

Azoxystrobin was found to be below the LOQ (0.01 mg/kg) in honey samples, except for trial S21-01128-01 in which residue was quantified at 0.02 mg/kg at 2 DALA. It should be noted the sampling in this trial occurs earlier (2 DALA) compared to the other trials (12-18 DALA). In all trials, honey was sampled mature at honeycomb-closure (honeybees started to cover the honey storage cells) or water content in honey was ~20 %.

Conclusion

Based on available data, no exceedance of the MRL (0.05\* mg/kg) will occur in honey when CA3642 is applied according to the GAP on oilseed rape.

**zRMS comments:**  
Data presented by Applicant in point 7.3.7 have been accepted and are sufficient to support the proposed uses.  
  
Additionally new residue study on oilseed rape have been submitted by the Applicant in the framework of this application (Appeltauer, 2022; Report S21-01128, access from Task Force). It should be noted that this study was reviewed and accepted by zRMS-PL in RR, Part B7 for PPP of Orondis Evo in June 2023.  
  
**Appeltauer, 2022; S21-01128**  
The study contained five field trials (four were performed successfully) on winter oilseed rape was conducted in northern/southern Europe. Azoxystrobin was applied to winter oilseed rape as A12705B, an SC formulation containing nominally 250 g azoxystrobin per litre. Two applications, (applied at growth stage 62-65 BBCH), separated by a 5-7 day interval were made at a nominal rate of 250 g ai/ha. Mature honey was then collected 2-18 days after last application (DALA).  
The ranges of residues of azoxystrobin were <0.01 – 0.02 mg/kg and R230310 were <0.01 mg/kg.  
No residues of azoxystrobin and its metabolite R230310 at or above the limit of quantification of 0.01 mg/kg were found in any of the untreated honey samples.  
Samples were stored frozen for a maximum period of 76 days from sampling to extraction. The residue data are valid with regard to storage stability.  
  
The residues arising from the proposed uses will not exceed the MRLs established for azoxystrobin for honey of 0.05 mg/kg in Reg. (EU) 2024/1078.  
No additional data are required.

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

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).  
As an ARfD was not deemed necessary, acute risk assessment is not relevant.

7.3.8.1 Input values for the consumer risk assessment

TMDI calculation was performed using the in-force MRLs (Reg. (EU) 2024/1078) and EFSA PRIMo rev.3.1.

Table 7.3-14: 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: Azoxystrobin				
Barley, Oat	1.5	EU MRL	Not relevant as setting of an ARfD was not necessary.	
Wheat, Rye	0.5	EU MRL		
Rapeseed	0.7	EU MRL		
Rapeseed, Poppy, Mustard, Gold of pleasure	0.5 <sup>a</sup>	EU MRL		
Linseed	0.4	EU MRL		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Swine: Muscle/meat	0.01 *	EU MRL		
Swine: Fat tissue	0.05	EU MRL		
Swine: Liver	0.07	EU MRL		
Swine: Kidney	0.07	EU MRL		
Bovine, Sheep, Goat, Equine muscle/meat	0.01 *	EU MRL		
Bovine, Sheep, Goat, Equine fat	0.05	EU MRL		
Bovine, Sheep, Goat, Equine liver	0.07	EU MRL		
Bovine, Sheep, Goat, Equine kidney	0.07	EU MRL		
Poultry, muscle, fat, liver, kidney	0.01 *	EU MRL		
Milk	0.01 *	EU MRL		
Eggs	0.01 *	EU MRL		
Honey	0.05 *	EU MRL		
All other commodities	EU MRLs	EU MRLs ( <del>Reg. (EU) 2022/476</del> <del>Reg. (EU) 2022/1363</del> <del>Reg. (EU) 2023/129</del> <del>Reg. (EU) 2024/1078</del> ) <sup>a</sup>		

<sup>a</sup>MRLs which are currently in force are from Reg. (EU) 2022/476. MRLs from Reg. (EU) 2022/1363 are not yet applicable. Please note there is no MRL change for the intended crops. In addition, in “Commission Regulation (EU) 2023/129 of 18 January 2023 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council” the MRLs of azoxystrobin in oilseed rape seeds and guavas were raised to 0.7 mg/kg and 0.2 mg/kg, respectively. No impact on the assessment conclusions is expected.

### 7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in A 2.2.

**Table 7.3-15: Consumer risk assessment**

TMDI (% ADI) according to EFSA PRIMo	82% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Not triggered
IESTI (% ARfD) according to EFSA PRIMo*	Not relevant as setting of an ARfD was not necessary.

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


\*\* if national model is available

The proposed uses of azoxystrobin in the formulation CA3642 do not represent unacceptable acute and chronic risks for the consumer.

#### **zRMS comment:**

The calculation of the TMDI using EFSA model (PRIMo ver. 3.1) and MRLs according to Reg. (EU) 2024/1078 has been conducted by evaluator and led to a utilisation of the ADI of 82% for the NL toddler diet being the population group with the highest value. For this diet, the highest contributor is oranges with 17% of the ADI. The intended uses will not result in a consumer chronic exposure exceeding the ADI.



 <p>European Food Safety Authority EFSA PRIMO revision 3.1; 2021/01/06</p>		<b>Azoxystrobin Reg. (EU) 2024/1078</b>		<b>Input values</b>							
		LOQs (mg/kg) range from: <b>0.01</b> to: <b>0.05</b>		Details - chronic risk assessment Supplementary results - chronic risk assessment							
		<b>Toxicological reference values</b>		Details - acute risk assessment/children Details - acute risk assessment/adults							
		ADI (mg/kg bw/day): <b>0.2</b> ARD (mg/kg bw): <b>Not necessary</b> Source of ADI: <b>EFSA</b> Source of ARD: Year of evaluation: <b>2010</b> Year of evaluation:									
Comments:											
<b>Normal mode</b>											
<b>Chronic risk assessment: JMPR methodology (IED/TMDI)</b>											
No of diets exceeding the ADI:											
TMDI (MED/IED) calculation (based on average food consumption)	Calculated exposure (in % of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Commodities not under assessment (in % of ADI)
	32%	NL toddler	164.58	17%	Oranges	15%	Potatoes	13%	Sugar beet roots	0.4%	
	69%	DE child	137.70	30%	Oranges	9%	Potatoes	3%	Mandarins	0.2%	
	68%	NL child	135.14	21%	Sugar beet roots	12%	Potatoes	11%	Oranges	0.2%	
	58%	FR child 3-15 yr	112.53	20%	Oranges	9%	Sugar beet roots	9%	Potatoes	0.2%	
	49%	GEMS/Food G06	98.93	7%	Oranges	7%	Potatoes	5%	Tomatoes	0.0%	
	48%	UK toddler	95.87	15%	Oranges	12%	Potatoes	8%	Sugar beet roots	0.1%	
	47%	E adult	93.60	8%	Potatoes	6%	Oranges	5%	Grapefruits	0.1%	
	46%	GEMS/Food G07	91.15	13%	Potatoes	10%	Oranges	2%	Wine grapes	0.1%	
	44%	GEMS/Food G10	88.60	10%	Potatoes	8%	Oranges	3%	Rice	0.1%	
	44%	FR toddler 2-3 yr	88.04	11%	Oranges	7%	Sugar beet roots	7%	Potatoes	0.2%	
	43%	DE women 14-50 yr	86.84	14%	Oranges	11%	Sugar beet roots	4%	Potatoes	0.1%	
	43%	GEMS/Food G11	86.73	14%	Potatoes	5%	Oranges	3%	Lemons	0.1%	
	42%	SE general	84.90	15%	Potatoes	6%	Oranges	3%	Mandarins	0.1%	
	41%	GEMS/Food G08	81.62	14%	Potatoes	3%	Oranges	3%	Onions	0.1%	
	40%	DE general	79.24	12%	Oranges	11%	Sugar beet roots	4%	Potatoes	0.1%	
	39%	GEMS/Food G15	78.00	12%	Potatoes	5%	Oranges	3%	Onions	0.1%	
	39%	PT general	77.09	19%	Potatoes	8%	Oranges	4%	Wine grapes	0.0%	
	38%	RO general	76.13	13%	Potatoes	4%	Onions	4%	Head cabbages	0.1%	
	36%	NL general	72.22	9%	Potatoes	8%	Oranges	7%	Sugar beet roots	0.1%	
	36%	ES child	72.21	16%	Oranges	2%	Potatoes	2%	Lettuces	0.0%	
	36%	UK infant	71.27	11%	Potatoes	10%	Oranges	4%	Sugar beet roots	0.2%	
	33%	FI 3 yr	66.89	17%	Potatoes	3%	Mandarins	2%	Onions	0.0%	
	27%	FI 6 yr	53.74	14%	Potatoes	2%	Mandarins	1%	Onions	0.0%	
	26%	ES adult	51.20	10%	Oranges	3%	Potatoes	3%	Lettuces	0.1%	
	23%	FR infant	46.40	7%	Potatoes	3%	Sugar beet roots	2%	Spinaches	0.1%	
	23%	UK vegetarian	46.20	6%	Oranges	5%	Potatoes	1%	Sugar beet roots	0.0%	
	23%	DK child	45.02	9%	Potatoes	1%	Rye	1%	Oranges	0.1%	
	21%	IT toddler	42.92	4%	Oranges	3%	Potatoes	2%	Tomatoes	0.0%	
	21%	FR adult	42.41	4%	Oranges	3%	Wine grapes	3%	Potatoes	0.0%	
	20%	PL general	39.50	12%	Potatoes	2%	Onions	1%	Tomatoes	0.0%	
	19%	IT adult	38.02	3%	Oranges	2%	Potatoes	2%	Lettuces	0.0%	
	19%	UK adult	37.99	5%	Potatoes	4%	Oranges	2%	Wine grapes	0.0%	
	16%	LT adult	32.50	11%	Potatoes	1.0%	Head cabbages	0.9%	Tomatoes	0.0%	
	14%	FI adult	28.97	4%	Potatoes	3%	Oranges	1%	Mandarins	0.0%	
	13%	DK adult	26.94	4%	Potatoes	1%	Wine grapes	1%	Oranges	0.0%	
	8%	E child	11.31	2%	Potatoes	0.7%	Rice	0.6%	Oranges	0.0%	
The refinement using STMRs is not required as the unrefined risk assessment does not represent unacceptable chronic risk to the consumer.											
An acute consumer risk assessment was not deemed necessary.											
The proposed uses of azoxystrobin in the product CA3642 (Joust Pro) do not represent unacceptable chronic risk for the consumer.											
No further data are required to support the proposed uses.											

## 7.4 Combined exposure and risk assessment

The product is a mixture of prothioconazole and azoxystrobin. Although no acute reference dose has been allocated to azoxystrobin, acute reference doses were set for the TDMs. Therefore, the risk assessment of combined exposure is relevant.

As first approach, dose-addition of residues of the individual active substances is assumed by making use of the Hazard Index (HI) concept. The Hazard Quotient (HQ) is calculated for all compounds in the PPP that are acutely toxic.

An ARfD has been established for prothioconazole, T, TA, TAA and TLA. An acute consumer risk assessment from combined exposure can be performed using Hazard Index (HI), calculated with the following formula:

$$HI = \sum HQ$$

with HQ (Hazard Quotient) = IESTI/ARfD

Results for each use are reported in the table hereafter.

The Hazard Index for the commodities under consideration is <1. Thus, combined exposure to all residues in CA3642 is not expected to present a consumer risk. No further refinement of the assessment is required.

**Table 7.4-1: Hazard Index (HI) for relevant commodities based on IESTI according to EFSA PRIMo Rev.3.1**

Commodity or group of commodities to which the MRLs apply	CHILDREN - Hazard Quotient (HQ)					Hazard Index (HI)	ADULT - Hazard Quotient (HQ)					Cumulative risk (HI)
	Prothioconazole	1,2,4-T	TA	TAA	TLA		Prothioconazole	1,2,4-T	TA	TAA	TLA	
Linseeds	0.0064	0.0000	0.0046	0.0000	0.0000	<b>0.0113</b>	0.0029	0.0000	0.0021	0.0000	0.0000	<b>0.0051</b>
Poppy seeds	no acute RA	no acute RA	no acute RA	no acute RA	no acute RA	<b>0.0000</b>	0.0042	0.0000	0.0030	0.0000	0.0000	<b>0.0074</b>
Rapeseeds/canola seeds	0.0083	0.0000	0.0060	0.0000	0.0000	<b>0.0145</b>	0.0032	0.0000	0.0023	0.0000	0.0000	<b>0.0056</b>
Mustard seeds	0.0061	0.0000	0.0044	0.0000	0.0000	<b>0.0108</b>	0.0042	0.0000	0.0030	0.0000	0.0000	<b>0.0074</b>
Barley	0.0337	0.0006	0.0039	0.0005	0.0003	<b>0.0387</b>	0.0290	0.0005	0.0034	0.0004	0.0003	<b>0.0333</b>
Oat	0.0067	0.0001	0.0008	0.0001	0.0001	<b>0.0077</b>	0.0038	0.0001	0.0004	0.0001	0.0000	<b>0.0044</b>
Rye	0.0379	0.0006	0.0131	0.0014	0.0014	<b>0.0533</b>	0.0291	0.0005	0.0100	0.0011	0.0011	<b>0.0409</b>
Wheat	0.0867	0.0014	0.0299	0.0033	0.0033	<b>0.1217</b>	0.0504	0.0008	0.0174	0.0019	0.0019	<b>0.0708</b>
Swine: Muscle/meat	0.0121	0.0206	0.0109	0.0005	0.0005	<b>0.0457</b>	0.0048	0.0082	0.0044	0.0002	0.0002	<b>0.0182</b>
Swine: Fat tissue	0.0017	0.0022	0.0008	0.0001	0.0001	<b>0.0052</b>	0.0020	0.0026	0.0009	0.0001	0.0001	<b>0.0063</b>
Swine: Liver	0.0012	0.0021	0.0025	0.0001	0.0001	<b>0.0060</b>	0.0014	0.0024	0.0029	0.0001	0.0001	<b>0.0069</b>
Swine: Kidney	0.0013	0.0025	0.0011	0.0002	0.0002	<b>0.0055</b>	0.0022	0.0044	0.0020	0.0003	0.0003	<b>0.0095</b>
Bovine: Muscle/meat	0.0072	0.0224	0.0149	0.0003	0.0003	<b>0.0457</b>	0.0057	0.0177	0.0118	0.0002	0.0002	<b>0.0361</b>
Bovine: Fat tissue	0.0021	0.0050	0.0024	0.0002	0.0002	<b>0.0103</b>	0.0010	0.0023	0.0011	0.0001	0.0001	<b>0.0048</b>
Bovine: Liver	0.0678	0.0290	0.0366	0.0004	0.0004	<b>0.1349</b>	0.0336	0.0144	0.0181	0.0002	0.0002	<b>0.0669</b>
Bovine: Kidney	0.0407	0.0128	0.0073	0.0008	0.0008	<b>0.0632</b>	0.0228	0.0072	0.0041	0.0005	0.0005	<b>0.0354</b>
Sheep: Muscle/meat	0.0054	0.0179	0.0123	0.0002	0.0002	<b>0.0366</b>	0.0047	0.0156	0.0107	0.0002	0.0002	<b>0.0319</b>
Sheep: Liver	no acute RA	no acute RA	no acute RA	no acute RA	no acute RA	<b>0.0000</b>	0.0235	0.0109	0.0168	0.0001	0.0001	<b>0.0518</b>
Sheep: Kidney	no acute RA	no acute RA	no acute RA	no acute RA	no acute RA	<b>0.0000</b>	0.0011	0.0004	0.0002	0.0000	0.0000	<b>0.0017</b>
Goat: Muscle/meat	no acute RA	no acute RA	no acute RA	no acute RA	no acute RA	<b>0.0000</b>	0.0016	0.0052	0.0035	0.0001	0.0001	<b>0.0105</b>
Equine: Muscle/meat	0.0060	0.0186	0.0124	0.0002	0.0002	<b>0.0381</b>	0.0048	0.0149	0.0099	0.0002	0.0002	<b>0.0304</b>
Poultry: Muscle/meat	0.0170	0.0068	0.0068	0.0007	0.0007	<b>0.0335</b>	0.0117	0.0047	0.0047	0.0005	0.0005	<b>0.0232</b>
Poultry: Fat tissue	0.0001	0.0000	0.0000	0.0000	0.0000	<b>0.0002</b>	0.0003	0.0001	0.0001	0.0000	0.0000	<b>0.0006</b>

Commodity or group of commodities to which the MRLs apply	CHILDREN - Hazard Quotient (HQ)					Hazard Index (HI)	ADULT - Hazard Quotient (HQ)					Cumulative risk (HI)
	Prothioconazole	1,2,4-T	TA	TAA	TLA		Prothioconazole	1,2,4-T	TA	TAA	TLA	
Poultry: Liver	0.0011	0.0004	0.0011	0.0001	0.0001	<b>0.0029</b>	0.0047	0.0019	0.0049	0.0002	0.0002	<b>0.0123</b>
Poultry: Kidney	no acute RA	no acute RA	no acute RA	no acute RA	no acute RA	<b>0.0000</b>	0.0013	0.0005	0.0003	0.0001	0.0001	<b>0.0023</b>
Milk: Cattle	0.0621	0.4348	0.0166	0.0050	0.0050	<b>0.5350</b>	0.0193	0.1350	0.0051	0.0015	0.0015	<b>0.1661</b>
Milk: Sheep	0.0018	0.0132	0.0005	0.0001	0.0001	<b>0.0161</b>	0.0076	0.0559	0.0020	0.0006	0.0006	<b>0.0681</b>
Milk: Goat	0.0121	0.0894	0.0032	0.0010	0.0010	<b>0.1089</b>	0.0092	0.0681	0.0025	0.0007	0.0007	<b>0.0829</b>
Eggs: Chicken	0.0124	0.0050	0.0025	0.0005	0.0005	<b>0.0220</b>	0.0043	0.0017	0.0009	0.0002	0.0002	<b>0.0075</b>
Eggs: Goose	no acute RA	no acute RA	no acute RA	no acute RA	no acute RA	<b>0.0000</b>	0.0005	0.0002	0.0001	0.0000	0.0000	<b>0.0009</b>
Eggs: Quail	no acute RA	no acute RA	no acute RA	no acute RA	no acute RA	<b>0.0000</b>	0.0014	0.0006	0.0003	0.0001	0.0001	<b>0.0025</b>
Honey and other apiculture products	0.0011	0.0001	0.0004	0.0002	0.0002	<b>0.0020</b>	0.0004	0.0000	0.0002	0.0001	0.0001	<b>0.0008</b>

**zRMS comment:**

Information presented by Applicant in point 7.4 has been accepted.

The Hazard Index for the commodities under consideration is <1. Thus, combined exposure to all residues in CA3642 (Joust Pro) is not expected to present a consumer risk. No further refinement of the assessment is required.

## 7.5 References

### **Prothioconazole**

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.

United Kingdom, 2018. Draft Renewal Assessment Report on the active substance Prothioconazole prepared by the rapporteur Member State United Kingdom in the framework of Commission Regulation (EU) N° 1107/2009 , February 2018 (Initial RAR).

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

EFSA (European Food Safety Authority), 2020. Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A. Reasoned Opinion on the evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for prothioconazole in celeriacs and rapeseeds. EFSA Journal 2020;18(2):5999, 50 pp. <https://doi.org/10.2903/j.efsa.2020.5999>

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.

### **Triazole Derivate Metabolites**

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

EFSA (European Food Safety Authority), 2018. Brancato A, Brocca D, Carrasco Cabrera L, Chiusolo A, Civitella C, Court Marques D, Crivellente F, De Lentdecker C, Erdos Z, Ferreira L, Goumenou M, Greco L, Istace F, Jarrah S, Kardassi D, Leuschner R, Medina P, Mineo D, Miron I, Molnar T, Nave S, Parra Morte JM, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Terron A, Theobald A, Vagenende B and Villamar-Bouza L. 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>

### **Azoxystrobin**

United Kingdom, 2009a. Draft assessment report on the active substance azoxystrobin prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, May 2009

United Kingdom, 2009b. Final addendum to the draft assessment report on the active substance azoxystrobin prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, compiled by EFSA, December 2009

EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance azoxystrobin. EFSA Journal 2010;8(4):1542, 110 pp.

doi:10.2903/j.efsa.2010.1542

EFSA (European Food Safety Authority), 2013. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for azoxystrobin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(12):3497, 97 pp. doi:10.2903/j.efsa.2013.3497

EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2020. Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for azoxystrobin. EFSA Journal 2020;18(8):6231, 42 pp. <https://doi.org/10.2903/j.efsa.2020.6231>

AIR4 M-CA S6, Azoxystrobin Task Force, Dec. 2021. Notification of an active substance under commission Regulation (EU) 2020/1740, Section 6 Residues in or on treated products, food and feed.

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

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner	Previously evaluated
<b>Prothioconazole and TDMs</b>						
KCA 6.1 <del>Bayer doc. No. M-777951-01-1</del>	<del>Stroech, K.</del>	<del>2021</del>	<del>Study Summaries of prothioconazole studies included in Data Access Agreement with Nufarm of September 27, 2021 Bayer AG Crop Science Division Edition Number: M-777951-01-1 Date: 2021-10-15 GLP/GEP: yes, unpublished</del>	<del>N</del>	<del>Bayer CropScience</del>	
KCA 6.1/01	Freitag, T.	2005	Storage stability of prothioconazole-desthio in/on canola, spinach, sugar beet, tomato, and pea during freezer storage for 24 months Bayer CropScience, Report No.: MR-07/282, Edition Number: M-258955-02-1 Date: 2005-10-14 ...Amended: 2007-06-04 GLP/GEP: yes, unpublished	N	Bayer CropScience	Yes, in RR, Part B7 for CA3301/Joust (01.2023)
KCA 6.1/02	Freitag, Th.	2011	Storage stability of prothioconazole-4-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio in/on tomato fruit, potato tuber, soybean, orange fruit and oil seed rape for 24 months Bayer CropScience, Report No.: MR-08/024, Edition Number: M-405410-01-1 Date: 2011-04-13 GLP/GEP: yes, unpublished	N	Bayer CropScience	Yes, in RR, Part B7 for CA3301/Joust (01.2023)
KCA 6.1/03	Kalathoor, R.	2021	Storage Stability of Prothioconazole and metabolites in different matrices under Deep Frozen Conditions Eurofins Agroscience Services Report No: S20-09716 GLP/GEP: yes, unpublished	N	Nufarm Europe	Yes, in RR, Part B7 for CA3301/Joust (01.2023)

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	Previously evaluated
<b>Prothioconazole and TDMs</b>						
KCA 6.1/04	Winter, O.	2023	Storage Stability of the Triazole Derivative Metabolites in Oilseed Rape under Deep Frozen Conditions Eurofins Agroscience Services Report No: S22-08287 (NUK-2201L) GLP/GEP: yes, unpublished	N	Nufarm Crop Products UK	No
KCA 6.3.1/01	Schoening, R.; Bauer, J.; Koester, P.	2011	Determination of the residues of BYF 00587, HEC 5725 and prothioconazole in/on barley after spray application of bixafen & fluoxastrobin & prothioconazole EC 190 in the field in the Netherlands and Germany Bayer CropScience, Report No.: 10-2204, Edition Number: M-414691-01-1 Date: 2011-09-28 GLP/GEP: yes, unpublished	N	Bayer CropScience  (Nufarm has a letter of access)	Yes, in RR, Part B7 for CA3301/Joust (01.2023)
KCA 6.3.1/02	Bellof, S.; van Berkum, S.	2014	Determination of the residues of fluoxastrobin and prothioconazole in/on barley and spring barley after spray application of Fluoxastrobin & Prothioconazole EC 200 in France (North) Bayer CropScience, Report No.: 13-2158, Edition Number: M-501503-01-1 Date: 2014-11-05 GLP/GEP: yes, unpublished	N	Bayer CropScience  (Nufarm has a letter of access)	Yes, in RR, Part B7 for CA3301/Joust (01.2023)
KCA 6.3.1/03	Glaubitz, J.	2014	Determination of the residues of fluoxastrobin and prothioconazole in/on spring barley after spray application of fluoxastrobin & prothioconazole EC 200 in Germany Bayer CropScience, Report No.: 13-2137, Edition Number: M-501711-03-1 Date: 2014-11-10 ...Amended: 2015-01-30 GLP/GEP: yes, unpublished	N	Bayer CropScience  (Nufarm has a letter of access)	Yes, in RR, Part B7 for CA3301/Joust (01.2023)
KCA 6.3.1/04	Meklat, N.; Kerkering, S.; Effertz, C.	2018	Determination of the residues of prothioconazole, spiroxamine and trifloxystrobin in/on barley after spray application of PTZ & SPX & TFS EC 280.3 in the Netherlands, Belgium, southern France and Italy Bayer Report No.: 17-2076 Edition Number: M-641462-01-1 Date: 2018-11-28 GLP/GEP: Yes, unpublished	N	Bayer CropScience  (not protected)	Yes, in RR, Part B7 for CA3301/Joust (01.2023)

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	Previously evaluated
<b>Prothioconazole and TDMs</b>						
KCA 6.3.2/01	Meklat, N.; Kerkerling, S.	2019	Determination of the residues of prothioconazole and spiroxamine in/on wheat after spray application of JAU 6476 & KWG 4168 EC 460 in Germany, northern France and the Netherlands Bayer CropScience, Report No.: 17-2015 Edition Number: M-659920-01-1 Date: 24-05-2019 GLP/GEP: yes, unpublished	N	Bayer CropScience  (Nufarm has a letter of access)	Yes, in RR, Part B7 for CA3301/ Joust (01.2023)
KCA 6.3.2/02	North, L.	2020	Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole in Wheat (outdoor) at 4 sites in Northern Europe and 4 sites in Southern Europe 2019 Eurofins Agrosience Services Report No.: S19-01268 GLP/GEP: Yes, unpublished	N	Nufarm Europe	Yes, in RR, Part B7 for CA3301/ Joust (01.2023)
KCA 6.3.2/03	Meklat, N.; Kerkerling, S.	2018	Determination of the residues of prothioconazole and spiroxamine in/on spring wheat and winter wheat after spray application of JAU 6476 & KWG 4168 EC 460 in the United Kingdom, Germany and the Netherlands Bayer Report No.: 16-2046 Edition Number: M-626175-01-1 Date: 2018-06-06 GLP/GEP: Yes, unpublished	N	Bayer CropScience  (not protected)	Yes, in RR, Part B7 for CA3301/ Joust (01.2023)
KCA 6.3.3/01	North, L.	2021	Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole 250EC in Oilseed rape (outdoor) at 4 sites in Northern Europe and 4 sites in Southern Europe 2019 Eurofins Agrosience Services Report No.: S19-01269 GLP/GEP: Yes, unpublished	N	Nufarm Europe	Yes, in RR, Part B7 for CA3301/ Joust (01.2023)
KCA 6.3.3/02	North, L.	2021	Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole 250EC in Oilseed rape (outdoor) at 4 sites in Northern Europe and 4 sites in Southern Europe 2020 Eurofins Agrosience Services Report No.: S20-01046 GLP/GEP: Yes, unpublished	N	Nufarm Europe	Yes, in RR, Part B7 for CA3301/ Joust (01.2023)



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	Previously evaluated
<b>Prothioconazole and TDMs</b>						
KCA 6.3.3/03	North, L.	2021	Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole in Oilseed rape (outdoor) at 1 site in Northern Europe in 2021 Eurofins Agrosience Services Report No.: S21-00259 GLP/GEP: Yes, unpublished	N	Nufarm Europe	Yes, in RR, Part B7 for CA3301/ Joust (01.2023)
KCA 6.3.3/06	North, L.	2023	Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole in Oilseed rape (outdoor) and its processed fractions at 3 sites in Northern Europe in 2022 Eurofins Agrosience Services Report No.: S22-00257 GLP: Yes, unpublished	N	Nufarm Crop Products UK	No
KCA 6.10/01	Knoll, M.	2021	Determination of Residues of Prothioconazole in Nectar, Pollen and Honey of Winter Oilseed Rape after Two Applications of CA3301 in a Semi-Field Residue Study in Central and Southern Europe in 2021 Eurofins Agrosience Services Report No.: S21-00428 GLP/GEP: Yes, unpublished	N	Nufarm Europe	Yes, in RR, Part B7 for CA3301/ Joust (01.2023)

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	Previously evaluated
<b>Azoxystrobin</b>						
KCA 6.3.1/08	Roussel, C-H.	2011	Magnitude Of The Residues Of Azoxystrobin In Summer Barley (RAC Grain And Straw) And Processed Fractions Following Two Applications Of NUL 2206, Poland, 2010 Staphyt Report No.: ChR-10-8230 GLP/GEP: Yes, unpublished	N	Nufarm SAS	No

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	Previously evaluated
<b>Azoxystrobin</b>						
KCA 6.3.1/09	Boissinot, J-C.	2011	Residues Of Azoxystrobin In Barley (RAC Whole Plant, Grain And Straw) Following Two Applications Of CA 2702 (NUL 2206), Northern & Southern Europe – 2011 Staphyt Report No.: JCB-11-10126 GLP/GEP: Yes, unpublished	N	Nufarm SAS	No
KCA 6.3.2/04	Roussel, C-H.	2011	Magnitude Of The Residues Of Azoxystrobin In Winter Wheat (RAC Grain And Straw) And Processed Fractions Following Two Applications Of NUL 2206, Poland, 2010 Staphyt Report No.: ChR-10-8231 GLP/GEP: Yes, unpublished	N	Nufarm SAS	No
KCA 6.3.2/05	Boissinot, J-C.	2011 (2012 amendme nt)	Residues Of Azoxystrobin In Wheat (RAC Whole Plant, Grain And Straw) Following Two Applications Of CA 2702 (NUL 2206), Northern & Southern Europe – 2011 Final report and Amendment 1 Staphyt Report No.: JCB-11-10125 GLP/GEP: Yes, unpublished	N	Nufarm SAS	No
KCA 6.3.3/04	Boileau, G.	2011	Residues Of Azoxystrobin In Oilseed Rape, Following One Application Of CA 2702 (NUL 2206), Northern & Southern Europe – 2011 Final report and Amendment 1 Staphyt Report No.: GBU-11-10127 GLP/GEP: Yes, unpublished	N	Nufarm SASe	No
KCA 6.3.3/05	Roussel, C-H.	2011	Magnitude Of The Residues Of Azoxystrobin In Oilseed Rape (RAC Grain) And Processed Fractions Following One Application Of NUL 2206, Poland, 2010 Staphyt Report No.: ChR-10-8214 GLP/GEP: Yes, unpublished	N	Nufarm SAS	No
KCA 6.3.3/07	North, L.	2024	Determination of residues of Azoxystrobin after a single application of CA2702 in Oilseed rape (outdoor) at 4 sites in Northern Europe 2023 Eurofins Agroscience Services Report No.: S23-100807 GLP/GEP: Yes, unpublished	N	Nufarm Crop Products UK	No

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	Previously evaluated
<b>Azoxystrobin</b>						
KCA 6.6.2/01	Roussel, C-H.	2011	Magnitude Of The Residues Of Azoxystrobin In Rotational Crops Following Two Applications Of NUL 2206 On Summer Barley, Poland, 2010-2011 Staphyt Report No.: ChR-10-8233 GLP/GEP: Yes, unpublished	N	Nufarm SAS	No
KCA 6.10/02	Appeltauer, A.	2022	Azoxystrobin – Determination of Residues of Azoxystrobin and R230310 (z-isomer) in Honey after Two Applications of A12705B to Winter Oilseed rape at 5 Sites in Northern and Southern Europe in 2021 Eurofins Agrosience services Report No.: S21-01128 GLP/GEP: Yes, unpublished <i>Study included in the AIR4 renewal of azoxystrobin (process currently ongoing)</i>	N	Syngenta Ltd. (Nufarm Crop Products UK has a letter of co-ownership)	Yes, in RR, Part B7 for A22773A/ Orondis Evo (06.2023)

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
<b>Prothioconazole and TDMs</b>					
KCA 6.1	Heinemann, O.	2001	18 months storage stability of residues of JAU 6476 and JAU 6476-Desthio during frozen storage in/on wheat matrices Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MR-282/00, Edition Number: M-072461-01-1 Date: 2001-09-13 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.2.1	Haas, M.; Bornatsch, W.	2000	Metabolism of JAU6476 in spring wheat (after foliar application) Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MR-198/99, Edition Number: M-041657-01-1 EPA MRID No.: 46246141 Date: 2000-07-10 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.2.1	Vogeler, K.; Sakamoto, H.; Brauner, A.	1993	Metabolism of SXX 0665 in summer wheat Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: PF3906, Edition Number: M-008633-01-1 Date: 1993-08-13 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.2.1	Duah, F. K.; Lopez, R. T.	2004	The metabolism of [triazole-3,5-14 C] JAU 6476 in wheat Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: 200733, Edition Number: M-001524-01-1 EPA MRID No.: 46246143 Date: 2004-03-12 GLP/GEP: yes, unpublished	N	Bayer CropScience

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
<b>Prothioconazole and TDMs</b>					
KCA 6.2.1	Haas, M.	2001	Metabolism of JAU 6476 in spring wheat after seed dressing Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: 110881, Edition Number: M-030412-01-3 EPA MRID No.: 46246142 Date: 2001-05-10 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.2.1 /05	Haas, M.	2001	Metabolism of [phenyl-UL-14C]JAU6476 in peanuts Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MR-193/01, Edition Number: M-033059-01-2 EPA MRID No.: 46246145 Date: 2001-11-27 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.2.1 /06	Haas, M.	2003	Metabolism of [triazole-UL-14C]JAU6476 in peanuts Bayer CropScience, Report No.: MR-194/02, Edition Number: M-103268-01-2 EPA MRID No.: 46246146 Date: 2003-12-01 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.6.1	Haas, M.	2001	Confined rotational crop study with JAU6476 Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: MR-159/00, Edition Number: M-049955-01-1 EPA MRID No.: 46246225 Date: 2001-05-14 GLP/GEP: yes, unpublished	N	Bayer CropScience

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
<b>Prothioconazole and TDMs</b>					
KCA 6.6.1	Duah, F. K.; Kraai, M. J.	2004	The accumulation of [triazole-3,5-14C] JAU6476 in confined rotational crops Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: 200623, Edition Number: M-000784-01-1 EPA MRID No.: 46246226 Date: 2004-03-05 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.2.2	██████████	2001	[Phenyl-UL-14C]JAU6476 – Absorption, distribution, excretion and metabolism in laying hens ██████████ Report No.: MR-309/01, Date: 2001-10-29 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCA 6.2.2	██████████	2003	[Triazole-UL-14C]JAU6476: Absorption, distribution, excretion, and metabolism in laying hens ██████████ Report No.: MEF-005/03, Date: 2003-06-23 ...Amended: 2003-07-14 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCA 6.2.3	██████████	2001	[Phenyl-UL-14C]JAU6476 – Absorption, distribution, excretion and metabolism in the lactating goat ██████████ Report No.: MR-092/01, ... amended: 2018-08-15 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCA 6.2.3	██████████	2002	[Phenyl-UL-14C]JAU6476-desthio – Absorption, distribution, excretion, and metabolism in the lactating goat ██████████ Report No.: MR-091/01, Date: 2002-02-28 GLP/GEP: yes, unpublished	Y	Bayer CropScience

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
<b>Prothioconazole and TDMs</b>					
KCA 6.2.3	██████████	2003	[Triazole-UL-14C]JAU 6476: Absorption, distribution, excretion, and metabolism in the lactating goat ██████████ Report No.: MR-448/02, Date: 2003-10-20 ...Amended: 2005-06-06 GLP/GEP: yes, unpublished	Y	Bayer CropScience
KCA 6.2.3	██████████	2006	[Phenyl-UL-14C]JAU 6476-desthio: Absorption, distribution, excretion and metabolism in the lactating goat – Subsequent identification of metabolite hydrolysis products ██████████ Report No.: MEF-06/469, Date: 2006-10-10 GLP/GEP: no, unpublished	Y	Bayer CropScience
KCA 6.3.1 /01	Heinemann, O.	2001	Determination of residues of JAU 6476-Desthio on spring wheat following seed treatment of JAU 6476 200 FS in Great Britain, Germany and France Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: RA-2010/99, Edition Number: M-073513-01-1 Date: 2001-09-18 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.3.1 /02	Heinemann, O.	2001	Determination of residues of JAU 6476-desthio on spring wheat following seed treatment of JAU 6476 200 FS in Germany and France Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: RA-2091/00, Edition Number: M-075017-01-1 Date: 2001-09-28 GLP/GEP: yes, unpublished	N	Bayer CropScience

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
<b>Prothioconazole and TDMs</b>					
KCA 6.3.1 /04	Heinemann, O.	2001	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, Leverkusen, Germany Bayer CropScience, Report No.: RA-2003/99, Edition Number: M-075134-01-1 Date: 2001-10-04 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.3.1 /05	Heinemann, O.	2001	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, Leverkusen, Germany Bayer CropScience, Report No.: RA-2104/00, Edition Number: M-088723-01-1 Date: 2001-11-29 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.3.2 /01	Heinemann, O.	2001	Determination of residues of JAU 6476-desthio on spring barley following seed treatment of JAU 6476 200 FS and spray application of JAU 6476 250 EC in Germany Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: RA-2150/98, Edition Number: M-073128-02-1 Date: 2001-09-18 ...Amended: 2001-09-24 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.3.2 /02	Heinemann, O.; Elke, K.	2001	Determination of residues of JAU 6476-desthio on spring barley following seed treatment of JAU 6476 200 FS and spray application of JAU 6476 250 EC in Germany, France and Great Britain Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: RA-2140/98, Edition Number: M-072786-02-1 Date: 2001-09-17 ...Amended: 2001-09-24 GLP/GEP: yes, unpublished	N	Bayer CropScience



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
<b>Prothioconazole and TDMs</b>					
KCA 6.3.2 /03	Heinemann, O.	2001	Determination of residues of JAU 6476-desthio on spring barley after spray application of JAU 6476 250 EC in Sweden, Germany, Northern France and Great Britain Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: RA-2101/00, Edition Number: M-086237-01-1 Date: 2001-11-21 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.3.3 /01	Heinemann, O.	2002	Determination of residues of JAU 6476-desthio on rape after spray application of JAU 6476 250 EC in Germany, Sweden, Northern France and Great Britain Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: RA-2088/00, Edition Number: M-091148-01-1 Date: 2002-01-14 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.3.3 /03	Heinemann, O.	2002	Determination of residues of JAU 6476-desthio on rape spray application of JAU 6476 250 EC in Germany, Northern France and Great Britain Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: RA-2178/01, Edition Number: M-035525-01-1 Date: 2002-02-08 GLP/GEP: yes, unpublished	N	Bayer CropScience
KCA 6.4.2	██████████	2001	JAU 6476-desthio – Dairy cattle feeding study ██████████ Report No.: MR-535/00, Date: 2001-10-15 GLP/GEP: yes, unpublished	Y	Bayer CropScience

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
<b>Azoxystrobin</b>					
IIA 6.1 (in DAR)	Allin, R. et al.	1995	ICIA5504: Metabolism in Winter Wheat RJ1888B RIP96-00104	N	Syngenta
IIA 6.1 (in DAR)	Earl, V.L. and Hadfield, S.T.	1994	ICI5504: Metabolism in Vines RJ1676B RIP96-00105	N	Syngenta
IIA 6.1 (in DAR)	Webb, J. et al.	1995	ICIA5504: Metabolism in Peanuts RJ1807B RIP96-00106	N	Syngenta
IIA 6.1 (in DAR)	Wilkinson, M.J. et al.	1994	ICIA5504: Metabolism in Winter Wheat RJ1682B RIP96-00103	N	Syngenta
IIA 6.1	Gill J. P. and Burke S. R.	2002 (minor report amendm ent issued 2005)	Azoxystrobin – Stability in Crops and Processed Commodities During Frozen Storage (Final Report) Report No. RJ3170B Document No. VV-340151	N	Syngenta
IIA 6.1	Burke S. R.	1996	Azoxystrobin and R230310: Storage Stability in Various Processed Crops Stored Deep Frozen for up to One Year. Final Report. Report No. RJ2221B Document No. VV-377264	N	Syngenta
IIA 6.1	Ryan J.	1996	Azoxystrobin – Storage Stability in Various Animal Tissues and Milk Stored Deep Frozen for Six Months Report No. RJ2014B Document No. VV-323713	N	Syngenta
IIA 6.1.2	Burke, S.R.	1997	Azoxystrobin and R230310: storage stability in various crops stored deep frozen for up to two years. Final report. ZENECA Agrochemicals Report RJ2404B	N	Syngenta
IIA 6.1.2	Sapiets, A.	1997	Azoxystrobin: Storage stability of residues in eggs and tissues Study 95JH229 ZENECA Agrochemicals Report Series RJ2352B	N	Syngenta
IIA 6.1.2	Hurt, A. and Campbell, A.J.	1999	Residue analytical method for the analysis of azoxystrobin, R230310, R234886, R401553 and R402173 in water RAM 292/02	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
<b>Azoxystrobin</b>					
IIA 6.1.2	Burke, S.R.	1995	ICIA5504 and R230310: Validation of a Method for the Determination of Residues in Peanuts and Pecans Jealott's Hill Research Station, UK RAM 260/01 Syngenta Unpublished Report RJ1787B Syngenta File No. ICI5504/0261	N	Syngenta
IIA 6.1.2 (in DAR)	████	1994	The metabolism of 14C-Pyrimidinyl labelled ICIA5504 in the laying hen. ISN331/942668 RIP96-00110	Y	Syngenta
IIA 6.1.2 (in DAR)	████	1995a	The metabolism of 14C-Phenyl acrylate labelled ICIA5504 in the laying hen ISN333/950182 RIP96-00111	Y	Syngenta
IIA 6.1.2 (in DAR)	████	1995	The metabolism of 14C-Cyanophenyl labelled ICIA5504 in the laying hen. ISN332/950918 RIP96-00109	Y	Syngenta
IIA 6.2 (in DAR)	████	1995	ICIA5504: Metabolism of Orally Administered Multiple Doses in the Lactating Goat RJ1805B RIP96-00107	Y	Syngenta
IIA 6.2 (in DAR)	████	1995	Further Investigation of Residues in Liver Following Oral Administration of Multiple Doses to the Lactating Goat RJ1957B RIP96-00108	Y	Syngenta
IIA 6.2.2/01	████	1996	14C-ICIA5504: Metabolism of Orally Administered Multiple Doses in Laying Hens Report No. RJ2084B Syngenta File No. ICI5504/0738	Y	Syngenta
IIA 6.2.2/02	████	1996	ICIA5504: Metabolism of Orally Administered Multiple Doses in the Lactating Goat. Report Number: RJ2083B Study dates: April 1993- January 1996 Syngenta File No. ICI5504/0739.	Y	Syngenta
IIA 6.3; IIA 6.5 (in DAR)	Bonfanti, F., Burke, R.S. and Sapiets, A.	1995	ICIA5504: Residue Levels in Grapes, Grape Process Fractions and Soil from a Trial carried out in Italy during 1993 RJ1739B RIP96-00134	N	Syngenta
IIA 6.3 (in DAR)	Burke, S.R.	1995b	ICIA5504 + R230310: Storage stability in Various Crops Stored Deep Frozen for up to Two Years, Interim Report 3 (Straw, Grapes and Wine). RJ1961B RIP96-00198	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
<b>Azoxystrobin</b>					
IIA 6.3 (in DAR)	Burke, S.R.	1995a	ICIA5504 and R230310: Storage Stability in Various Crops Stored Deep Frozen for up to Two Years. Interim Report 1 (Cereals, Grapes and Wine). RJ1858B R1P96-00140	N	Syngenta
IIA 6.3 (in DAR)	Burke, S.R. and Sapiets, A.	1995	ICIA5504 and R230310: Validation of a method for the determination of residue in cereals and vines, Final report; Zeneca RJ1729B RIP96-00474	N	Syngenta
IIA 6.3 (in DAR)	Clarke, D.M. and Sapiets, A.	1994	ICIA5504 and R230310: Validation of a method [RAM 243/02] for the determination of residue in cereals and vines. Zeneca RJ 1557B RIP96-00475	N	Syngenta
IIA 6.3 (in DAR)	Sapiets, A., Chamier, O. And Dittrich, R.	1996	ICIA5504: Residue Levels in Wheat Grain and Milled Process Fractions from a Trial carried out in Germany during 1995 RJ2065B RIP96-00191	N	Syngenta
IIA 6.4 (in DAR)	██████	1997	ICIA5504: Residue Transfer Study in Dairy Cows Fed on a Diet containing ICIA5504 RJ1878B RIP96-00141	Y	Syngenta
IIA 6.4.1/03	██████	1997	Azoxystrobin: Residue Transfer in Laying Hens Report No. RJ2349B Syngenta File No. ICI5504/0743	Y	Syngenta
IIA 6.5	Sapiets, A. and Charnier, O.	1997	ICIA5504: Residue Levels in Malting Barley and Process Fractions from Studies Conducted in Germany during 1996 GLP Unpublished RJ2382B	N	Syngenta
IIA 6.5	Sapiets, A. and Hall, G.	1998	ICIA5504: Residue Levels in Malting Barley and Brewing Fractions from a Trial conducted in the United Kingdom during 1996 GLP Unpublished RJ2452B	N	Syngenta
IIA 6.5	Jones, R.N. and Lake, A.	2000	Azoxystrobin: Dissipation in an Outdoor Experimental Pond Zeneca Agrochemicals, UK Syngenta Unpublished Report RJ3062B Syngenta File No. ICI5504/0831	N	Syngenta
IIA 6.5	Sapiets, A., Chamier, O. And Dittrich, R.	1996	Processing study: milling/baking of wheat RJ2065B ICI5504/0718	N	Syngenta
IIA 6.5	Clarke, D.M. and Chamier, O.D.	1997	Processing study: milling/baking of wheat RJ2297B	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
<b>Azoxystrobin</b>					
IIA 6.5	Evans, P.	2009	Response to PSD e-mail's of 9 and 20 January 2009 requesting Syngenta's clarification & comment on a number of points arising during the Dietary Safety assessment of the dossier	N	Syngenta
IIA 6.5	Evans, P	2009a	Response to PSD e-mail's of 13 February 2009 and 2 March 2009 requesting Syngenta's clarification & comment regarding analytical methods '	N	Syngenta
IIA 6.5.1/01	Grout S. J.	2002	14C-Phenyl acryl ate Azoxystrobin: Aqueous hydrolysis at 90, 100 & 120°C. Report Number: RJ3296B Syngenta, UK. Syngenta File No. 1C15504/1393	N	Syngenta
IIA 6.5.3/01	Gill, J.P. et al.	2000	Azoxystrobin: Residue Levels in Beans (with Pods) and Processed Beans from Trials carried out in Italy during 1999 Report No. RJ2964B Zeneca, Jealott's Hill International Research Centre Syngenta File No. ICI5504/0417	N	Syngenta
IIA 6.5.3/02	Gill, J.P. and Picard J.M.	2000	Azoxystrobin: Residue Levels in Beans (with Pods), Fresh and Processed, from Trials carried out in France during 1999 Report No. RJ3007B Zeneca, Jealott's Hill International Research Centre Syngenta File No. ICI5504/0419	N	Syngenta
IIA 6.5.3/03	Simon, P.	2006	Azoxystrobin: Residue Study in or on Barley and Processed Barley Products in Germany 2004 (Test Product: A12705B) Report No. gba210004 Syngenta Agro GMBH, Germany Syngenta File No. ICI5504/3546	N	'Syngenta
IIA 6.5.3/04	Heillaut, C.	2008	Azoxystrobin (ICI5504): Residue Study on Wheat and Processed Wheat Products from Switzerland in 2006. Report No. T000676-06-REG. ADME Bioanalyses, France Syngenta File No. ICI5504/3940	N	Syngenta
11A 6.6 (in DAR)	Goldsby, G. et al.	1995	ICIA5504 (14C-pyrimidinyl): Confined Rotational Crop Study. RR 95-034B RIP96-00143	N	Syngenta
IIA 6.6 (in DAR)	Miller, M.M. and Wilson, W.	1995	ICIA5504-Cyanophenyl: Confined Rotational Crop Study RR 95-017B RIP96-00144	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
<b>Azoxystrobin</b>					
IIA 6.6 (in DAR)	Ta.mbling, D.R., Labatore, D.N. and Walker, F.H.	1995	ICIA5504 (14C-phenylacrylate): Confined Rotational Crop Study RR 95-011B RIP96-00142	N	Syngenta
IIA 6.6	Grant, C. L. Et al.	1996	ICI5504: Residue Levels on Rotated Crops from Trials Carried Out in The United States during 1995 RR 96-034B Syngenta File No. ICI5504/0732	N	Syngenta
IIA 6.6	Roper, E. M	1996	ICI5504: Residue Levels on Rotated Crops from Trials Carried Out in The United States during 1995-1996 RR 96-092B Syngenta File No. ICI5504/0733	N	Syngenta
IIA 6.6	Ediger, K	2002	Azoxystrobin – Magnitude of the Residues in Rotational Crops 492-01 Syngenta File No. ICI5504/1966	N	Syngenta
IIA 6.7	██████	1995	R230310 – Acute Oral Toxicity to the Mouse Syngenta Unpublished Report Syngenta File No, ICI5504/0234)	Y	Syngenta
IIA 6.7	██████	1995	R230310 – An Evaluation of Mutagenic Potential using <i>S.typhimuri</i> um and <i>E.coli</i> . ██████ Syngenta Unpublished Report CTL/P/4711 Syngenta File No. ICI5504/0235	Y	Syngenta
IIA 6.7	Saunders, J.	1997	ICIA5504 (Azoxystrobin) Metabolites: Bioefficacy Data. Zeneca Agrochemicals UK. Syngenta Unpublished Report TMJ3931B Syngenta File No. ICI5504_11353	N	Syngenta
IIA 6.7	Wollerton, C.	1997	Physical and Chemical Properties of Azoxystrobin (Storage Stability) Zeneca Agrochemicals UK. Syngenta Unpublished Report MAS 34 Syngenta File No. ICI5504/0038	N	Syngenta

List of data submitted by the applicant and not relied on

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

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

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

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

### A 2.1 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 1 MR-07/282)

Comments of zRMS:	<p>It should be noted that the study of Freitag (MR-07/282) is currently under review in the EU approval renewal process for prothioconazole.</p> <p>The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application. The conclusions of the assessment are presented below:</p> <p><i>The analysis results indicate that prothioconazole-desthio is stable under frozen storage at -18 °C or below for at least 734 days (approx 24 months) in canola (seed, pod, straw), spinach (leaves), sugar beet (root, leaf with root collar), tomato (fruit), and field pea (field pea dried). Mean procedural recoveries were in the range of 85 - 106% for all matrices.</i></p> <p><i>It is noted that samples were fortified at 50x rather than 10x the LOQ as outlined in OECD 506. Nevertheless, this is considered to fulfil the aim of avoiding highly variable recoveries that would prevent the determination of the stability of the residues.</i></p> <p><i>The study is acceptable.</i></p>
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Reference:	KCA 6.1/01
Report	Storage stability of prothioconazole-desthio in/on canola, spinach, sugar beet, tomato, and pea during freezer storage for 24 months Freitag, T., 04.06.2007 Report No: M-258955-02-1 Reference No: MR-07/282
Guideline(s):	Not specified
Deviations:	None
GLP:	Yes
Owner:	Bayer CropScience AG (Nufarm has a letter of access)
Acceptability:	Yes

**The following study is currently under review in the EU approval renewal process for prothioconazole.**

#### Materials and methods

A deep-freezer storage stability study was conducted with prothioconazole-desthio in/on canola (seed, pod, straw), spinach (leaves), sugar beet (body, leaf with root collar), tomato (fruit), and field pea (field pea dried). Individual aliquots of the homogenised sample materials were fortified with 0.50 mg/kg of prothioconazole-desthio which corresponds to the 50-fold limit of quantitation of the residue analytical method. The fortified samples were stored in a freezer at about minus 18°C or below for up to ca. 24 months. Control samples that had not been fortified with prothioconazole-desthio were stored under the same conditions to allow procedural recovery determination from freshly fortified samples. Samples were analysed after nominal storage periods of 0, 2, 4, 6, 12, and 24 months.

Three stored fortified samples (except for the day 0 samples where five samples have been spiked with



prothioconazole-desthio), one stored control sample, and two stored control sample freshly fortified with prothioconazole-desthio at the same level as the stored fortified samples, were analysed for each matrix at each of the investigated storage periods. In addition, the analytical method was validated prior to analysis by running a set of two recoveries at the limit of quantitation (0.01 mg/kg).

Residues of prothioconazole-desthio were determined according to method 00647/E001 by HPLC-MS/MS in the multiple-reaction-monitoring mode (MRM) using an electrospray interface (ESI) after extraction, filtration, and dilution.

## Results and discussions

The analytical method was validated prior to analysis by running a set of recoveries at the limit of quantitation (0.01 mg/kg). In addition, during analysis of the stored samples concurrent recoveries were determined at 0.50 mg/kg. Both validation and concurrent recovery experiments shown in **Błąd! Nie można odnaleźć źródła odwołania.** were performed by spiking two control samples with prothioconazole-desthio at each storage period.

In the case of recovery experiments for method validation, recoveries at the respective LOQ were performed at 0.01 mg/kg. The recovery rates for prothioconazole-desthio were in the range of 84 to 111%. For concurrent recoveries, control samples were fortified at 0.50 mg/kg. The recovery rates for prothioconazole-desthio were in the range of 84 to 107%. This demonstrates the accuracy of the analytical determination.

**Błąd! Nie można odnaleźć źródła odwołania.** summarises the amount of prothioconazole-desthio recovered in the stored samples after the various storage intervals. The values presented in these tables were neither corrected for the concurrent recoveries at the respective intervals nor for the recoveries at day 0, since the mean concurrent recoveries are in general within a range of 70% and 110%.

This storage stability study revealed that residues of prothioconazole-desthio were stable for a deep-freezer period of 24 months, in/on canola (seed, pod, straw), spinach (leaves), sugar beet (body, leaf with root collar), tomato (fruit), and field pea (field pea dried). Mean recovery rates for prothioconazole-desthio were between 94 and 107% (normalised to day 0).

## Conclusion

The results of the study demonstrate the stability of prothioconazole-desthio residues upon deep frozen storage for up to 24 months in/on canola (seed, pod, straw), spinach (leaves), sugar beet (body, leaf with root collar), tomato (fruit), and field pea (field pea dried).

**Table A 1: Method Validation Data (Fortification levels: 0.01 mg/kg for method validation and 0.50 mg/kg for concurrent recoveries)**

Sample material	Storage interval (days)	Mean of recovery rates from two freshly fortified samples (%)	
		Method Validation	Concurrent Recoveries
Canola (Seed)	0	98	90
	64	--	88
	128	--	88
	174	88	86
	336	92	89
	735	90	85
Canola (Pod)	0	107	100
	64	--	102
	128	--	100
	174	109	99
	336	98	102
	735	102	99
Canola (Straw)	0	96	98
	64	--	100
	128	--	100
	174	99	98
	336	102	98
	735	101	97

Sample material	Storage interval (days)	Mean of recovery rates from two freshly fortified samples (%)	
		Method Validation	Concurrent Recoveries
Spinach (Leaves)	0	100	105
	64	--	102
	128	--	98
	174	101	98
	336	104	104
	735	100	98
Sugar Beet (body)	0	101	95
	63	--	96
	127	--	98
	173	98	97
	336	96	98
	734	102	96
Sugar Beet (leaf with root collar)	0	95	93
	63	--	97
	127	--	95
	173	98	101
	336	104	101
	734	102	96
Tomato (fruit)	0	99	101
	63	--	102
	127	--	99
	173	103	106
	336	101	100
	734	105	99
Field pea (dried)	0	106	95
	63	--	90
	127	--	92
	173	94	94
	336	102	100
	734	97	90

**Table A 2: Storage stability of prothioconazole-desthio in/on various crops for up to 24 months (Fortification levels: 0.50 mg/kg)**

Commodity	Storage period (days/months)*	Residue Level in Freezer Storage Stability Sample (mg/kg)	Mean* (mg/kg)	Residue Level in Freezer Storage Stability Sample (% of nominal spiking level) (range plus mean)	Residue Level in Freezer Storage Stability Sample (% of day 0)	Procedural Recovery for Freshly Spiked Control Sample (%) Mean values in brackets
Canola Seed	0	0.464, 0.402, 0.434, 0.445, 0.421	0.433	80-93 (87)	100	88, 91 (90)
	64/2	0.436, 0.460, 0.446	0.447	87-92 (89)	103	86, 89 (88)
	128/4	0.449, 0.463, 0.450	0.454	90-93 (91)	105	89, 87 (88)
	174/6	0.419, 0.433, 0.423	0.425	84- 87 (85)	98	87, 85 (86)
	336/11	0.456, 0.442, 0.468	0.455	88-94 (91)	105	86, 91 (89)
	735/24	0.422, 0.428, 0.421	0.424	84-86 (85)	98	84, 86 (85)
Canola (Pod)	0	0.502, 0.478, 0.496, 0.495, 0.476	0.489	95-100 (98)	100	99, 100 (100)
	64/2	0.506, 0.504, 0.503	0.504	101-101 (101)	103	101, 103 (102)
	128/4	0.545, 0.516, 0.504	0.522	101-109 (104)	107	100, 100 (100)
	174/6	0.490, 0.489, 0.499	0.493	98-100 (99)	101	96, 101 (99)
	336/11	0.498, 0.497, 0.500	0.498	99-100 (100)	102	104, 100 (102)
	735/24	0.484, 0.489, 0.484	0.486	97-98 (97)	99	99, 99 (99)
Canola (Straw)	0	0.520, 0.507, 0.511, 0.489, 0.507	0.507	98-104 (101)	100	96, 100 (98)
	64/2	0.490, 0.488, 0.468	0.482	94-98 (96)	95	103, 96 (100)
	128/4	0.501, 0.511, 0.525	0.512	100-105 (102)	101	98, 101 (100)
	174/6	0.485, 0.480, 0.474	0.480	95-97(96)	95	104, 92 (98)

Commodity	Storage period (days/months)*	Residue Level in Freezer Storage Stability Sample (mg/kg)	Mean* (mg/kg)	Residue Level in Freezer Storage Stability Sample (% of nominal spiking level) (range plus mean)	Residue Level in Freezer Storage Stability Sample (% of day 0)	Procedural Recovery for Freshly Spiked Control Sample (%) Mean values in brackets
	336/11	0.496, 0.495, 0.489	0.493	98-99 (99)	97	100, 95 (98)
	735/24	0.493, 0.481, 0.491	0.488	96-99 (98)	96	97, 96 (97)
Spinach (Leaves)	0	0.520, 0.506, 0.539, 0.505, 0.504	0.515	101-108 (103)	100	104, 105 (105)
	64/2	0.500, 0.489, 0.506	0.498	98-101 (100)	97	102, 102 (102)
	128/4	0.495, 0.490, 0.506	0.497	98-101 (99)	97	98, 98 (98)
	174/6	0.507, 0.501, 0.490	0.499	98-101 (100)	97	97, 99 (98)
	336/11	0.501, 0.522, 0.515	0.513	100-104 (103)	100	103, 104 (104)
	735/24	0.486, 0.486, 0.482	0.485	96-97(97)	94	98, 97 (98)
Sugar beet (Body)	0	0.470, 0.463, 0.473, 0.486, 0.491	0.477	93-98 (95)	100	93, 97 (95)
	64/2	0.484, 0.489, 0.487	0.487	97-98(97)	102	95, 97 (96)
	128/4	0.491, 0.487, 0.485	0.488	97-98 (98)	102	97, 98 (97)
	174/6	0.484, 0.484, 0.498	0.489	97-100 (98)	103	96, 98 (97)
	336/11	0.496, 0.505, 0.500	0.500	99-101 (100)	105	98, 98 (98)
	735/24	0.481, 0.476, 0.473	0.477	95-96 (95)	100	96, 96 (96)
Sugar Beet (Leaf with Root Collar)	0	0.480, 0.493, 0.456, 0.473, 0.466	0.474	91-99 (95)	100	94, 91 (93)
	64/2	0.497, 0.471, 0.479	0.482	94-96 (96)	102	98, 96 (97)
	128/4	0.460, 0.468, 0.506	0.478	92-101 (96)	101	94, 95 (95)
	174/6	0.482, 0.469, 0.457	0.469	91-96 (94)	99	100, 101 (101)
	336/11	0.480, 0.488, 0.496	0.488	96-99 (98)	103	101, 101 (101)
	735/24	0.473, 0.461, 0.456	0.463	91-95 (93)	98	96, 96 (96)
Tomato (Fruit)	0	0.510, 0.500, 0.507, 0.511, 0.501	0.506	100-102 (101)	100	100, 101 (101)
	64/2	0.503, 0.489, 0.497	0.496	98-101 (99)	98	101, 102 (102)
	128/4	0.514, 0.526, 0.522	0.521	103-105 (104)	103	97, 100 (99)
	174/6	0.498, 0.496, 0.521	0.505	99- 104 (101)	100	107, 105 (106)
	336/11	0.505, 0.513, 0.521	0.513	101-104 (103)	101	99, 100 (100)
	735/24	0.494, 0.476, 0.490	0.487	95-99 (97)	96	99, 98 (99)
Pea (Pea Dried)	0	0.484, 0.469, 0.461, 0.474, 0.473	0.472	92-97 (94)	100	96, 93 (95)
	64/2	0.463, 0.434, 0.444	0.447	87-93 (89)	95	90, 90 (90)
	128/4	0.455, 0.474, 0.442	0.457	88-95 (91)	97	93, 91 (92)
	174/6	0.458, 0.440, 0.455	0.451	88-92 (90)	96	95, 92 (94)
	336/11	0.512, 0.507, 0.496	0.505	99-102 (101)	107	100, 99 (100)
	735/24	0.464, 0.457, 0.474	0.465	91-95 (93)	98	86, 94 (90)

\* Mean from three analysed samples (except at day 0 where five samples have been spiked)

## A 2.1.1.1.1.2 Study 2 MR-08/024)

Comments of zRMS:	<p>It should be noted that the study of Freitag (MR-08/284) is currently under review in the EU approval renewal process for prothioconazole.</p> <p>The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application. The conclusions of the assessment are presented below:  <i>The data suggests that prothioconazole-<math>\alpha</math>-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio are stable under frozen storage at -18 °C or below for at least 759 days (approx 25 months) in tomato fruit, potato tuber, soybean, orange fruit and oil seed rape.</i>  <i>Mean recovery rates at nominal 24 month storage intervals for all analytes were between 71 - 103%.</i>  <i>The study is acceptable.</i></p>
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Reference:	KCA 6.1/02
Report	<p>Storage stability of prothioconazole-<math>\alpha</math>-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio in/on tomato fruit, potato tuber, soybean, orange fruit and oil seed rape for 24 months  Freitag, T., 13.04.2011  Report No: M-405410-01-1  Reference No: MR-08/024</p>
Guideline(s):	Not specified
Deviations:	None
GLP:	Yes
Owner:	Bayer CropScience AG (Nufarm has a letter of access)
Acceptability:	Yes

**The following study is currently under review in the EU approval renewal process for prothioconazole.**

### Materials and methods

Report MR-08/024 describes the stability of residues of the metabolites prothioconazole- $\alpha$ -hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio in fortified control samples of plant origin (tomato fruit, potato tuber, soybean, orange fruit and oil seed rape) during freezer storage for 24 months. The samples were fortified with a mixture containing all the analytes at a level of 0.10 mg/kg each (each expressed as parent equivalent).

The samples were stored in amber glass bottles at – 18 °C or below and were analysed at nominal intervals of 0, 30, 60, 90, 180, 360, 540 and 720 days.

5 g aliquots of the homogenised control materials were weighed into the bottles. These samples were fortified, resulting in levels of 0.10 mg/kg in all matrices. After fortification, the solvent was allowed to evaporate for about 15 - 30 min. In addition, untreated samples of each sample material were prepared for control and recovery experiments. Subsequently, the bottles were closed and deep-frozen until analysis. Samples were analysed in the 24 hours following their extraction.

Residues of the hydroxy metabolites of prothioconazole-desthio were determined by LC/MS/MS according to method 00979/M001.

### Results and discussions

The analytical method was validated prior to analysis by running a set of recoveries for method validation.

In addition, during analysis of the stored samples concurrent recoveries were determined.

At each storage interval, the samples for the determination of the method performance (concurrent recoveries and method validation) were extracted and analysed concurrently with the control sample and the spiked stored samples.

In the control samples (at each sampling event at least one control sample per matrix was analysed), the residues of each analyte were always below 30% of the LOQ.

Overall recoveries for method validation as well as overall concurrent recoveries were within the acceptable range of 70-110%. Overall RSDs were below 20%.

#### Recoveries for Method Validation:

To demonstrate the accuracy of prothioconazole- $\alpha$ -hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio determination during this study, a set of two recovery experiments were performed for each plant matrix at the nominal storage intervals of 0, 30 (except tomato and soybean), 180, 360, 540 and 720 days. For this purpose, control samples were freshly fortified with a mixture containing all analytes at 0.01 mg/kg each (expressed as prothioconazole-desthio equivalents) and then analysed.

#### Procedural (or “Concurrent”) Recoveries:

During analysis of the samples concurrent recovery experiments were performed by spiking control samples with a mixture containing all analytes. Concurrent recoveries were conducted in each plant matrix at the nominal storage intervals of 30, 60, 90 (except orange and potato), 180, 360, 540 and 720 days. On day 0 (zero time analyses) samples were analysed during the analysis of storage samples. Since these samples are recovery samples, it was not necessary to include concurrent recoveries. For this purpose, stored control samples were freshly fortified with a mixture containing all analytes at 0.10 mg/kg each (expressed as prothioconazole-desthio equivalents). The freshly fortified samples were then extracted and analysed concurrently with the control and spiked samples of these actual storage intervals. The obtained concurrent recovery data are presented in **Błąd! Nie można odnaleźć źródła odwołania.** to **Błąd! Nie można odnaleźć źródła odwołania.**

**Błąd! Nie można odnaleźć źródła odwołania.** to **Błąd! Nie można odnaleźć źródła odwołania.** summarises the amount of each prothioconazole-hydroxy-desthio metabolite recovered in the stored samples after the various storage intervals. The values presented in these tables were not corrected for the concurrent recoveries at the respective intervals.

After a deep-freezer storage period of 24 months, mean recovery rates for all compounds analysed and in all plant matrices ranged between 71 and 103%. No degradation during the deep-freezer storage could be observed.

It is concluded that residues of prothioconazole- $\alpha$ -hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio are stable for at least 24 months under deep-freezer storage conditions in samples of plant origin (rape oil seed, orange fruit, potato tuber, tomato fruit and soybean).

#### **Conclusion**

The results of the study demonstrate the stability of residues of prothioconazole- $\alpha$ -hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio upon deep frozen storage at – 18 °C for up to 25 months in all tested matrices of plant origin (rape oil seed, orange fruit, potato tuber, tomato fruit and soybean).

**Table A 3: Method performance for prothioconazole- $\alpha$ -hydroxy-desthio**

Date of Extraction	Sample Material	Storage Interval [days]		Method Validation [%] FL 0.01 mg/kg*			Concurrent Recoveries [%] FL 0.10 mg/kg*		
		nominal	actual	Single Values		Mean	Single Values		Mean
2009-01-16	Rape Oil seed	0	0	96	97	97	---	---	---
2009-01-06		30	35	91	96	94	89	---	---
2009-02-02		60	62	---	---	---	86	86	86
2009-03-09		90	97	---	---	---	100	99	100
2009-06-09		180	189	106	111	109	94	97	96
2009-11-30		360	363	89	95	92	87	81	84
2010-09-06		540	643	105	102	104	104	103	104
2011-01-05		720	764	91	---	91	91	90	91
Overall and RSD [%]				98	7.2		93	7.8	
2008-12-03	Orange Fruit	0	0	92	83	88	---	---	---
2009-01-07		30	35	---	---	---	89	---	89
2009-02-03		60	61	---	---	---	89	93	91
2009-03-11		90	98	98	89	94	---	---	---
2009-06-10		180	189	101	92	97	104	95	100
2009-12-01		360	363	97	101	99	99	100	100
2010-09-08		540	644	98	100	99	106	108	107
2011-01-06		720	764	83	---	83	96	96	96
Overall and RSD [%]				94	7.1		98	6.5	
2008-12-08	Potato Tuber	0	0	95	97	96	---	---	---
2009-01-08		30	31	---	---	---	96	95	96
2009-02-06		60	60	---	---	---	93	96	95
2009-03-11		90	95	98	89	94	---	---	---
2009-06-23		180	197	90	96	93	97	93	95
2009-12-02		360	359	99	101	100	97	93	95
2010-10-07		540	668	105	97	101	97	101	99
2011-01-06		720	759	108	110	109	105	103	104
Overall and RSD [%]				99	6.5		97	4.0	
2008-12-09	Tomato Fruit	0	0	117	114	116	---	---	---
2009-01-13		30	35	---	---	---	91	94	93
2009-02-09		60	62	---	---	---	110	95	103
2009-03-13		90	94	---	---	---	106	104	105
2009-06-24		180	197	94	99	97	99	98	99
2009-12-03		360	359	83	98	91	92	100	96
2010-10-07		540	667	96	98	97	92	103	98
2010-01-10		720	762	108	106	107	104	104	104
Overall and RSD [%]				101	10.0		99	6.0	
2008-12-10	Soybean	0	0	105	98	102	---	---	---
2009-01-12		30	33	---	---	---	99	98	99
2009-02-09		60	61	---	---	---	94	96	95
2009-03-13		90	93	---	---	---	97	98	98
2009-06-25		180	197	101	96	99	101	101	101
2009-12-09		360	364	105	119	112	120	117	119
2010-10-07		540	666	87	99	93	95	100	98
2011-01-10		720	761	92	101	97	92	91	92
Overall and RSD [%]				100	8.6		100	8.5	

**Table A 4: Method performance for prothioconazole-3-hydroxy-desthio**

Table 14. Method performance for protocatechuate 3-hydroxy-acylase									
Date of Extraction	Sample Material	Storage Interval [days]		Method Validation [%] FL 0.01 mg/kg*			Concurrent Recoveries [%] FL 0.10 mg/kg*		
		nominal	actual	Single Values		Mean	Single Values		Mean
2009-01-16	Rape Oil seed	0	0	99	102	101	---	---	---
2009-01-06		30	35	93	96	94	87	---	87
2009-02-02		60	62	---	---	---	88	88	88
2009-03-09		90	97	---	---	---	102	100	101
2009-06-09		180	189	91	98	95	92	98	95
2009-11-30		360	363	95	92	94	85	80	83
2010-09-06		540	643	101	97	99	105	105	105
2011-01-05		720	764	75		75	85	82	84
Overall and RSD [%]				94	7.8		92	9.6	
2008-12-03	Orange Fruit	0	0	78	79	79	---	---	---
2009-01-07		30	35	---	---	---	90	---	90
2009-02-03		60	61	---	---	---	90	95	93
2009-03-11		90	98	95	87	91	---	---	---
2009-06-10		180	189	99	92	96	100	98	99
2009-12-01		360	363	89	99	94	95	93	94
2010-09-08		540	644	101	100	101	109	111	110
2011-01-06		720	764	72	---	72	90	91	91
Overall and RSD [%]				90	11.2		97	7.7	
2008-12-08	Potato Tuber	0	0	101	97	99	---	---	---
2009-01-08		30	31	---	---	---	99	100	100
2009-02-06		60	60	---	---	---	97	99	98
2009-03-11		90	95	98	90	94	---	---	---
2009-06-23		180	197	96	96	96	97	93	95
2009-12-02		360	359	98	99	99	96	95	96
2010-10-07		540	668	115	104	110	112	116	114
2011-01-06		720	759	94	95	95	103	99	101
Overall and RSD [%]				99	6.3		101	6.8	
2008-12-09	Tomato Fruit	0	0	96	96	96	---	---	---
2009-01-13		30	35	---	---	---	92	98	95
2009-02-09		60	62	---	---	---	111	98	105
2009-03-13		90	94	---	---	---	108	105	107
2009-06-24		180	197	95	99	97	99	98	99
2009-12-03		360	359	84	92	88	103	102	103
2010-10-07		540	667	100	105	103	106	115	111
2010-01-10		720	762	95	93	94	101	100	101
Overall and RSD [%]				96	5.8		103	5.9	
2008-12-10	Soybean	0	0	86	75	81	---	---	---
2009-01-12		30	33	---	---	---	102	103	103
2009-02-09		60	61	---	---	---	98	97	98
2009-03-13		90	93	---	---	---	96	97	97
2009-06-25		180	197	102	100	101	98	101	100
2009-12-09		360	364	106	115	111	110	110	110
2010-10-07		540	666	96	108	102	108	113	111
2011-01-10		720	761	81	84	83	90	90	90
Overall and RSD [%]				95	13.8		101	7.1	

\* FL: Fortification level expressed as prothioconazole-desthio equivalents

**Table A 5: Method performance for prothioconazole-4-hydroxy-desthio**

Date of Extraction	Sample Material	Storage Interval [days]		Method Validation [%] FL 0.01 mg/kg*			Concurrent Recoveries [%] FL 0.10 mg/kg*		
		nominal	actual	Single Values		Mean	Single Values		Mean
2009-01-16	Rape Oil seed	0	0	94	95	95	---	---	---
2009-01-06		30	35	89	93	91	83	---	83
2009-02-02		60	62	---	---	---	80	82	81
2009-03-09		90	97	---	---	---	100	100	100
2009-06-09		180	189	94	100	97	92	98	95
2009-11-30		360	363	88	84	86	80	76	78
2010-09-06		540	643	90	102	96	102	98	100
2011-01-05		720	764	82	---	82	85	82	84
Overall and RSD [%]				92	6.7		89	10.6	
2008-12-03	Orange Fruit	0	0	73	74	74	---	---	---
2009-01-07		30	35	---	---	---	87	---	---
2009-02-03		60	61	---	---	---	85	89	87
2009-03-11		90	98	93	84	89	---	---	---
2009-06-10		180	189	99	92	96	99	96	98
2009-12-01		360	363	96	98	97	90	93	92
2010-09-08		540	644	101	98	100	103	106	105
2011-01-06		720	764	73	---	73	89	93	91
Overall and RSD [%]				89	12.5		94	7.2	
2008-12-08	Potato Tuber	0	0	94	91	93	---	---	---
2009-01-08		30	31	---	---	---	95	97	96
2009-02-06		60	60	---	---	---	94	93	94
2009-03-11		90	95	97	91	94	---	---	---
2009-06-23		180	197	93	98	96	97	93	95
2009-12-02		360	359	93	99	96	91	93	92
2010-10-07		540	668	99	98	99	96	100	98
2011-01-06		720	759	106	105	106	102	101	102
Overall and RSD [%]				97	5.1		96	3.7	
2008-12-09	Tomato Fruit	0	0	95	97	96	---	---	---
2009-01-13		30	35	---	---	---	90	93	92
2009-02-09		60	62	---	---	---	104	93	99
2009-03-13		90	94	---	---	---	106	102	104
2009-06-24		180	197	92	97	95	99	98	99
2009-12-03		360	359	82	92	87	90	96	93
2010-10-07		540	667	88	100	94	89	98	94
2010-01-10		720	762	106	102	104	99	97	98
Overall and RSD [%]				95	7.3		97	5.4	
2008-12-10	Soybean	0	0	89	78	84	---	---	---
2009-01-12		30	33	---	---	---	98	97	98
2009-02-09		60	61	---	---	---	91	94	93
2009-03-13		90	93	---	---	---	94	94	94
2009-06-25		180	197	102	95	99	95	97	96
2009-12-09		360	364	106	107	107	113	115	114
2010-10-07		540	666	91	96	94	96	99	98
2011-01-10		720	761	89	94	92	89	88	89
Overall and RSD [%]				95	9.3		97	8.1	

\* FL: Fortification level expressed as prothioconazole-desthio equivalents



**Table A 6: Method performance for prothioconazole-5-hydroxy-desthio**

Date of Extraction	Sample Material	Storage Interval [days]		Method Validation [%] FL 0.01 mg/kg*			Concurrent Recoveries [%] FL 0.10 mg/kg*		
		nominal	actual	Single Values		Mean	Single Values		Mean
2009-01-16	Rape Oil seed	0	0	99	98	99	---	---	---
2009-01-06		30	35	87	92	90	80	---	80
2009-02-02		60	62	---	---	---	82	84	83
2009-03-09		90	97	---	---	---	100	100	100
2009-06-09		180	189	89	102	96	92	98	95
2009-11-30		360	363	89	90	90	76	75	76
2010-09-06		540	643	91	99	95	102	102	102
2011-01-05		720	764	83	---	83	84	83	84
<b>Overall and RSD [%]</b>				<b>93</b>	<b>6.5</b>		<b>89</b>	<b>11.5</b>	
2008-12-03	Orange Fruit	0	0	76	71	74	---	---	---
2009-01-07		30	35	---	---	---	87	---	---
2009-02-03		60	61	---	---	---	86	92	89
2009-03-11		90	98	96	86	91	---	---	---
2009-06-10		180	189	89	87	88	99	97	98
2009-12-01		360	363	92	98	95	97	90	94
2010-09-08		540	644	100	98	99	104	107	106
2011-01-06		720	764	73	---	73	88	89	89
<b>Overall and RSD [%]</b>				<b>88</b>	<b>11.9</b>		<b>94</b>	<b>7.6</b>	
2008-12-08	Potato Tuber	0	0	95	91	93	---	---	---
2009-01-08		30	31	---	---	---	97	97	97
2009-02-06		60	60	---	---	---	93	95	94
2009-03-11		90	95	97	90	94	---	---	---
2009-06-23		180	197	95	104	100	97	93	95
2009-12-02		360	359	92	98	95	94	93	94
2010-10-07		540	668	106	98	102	96	101	99
2011-01-06		720	759	98	99	99	99	97	98
<b>Overall and RSD [%]</b>				<b>97</b>	<b>5.0</b>		<b>96</b>	<b>2.6</b>	
2008-12-09	Tomato Fruit	0	0	94	99	97	---	---	---
2009-01-13		30	35	---	---	---	89	92	91
2009-02-09		60	62	---	---	---	106	95	101
2009-03-13		90	94	---	---	---	104	103	104
2009-06-24		180	197	94	97	96	99	98	99
2009-12-03		360	359	84	97	91	100	99	100
2010-10-07		540	667	91	98	95	90	100	95
2010-01-10		720	762	100	100	100	97	93	95
<b>Overall and RSD [%]</b>				<b>95</b>	<b>5.2</b>		<b>98</b>	<b>5.3</b>	
2008-12-10	Soybean	0	0	92	82	87	---	---	---
2009-01-12		30	33	---	---	---	97	98	98
2009-02-09		60	61	---	---	---	93	96	95
2009-03-13		90	93	---	---	---	94	94	94
2009-06-25		180	197	101	94	98	100	100	100
2009-12-09		360	364	108	107	108	106	110	108
2010-10-07		540	666	86	93	90	96	99	98
2011-01-10		720	761	89	90	90	85	87	86
<b>Overall and RSD [%]</b>				<b>94</b>	<b>9.1</b>		<b>97</b>	<b>6.7</b>	

\* FL: Fortification level expressed as prothioconazole-desthio equivalents

**Table A 7: Method performance for prothioconazole-6-hydroxy-desthio**

Date of Extraction	Sample Material	Storage Interval [days]		Method Validation [%] FL 0.01 mg/kg*			Concurrent Recoveries [%] FL 0.10 mg/kg*		
		nominal	actual	Single Values		Mean	Single Values		Mean
2009-01-16	Rape Oil seed	0	0	84	88	86	---	---	---
2009-01-06		30	35	77	84	81	71	---	71
2009-02-02		60	62	---	---	---	73	80	77
2009-03-09		90	97	---	---	---	102	101	102
2009-06-09		180	189	86	87	87	92	98	95
2009-11-30		360	363	83	80	82	81	68	75
2010-09-06		540	643	87	85	86	92	88	90
2011-01-05		720	764	70	---	70	74	75	75
Overall and RSD [%]				83	6.5		84	14.1	
2008-12-03	Orange Fruit	0	0	88	85	87	---	---	---
2009-01-07		30	35	---	---	---	77	---	77
2009-02-03		60	61	---	---	---	84	87	86
2009-03-11		90	98	89	82	86	---	---	---
2009-06-10		180	189	93	97	95	90	92	91
2009-12-01		360	363	82	93	88	86	85	86
2010-09-08		540	644	93	92	93	98	101	100
2011-01-06		720	764	62	---	62	75	76	76
Overall and RSD [%]				87	11.0		86	9.9	
2008-12-08	Potato Tuber	0	0	108	108	108	---	---	---
2009-01-08		30	31	---	---	---	98	98	98
2009-02-06		60	60	---	---	---	97	96	97
2009-03-11		90	95	92	86	89	---	---	---
2009-06-23		180	197	92	98	95	97	93	95
2009-12-02		360	359	100	100	100	95	99	97
2010-10-07		540	668	99	89	94	87	99	93
2011-01-06		720	759	93	94	94	92	91	92
Overall and RSD [%]				97	7.1		95	3.9	
2008-12-09	Tomato Fruit	0	0	96	102	99	---	---	---
2009-01-13		30	35	---	---	---	84	92	88
2009-02-09		60	62	---	---	---	105	93	99
2009-03-13		90	94	---	---	---	103	102	103
2009-06-24		180	197	93	98	96	99	98	99
2009-12-03		360	359	76	88	82	96	101	99
2010-10-07		540	667	94	89	92	86	93	90
2010-01-10		720	762	89	87	88	87	85	86
Overall and RSD [%]				91	7.9		95	7.5	
2008-12-10	Soybean	0	0	91	81	86	---	---	---
2009-01-12		30	33	---	---	---	98	97	98
2009-02-09		60	61	---	---	---	89	92	91
2009-03-13		90	93	---	---	---	95	95	95
2009-06-25		180	197	100	94	97	103	103	103
2009-12-09		360	364	100	107	104	105	106	106
2010-10-07		540	666	80	87	84	89	91	90
2011-01-10		720	761	80	74	77	82	84	83
Overall and RSD [%]				89	12.1		95	8.0	

\* FL: Fortification level expressed as prothioconazole-desthio equivalents

**Table A 8: Storage stability of Prothioconazole- $\alpha$ -hydroxy-desthio**

Commodity	Analyte	Storage period (days/months)*	Residue Level in Freezer Storage Stability Sample (mg/kg)	Residue Level in Freezer Storage Stability Sample (% of nominal spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)
Rape oil seed	Prothioconazole- $\alpha$ -hydroxy-desthio	0	0.091, 0.096, 0.098, 0.097, 0.098	91-98 (96)	--, --, (--)
		33/1	0.088, 0.091, 0.095	88-95 (91)	89, -- (--)
		61/2	0.087, 0.088, 0.099	87-99 (91)	86, 86 (86)
		93/3	0.102, 0.100, 0.104	100-104 (102)	100, 99 (100)
		197/6.5	0.097, 0.097, 0.097	91-97 (97)	94, 97 (96)
		364/12	0.089, 0.082, 0.078	78-89 (83)	87, 81 (84)
		666/22	0.102, 0.098, 0.098	98-102 (99)	104, 103 (104)
		761/25	0.092, 0.095, 0.090	90-95 (92)	91, 90 (91)
Orange fruit	Prothioconazole- $\alpha$ -hydroxy-desthio	0	0.080, 0.084, 0.078, 0.083, 0.083	78-84 (82)	---, --- (---)
		33/1	0.093, 0.098, 0.092	92-98 (94)	89, --- (89)
		61/2	0.091, 0.092, 0.097	91-97 (93)	89, 93 (91)
		93/3	0.102, 0.102, 0.101	101-102 (102)	---, --- (---)
		197/6.5	0.104, 0.101, 0.099	99-104 (101)	104, 95 (100)
		364/12	0.094, 0.093, 0.098	93-98 (95)	99, 100 (100)
		666/22	0.099, 0.098, 0.101	98-101 (99)	106, 108 (107)
		761/25	0.108, 0.108, 0.093, 0.098	93-108 (100)	96, 96 (96)
Potato tuber	Prothioconazole- $\alpha$ -hydroxy-desthio	0	0.092, 0.090, 0.088, 0.091, 0.089	88-92 (90)	---, --- (---)
		33/1	0.094, 0.097	94-97 (96)	96, 95 (96)
		61/2	0.095, 0.093, 0.093	93-95 (94)	93, 96 (95)
		93/3	0.099, 0.102, 0.099	99-102 (100)	---, --- (---)
		197/6.5	0.099, 0.089, 0.093	89-99 (94)	97, 93 (95)
		364/12	0.079, 0.078, 0.080	78-80 (79)	97, 93 (95)
		666/22	0.092, 0.094, 0.098	92-98 (95)	97, 101 (99)
		761/25	0.099, 0.098, 0.095	95-99 (97)	105, 103 (104)
Tomato fruit	Prothioconazole- $\alpha$ -hydroxy-desthio	0	0.097, 0.096, 0.092, 0.086, 0.089	86-97 (92)	--- --- ---
		33/1	0.092, 0.091, 0.100	91-100 (94)	91, 94 (93)
		61/2	0.096, 0.097, 0.096	96-97 (96)	110, 95 (103)
		93/3	0.103, 0.103, 0.101	101-103 (102)	106, 104 (105)
		197/6.5	0.101, 0.101, 0.098	98-101 (100)	99, 98 (99)
		364/12	0.094, 0.092, 0.089	89-94 (92)	92, 100 (96)
		666/22	0.102, 0.101, 0.099	99-102 (101)	92, 103 (98)
		761/25	0.093, 0.095, 0.100	93-100 (96)	104, 104 (104)
Soybean	Prothioconazole- $\alpha$ -hydroxy-desthio	0	0.091, 0.093, 0.074, 0.067, 0.074	67-93 (80)	--- --- ---
		33/1	0.101, 0.095, 0.099	95-101 (98)	99, 98 (99)
		61/2	0.090, 0.096, 0.095	90-96 (94)	94, 96 (95)
		93/3	0.098, 0.102, 0.103	98-103 (101)	97, 98 (98)
		197/6.5	0.099, 0.101, 0.100	99-101 (100)	101, 101 (101)
		364/12	0.114, 0.109, 0.099	99-114 (107)	120, 117 (119)
		666/22	0.098, 0.099, 0.095	95-99 (97)	95, 100 (98)
		761/25	0.074, 0.083, 0.088	74-88 (82)	92, 91 (92)

\*in the study report storage periods are given in days, in order to keep the OECD template requirements the storage period are here recalculated for months with the following assumption: 1 month = 30.5 day.

**Table A 9: Storage stability of Prothioconazole-3-hydroxy-desthio**

Commodity	Analyte	Storage period (days/months)*	Residue Level in Freezer Storage Stability Sample (mg/kg)	Residue Level in Freezer Storage Stability Sample (% of nominal spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)
Rape oil seed	Prothioconazole-3-hydroxy-desthio	0	0.096,0.0 98, 0.100 0.099, 0.099	96-100 (98)	---, --- (---)
		33/1	0.090, 0.092, 0.093	90-93(92)	87, --- (87)
		61/2	0.087, 0.090, 0.102	87-102 (93)	88, 88 (88)
		93/3	0.101, 0.102, 0.104	101-104 (102)	102, 100 (101)
		197/6.5	0.097, 0.094, 0.098	94-98 (96)	92, 98 (95)
		364/12	0.082, 0.073, 0.076	73-82 (77)	85, 80 (83)
		666/22	0.104, 0.103, 0.100	100-104 (102)	105, 105 (105)
		761/25	0.083, 0.079, 0.079	79-83 (80)	85, 82 (84)
Orange fruit	Prothioconazole-3-hydroxy-desthio	0	0.071, 0.073, 0.069, 0.075, 0.073	69-75 (72)	---, --- (---)
		33/1	0.091, 0.100, 0.091	91-100 (94)	90, --- (90)
		61/2	0.092, 0.095, 0.100	92-100 (96)	90, 95 (93)
		93/3	0.100, 0.101, 0.101	101-101 (101)	---, --- (---)
		197/6.5	0.102, 0.102, 0.096	96-102 (100)	100, 98 (99)
		364/12	0.081, 0.086, 0.085	81-86 (84)	95, 93 (94)
		666/22	0.103, 0.102, 0.105	102-105 (103)	109, 111 (110)
		761/25	0.107, 0.092, 0.096	92-107 (98)	90, 91 (91)
Potato tuber	Prothioconazole-3-hydroxy-desthio	0	0.093, 0.092, 0.089, 0.092, 0.090	89-93 (91)	---, --- (---)
		33/1	0.096, 0.101	96-101 (99)	99, 100 (100)
		61/2	0.096, 0.097, 0.095	95-97 (96)	97, 99 (98)
		93/3	0.099, 0.102, 0.100	99-102 (100)	---, --- (---)
		197/6.5	0.101, 0.094, 0.096	94-101 (97)	97, 93 (95)
		364/12	0.079, 0.079, 0.080	79-80 (79)	96, 95 (96)
		666/22	0.103, 0.104, 0.110	103-110 (106)	112, 116 (114)
		761/25	0.092, 0.092, 0.088	88-92 (91)	103, 99 (101)
Tomato fruit	Prothioconazole-3-hydroxy-desthio	0	0.085, 0.082, 0.079 0.074, 0.075	74-85 (79)	---, --- ---
		33/1	0.095, 0.093, 0.103	93-103 (97)	92, 98 (95)
		61/2	0.100, 0.100, 0.101	100-101 (100)	111, 98 (105)
		93/3	0.102, 0.101, 0.101	101-102 (101)	108, 105 (107)
		197/6.5	0.101, 0.100, 0.099	99-101 (100)	99, 98 (99)
		364/12	0.086, 0.084, 0.080	80-86 (83)	103, 102 (103)
		666/22	0.116, 0.116, 0.112	112-116 (115)	106, 115 (111)
		761/25	0.093, 0.091, 0.100	91-100 (95)	101, 100 (101)
Soybean	Prothioconazole-3-hydroxy-desthio	0	0.077, 0.077, 0.064, 0.059, 0.065	59-77 (68)	--- --- ---
		33/1	0.103, 0.097, 0.101	97-103 (100)	102, 103 (103)
		61/2	0.096, 0.105, 0.100	96-105 (100)	98, 97 (98)
		93/3	0.096, 0.108, 0.101	96-108 (102)	96, 97 (97)
		197/6.5	0.102, 0.101, 0.101	101-102 (101)	98, 101 (100)
		364/12	0.109, 0.108, 0.115	108-115 (111)	110, 110 (110)
		666/22	0.109, 0.112, 0.106	106-112 (109)	108, 113 (111)
		761/25	0.073, 0.081, 0.087	73-87 (80)	90, 90 (90)

\*in the study report storage periods are given in days, in order to keep the OECD template requirements the storage period are here recalculated for months with the following assumption: 1 month = 30.5 day.

**Table A 10: Storage stability of Prothioconazole-4-hydroxy-desthio**

Commodity	Analyte	Storage period (days/months)*	Residue Level in Freezer Storage Stability Sample (mg/kg)	Residue Level in Freezer Storage Stability Sample (% of nominal spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)
Rape oil seed	Prothioconazole-4-hydroxy-desthio	0	0.094, 0.095, 0.095, 0.095, 0.095	94-95 (95)	---, --- (---)
		33/1	0.084, 0.086, 0.086	84-86 (85)	83, --- (83)
		61/2	0.079, 0.084, 0.090	79-90 (84)	80, 82 (81)
		93/3	0.093, 0.093, 0.096	93-96 (94)	100, 100 (100)
		197/6.5	0.084, 0.086, 0.089	84-89 (86)	92, 98 (95)
		364/12	0.085, 0.081, 0.080	80-85 (82)	80, 76 (78)
		666/22	0.097, 0.096, 0.092	92-97 (95)	102, 98 (100)
		761/25	0.085, 0.090, 0.077	77-90 (84)	85, 82 (84)
Orange fruit	Prothioconazole-4-hydroxy-desthio	0	0.068, 0.070, 0.064, 0.071, 0.071	64-71 (69)	---, --- (---)
		33/1	0.088, 0.096, 0.089	88-96 (91)	87, --- (---)
		61/2	0.089, 0.091, 0.094	89-94 (91)	85, 89 (87)
		93/3	0.094, 0.096, 0.095	94-96 (95)	---, --- (---)
		197/6.5	0.093, 0.092, 0.085	85-93 (90)	99, 96 (98)
		364/12	0.092, 0.093, 0.090	90-93 (92)	90, 93 (92)
		666/22	0.096, 0.096, 0.099	96-99 (97)	103, 106 (105)
		761/25	0.105, 0.088, 0.117	88-117 (103)	89, 93 (91)
Potato tuber	Prothioconazole-4-hydroxy-desthio	0	0.086, 0.085, 0.081, 0.086, 0.083	81-86 (84)	---, --- (---)
		33/1	0.092, 0.095	92-95 (94)	95, 97 (96)
		61/2	0.091, 0.091, 0.089	89-91 (90)	94, 93 (94)
		93/3	0.093, 0.095, 0.094	93-95 (94)	---, --- (---)
		197/6.5	0.094, 0.084, 0.087	84-94 (88)	97, 93 (95)
		364/12	0.081, 0.082, 0.076	76-82 (80)	91, 93 (92)
		666/22	0.091, 0.091, 0.096	91-96 (93)	96, 100 (98)
		761/25	0.090, 0.091, 0.086	86-91 (89)	102, 101 (102)
Tomato fruit	Prothioconazole-4-hydroxy-desthio	0	0.084, 0.083, 0.079, 0.076, 0.076	76-84 (80)	--- --- ---
		33/1	0.090, 0.089, 0.098	89-98 (92)	90, 93 (92)
		61/2	0.096, 0.097, 0.096	96-97 (96)	104, 93 (99)
		93/3	0.097, 0.095, 0.096	95-97 (96)	106, 102 (104)
		197/6.5	0.093, 0.090, 0.091	90-93 (91)	99, 98 (99)
		364/12	0.094, 0.096, 0.092	92-96 (94)	90, 96 (93)
		666/22	0.100, 0.101, 0.098	98-101 (100)	89, 98 (94)
		761/25	0.092, 0.088, 0.098	88-98 (93)	99, 97 (98)
Soybean	Prothioconazole-4-hydroxy-desthio	0	0.078, 0.078, 0.065, 0.059, 0.063	59-78 (69)	--- --- ---
		33/1	0.100, 0.095, 0.099	95-100 (98)	98, 97 (98)
		61/2	0.091, 0.097, 0.095	91-97 (94)	91, 94 (93)
		93/3	0.090, 0.100, 0.096	90-100 (95)	94, 94 (94)
		197/6.5	0.093, 0.096, 0.093	93-96 (94)	95, 97 (96)
		364/12	0.117, 0.114, 0.111	111-117 (114)	113, 115 (114)
		666/22	0.085, 0.091, 0.082	82-91 (86)	96, 99 (98)
		761/25	0.071, 0.082, 0.085	71-85 (79)	89, 88 (89)

\*in the study report storage periods are given in days, in order to keep the OECD template requirements the storage period are here recalculated for months with the following assumption: 1 month = 30.5 day.

**Table A 11: Storage stability of Prothioconazole-5-hydroxy-desthio**

Commodity	Analyte	Storage period (days/months)*	Residue Level in Freezer Storage Stability Sample (mg/kg)	Residue Level in Freezer Storage Stability Sample (% of nominal spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)
Rape oil seed	Prothioconazole-5-hydroxy-desthio	0	0.093, 0.095, 0.098, 0.097, 0.095	93-98 (96)	---, --- (---)
		33/1	0.083, 0.087, 0.084	83-87(85)	80, --- (80)
		61/2	0.085, 0.085, 0.098	85-98 (89)	82, 84 (83)
		93/3	0.100, 0.101, 0.104	100-104 (102)	100, 100 (100)
		197/6.5	0.097, 0.095, 0.099	95-99 (97)	92, 98 (95)
		364/12	0.086, 0.080, 0.076	76-86 (81)	76, 75 (76)
		666/22	0.101, 0.098, 0.096	96-101 (98)	102, 102 (102)
		761/25	0.086, 0.089, 0.076	76-89 (84)	84, 83 (84)
Orange fruit	Prothioconazole-5-hydroxy-desthio	0	0.068, 0.068, 0.065, 0.072, 0.070	65-72 (69)	---, --- (---)
		33/1	0.089, 0.096, 0.087	87-96 (91)	87, --- (87)
		61/2	0.090, 0.092, 0.095	90-95 (92)	86, 92 (89)
		93/3	0.102, 0.101, 0.103	101-103 (102)	---, --- (---)
		197/6.5	0.104, 0.102, 0.099	99-104 (102)	99, 97 (98)
		364/12	0.090, 0.094, 0.093	90-94 (92)	97, 90 (94)
		666/22	0.099, 0.097, 0.101	97-101 (99)	104, 107 (106)
		761/25	0.101, 0.084, 0.089	84-101 (91)	88, 89 (89)
Potato tuber	Prothioconazole-5-hydroxy-desthio	0	0.089, 0.086, 0.084, 0.086, 0.085	84-89 (86)	---, --- (---)
		33/1	0.093, 0.097	93-97 (95)	97, 97 (97)
		61/2	0.094, 0.093, 0.092	93-94 (93)	93, 95 (94)
		93/3	0.102, 0.104, 0.102	102-104 (103)	---, --- (---)
		197/6.5	0.103, 0.098, 0.101	98-103 (101)	97, 93 (95)
		364/12	0.086, 0.085, 0.087	85-87 (86)	94, 93 (94)
		666/22	0.092, 0.094, 0.098	92-98 (95)	96, 101 (99)
		761/25	0.092, 0.096, 0.091	91-96 (93)	99, 97 (98)
Tomato fruit	Prothioconazole-5-hydroxy-desthio	0	0.085, 0.083, 0.082, 0.078, 0.079	78-85 (81)	---, --- (---)
		33/1	0.092, 0.090, 0.099	90-99 (94)	89, 92 (91)
		61/2	0.096, 0.097, 0.097	96-97 (97)	106, 95 (101)
		93/3	0.104, 0.103, 0.103	103-104 (103)	104, 103 (104)
		197/6.5	0.104, 0.101, 0.100	100-104 (102)	99, 98 (99)
		364/12	0.092, 0.089, 0.091	89-92 (91)	100, 99 (100)
		666/22	0.100, 0.102, 0.097	97-102 (100)	90, 100 (95)
		761/25	0.090, 0.083, 0.095	83-95 (89)	97, 93 (95)
Soybean	Prothioconazole-5-hydroxy-desthio	0	0.081, 0.079, 0.064, 0.058, 0.065	58-81 (69)	---, --- (---)
		33/1	0.100, 0.095, 0.099	95-100 (98)	97, 98 (98)
		61/2	0.091, 0.095, 0.096	91-96 (94)	93, 96 (95)
		93/3	0.098, 0.104, 0.102	98-104 (101)	94, 94 (94)
		197/6.5	0.100, 0.101, 0.101	100-101 (101)	100, 100 (100)
		364/12	0.111, 0.105, 0.108	105-111 (108)	106, 110 (108)
		666/22	0.097, 0.099, 0.093	93-99 (96)	96, 99 (98)
		761/25	0.070, 0.081, 0.086	70-86 (79)	85, 87 (86)

\*in the study report storage periods are given in days, in order to keep the OECD template requirements the storage period are here recalculated for months with the following assumption: 1 month = 30.5 day.

**Table A 12: Storage stability of Prothioconazole-6-hydroxy-desthio**

Commodity	Analyte	Storage period (days/months)*	Residue Level in Freezer Storage Stability Sample (mg/kg)	Residue Level in Freezer Storage Stability Sample (% of nominal spiking level) (range plus mean)	Procedural Recovery for Freshly Spiked Control Sample (%)
Rape oil seed	Prothioconazole-6-hydroxy-desthio	0	0.082, 0.086, 0.088, 0.089, 0.087	82-89 (86)	---, --- (---)
		33/1	0.073, 0.077, 0.070	70-77 (73)	71, --- (71)
		61/2	0.073, 0.072, 0.092	72-92 (79)	73, 80 (77)
		93/3	0.088, 0.091, 0.091	88-91 (90)	102, 101 (102)
		197/6.5	0.087, 0.086, 0.093	86-93 (89)	92, 98 (95)
		364/12	0.079, 0.068, 0.074	68-79 (74)	81, 68 (75)
		666/22	0.094, 0.092, 0.085	85-94 (90)	92, 88 (90)
		761/25	0.070, 0.080, 0.064	64-80 (71)	74, 75 (75)
Orange fruit	Prothioconazole-6-hydroxy-desthio	0	0.086, 0.091, 0.086 0.095, 0.093	86-95 (90)	---, --- (---)
		33/1	0.083, 0.089, 0.079	79-89 (84)	77, --- (77)
		61/2	0.082, 0.089, 0.092	82-92 (88)	84, 87 (86)
		93/3	0.098, 0.098, 0.096	96-98 (97)	---, --- (---)
		197/6.5	0.098, 0.099, 0.094	94-99 (97)	90, 92 (91)
		364/12	0.081, 0.084, 0.087	81-87 (84)	86, 85 (86)
		666/22	0.095, 0.095, 0.099	95-99 (96)	98, 101 (100)
		761/25	0.094, 0.078, 0.081	78-94 (84)	75, 76 (76)
Potato tuber	Prothioconazole-6-hydroxy-desthio	0	0.109, 0.109, 0.105, 0.106, 0.105	105-109 (107)	---, --- (---)
		33/1	0.096, 0.097	96-97 (97)	98, 98 (98)
		61/2	0.093, 0.096, 0.093	93-96 (94)	97, 96 (97)
		93/3	0.098, 0.101, 0.100	98-101 (100)	---, --- (---)
		197/6.5	0.103, 0.094, 0.100	94-103 (99)	97, 93 (95)
		364/12	0.086, 0.084, 0.095	84-95 (88)	95, 99 (97)
		666/22	0.087, 0.089, 0.093	87-93 (90)	87, 99 (93)
		761/25	0.089, 0.092, 0.086	86-92 (89)	92, 91 (92)
Tomato fruit	Prothioconazole-6-hydroxy-desthio	0	0.094, 0.092, 0.091, 0.085, 0.088	85-94 (90)	--- --- ---
		33/1	0.089, 0.088, 0.096	88-96 (91)	84, 92 (88)
		61/2	0.094, 0.096, 0.096	94-96 (95)	105, 93 (99)
		93/3	0.100, 0.100, 0.099	99-100 (100)	103, 102 (103)
		197/6.5	0.104, 0.099, 0.095	95-104 (99)	99, 98 (99)
		364/12	0.097, 0.090, 0.092	90-97 (93)	96, 101 (99)
		666/22	0.096, 0.095, 0.089	89-96 (93)	86, 93 (90)
		761/25	0.083, 0.075, 0.084	75-84 (81)	87, 85 (86)
Soybean	Prothioconazole-6-hydroxy-desthio	0	0.088, 0.082, 0.070, 0.059, 0.070	59-88 (74)	---, --- (---)
		33/1	0.099, 0.094, 0.096	94-99 (96)	98, 97 (98)
		61/2	0.089, 0.092, 0.093	89-93 (91)	89, 92 (91)
		93/3	0.097, 0.102, 0.100	97-102 (100)	95, 95 (95)
		197/6.5	0.098, 0.101, 0.101	98-101 (100)	103, 103 (103)
		364/12	0.111, 0.108, 0.108	108-111 (109)	105, 106 (106)
		666/22	0.090, 0.091, 0.086	86-91 (89)	89, 91 (90)
		761/25	0.067, 0.077, 0.081	67-81 (75)	82, 84 (83)

\*in the study report storage periods are given in days, in order to keep the OECD template requirements the storage period are here recalculated for months with the following assumption: 1 month = 30.5 day.

## A 2.1.1.1.2 Storage stability of residues in animal products

### A 2.1.1.1.2.1 Study 3 (S20-09716)

Comments of zRMS:	<p>The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application. The conclusions of the assessment are presented below:</p> <p><i>The study was conducted to check the storage stability of</i></p> <ul style="list-style-type: none"> <li>- <i>prothioconazole, prothioconazole-desthio (Group 1),</i></li> <li>- <i>prothioconazole-alpha-hydroxy-desthio, -3-hydroxy-desthio, -4-hydroxy-desthio, -5-hydroxy-desthio and -6-hydroxy-desthio (Group 2),</i></li> <li>- <i>1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid (Group 3)</i></li> </ul> <p><i>in bee products (honey, nectar and pollen) stored up to 6 months at <math>\leq -18^{\circ}\text{C}</math> in the dark.</i></p> <p><u>Group 1:</u> <i>The study is deemed sufficient for assessing the stability of prothioconazole-desthio in homogenates of matrices honey, nectar and pollen upon storage at <math>\leq -18^{\circ}\text{C}</math> for over 6 months (182 days for honey, 183 days for pollen, 198 days for nectar).</i></p> <p><i>The study is deemed sufficient for assessing the stability of prothioconazole upon storage at <math>\leq -18^{\circ}\text{C}</math> in homogenates of matrices nectar for more than 6 months (198 days) and for pollen for 3 months (91 days).</i></p> <p><u>Group 2:</u> <i>The study is deemed sufficient for assessing the stability of prothioconazole-alpha-hydroxy-desthio in homogenates of matrices honey, nectar and pollen upon storage at <math>\leq -18^{\circ}\text{C}</math> for 4.5 months (134 days for honey and nectar, 136 days for pollen).</i></p> <p><i>The study is deemed sufficient for assessing the stability of prothioconazole-3, -4, -5 and -6-hydroxy-desthio in homogenates of matrices honey, nectar and pollen upon storage at <math>\leq -18^{\circ}\text{C}</math> for 5 months (157 days).</i></p> <p><u>Group 3:</u> <i>The study is deemed sufficient for assessing the stability of 1,2,4-triazole, triazole alanine, triazole lactic acid and triazole acetic acid in homogenates of matrices honey, nectar and pollen upon storage at <math>\leq -18^{\circ}\text{C}</math> for 6 months (182 days for honey and pollen, 185 days for nectar).</i></p> <p><i>The study was conducted according to the OECD 506.</i></p> <p><i>The study is acceptable.</i></p>
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Reference:	KCA 6.1/03
Report	Storage Stability of Prothioconazole and metabolites in different matrices under Deep Frozen Conditions Kalathoor, R., 2021 Report No S20-09716
Guideline(s):	OECD 506, 2007; OECD Guideline for the Testing of Chemicals – Stability of Pesticide Residues in Stored Commodities
Deviations:	None
GLP:	Yes
Owner:	Nufarm Crop Products UK
Acceptability:	Yes

The storage stability of prothioconazole-desthio (Group 1), prothioconazole-alpha-hydroxy-desthio, -3-hydroxy-desthio, -4-hydroxy-desthio, -5-hydroxy-desthio and -6-hydroxy-desthio (Group 2), as well as 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid (Group 3) was investigated in bee products (honey, nectar and pollen) stored at  $\leq -18^{\circ}\text{C}$  (target) in the dark. The storage stability of prothioconazole was investigated in nectar and pollen only (not analysed in honey).

#### Materials and methods

The fortification level for storage samples was at ten times the limit of quantification (LOQ) of the method (i.e. 0.1 mg/kg) with all analytes fortified separately on aliquots of homogenised control sample material.



Storage samples were kept at  $\leq -18^{\circ}\text{C}$  in the dark and analysed at different intervals. All testing intervals were accompanied by analysis of a control sample and two procedural recoveries.

Sample extraction and determination of residues was performed according to the analytical methods that was previously validated at Eurofins Agroscience Services EcoChem GmbH according to SANTE/2020/12830, rev. 1 for risk assessment for matrices nectar and pollen and for monitoring for matrix honey in study S20-09747. Additional 5 procedural recoveries at LOQ level were done for prothioconazole-desthio in matrix honey since a minor modification was applied to the method.

In brief, samples of honey and pollen for group 1 and 2 were extracted with acetonitrile and if necessary, after addition of water containing cysteine hydrochloride solution. A salt mixture containing magnesium sulphate, sodium chloride and sodium citrate was added, and the extract was shaken to obtain phase separation after centrifugation.

For pollen, an aliquot of the acetonitrile phase was cleaned by adding primary secondary amine (PSA). For nectar direct dilution with acetonitrile/water was done for group 1 and group 2 samples. In final steps for nectar, samples were diluted with methanol/water, and for pollen and honey the same solvent mixture containing cysteine hydrochloride (in excess) for stabilization of PTZ (group 1). Whereas, for group 2 final dilution of nectar, pollen and honey was done with aqueous solution of ammonium formate.

Group 3 analytes containing 1,2,4-triazole and triazole derivated metabolites, extraction with a mixture of methanol/water was done for pollen. After evaporation of the methanol phase, samples were diluted with HPLC water. All soluble matrices as nectar and honey were directly diluted in HPLC water and analysed.

Fortification was done for recovery samples.

Quantification was performed by use of LC-MS/MS (group 1 and 2) and LC-DMS-MS/MS (group 3) detection using matrix matched calibration.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ). For group 2 analytes, the LOQ is expressed as prothioconazole-desthio equivalent.

## Results and discussions

### Group 1: Prothioconazole (PTZ) and/or Prothioconazole-desthio

**Table A 13: Storage stability of Prothioconazole-desthio in Honey**

Storage Period (days)	Procedural Recoveries		Storage Samples			
	Single Values (%)	Mean (%) <sup>a</sup>	Residue Level in Storage Samples (mg/kg)	Percentage of analyte found relative to the nominal fortification level (%)		Percentage recovered relative to the mean percentage recovered at day 0
				Single Values (%) <sup>b</sup>	Mean (%) <sup>a</sup>	
Prothioconazole-desthio (PTZ-desthio) Mass Transition 312→125 m/z mg/kg (10x LOQ)				Nominal Fortification Level: 0.1		
0	99,101	100	0.0990,0.0990	99,99	99	100
90	102,99	100	0.0930,0.0940	93,94	94	95
182	97,99	98	0.0810,0.0885	81,89	85	86

<sup>a</sup> calculated from unrounded values; <sup>b</sup> not corrected for procedural recoveries

**Table A 14: Storage stability of Prothioconazole and Prothioconazole-desthio in Nectar**

Storage Period (days)	Procedural Recoveries		Storage Samples			
	Single Values (%)	Mean (%) <sup>a</sup>	Residue Level in Storage Samples (mg/kg)	Percentage of analyte found relative to the nominal fortification level (%)		Percentage recovered relative to the mean percentage recovered at day 0
				Single Values (%) <sup>b</sup>	Mean (%) <sup>a</sup>	
Prothioconazole-desthio (PTZ-desthio) Mass Transition 312→125 m/z mg/kg (10x LOQ)			Nominal Fortification Level: 0.1			
0	103,99	101	0.102,0.0998	102,100	101	100
90	105,103	104	0.0960,0.0958	96,96	96	95
198	99,100	100	0.0834,0.0905	83,91	87	88
Prothioconazole (PTZ) Mass Transition 344→154 m/z mg/kg (10x LOQ)			Nominal Fortification Level: 0.1			
0	94,93	93	0.0911,0.0939	91,94	93	100
90	99,100	99	0.0727,0.0782	73,78	75	81
198	96,92	94	0.0759,0.0778	76,78	77	83

<sup>a</sup> calculated from unrounded values; <sup>b</sup> not corrected for procedural recoveries

**Table A 15: Storage stability of Prothioconazole and Prothioconazole-desthio in Pollen**

Storage Period (days)	Procedural Recoveries		Storage Samples			
	Single Values (%)	Mean (%) <sup>a</sup>	Residue Level in Storage Samples (mg/kg)	Percentage of analyte found relative to the nominal fortification level (%)		Percentage recovered relative to the mean percentage recovered at day 0
				Single Values (%) <sup>b</sup>	Mean (%) <sup>a</sup>	
Prothioconazole-desthio (PTZ-desthio) Mass Transition 312→125 m/z LOQ)			Nominal Fortification Level: 0.1 mg/kg (10x			
0	98,98	98	0.100,0.100	100,100	100	100
90	97,97	97	0.0960,0.0984	96,98	97	97
183	111,117	114	0.107,0.103	107,103	105	105
Prothioconazole (PTZ) Mass Transition 344→154 m/z mg/kg (10x LOQ)			Nominal Fortification Level: 0.1			
0	106,105	106	0.111,0.103	111,103	107	100
50	99,89	94	0.0789,0.0741	79,74	77	72
66	95,114	105	0.0768,0.0756	77,76	77	72
80	101,93	97	0.0792,0.0864	79,86	83	78
91	109,113	111	0.0849,0.0675	85,68	77	72

<sup>a</sup> calculated from unrounded values; <sup>b</sup> not corrected for procedural recoveries

Group 2: Prothioconazole- $\alpha$ -OH-,3-OH, 4-OH, 5-OH, 6-OH –Desthio (5 analytes) expressed as prothioconazole-desthio equivalent.

**Table A 16: Storage stability of Prothioconazole-desthio hydroxies in Honey**

Storage Period (days)	Procedural Recoveries		Storage Samples		
	Single Values (%)	Mean (%) <sup>a</sup>	Residue Level in Storage Samples (mg/kg)*	Percentage of analyte found relative to the nominal fortification level (%)	Percentage recovered relative to the mean

				Single Values (%) <sup>b</sup>	Mean (%) <sup>a</sup>	percentage recovered at day 0
Prothioconazole-alpha-hydroxy-desthio (alpha-OH) Mass Transition 328→70 m/z mg/kg (10x LOQ)*				Nominal Fortification Level: 0.1		
0	97,97	97	0.0968,0.0952	97,95	96	100
94	108,111	110	0.113,0.109	113,109	111	116
134	104,102	103	0.100,0.0980	100,98	99	103
Prothioconazole-3-hydroxy-desthio (3-OH) Mass Transition 328→70 m/z Level: 0.1 mg/kg (10x LOQ)*				Nominal Fortification		
0	94,97	95	0.101,0.100	101,100	101	100
91	104,106	105	0.106,0.100	106,100	103	102
156	102,107	105	0.108,0.110	108,110	109	108
Prothioconazole-4-hydroxy-desthio (4-OH) Mass Transition 328→70 m/z mg/kg (10x LOQ)*				Nominal Fortification Level: 0.1		
0	97,98	98	0.104,0.102	104,102	103	100
91	101,102	102	0.102,0.102	102,102	102	99
156	104,106	105	0.110,0.112	110,112	111	108
Prothioconazole-5-hydroxy-desthio (5-OH) Mass Transition 328→70 m/z Level: 0.1 mg/kg (10x LOQ)*				Nominal Fortification		
0	98,96	97	0.103,0.104	103,104	104	100
91	102,108	105	0.0976,0.102	98,102	100	96
156	104,106	105	0.112,0.110	112,110	111	107
Prothioconazole-6-hydroxy-desthio (6-OH) Mass Transition 328→70 m/z Level: 0.1 mg/kg (10x LOQ)*				Nominal Fortification		
0	98,97	97	0.0960,0.0972	96,97	97	100
91	103,105	104	0.0996,0.103	100,103	101	104
156	103,105	104	0.102,0.0860	102,86	94	97

<sup>a</sup> calculated from unrounded values; <sup>b</sup> not corrected for procedural recoveries; \* as prothioconazole-desthio equivalent

**Table A 17: Storage stability of Prothioconazole-desthio hydroxies in Nectar**

Storage Period (days)	Procedural Recoveries		Storage Samples			
	Single Values (%)	Mean (%) <sup>a</sup>	Residue Level in Storage Samples (mg/kg)*	Percentage of analyte found relative to the nominal fortification level (%)		Percentage recovered relative to the mean percentage recovered at day 0
				Single Values (%) <sup>b</sup>	Mean (%) <sup>a</sup>	
Prothioconazole- $\alpha$ -hydroxy-desthio ( $\alpha$ -OH) Mass Transition 328 $\rightarrow$ 70 m/z mg/kg (10x LOQ)*						
0	98,98	98	0.0940,0.0984	94,98	96	100
94	98,98	98	0.0948,0.0968	95,97	96	100
134	105,104	105	0.0980,0.101	98,101	100	104
Prothioconazole-3-hydroxy-desthio (3-OH) Mass Transition 328 $\rightarrow$ 70 m/z mg/kg (10x LOQ)*						
0	102,108	105	0.100,0.100	100,100	100	100
91	92,96	94	0.0928,0.0924	93,92	93	93

157	96,97	96	0.0924,0.0864	92,86	89	89
Prothioconazole-4-hydroxy-desthio (4-OH) Mass Transition 328→70 m/z				Nominal Fortification Level: 0.1 mg/kg (10x LOQ)*		
0	103,107	105	0.102,0.103	102,103	103	100
91	94,93	94	0.0932,0.0940	93,94	94	91
157	100,102	101	0.0944,0.0952	94,95	95	92
Prothioconazole-5-hydroxy-desthio (5-OH) Mass Transition 328→70 m/z				Nominal Fortification Level: 0.1 mg/kg (10x LOQ)*		
0	102,107	105	0.103,0.101	103,101	102	100
91	93,94	94	0.0876,0.0896	88,90	89	87
157	99,100	99	0.0924,0.0952	92,95	94	92
Prothioconazole-6-hydroxy-desthio (6-OH) Mass Transition 328→70 m/z				Nominal Fortification Level: 0.1 mg/kg (10x LOQ)*		
0	103,104	104	0.0980,0.0988	98,99	98	100
91	92,95	94	0.0912,0.0904	91,90	91	93
157	101,104	103	0.0964,0.0972	96,97	97	99

<sup>a</sup> calculated from unrounded values; <sup>b</sup> not corrected for procedural recoveries; \* as prothioconazole-desthio equivalent

**Table A 18: Storage stability of Prothioconazole-desthio hydroxies in Pollen**

Storage Period (days)	Procedural Recoveries		Storage Samples			
	Single Values (%)	Mean (%) <sup>a</sup>	Residue Level in Storage Samples (mg/kg)*	Percentage of analyte found relative to the nominal fortification level (%)		Percentage recovered relative to the mean percentage recovered at day 0
				Single Values (%) <sup>b</sup>	Mean (%) <sup>a</sup>	
Prothioconazole- $\alpha$ -hydroxy-desthio ( $\alpha$ -OH) Mass Transition 328→70 m/z Level: 0.1 mg/kg (10x LOQ)*						
0	101,100	101	0.0984,0.0945	98,95	96	100
94	103,102	103	0.0999,0.101	100,101	100	104
136	114,107	111	0.111,0.111	111,111	111	116
Prothioconazole-3-hydroxy-desthio (3-OH) Mass Transition 328→70 m/z mg/kg (10x LOQ)*						
0	92,93	93	0.0927,0.0954	93,95	94	100
91	99,96	97	0.0927,0.0936	93,94	93	99
157	107,101	104	0.100,0.101	100,101	101	107
Prothioconazole-4-hydroxy-desthio (4-OH) Mass Transition 328→70 m/z mg/kg (10x LOQ)*						
0	93,94	93	0.0960,0.0939	96,94	95	100
91	99,98	98	0.0984,0.0978	98,98	98	103
157	105,100	103	0.0993,0.0999	99,100	100	105
Prothioconazole-5-hydroxy-desthio (5-OH) Mass Transition 328→70 m/z mg/kg (10x LOQ)*						
0	93,93	93	0.0963,0.0963	96,96	96	100
91	100,99	100	0.0918,0.0921	92,92	92	96
157	103,103	103	0.0963,0.0996	96,100	98	102
Prothioconazole-6-hydroxy-desthio (6-OH) Mass Transition 328→70 m/z mg/kg (10x LOQ)*						
0	91,91	91	0.0915,0.0933	92,93	92	100
91	100,99	100	0.0903,0.0906	90,91	90	98
157	101,102	102	0.0906,0.0873	91,87	89	97

<sup>a</sup> calculated from unrounded values; <sup>b</sup> not corrected for procedural recoveries; \* as prothioconazole-desthio equivalent

**Group 3: 1,2,4-Triazole (Tz), Triazole Alanine (TA), Triazole Acetic Acid (TAA), Triazole Lactic Acid (TLA)**

**Table A 19: Storage stability of Triazole Derivative Metabolite (TDM) in Honey**

Storage Period (days)	Procedural Recoveries		Storage Samples			
	Single Values (%)	Mean (%) <sup>a</sup>	Residue Level in Storage Samples (mg/kg)	Percentage of analyte found relative to the nominal fortification level (%)		Percentage recovered relative to the mean percentage recovered at day 0
				Single Values (%) <sup>b</sup>	Mean (%) <sup>a</sup>	
1,2,4-Triazole (Tz) Mass Transition 70→43 <i>m/z</i> <span style="float:right">Nominal Fortification Level: 0.1 mg/kg (10x LOQ)</span>						
0	101,93	97	0.104,0.105	104,105	105	100
92	94,97	96	0.0974,0.0950	97,95	96	92
182	89,97	93	0.103,0.0926	103,93	98	94
Triazole Alanine (TA) Mass Transition 157→70 <i>m/z</i> <span style="float:right">Nominal Fortification Level: 0.1 mg/kg (10x LOQ)</span>						
0	96,92	94	0.0992,0.101	99,101	100	100
92	98,105	102	0.0974,0.0932	97,93	95	95
182	84,98	91	0.111,0.109	111,109	110	110
Triazole Acetic Acid (TAA) Mass Transition 128→70 <i>m/z</i> <span style="float:right">Nominal Fortification Level: 0.1 mg/kg (10x LOQ)</span>						
0	101,103	102	0.103,0.105	103,105	104	100
92	96,99	97	0.103,0.103	103,103	103	99
182	98,90	94	0.112,0.114	112,114	113	109
Triazole Lactic Acid (TLA) Mass Transition 158→70 <i>m/z</i> <span style="float:right">Nominal Fortification Level: 0.1 mg/kg (10x LOQ)</span>						
0	97,100	99	0.0922,0.0910	92,91	92	100
92	94,92	93	0.0880,0.0912	88,91	90	98
182	100,97	99	0.107,0.108	107,108	108	117

<sup>a</sup> calculated from unrounded values; <sup>b</sup> not corrected for procedural recoveries

**Table A 20: Storage stability of Triazole Derivative Metabolite (TDM) in Nectar**

Storage Period (days)	Procedural Recoveries		Storage Samples			
	Single Values (%)	Mean (%) <sup>a</sup>	Residue Level in Storage Samples (mg/kg)	Percentage of analyte found relative to the nominal fortification level (%)		Percentage recovered relative to the mean percentage recovered at day 0
				Single Values (%) <sup>b</sup>	Mean (%) <sup>a</sup>	
1,2,4-Triazole (Tz) Mass Transition 70→43 <i>m/z</i> <span style="float:right">Nominal Fortification Level: 0.1 mg/kg (10x LOQ)</span>						
0	100,97	98	0.0992,0.0972	99,97	98	100
90	103,100	101	0.0928,0.0992	93,99	96	98
185	86,97	91	0.0928,0.103	93,103	98	100
Triazole Alanine (TA) Mass Transition 157→70 <i>m/z</i> <span style="float:right">Nominal Fortification Level: 0.1 mg/kg (10x LOQ)</span>						
0	100,99	99	0.107,0.104	107,104	106	100
90	102,98	100	0.107,0.102	107,102	105	99
185	114,112	113	0.114,0.108	114,108	111	105
Triazole Acetic Acid (TAA) Mass Transition 128→70 <i>m/z</i> <span style="float:right">Nominal Fortification Level: 0.1 mg/kg (10x LOQ)</span>						
0	99,98	99	0.103,0.104	103,104	104	100
90	104,101	103	0.102,0.0980	102,98	100	96
185	104,101	103	0.111,0.109	111,109	110	106
Triazole Lactic Acid (TLA) Mass Transition 158→70 <i>m/z</i> <span style="float:right">Nominal Fortification Level: 0.1 mg/kg (10x LOQ)</span>						
0	100,98	99	0.0980,0.0960	98,96	97	100
90	103,101	102	0.0976,0.0948	98,95	96	99
185	99,100	99	0.100,0.104	100,104	102	105

<sup>a</sup> calculated from unrounded values; <sup>b</sup> not corrected for procedural recoveries

**Table A 21: Storage stability of Triazole Derivative Metabolite (TDM) in Pollen**

Storage Period (days)	Procedural Recoveries		Storage Samples			
	Single Values (%)	Mean (%) <sup>a</sup>	Residue Level in Storage Samples (mg/kg)	Percentage of analyte found relative to the nominal fortification level (%)		Percentage recovered relative to the mean percentage recovered at day 0
				Single Values (%) <sup>b</sup>	Mean (%) <sup>a</sup>	
1,2,4-Triazole (Tz) Mass Transition 70→43 <i>m/z</i> <span style="float:right">Nominal Fortification Level: 0.1 mg/kg (10x LOQ)</span>						
0	108,105	107	0.0880,0.0870	88,87	88	100
92	109,103	106	0.0693,0.0743	69,74	72	82
182	85,77	81	0.0757,0.0647	76,65	70	80
Triazole Alanine (TA) Mass Transition 157→70 <i>m/z</i> <span style="float:right">Nominal Fortification Level: 0.1 mg/kg (10x LOQ)</span>						
0	102,104	103	0.109,0.109	109,109	109	100
92	94,91	92	0.0877,0.0873	88,87	88	81
182	86,97	91	0.106,0.105	106,105	106	97
Triazole Acetic Acid (TAA) Mass Transition 128→70 <i>m/z</i> <span style="float:right">Nominal Fortification Level: 0.1 mg/kg (10x LOQ)</span>						
0	109,105	107	0.111,0.110	111,110	111	100
92	87,90	89	0.103,0.0987	103,99	101	91
182	102,100	101	0.110,0.106	110,106	108	97
Triazole Lactic Acid (TLA) Mass Transition 158→70 <i>m/z</i> <span style="float:right">Nominal Fortification Level: 0.1 mg/kg (10x LOQ)</span>						
0	106,110	108	0.101,0.104	101,104	103	100
92	83,84	83	0.0883,0.0853	88,85	87	84
182	97,103	100	0.0847,0.0870	85,87	86	83

<sup>a</sup> calculated from unrounded values; <sup>b</sup> not corrected for procedural recoveries

## Conclusion

The stability of Prothioconazole-desthio when stored at ≤ -18 °C is demonstrated for 182 days in honey, 198 days in nectar and 183 days in pollen. The stability of Prothioconazole when stored at ≤ -18 °C is demonstrated for 198 days in nectar and for 91 days in pollen.

The stability of prothioconazole-alpha-hydroxy-desthio when stored at ≤ -18 °C is demonstrated for 134 days in honey, 134 days in nectar and 136 days in pollen.

The stability of prothioconazole-3, -4, -5 and -6-hydroxy-desthio when stored at ≤ -18 °C is demonstrated for 157 days in honey, nectar and pollen.

The stability of 1,2,4-triazole, triazole alanine, triazole lactic acid and triazole acetic acid when stored at ≤ -18 °C is demonstrated for 182 days in honey, 185 days in nectar and 182 days in pollen.

### A 2.1.1.1.3 New storage stability of residues in plant products

#### A 2.1.1.1.3.1 Study S22-08287

Comments of zRMS:	<p>The results of the study demonstrate that triazole metabolites 1,2,4-triazole (T), triazole alanine (TA) in homogenates of oilseed rape (grain) as well as of 1,2,4-triazole (T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in homogenates of oilseed rape (straw) are stable under frozen storage at -18 °C or below for 55 days.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix.</p> <p>The mean recoveries over all testing intervals were within 70% - 110% with the relative standard deviations ≤ 20 % for all analytes and matrices (oilseed rape (grain and straw)).</p>
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	The study is acceptable.
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Reference:	KCA 6.1/04
Report	Storage Stability of the Triazole Derivative Metabolites in Oilseed Rape under Deep Frozen Conditions Winter, O. <i>et al.</i> , 26.05.2023 Report No: S22-08287 (NUK-2201L)
Guideline(s):	- EC Guideline 7032/VI/95, rev. 5, July 1997; Appendix H of working document - 1607/VI/97, rev. 2, June 1999 – Storage Stability of Residue Samples - OECD 506, 2007; OECD Guideline for the Testing of Chemicals – Stability of Pesticide Residues in Stored Commodities - ENV/JM/MONO(2007)17 (OECD guidance document on pesticide residue analytical methods)
Deviations:	None
GLP:	Yes
Owner:	Nufarm Crop Products UK
Acceptability:	Yes

## Materials and methods

A deep-freezer storage stability study was conducted to obtain data about the storage stability of the triazole metabolites 1,2,4-triazole (T), triazole alanine (TA) in oilseed rape (grain) as well as of 1,2,4-triazole (T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in oilseed rape (straw).

The fortification level for storage samples was at 100 times the limit of quantification (LOQ) of the method (1.0 mg/kg), except for triazole alanine in oilseed rape (grain) where the fortification level was at 200 times the limit of quantification (LOQ) 2.0 mg/kg). All analytes have been fortified separately on aliquots of homogenised control sample material.

The fortified samples were stored in a freezer at about minus 18°C for up to 55 days. Control samples that had not been fortified with triazole metabolites were stored under the same conditions to allow procedural recovery determination from freshly fortified samples.

Samples were analysed after nominal storage periods of 0, 45-47, 55 days.

Sample extraction and determination of analyte levels was performed according to the analytical method as validated in S15-03542<sup>12</sup> and quantification was performed by use of LC-MS/MS detection with isotopically labelled internal standards.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ).

The maximum storage interval of final sample extracts at typically 1 °C to 10 °C from extraction until injection to LC-MS/MS was 5 days.

## Results and discussions

### Accuracy and Precision

For 1,2,4-triazole the mean recovery for samples extracted without any storage (day 0 storage samples and concurrent recoveries) was 87 % for oilseed rape (grain) and 99 % for oilseed rape (straw).

For triazole alanine the mean recovery for samples extracted without any storage (day 0 storage samples and concurrent recoveries) was 94 % for oilseed rape (grain) and 96 % for oilseed rape (straw).

For triazole acetic acid the mean recovery for samples extracted without any storage (day 0 storage samples and concurrent recoveries) was 104 % for oilseed rape (straw).

For triazole lactic acid the mean recovery for samples extracted without any storage (day 0 storage samples and concurrent recoveries) was 84 % for oilseed rape (straw).

<sup>12</sup> “Validation of an Analytical Method for the Determination of Triazole and Triazole-based Metabolites in the Agricultural Commodity Wheat, Barley, Grape and Rape“, Nina Schernikau, Carolina Suaza Colorado, S15-03542 (GAB-1537V), Eurofins Agroscience Services Chem GmbH, 05 Apr 2016

Relative standard deviation was  $\leq 20\%$  for all analytes and matrices.

For duplicate analysis of storage samples from the same time point the difference between the highest and lowest recovery did not exceed 20 %.

These values demonstrate satisfying analytical performance for all analytes and matrices while analysing the storage samples. See the following tables.

#### Applicability/Suitability

For oilseed rape (grain and straw) the applicability/suitability of the method according to SANTE/2020/12830, rev. 1 was demonstrated within this study by a minimum of 3 recoveries at 100x LOQ for all analytes, with the exception of 200x LOQ for triazole alanine in oilseed rape (grain). Furthermore, the applicability/suitability of the method for matrices of oilseed rape (grain and straw) was demonstrated by concurrent recoveries at LOQ (0.01 mg/kg) and 10x LOQ 0.1 mg/kg within the analytical phase of study S22-0257<sup>13</sup>.

For all combinations of analytes and matrices the average amount of analyte recovered relative to the initial mean recovery at day 0 was  $\geq 70\%$  at any testing interval.

**Table A 22: Storage stability of triazole metabolites in oilseed rape (grain)**

Storage Period (days)	Concurrent Recoveries		Storage Samples				
	Single Values (%)	Mean (%) <sup>a</sup> in brackets: rel. std. deviation %	Residue Level in Storage Samples (mg/kg) <sup>b</sup>	Percentage of analyte found relative to the nominal fortification level (%)		Percentage recovered corrected for the (mean) concurrent recovery of the individual date of extraction <sup>a</sup>	Percentage recovered relative to the mean percentage recovered at day 0 <sup>a</sup>
				Single Values (%) <sup>b</sup>	Mean (%) <sup>a</sup> in brackets: rel. std. deviation %		
Analyte: 1,2,4-triazole      Nominal Fortification Level: 1.0 mg/kg (100x LOQ)							
0 day	-	-	0.98, 0.89, 0.96	98, 89, 96	95 (4.8)	-	-
47 days	83, 82	82	0.84, 0.83	84, 83	83	101	87
55 days	89, 76	82	0.73, 0.62	73, 62	67	82	71
Analyte: triazole alanine      Nominal Fortification Level: 2.0 mg/kg (100x LOQ)							
0 day	-	-	0.86 (1.2), 0.88 (1.2), 0.88 (1.2)	86 (120), 88 (122), 88 (123)	87 (1.6)	-	-
45 days	109 (158), 111 (161)	110	0.84 (1.3), 0.96 (1.5)	84 (133), 96 (146)	90	82	103
55 days	96 (142), 79 (125)	88	0.84 (1.3), 0.67 (1.1)	84 (130), 67 (113)	76	86	87

<sup>a</sup> calculated from unrounded values; <sup>b</sup> if corrected for concurrent recoveries, then uncorrected values are shown in brackets

**Table A 23: Storage stability of triazole metabolites in oilseed rape (straw)**

Storage Period (days)	Concurrent Recoveries		Storage Samples				
	Single Values (%)	Mean (%) <sup>a</sup> in brackets: rel. std. deviation %	Residue Level in Storage Samples (mg/kg) <sub>b</sub>	Percentage of analyte found relative to the nominal fortification level (%)		Percentage recovered corrected for the (mean) concurrent recovery of the individual date of extraction <sup>a</sup>	Percentage recovered relative to the mean percentage recovered at day 0 <sup>a</sup>
				Single Values (%) <sup>b</sup>	Mean (%) <sup>a</sup> in brackets: rel. std. deviation %		
Analyte: 1,2,4-triazole      Nominal Fortification Level: 1.0 mg/kg (100x LOQ)							
0 day	-	-	1.1, 1.0, 1.0	108, 100, 100	103 (4.4)	-	-

<sup>13</sup> “Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole in Oilseed rape (outdoor) at 3 sites in Northern Europe in 2022 “, Olga Winter, Hannah Graf, S22-00257 (EAS-2206), Eurofins Agrosience Services Chem GmbH

Storage Period (days)	Concurrent Recoveries		Storage Samples				
	Single Values (%)	Mean (%) <sup>a</sup> in brackets: rel. std. deviation %	Residue Level in Storage Samples (mg/kg) <sup>b</sup>	Percentage of analyte found relative to the nominal fortification level (%)		Percentage recovered corrected for the (mean) concurrent recovery of the individual date of extraction <sup>a</sup>	Percentage recovered relative to the mean percentage recovered at day 0 <sup>a</sup>
				Single Values (%) <sup>b</sup>	Mean (%) <sup>a</sup> in brackets: rel. std. deviation %		
45 days	95, 93	94	0.82, 0.86	82, 86	84	89	82
55 days	92, 102	97	0.84, 0.92	84, 92	88	91	85
Analyte: triazole alanine Nominal Fortification Level: 1.0 mg/kg (100x LOQ)							
0 day	-	-	0.83, 0.84, 0.82	83, 84, 82	83 (1.3)	-	-
45 days	114 (117), 104 (107)	109	0.79 (0.82), 0.79 (0.82)	79 (82), 79 (82)	79	72	95
55 days	101 (104), 105 (108)	103	0.78 (0.80), 0.79 (0.82)	78 (80), 79 (82)	79	77	95
Analyte: acetic acid Nominal Fortification Level: 1.0 mg/kg (100x LOQ)							
0 day	-	-	1.1, 1.1, 1.1	108, 106, 108	108 (0.9)	-	-
45 days	101 (104), 98 (101)	100	0.99 (1.0), 0.88 (0.92)	99 (102), 88 (92)	94	94	87
55 days	104 (108), 101 (105)	103	1.0 (1.1), 1.1 (1.1)	101 (105), 105 (108)	103	100	95
Analyte: lactic acid Nominal Fortification Level: 1.0 mg/kg (100x LOQ)							
0 day	-	-	0.96, 0.94, 0.99	96, 94, 99	96 (2.3)	-	-
47 days	76 (79), 79 (82)	78	0.77 (0.80), 0.83 (0.85)	77 (80), 83 (85)	78	100	81
55 days	73 (75), 74 (76)	74	0.71 (0.72), 0.70 (0.72)	71 (72), 70 (72)	71	96	74

<sup>a</sup> calculated from unrounded values; <sup>b</sup> if corrected for concurrent recoveries, then uncorrected values are shown in brackets

## Conclusion

The results of the study demonstrate the stability of triazole metabolites 1,2,4-triazole (T), triazole alanine (TA) in homogenates of oilseed rape (grain) as well as of 1,2,4-triazole (T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in homogenates of oilseed rape (straw) upon storage at ≤ 18 °C for 55 days.

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

#### A 2.1.2.1 Nature of residue in plants

##### A 2.1.2.1.1 Nature of residue in primary crops

No new data submitted.

##### A 2.1.2.1.2 Nature of residue in rotational crops

No new data submitted.

##### A 2.1.2.1.3 Nature of residues in processed commodities

No new data submitted.

#### A 2.1.2.2 Nature of residues in livestock

No new data submitted.

### A 2.1.3 Magnitude of residues in plants

### A 2.1.3.1 Barley, Oat

**Table A 24: Comparison of intended and critical EU GAPs – Barley & Oat**

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP NEU(DAR, UK, 2007)	2	200	14-21	BBCH 30-61	35
cGAP NEU(Art. 12, EFSA, 2020)	2	200	14-21	NEU: BBCH 30-69 SEU: BBCH 32-61	28
Intended cGAP CEU	2	150	14-21	BBCH 30-61	35

#### A 2.1.3.1.1 Study 10-2204 – NEU

Comments of zRMS:	<p>It should be noted that the study of Schoening, Bauer and Koester (10-2204) is currently under review in the EU approval renewal process for prothioconazole.</p> <p>The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application. The conclusions of the assessment are presented below:</p> <p><i>Two residue trials on spring barley were conducted in northern Europe to determine residue of prothioconazole-desthio and prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio.</i></p> <p><i>Barley was treated twice at application rate of 0.150 kg a.s./ha of prothioconazole with 14 days interval between applications. The time of application was:</i></p> <ol style="list-style-type: none"> <li><i>1. at BBCH 37-39,</i></li> <li><i>2. at BBCH 61.</i></li> </ol> <p><i>Samples were taken at harvest.</i></p> <p><i>Analytical method for determination of prothioconazole-desthio - method 01013.</i></p> <p><i>Analytical method for determination of prothioconazole -alpha-hydroxy-desthio, -3-hydroxy-desthio, -4-hydroxy-desthio, -5-hydroxy-desthio and -6-hydroxy-desthio – method 00979/M001.</i></p> <p><i>Limit of quantitation of 0.01 mg/kg for grain, green material and straw.</i></p> <p><i>Mean recoveries in acceptable range (70 - 110%), RSD &lt;20%.</i></p> <p><i>Maximum storage period - 387 days.</i></p> <p><i>The residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio in barley grain at harvest were &lt;0.01 mg/kg. In grain at harvest, the total residue was always &lt;0.06 mg/kg.</i></p> <p><i>The study is acceptable.</i></p>
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Reference: KCA 6.3.1/01

Report Determination of the residues of BYF 00587, HEC 5725 and prothioconazole in/on barley after spray application of bixafen & fluoxastrobin & prothioconazole EC 190 in the field in the Netherlands and Germany  
Schoening, R.; Bauer, J.; Koester, P., 28.09.2011  
Report No: M-414691-01-1  
Reference No: 10-2204

Guideline(s): EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8  
Residues in or on Treated Products, Food and Feed  
EC guidance working document 7029/VI/95 rev. 5 (1997-07-22)

Deviations:	Not specified
GLP:	Yes
Owner:	Bayer CropScience AG (Nufarm has a letter of access)
Acceptability:	Yes

**The following study is currently under review in the EU approval renewal process for prothioconazole.**

### Materials and Methods

In the vegetation period of 2010, a set of 2 residue trials on spring barley was conducted in northern Europe. The trials were performed in the Netherlands and Germany.

In each trial, barley was treated twice at a product rate of 1.5 L/ha Bixafen & Fluoxastrobin & Prothioconazole EC 190 corresponding to 0.150 kg a.s./ha of prothioconazole. The water rate was 300 L/ha. The spray interval was 14 days. The time of application was:

1. when the flag leaf is just visible (still rolled) and at the flag leaf stage (flag leaf fully unrolled, ligule just visible) (BBCH 37-39), and
2. at the beginning of flowering (BBCH 61).

Samples were taken at the following intervals:

- prior to and immediately after the final application.
- at a pre-harvest interval of 35 (34) days after the final treatment.
- at harvest (BBCH 89)

Plant material was collected at a pre-harvest interval of 35 days as well as at one later date to obtain harvest values. This additional date was needed to ensure that samples of mature plants were available independent of the growth stage reached following the proposed pre-harvest interval of 35 days.

Residues of prothioconazole-desthio were determined according to method 01013 with a limit of quantitation of 0.01 mg/kg for grain, green material and straw.

Residues of prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio were determined according to method 00979/M001 with a limit of quantitation of 0.01 mg/kg for grain, green material and straw.

### Findings

#### Storage stability:

The maximum storage periods for prothioconazole-desthio in barley samples from the supplementary residue field trials are presented below.

**Table A 25: Maximum storage periods of field samples from supplementary residue trials**

Crops	Substance	Sample Material	Storage period (days)	Storage period (months)	Study No.
barley	prothioconazole-desthio	grain	352	11.7	10-2204 M-414691- 01-1
		green material	387	12.9	
		straw	352	11.7	
		grain	281	9.4	
		green material	301	10	

	prothioconazole-alpha-hydroxy-desthio prothioconazole-3-hydroxy-desthio prothioconazole-4-hydroxy-desthio prothioconazole-5-hydroxy-desthio prothioconazole-6-hydroxy-desthio	straw	282	9.4	
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These storage periods are covered by the storage stability studies, *i.e.* analytes were shown to be stable for a period of at least 24 months.

Sample extracts were measured within 24 hours, or if not, acceptable recoveries measured concurrently with each set of samples ensured integrity of the sample extracts during the period of time between extraction and analysis.

No residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio above 30% of the LOQ was found in the control samples.

#### Method performance:

Recovery rates were determined concurrently with the sample analysis in order to check the accuracy of the residue levels. Recovery means by fortification levels were within the acceptable range of 70-110% except for prothioconazole-desthio in green material at the LOQ level (112%) and for prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio in straw at 0.50 mg/kg (68%, 69% and 68% respectively). The single and overall mean recoveries are shown in the following tables below. All results of the method validation are in accordance with the general requirements for residue analytical methods, therefore the method was validated successfully.

**Table A 26: 10-2204: Concurrent recoveries for the determination of prothioconazole-desthio in cereal**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]*		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
Prothioconazole-desthio	Cereal grain	0.01	108	-	-	0.01
		2.5	86 ; 99	93	-	
		Overall Recovery (n = 3)		98	11.3	
	Cereal green material	0.01	108; 108; 116; 111; 117	112 <sup>a</sup>	3.8	0.01
		0.10	97	-	-	
		2.0	84; 104	94	-	
		2.5	92; 95; 94; 89	93	2.9	
		Overall Recovery (n = 12)		101	10.7	
	Cereal straw	2.5	73	-	-	0.01
		Overall Recovery (n = 1)		73	-	

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with JAU 6476-desthio, determined as JAU 6476-desthio and calculated as JAU 6476-desthio

\*These recoveries were performed with sample material from studies 10-2204, 10-2205, 10-2206 and 10-2207.

Cereal summarises barley and wheat.

<sup>a</sup>This value was accepted due to a RSD below 20% and an overall mean in the range of 70-110%.

**Table A 27: 10-2204: Concurrent recoveries for the determination of prothioconazole-alpha-hydroxy-desthio in cereal**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]*		RSD [%]	LOQ [mg/kg]
			Single Values**	Mean		
prothioconazole-alpha-hydroxy-desthio	Cereal grain	0.01	89; 90; 118; 120; 89; 89; 94; 100; 95; 96	98	11.9	0.01
		0.50	89; 98; 89; 95	93	4.9	
		Overall Recovery (n = 14)		97	10.6	
	Cereal green material	0.01	80; 99; 104; 99; 104; 93; 98; 100; 102; 85; 85; 91; 92	95	8.2	0.01
		0.50	101; 95; 100; 101; 83; 85	94	8.7	
		Overall Recovery (n = 19)		95	8.1	

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]*		RSD [%]	LOQ [mg/kg]
			Single Values**	Mean		
	Cereal straw	0.01	77; 79; 88; 97; 81; 84	84	8.7	0.01
		0.50	72; 71; 88; 78; 92	80	11.8	
		Overall Recovery (n = 11)		82	9.9	

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with JAU 6476-alpha-hydroxy-desthio, determined as JAU 6476-alpha-hydroxy-desthio and calculated as JAU 6476-desthio.

\*These recoveries were performed with sample material from studies 10-2204, 10-2205, 10-2206 and 10-2207.

Cereal summarises barley and wheat.

\*\* : mean of double injection

**Table A 28: 10-2204: Concurrent recoveries for the determination of prothioconazole-3-hydroxy-desthio in cereal**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]*		RSD [%]	LOQ [mg/kg]
			Single Values**	Mean		
prothioconazole-3-hydroxy-desthio	Cereal grain	0.01	73; 82; 109; 113; 85; 88; 89; 90; 88; 94	91	13.1	0.01
		0.50	83; 93; 78; 81	84	7.8	
		Overall Recovery (n =14)		89	12.3	
	Cereal green material	0.01	70; 90; 101; 91; 103; 91; 94; 94; 94; 70; 71; 75; 77	86	13.8	0.01
		0.50	85; 82; 98; 104; 70; 74	86	15.5	
		Overall Recovery (n =19)		86	14.0	
	Cereal straw	0.01	80; 80; 83; 86; 98; 107	89	12.4	0.01
		0.50	62; 63; 81; 67; 76	70	12.0	
		Overall Recovery (n =11)		80	17.2	

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-3-hydroxy-desthio, determined as prothioconazole-3-hydroxy-desthio and calculated as prothioconazole-desthio

\*These recoveries were performed with sample material from studies 10-2204, 10-2205, 10-2206 and 10-2207.

Cereal summarises barley and wheat.

\*\* : mean of double injection

**Table A 29: 10-2204: Concurrent recoveries for the determination of prothioconazole-4-hydroxy-desthio in cereal**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]*		RSD [%]	LOQ [mg/kg]
			Single Values**	Mean		
prothioconazole-4-hydroxy-desthio	Cereal grain	0.01	65; 72; 99; 105; 60; 67; 68; 70; 71; 73	75	19.7	0.01
		0.50	87; 95; 72; 76	83	12.7	
		Overall Recovery (n = 14)		77	17.8	
	Cereal green material	0.01	68; 80; 99; 79; 83; 65; 66; 73; 74; 63; 64; 74; 76	74	13.3	0.01
		0.50	88; 84; 95; 102; 71 ;75	86	13.7	
		Overall Recovery (n = 19)		78	14.9	
	Cereal straw	0.01	67; 64; 67; 77; 77; 81	72	9.7	0.01
		0.50	67; 62; 79; 62; 70	68***	10.3	
		Overall Recovery (n = 11)		70	10.0	

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-4-hydroxy-desthio, determined as prothioconazole-4-hydroxy-desthio and calculated as prothioconazole-desthio

\*These recoveries were performed with sample material from studies 10-2204, 10-2205, 10-2206 and 10-2207.

Cereal summarises barley and wheat.

\*\* : mean of double injection

\*\*\*: This value was accepted due to a RSD below 20% and an overall mean value in the range of 70-110%.

**Table A 30: 10-2204: Concurrent recoveries for the determination of prothioconazole-5-hydroxy-desthio in cereal**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]*		RSD [%]	LOQ [mg/kg]
			Single Values**	Mean		
prothioconazole-5-hydroxy-desthio	Cereal grain	0.01	74; 77; 108; 108; 75; 83; 86; 88; 78; 86	86	14.4	0.01
		0.50	80;86;83;83	83	3.0	
		Overall Recovery (n = 14)		85	12.3	
	Cereal green material	0.01	73; 93; 99; 95; 95; 76; 77; 78; 82; 72; 73; 78; 79	82	11.7	0.01
		0.50	90; 85; 92; 98; 70; 73	85	13.1	
		Overall Recovery (n = 19)		83	11.9	
	Cereal straw	0.01	80; 71; 79; 84; 78; 88	80	7.2	0.01
		0.50	62; 64; 80; 66; 75	69***	11.1	
		Overall Recovery (n = 11)		75	11.2	

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-5-hydroxy-desthio, determined as prothioconazole-5-hydroxy-desthio and calculated as prothioconazole-desthio

\*These recoveries were performed with sample material from studies 10-2204, 10-2205, 10-2206 and 10-2207.

Cereal summarises barley and wheat.

\*\* : mean of double injection

\*\*\* : This value was accepted due to a RSD below 20% and an overall mean value in the range of 70-110%.

**Table A 31: Concurrent recoveries for the determination of prothioconazole-6-hydroxy-desthio in cereal**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]*		RSD [%]	LOQ [mg/kg]
			Single Values**	Mean		
prothioconazole-6-hydroxy-desthio	Cereal grain	0.01	69; 75; 99; 101; 94; 96; 97; 100; 93; 97	92	11.9	0.01
		0.50	79;84;79;82	81	3.0	
		Overall Recovery (n = 14)		89	11.9	
	Cereal green material	0.01	73; 102; 103; 92; 99; 87; 93; 95; 99; 69; 75; 77; 77	88	13.8	0.01
		0.50	79; 75; 89; 91; 70; 79	81	10.1	
		Overall Recovery (n = 19)		85	13.2	
	Cereal straw	0.01	82; 74; 75; 78; 75; 82	78	4.7	0.01
		0.50	68; 68; 80; 60; 62	68***	11.5	
		Overall Recovery (n = 11)		73	10.5	

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-6-hydroxy-desthio, determined as prothioconazole-6-hydroxy-desthio and calculated as prothioconazole-desthio

\*These recoveries were performed with sample material from studies 10-2204, 10-2205, 10-2206 and 10-2207.

Cereal summarises barley and wheat.

\*\* : mean of double injection

\*\*\* : This value was accepted due to a RSD below 20% and an overall mean value in the range of 70-110%.

### Residue results:

The residue results are summarised in the table hereafter.

In the 2 trials conducted in 2010 (report 10-2204), residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio in barley grain at harvest were <0.01 mg/kg. In grain at harvest, the total residue was always <0.06 mg/kg.

In straw, the residues at harvest ranged as follows:

- between 0.05 mg/kg and 0.17 mg/kg for prothioconazole-desthio
- <0.01 mg/kg mg/kg for prothioconazole-alpha-hydroxy,
- between 0.04 mg/kg and 0.17 mg/kg for prothioconazole-3-hydroxy-desthio,
- between 0.04 mg/kg and 0.12 mg/kg for prothioconazole-4-hydroxy-desthio,
- between 0.02 mg/kg and 0.08 mg/kg for prothioconazole-5-hydroxy-desthio,
- <0.01 mg/kg mg/kg for prothioconazole-6-hydroxy-desthio,
- between 0.17 mg/kg and 0.56 mg/kg for the total residue.



## Conclusion

Two barley residue trials were conducted with Bixafen & Fluoxastrobin & Prothioconazole EC 190 in northern Europe. The product application corresponded to a prothioconazole rate of 2x150 g a.s./ha.

Residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio in barley grain at harvest were <0.01 mg/kg. In grain at harvest, the total residue was always <0.06 mg/kg.

In straw, the residues at harvest ranged as follows:

- between 0.05 mg/kg and 0.17 mg/kg for prothioconazole-desthio,
- <0.01 mg/kg mg/kg for prothioconazole-alpha-hydroxy,
- between 0.04 mg/kg and 0.17 mg/kg for prothioconazole-3-hydroxy-desthio,
- between 0.04 mg/kg and 0.12 mg/kg for prothioconazole-4-hydroxy-desthio,
- between 0.02 mg/kg and 0.08 mg/kg for prothioconazole-5-hydroxy-desthio,
- <0.01 mg/kg mg/kg for prothioconazole-6-hydroxy-desthio, between 0.17 mg/kg and 0.56 mg/kg for the total residue.

**Table A 32: Summary of the 10-2204 trials**

Study Trial No. GLP Year	Crop Variety	Country	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application					Residues (mg/kg)									
				FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Dates of treatment or no. of treatments and last date	Portion analysed	DAL T (days)	PTZ-desthio	PTZ-alpha-hydroxy-desthio	PTZ-3-hydroxy-desthio	PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio	Total (PTZ-desthio+hydroxy=RD-RA1)*
10-2204-01 GLP: yes 2010	Barley, spring Tipple	Netherlands 1175 LD Lynden Europe, North	1) 14.04.2010 3) 01.08.2010 - 20.08.2010	190 EC	2	0.150	0.050	61	1)15/06/10 2)29/06/10	green material	0 <sup>(1)</sup> 0	0.36 0.51	<0.01 <0.01	0.05 0.05	0.07 0.08	0.03 0.03	<0.01 <0.01	0.53 0.69
										grain	35 43	<u>&lt;0.01</u> <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<u>&lt;0.06</u> <0.06
										straw	35 43	<u>0.11</u> 0.05	<0.01 <0.01	0.10 0.04	0.12 0.04	0.06 0.02	<0.01 <0.01	<u>0.41</u> 0.17
10-2204-02 GLP: yes 2010	Barley, spring Quench	Germany 51399 Burscheid Europe, North	1) 06.04.2010 2) 21.06.2010 - 28.06.2010 3) 01.08.2010 - 15.08.2010	190 EC	2	0.150	0.050	61	1)07/06/10 2)21/06/10	green material	0 <sup>(1)</sup> 0	0.53 1.5	<0.01 <0.01	0.09 0.10	0.09 0.09	0.05 0.06	<0.01 <0.01	0.78 1.8
										grain	34 46	<u>&lt;0.01</u> <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<0.01 <0.01	<u>&lt;0.06</u> <0.06
										straw	34 46	<u>0.54</u> 0.17	<0.01 <0.01	0.32 0.17	0.25 0.12	0.10 0.08	0.01 <0.01	<u>1.2</u> 0.56

(1): before last treatment \* for the sum, values <0.01 mg/kg were considered to be equal to 0.01 mg/kg, unless all the values were <0.01 mg/kg.

Residues for PTZ-desthio were determined as PTZ-desthio and calculated as PTZ-desthio

Residues for PTZ-alpha-hydroxy-desthio were determined as PTZ-alpha-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-3-hydroxy-desthio were determined as PTZ-3-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-4-hydroxy-desthio were determined as PTZ-4-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-5-hydroxy-desthio were determined as PTZ-5-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-6-hydroxy-desthio were determined as PTZ-6-hydroxy-desthio and calculated as PTZ-desthio

### A 2.1.3.1.2 Studies 13-2158 & 13-2137 – NEU

Comments of zRMS:	<p>It should be noted that the studies of Bellof and van Berkum (13-2158) and Glaubitz (13-2137) are currently under review in the EU approval renewal process for prothioconazole.</p> <p>The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application. The conclusions of the assessment are presented below:</p> <p><i>Four residue trials on spring and winter barley were conducted in northern Europe to determine residue of prothioconazole-desthio and prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio.</i></p> <p><i>Barley was treated twice at application rate of 0.125 kg a.s./ha of prothioconazole with 6-20 days interval between applications. The time of application was</i></p> <ol style="list-style-type: none"> <li><i>1. at BBCH 32-57,</i></li> <li><i>2. at BBCH 61.</i></li> </ol> <p><i>Samples were taken at harvest.</i></p> <p><i>Analytical method for determination of prothioconazole-desthio - method 01013.</i></p> <p><i>Analytical method for determination of prothioconazole -alpha-hydroxy-desthio, -3-hydroxy-desthio, -4-hydroxy-desthio, -5-hydroxy-desthio and -6-hydroxy-desthio – method 00979/M001.</i></p> <p><i>Limit of quantitation of 0.01 mg/kg for grain, green material and straw.</i></p> <p><i>Mean recoveries in acceptable range (70 - 110%), RSD &lt;20%.</i></p> <p><i>Maximum storage period – 15 months.</i></p> <p><i>The residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio in barley grain at harvest were &lt;0.01 mg/kg. In grain at harvest, the total residue was always &lt;0.06 mg/kg except for trial 13-2137-02 where the total residue reached 0.061 mg/kg.</i></p> <p><i>The study is acceptable.</i></p>
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Reference:	KCA 6.3.1/02
Report	<p>Determination of the residues of fluoxastrobin and prothioconazole in/on barley and spring barley after spray application of Fluoxastrobin &amp; Prothioconazole EC 200 in France (North)</p> <p>Bellof, S.; van Berkum, S., 05.11.2014</p> <p>Report No: M-501503-01-1</p> <p>Reference No: 13-2158</p>
Guideline(s):	<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 79/117/EEC and 91/414/EEC</p> <p>EC Guidance working document 7029/VI/95 rev.5 (1997-07-22)</p> <p>OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial</p> <p>US EPA OCSPP Guideline No. 860.1500</p>
Deviations:	None
GLP:	Yes
Owner:	Bayer CropScience AG (Nufarm has a letter of access)
Acceptability:	Yes

Reference:	KCA 6.3.1/03
Report	Determination of the residues of fluoxastrobin and prothioconazole in/on spring barley after spray application of fluoxastrobin & prothioconazole EC 200 in Germany Glaubitz, J., 30.01.2015 Report No: M-501711-03-1 Reference No: 13-2137
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC EC Guidance working document 7029/VI/95 rev.5 (1997-07-22), OECD 509 Adopted 2009-09-07, OECD GUIDELINE FOR THE TESTING OF CHEMICALS, Crop Field Trial US EPA OCSPP Guideline No. 860.1500
Deviations:	None
GLP:	Yes
Owner:	Bayer CropScience AG (Nufarm has a letter of access)
Acceptability:	Yes

**The following study is currently under review in the EU approval renewal process for prothioconazole.**

### Materials and Methods

In the vegetation period of 2013, a set of 4 residue trials on spring and winter barley was conducted in northern Europe. The trials were located in northern France and Germany.

In each trial, barley was treated twice at a product rate of 1.25 L/ha fluoxastrobin & prothioconazole EC 200 corresponding to 0.125 kg a.s./ha of prothioconazole. In trial 13-2158-02, the two applications were overdosed by 6.3% and 8.3%, respectively. The water rate was 200-400 L/ha. The spray interval ranged from 6-20 days. The time of application was:

1. when node 2 is at least 2 cm above node 1 until 70% of inflorescence emerged (BBCH 32-57), and
2. at the beginning of flowering (BBCH 61).

Samples were taken at the following intervals:

- prior to and immediately after the final application,
- at days 7, 14, 21 and 28 (except for the trial 13-2158-02) after final application,
- at a pre-harvest interval of 35 days (except for the trial 13-2137-02) after the final application,
- at harvest (BBCH 89). Additional samples were taken at days 17 (trial 13-2158-02), 31 (trial 13-2158-01) and 42 (trial 13-2137-02) after final application.

Plant material was collected at a pre-harvest interval of 35 days as well as at one later date to obtain harvest values. This additional date was needed to ensure that samples of mature plants were available independent of the growth stage reached following the proposed pre-harvest interval of 35 days.

Residues of prothioconazole-desthio were determined according to method 01013 with a limit of quantitation of 0.01 mg/kg for grain, green material and straw.

Residues of prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio were determined according to method 00979/M001 with a limit of quantitation of 0.01 mg/kg for grain, green material and straw.

### Findings

- Storage stability:

The maximum storage periods for prothioconazole-desthio in barley samples from the supplementary residue field trials are presented below.

**Table A 33: Maximum storage periods of field samples from supplementary residue trials**

Crops	Substance	Sample Material	Storage period (days)	Storage period (months)	Study No.
barley	prothioconazole-desthio	grain	337	11.2	13-2158 M-501503-01-1
		green material	366	12.2	
		straw	337	11.2	
	prothioconazole-alpha-hydroxy-desthio prothioconazole-3-hydroxy-desthio prothioconazole-4-hydroxy-desthio prothioconazole-5-hydroxy-desthio prothioconazole-6-hydroxy-desthio	grain	415	13.8	
		green material	451	15.0	
		straw	424	14.1	

These storage periods are covered by the storage stability studies, *i.e.* analytes were shown to be stable for a period of at least 24 months.

Sample extracts were measured within 24 hours, or if not, acceptable recoveries measured concurrently with each set of samples ensured integrity of the sample extracts during the period of time between extraction and analysis.

No residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio above 30% of the LOQ was found in the control samples.

**- Method performance:**

Recovery rates were determined concurrently with the sample analysis in order to check the accuracy of the residue levels. Recovery means by fortification levels were within the acceptable range of 70-110% except for prothioconazole-3-hydroxy-desthio in green material at the LOQ level (68%), for prothioconazole-4-hydroxy-desthio at the LOQ level in grain (68%) and in straw (64%) and prothioconazole-6-hydroxy-desthio in grain at the LOQ level (117%). The single and overall mean recoveries are shown in the following tables below. All results of the method validation are in accordance with the general requirements for residue analytical methods, therefore the method was validated successfully.

**Table A 34: 13-2158 and 13-2137: Concurrent recoveries for the determination of prothioconazole-desthio in barley**

Analyte	Study	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
				Single Values	Mean		
Prothioconazole-desthio	13-2158	barley grain	0.01	103	-	-	0.01
			0.10	104	-	-	
			Overall Recovery (n = 2)		104	-	
		barley green material	0.01	104*	-	-	0.01
			0.10	113	-	-	
			1.0	88	-	-	
			Overall Recovery (n = 3)		102	12.5	
		barley straw	0.01	107*	-	-	0.01
			0.10	108	-	-	
			1.0	91	-	-	
			Overall Recovery (n = 3)		102	9.4	
Prothioconazole-desthio	13-2137	barley grain	0.01	99	-	-	0.01
			0.10	98	-	-	
			Overall Recovery (n = 2)		99	-	
		barley green material	0.01	118	-	-	0.01
			0.10	100	-	-	

Analyte	Study	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
				Single Values	Mean		
			Overall Recovery (n = 2)		109		
		barley straw	0.01	97	-	-	0.01
			0.10	96	-	-	
			Overall Recovery (n = 2)		97	-	

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-desthio, determined as prothioconazole-desthio and calculated as prothioconazole-desthio

\* : corrected for residue level in control sample (29% of the LOQ for green material and 24% of the LOQ for straw). Uncorrected values are 133% (green material) and 132% (straw).

**Table A 35: 13-2158 and 13-2137: Concurrent recoveries for the determination of prothioconazole-alpha-hydroxy-desthio in barley**

Analyte	Study	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
				Single Values	Mean		
prothioconazole-alpha -hydroxy-desthio	13-2158	barley grain	0.01	81; 82	82	-	0.01
			0.10	76; 80	78	-	
			Overall recovery (n = 4)		80	3.3	
		barley green material	0.01	78; 80	79	-	0.01
			0.10	95; 99	97	-	
			0.30	99; 100	100	-	
			Overall recovery (n = 6)		92	11.0	
		barley straw	0.01	63; 69; 76; 81	72	10.9	0.01
			0.10	87; 88	88	-	
			0.60	87; 100	94	-	
			Overall recovery (n = 8)		81	14.5	
prothioconazole-alpha-hydroxy-desthio	13-2137	barley grain	0.01	77 ; 78	78	-	0.01
			0.10	93 ; 93	93	-	
			Overall Recovery (n = 4)		85	10.5	
		barley green material	0.01	85 ; 94 ; 109	96	12.6	0.01
			0.10	85 ; 86	86	-	
			Overall Recovery (n = 5)		92	11.3	
		barley straw	0.01	85 ; 86	86	-	0.01
			0.20	88 ; 90 ; 97 ; 100	94	6.1	
			Overall Recovery (n = 6)		91	6.7	

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-alpha-hydroxy-desthio, determined as prothioconazole-alpha-hydroxy-desthio and calculated as prothioconazole-desthio

**Table A 36: 13-2158 and 13-2137: Concurrent recoveries for the determination of prothioconazole-3-hydroxy-desthio in barley**

Analyte	Study	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
				Single Values	Mean		
prothioconazole-3-hydroxy-desthio	13-2158	barley grain	0.01	83; 86	85	-	0.01
			0.10	74; 75	75	-	
			<b>Overall recovery (n = 4)</b>		<b>80</b>	<b>7.4</b>	
		barley green material	0.01	68; 68	68*	-	0.01
			0.10	88; 91	90	-	
			0.30	96; 97	97	-	
			<b>Overall recovery (n = 6)</b>		<b>85</b>	<b>15.7</b>	
		barley straw	0.01	67; 67; 78; 86	75	12.4	0.01
			0.10	79; 86	83	-	
			0.60	86; 96	91	-	
			<b>Overall recovery (n = 8)</b>		<b>81</b>	<b>12.4</b>	
prothioconazole-3-hydroxy-desthio	13-2137	barley grain	0.01	86 ; 87	87	-	0.01
			0.10	87 ; 87	87	-	
			<b>Overall Recovery (n = 4)</b>		<b>87</b>	<b>0.6</b>	
		barley green material	0.01	81 ; 96 ; 108	95	14.2	0.01
			0.10	85 ; 93	89	-	
			<b>Overall Recovery (n = 5)</b>		<b>93</b>	<b>11.3</b>	
		barley straw	0.01	89 ; 89	89	-	0.01
			0.20	85 ; 85 ; 91 ; 97	90	6.4	
			<b>Overall Recovery (n = 6)</b>		<b>89</b>	<b>5.0</b>	

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-hydroxy-desthio, determined as prothioconazole-hydroxy-desthio and calculated as prothioconazole-desthio \* : This value was accepted due to a RSD below 20% and an overall mean value in the range of 70-110%.

**Table A 37: 13-2158 and 13-2137: Concurrent recoveries for the determination of prothioconazole-4-hydroxy-desthio in barley**

Analyte	Study	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
				Single Values	Mean		
prothioconazole-4-hydroxy-desthio	13-2158	barley grain	0.01	65; 70	68*	-	0.01
			0.10	70; 76	73	-	
			<b>Overall recovery (n = 4)</b>		<b>70</b>	<b>6.4</b>	
		barley green material	0.01	69; 70	70	-	0.01
			0.10	91; 96	94	-	
			0.30	90; 95	93	-	
			<b>Overall recovery (n = 6)</b>		<b>85</b>	<b>14.5</b>	
		barley straw	0.01	62; 65; 71	66*	6.9	0.01
			0.10	71; 80	76	-	
			0.60	83; 96	90	-	
			<b>Overall recovery (n = 7)</b>		<b>75</b>	<b>15.6</b>	
prothioconazole-4-hydroxy-desthio	13-2137	barley grain	0.01	66 ; 67	67	-	0.01
			0.10	83 ; 85	84	-	
			<b>Overall Recovery (n = 4)</b>		<b>75</b>	<b>13.5</b>	
		barley green material	0.01	83 ; 95	89	-	0.01
			0.10	76 ; 80	78	-	
			<b>Overall Recovery (n = 4)</b>		<b>84</b>	<b>9.8</b>	
		barley straw	0.01	63 ; 64	64	-	0.01
			0.20	86 ; 87 ; 84 ; 86	86	1.5	
			<b>Overall Recovery (n = 6)</b>		<b>78</b>	<b>14.7</b>	

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-4-hydroxy-desthio, determined as prothioconazole-4-hydroxy-desthio and calculated as prothioconazole-desthio

\* : This value was accepted due to a RSD below 20% and an overall mean value in the range of 70-110%.



**Table A 38: 13-2158 and 13-2137: Concurrent recoveries for the determination of prothioconazole-5-hydroxy-desthio in barley**

Analyte	Study	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
				Single Values	Mean		
prothioconazole-5-hydroxy-desthio	13-2158	barley grain	0.01	73; 77	75	-	0.01
			0.10	77; 82	80	-	
			Overall recovery (n = 4)		77	4.8	
		barley green material	0.01	67; 83	75	-	0.01
			0.10	91; 94	93	-	
			0.30	96; 98	97	-	
			Overall recovery (n = 6)		88	13.2	
		barley straw	0.01	76; 77; 86	80	6.9	0.01
			0.10	81; 87	84	-	
			0.60	81; 94	88	-	
			Overall recovery (n = 7)		83	7.6	
prothioconazole-5-hydroxy-desthio	13-2137	barley grain	0.01	87 ; 87	87	-	0.01
			0.10	85 ; 91	88	-	
			Overall Recovery (n = 4)		88	2.9	
		barley green material	0.01	79 ; 81 ; 92	84	8.3	0.01
			0.10	78 ; 85	82	-	
			Overall Recovery (n = 5)		83	6.9	
		barley straw	0.01	82 ; 85	84	-	0.01
			0.20	85 ; 86 ; 91 ; 97	90	6.1	
			Overall Recovery (n = 6)		88	6.2	

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-5-hydroxy-desthio, determined as prothioconazole-5-hydroxy-desthio and calculated as prothioconazole-desthio

**Table A 39: 13-2158 and 13-2137: Concurrent recoveries for the determination of prothioconazole-6-hydroxy-desthio in barley**

Analyte	Study	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
				Single Values	Mean		
prothioconazole-6-hydroxy-desthio	13-2158	barley grain	0.01	115; 118	117*	-	0.01
			0.10	87; 92	90	-	
			Overall recovery (n = 4)		103	15.3	
		barley green material	0.01	73; 79	76	-	0.01
			0.10	88; 89	89	-	
			0.30	85; 91	88	-	
			Overall recovery (n = 6)		84	8.2	
		barley straw	0.01	70; 77; 78; 83	77	7.0	0.01
			0.10	78; 84	81	-	
			0.60	86; 95	91	-	
			Overall recovery (n = 8)		81	9.1	
prothioconazole-6-hydroxy-desthio	13-2137	barley grain	0.01	90 ; 92	91	-	0.01
			0.10	83 ; 88	86	-	
			Overall Recovery (n = 4)		88	4.4	
		barley green material	0.01	93 ; 101 ; 109	101	7.9	0.01
			0.10	87 ; 93	90	-	
			Overall Recovery (n = 5)		97	8.8	
		barley straw	0.01	87 ; 87	87	-	0.01
			0.20	90 ; 93 ; 93 ; 96	93	2.6	
			Overall Recovery (n = 6)		91	4.0	

RSD = Relative Standard Deviation, LOQ = Practical Limit of Quantification

Fortified with prothioconazole-6-hydroxy-desthio, determined as prothioconazole-6-hydroxy-desthio and calculated as prothioconazole-desthio \* : This value was accepted due to a RSD below 20% and an overall mean value in the range of 70-110%

#### - Residue results:

The residue results are summarised in the tables hereafter.

In the 4 trials conducted in 2013 (reports 13-2137 and 13-2158), residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio in barley grain at harvest were < 0.01 mg/kg. In grain at harvest, the total residue was always <0.06 mg/kg except for trial 13-2137-02 where the total residue reached 0.061 mg/kg.

In straw, the residues at harvest ranged as follows:

- between 0.036 mg/kg and 0.81 mg/kg for prothioconazole-desthio
- between < 0.01 mg/kg and 0.023 mg/kg for prothioconazole-alpha-hydroxy
- between 0.020 mg/kg and 0.55 mg/kg for prothioconazole-3-hydroxy-desthio
- between <0.01 mg/kg and 0.55 mg/kg for prothioconazole-4-hydroxy-desthio
- between <0.01 mg/kg and 0.23 mg/kg for prothioconazole-5-hydroxy-desthio
- between < 0.01 mg/kg and 0.042 mg/kg mg/kg for prothioconazole-6-hydroxy-desthio
- between 0.10 mg/kg and 2.2 mg/kg for total residue calc.

#### Conclusion

Four barley residue trials were conducted with Fluoxastrobin & Prothioconazole EC 200 in northern Europe. The product application corresponded to a prothioconazole rate of 2x125 g a.s./ha with the exception of trial 13-2158-02 where the two applications were overdosed by 6.3% and 8.3%, respectively. Residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio in barley grain at harvest were < 0.01 mg/kg. In grain at harvest, the total residue was always <0.06 mg/kg.

In straw, the residues at harvest ranged as follows:

- between 0.036 mg/kg and 0.81 mg/kg for prothioconazole-desthio
- between < 0.01 mg/kg and 0.023 mg/kg for prothioconazole-alpha-hydroxy
- between 0.020 mg/kg and 0.55 mg/kg for prothioconazole-3-hydroxy-desthio
- between <0.01 mg/kg and 0.55 mg/kg for prothioconazole-4-hydroxy-desthio
- between <0.01 mg/kg and 0.23 mg/kg for prothioconazole-5-hydroxy-desthio

- between < 0.01 mg/kg and 0.042 mg/kg mg/kg for prothioconazole-6-hydroxy-desthio
- between 0.10 mg/kg and 2.2 mg/kg for total residue calc.

**Table A 40: Summary of the 13-2137 trials**

Study Trial No. GLP Year	Crop Variety	Country	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application					Dates of treatment or no. of treatments and last date	Residues (mg/kg)								Total (PTZ-desthio+hydroxy =RD-RA1)*
				FL	No	kg/ha (a.s.)	kg/h L (a.s.)	G S		Portion analysed	DAL T (days)	PTZ-desthio	PTZ-alpha-hydroxy-desthio	PTZ-3-hydroxy-desthio	PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio	
13-2137-01 GLP: yes 2013	Barley, spring Conchitana	Germany 51399 Burscheid Europe, North	1) 28.03.2013	200 EC	2	0.125	0.042	61	1)31/05/13 2)14/06/13	green material	0 <sup>(1)</sup>	0.27	<0.01	0.023	0.032	0.018	<0.01	0.36
			2) 14.06.2013 - 21.06.2013								0	0.94	<0.01	0.032	0.044	0.024	<0.01	1.1
			3) 15.08.2013 - 31.08.2013								7	0.88	<0.01	0.062	0.075	0.044	<0.01	1.1
			1) 28.03.2013								14	0.42	<0.01	0.093	0.091	0.059	<0.01	0.68
			2) 14.06.2013 - 21.06.2013								21	0.15	<0.01	0.084	0.080	0.053	<0.01	0.39
			3) 15.08.2013 - 31.08.2013								28	0.067	<0.01	0.074	0.066	0.039	<0.01	0.27
											35	0.049	<0.01	0.079	0.064	0.038	<0.01	0.25
										grain	35	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.06
											69	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.06
										straw	35	0.087	<0.01	0.14	0.12	0.067	<0.01	0.43
											69	0.036	<0.01	0.029	0.030	0.020	<0.01	0.14
13-2137-02 GLP: yes 2013	Barley, spring Grace	Germany 49377 Langföörden Europe, North	1) 09.04.2013	200 EC	2	0.125	0.031-0.042	61	1)12/06/13 2)18/06/13	green material	0 <sup>(1)</sup>	0.50	<0.01	0.023	0.010	0.013	<0.01	0.57
			2) 17.06.2013 - 22.06.2013								0	1.1	<0.01	0.026	0.012	0.013	<0.01	1.2
			3) 15.08.2013 - 25.08.2013								7	0.47	0.010	0.070	0.025	0.030	<0.01	0.62
											14	0.22	0.013	0.080	0.027	0.032	<0.01	0.38
											21	0.098	0.013	0.092	0.028	0.029	<0.01	0.27
											28	0.067	0.011	0.078	0.025	0.024	<0.01	0.22
											42	0.041	<0.01	0.038	0.012	0.013	<0.01	0.12
										grain	68	0.011	<0.01	<0.01	<0.01	<0.01	<0.01	0.061
										straw	68	0.044	<0.01	0.020	<0.01	<0.01	<0.01	0.10

(1): before last treatment \* for the sum, values <0.01 mg/kg were considered to be equal to 0.01 mg/kg, unless all the values were <0.01 mg/kg.

Residues for PTZ-desthio were determined as PTZ-desthio and calculated as PTZ-desthio

Residues for PTZ-alpha-hydroxy-desthio were determined as PTZ-alpha-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-3-hydroxy-desthio were determined as PTZ-3-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-4-hydroxy-desthio were determined as PTZ-4-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-5-hydroxy-desthio were determined as PTZ-5-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-6-hydroxy-desthio were determined as PTZ-6-hydroxy-desthio and calculated as PTZ-desthio

**Table A 41: Summary of the 13-2158 trials**

Study Trial No. GLP Year	Crop Variety	Country	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application					Residues (mg/kg)									Total (PTZ-desthio+hydroxy=RD-RA1)*
				FL	No	kg/ha (a.s.)	kg/h L (a.s.)	G S	Dates of treatment or no. of treatments and last date	Portion analysed	DAL T (days)	PTZ-desthio	PTZ-alpha-hydroxy-desthio	PTZ-3-hydroxy-desthio	PTZ-4-hydroxy-desthio	PTZ-5-hydroxy-desthio	PTZ-6-hydroxy-desthio	
13-2158-01 GLP: yes 2013	Barley Esterel	France 71150 Fontaines Europe, North	1) 02.10.2012 3) 09.07.2013	200 EC	2	0.125	0.063	61	1)07/05/13 2)27/06/13	green material	0 <sup>(1)</sup>	0.17	<0.01	0.051	0.047	0.044	<0.01	0.33
											0	1.5	<0.01	0.056	0.049	0.044	<0.01	1.7
											7	0.46	0.012	0.076	0.068	0.065	<0.01	0.69
											14	0.14	<0.01	0.080	0.065	0.059	<0.01	0.36
											21	0.078	<0.01	0.088	0.074	0.058	<0.01	0.32
											28	0.067	<0.01	0.057	0.046	0.039	<0.01	0.23
											31	0.079	<0.01	0.067	0.057	0.048	<0.01	0.27
										grain	35	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.06
											43	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.06
13-2158-02 GLP: yes 2013	Barley, spring Sébastien	France 71570 La Chapelle de Guinchay Europe, North	1) 21.02.2013 3) 23.07.2013	200 EC	2	0.133-0.135	0.062-0.063	61	1)03/06/13 2)18/06/13	green material	0 <sup>(1)</sup>	0.33	<0.01	0.11	0.15	0.078	<0.01	0.69
											0	0.89	<0.01	0.13	0.16	0.091	<0.01	1.3
											7	0.72	<0.01	0.17	0.21	0.10	<0.01	1.2
											14	0.49	<0.01	0.16	0.20	0.082	0.010	0.95
											21	0.40	<0.01	0.15	0.16	0.065	0.010	0.80
											17	0.44	<0.01	0.16	0.17	0.077	<0.01	0.87
										grain	35	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.06
											43	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.06
										straw	35	0.81	0.023	0.55	0.55	0.23	0.042	2.2
											43	0.15	<0.01	0.11	0.083	0.092	<0.01	0.46

(1): before last treatment \* for the sum, values <0.01 mg/kg were considered to be equal to 0.01 mg/kg, unless all the values were <0.01 mg/kg.

Residues for PTZ-desthio were determined as PTZ-desthio and calculated as PTZ-desthio

Residues for PTZ-alpha-hydroxy-desthio were determined as PTZ-alpha-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-3-hydroxy-desthio were determined as PTZ-3-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-4-hydroxy-desthio were determined as PTZ-4-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-5-hydroxy-desthio were determined as PTZ-5-hydroxy-desthio and calculated as PTZ-desthio

Residues for PTZ-6-hydroxy-desthio were determined as PTZ-6-hydroxy-desthio and calculated as PTZ-desthio

### A 2.1.3.1.3 Study 17-2076 – NEU + SEU

Comments of zRMS:	<p>It should be noted that the study of Meklat, Kerkerling, Effertz (17-2076) is currently under review in the EU approval renewal process for prothioconazole.</p> <p>The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application. The conclusions of the assessment are presented below:</p> <p><i>Two residue trials on spring and winter barley were conducted in northern Europe to determine residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio and TDMs.</i></p> <p><i>Barley was treated twice at application rate of 0.140 kg a.s./ha of prothioconazole with 6-20 days interval between applications. The time of application was</i></p> <ol style="list-style-type: none"> <li><i>1. at BBCH 32-49,</i></li> <li><i>2. at BBCH 51-61.</i></li> </ol> <p><i>Samples were taken at harvest.</i></p> <p><i>Analytical method for determination of prothioconazole-desthio - method 01013.</i></p> <p><i>Analytical method for determination of prothioconazole -alpha-hydroxy-desthio, -3-hydroxy-desthio, -4-hydroxy-desthio, -5-hydroxy-desthio and -6-hydroxy-desthio – method 00979/M02.</i></p> <p><i>The residues of 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in/on plant material were analysed according to the method 01062/M004.</i></p> <p><i>Limit of quantitation of 0.01 mg/kg for grain, green material and straw.</i></p> <p><i>Mean recoveries in acceptable range (70 - 110%), RSD &lt;20%.</i></p> <p><i>Maximum storage period – 15 months.</i></p> <p><i>Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in barley grain at harvest were &lt;0.01 mg/kg. In grain at harvest, the total residue was always &lt;0.06 mg/kg.</i></p> <p><i>Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in straw at harvest ranged between &lt;0.06 mg/kg and 2.44 mg/kg.</i></p> <p><u><i>TDMs</i></u></p> <p><i>Residues of 1,2,4-triazole and of triazole lactic acid in barley grain at harvest were &lt; 0.01 mg/kg.</i></p> <p><i>Residues of triazole alanine in barley grain at harvest ranged between 0.052 and 0.13 mg/kg.</i></p> <p><i>Residues of triazole acetic acid in barley grain at harvest ranged between 0.024 and 0.078 mg/kg.</i></p> <p><i>The study is acceptable.</i></p>
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Reference: KCA 6.3.1/04

Report Determination of the residues of prothioconazole, spiroxamine and trifloxystrobin in/on barley after spray application of PTZ & SPX & TFS EC 280.3 in the Netherlands, Belgium, southern France and Italy  
Meklat, N.; Kerkerling, S.; Effertz, C., 28.11.2018  
Report No: M-641462-01-1  
Reference No: 17-2076

Guideline(s): Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market  
OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)  
US EPA OCSP 860.1500, Crop Field Trial

Deviations: None  
GLP: Yes  
Owner: Bayer CropScience AG (Nufarm has a letter of access)  
Acceptability: Yes

**The following study is currently under review in the EU approval renewal process for prothioconazole.**

### Materials and Methods

Four field trials were conducted in/on winter and spring barley during the 2017 growing season. The trials were located in the Netherlands, Belgium, Italy and southern France).

In each trial the emulsifiable concentrate (EC) formulation was applied twice at a nominal rate of prothioconazole of 140 g a.s./ha. The applications were carried out at the growth stages BBCH 32-49 and BBCH 51-61, respectively, using 250-400 L/ha of water. The spray intervals ranged between 7 and 21 days.

Samples of green material were taken for analysis on the day of the last application (day 0) while samples of grain and straw were taken at harvest.

Residues of prothioconazole-desthio were determined according to method 01013 with a limit of quantitation of 0.01 mg/kg for grain, green material and straw. Residues of prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio were determined according to method 00979/M002 with a limit of quantitation of 0.01 mg/kg for grain, green material and straw.

The residues of 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in/on plant material were analysed according to the method 01062/M004.

### Findings

#### - Storage stability:

The maximum storage periods for prothioconazole-desthio and TDMs in barley samples from the supplementary residue field trials are presented in the table below.

**Table A 42: Maximum storage periods of field samples from supplementary residue trials**

Crop	Substance	Sample Material	Storage period (days)	Storage period (months)
Barley	prothioconazole-desthio	grain	422	14.1
		green material	449	15.0
		straw	413	13.8
	prothioconazole-alpha-hydroxy-desthio prothioconazole-3-hydroxy-desthio prothioconazole-4-hydroxy-desthio prothioconazole-5-hydroxy-desthio prothioconazole-6-hydroxy-desthio	grain	400	13.3
		green material	440	14.7
		straw	411	13.7
	TAA; 1,2,4-T, TA	grain	386	12.9
		green material	426	14.2
		straw	384	12.8

\* the storage stability of TLA was not investigated in straw, but there is no need, as its stability has been shown for 48 months in representative commodities covering the five categories described in the OECD guideline 506 for the testing of chemicals.

Sample extracts were measured within 24 hours, or if not, acceptable recoveries measured concurrently

with each set of samples ensured integrity of the sample extracts during the period of time between extraction and analysis.

No residue above the LOQ was found in the control samples, with the following exceptions:

-triazole alanine:	green material:	17-2076-01-0009E (0.019 mg/kg)
	grain:	17-2076-01-0023E (0.020 mg/kg)
		17-2076-02-0023E (0.010 mg/kg)
		17-2076-03-0023E (0.016 mg/kg)
-triazole acetic acid:	straw:	17-2076-01-0024E (0.017 mg/kg)
	green material:	17-2076-01-0009E (0.010 mg/kg)
	grain:	17-2076-01-0023E (0.019 mg/kg)
		17-2076-03-0023E (0.012 mg/kg)
-triazole lactic acid:	straw:	17-2076-01-0024E (0.023 mg/kg)
	green material:	17-2076-01-0009E (0.022 mg/kg)
	straw:	17-2076-01-0011E (0.014 mg/kg)

The significant number of control samples showing residues of the triazole derived metabolites is due to the ubiquitous nature of these compounds.

#### - Method performance:

The apparent residues in the control samples used for the performance of recoveries were below 30% of the LOQ, with some exceptions. Due to the presence of apparent residues at relevant levels in the control samples used for fortification, some of the recoveries for triazole alanine, triazole acetic acid, and triazole lactic acid had to be background corrected. Whenever this is the case both the uncorrected and the corrected recoveries are presented in the result tables. The average recoveries per fortification level were within the range of 70 – 110%.

Remark: For some recovery samples the actual fortification levels (FL) are slightly below the nominal FL of 0.01 mg/kg. To facilitate the calculation of the mean recovery and RSD values, recoveries at 0.009 mg/kg and at 0.01 mg/kg were combined. Note that the calculation of the recovery values is always based on the actual fortification.

**Table A 43: 17-2076: Concurrent recoveries for the determination of prothioconazole-desthio in barley**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
Prothio-conazole-desthio	Barley green material	0.01	98, 110, 112	107	7.1	0.01
		0.10	103, 105, 107	105	1.9	
		2.5	109, 110	110	-	
		Overall Recovery (n = 8)		107	4.3	
	Barley grain	0.01	90, 93, 98, 102	96	5.6	0.01
		0.10	100, 101, 102	101	1.0	
		Overall Recovery (n = 7)		98	4.8	
	Barley straw	0.01	102, 105, 107	105	2.4	0.01
		0.10	106, 106, 112	108	3.2	
		2.0	109, 111	110	-	
		Overall Recovery (n = 8)		107	3.1	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-desthio, determined as JAU 6476-desthio and calculated as JAU 6476-desthio

**Table A 44: 17-2076: Concurrent recoveries for the determination of alpha-hydroxy-prothioconazole-desthio in barley**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
Alpha-hydroxy-prothio-conazole-desthio	Barley green material	0.009 / 0.01	94, 102*, 103	100	4.9	0.01
		0.10	104, 105, 107	105	1.5	
		Overall Recovery (n = 6)		103	4.4	
	Barley grain	0.01	95, 99, 99	98	2.4	0.01
		0.10	91, 91, 101	94	6.1	
		Overall Recovery (n = 6)		96	4.5	



Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
	Barley straw	0.01	106, 109, 110	108	1.9	0.01
		0.10	106, 107, 113	109	3.5	
		0.30	101, 104	103	-	
		1.0	96, 101	99	-	
		Overall Recovery (n = 10)		105	4.7	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-alpha-hydroxy-desthio, determined as JAU 6476-alpha-hydroxy-desthio and calculated as JAU 6476-desthio, \* the Fortification Level for this value is 0.009 mg/kg

**Table A 45: 17-2076: Concurrent recoveries for the determination of 3-hydroxy-prothioconazole-desthio in barley**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
3-hydroxy-prothioconazole-desthio	Barley green material	0.009 / 0.01	96, 104*, 105	102	4.9	0.01
		0.10	99, 101, 102	101	1.5	
		Overall Recovery (n = 6)		101	3.3	
	Barley grain	0.01	92, 92, 96	93	2.5	0.01
		0.10	85, 86, 93	88	5.0	
		Overall Recovery (n = 6)		91	4.7	
	Barley straw	0.01	104, 105, 105	105	0.6	0.01
		0.10	98, 98, 101	99	1.7	
		0.30	96, 97	97	-	
		1.0	92, 96	94	-	
		Overall Recovery (n = 10)		99	4.4	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-3-hydroxy-desthio, determined as JAU 6476-3-hydroxy-desthio and calculated as JAU 6476-desthio, \* the Fortification Level for this value is 0.009 mg/kg

**Table A 46: 17-2076: Concurrent recoveries for the determination of 4-hydroxy-prothioconazole-desthio in barley**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
4-hydroxy-prothioconazole-desthio	Barley green material	0.009 / 0.01	93, 97*, 97	96	2.4	0.01
		0.10	96, 98, 99	98	1.6	
		Overall Recovery (n = 6)		97	2.1	
	Barley grain	0.01	90, 94, 94	93	2.5	0.01
		0.10	87, 87, 97	90	6.4	
		Overall Recovery (n = 6)		92	4.5	
	Barley straw	0.01	100, 102, 102	101	1.1	0.01
		0.10	100, 102, 103	102	1.5	
		0.30	97, 102	100	-	
		1.0	87, 87	87	-	
		Overall Recovery (n = 10)		98	6.3	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-4-hydroxy-desthio, determined as JAU 6476-4-hydroxy-desthio and calculated as JAU 6476-desthio, \* the Fortification Level for this value is 0.009 mg/kg

**Table A 47: 17-2076: Concurrent recoveries for the determination of 5-hydroxy-prothioconazole-desthio in barley**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
5-hydroxy-prothioconazole-desthio	Barley green material	0.009 / 0.01	93, 98*, 103	98	5.1	0.01
		0.10	98, 102, 105	102	3.5	
		Overall Recovery (n = 6)		100	4.4	
	Barley grain	0.01	91, 92, 95	93	2.2	0.01
		0.10	88, 91, 97	92	5.0	
		Overall Recovery (n = 6)		92	3.5	
	Barley straw	0.01	103, 109, 110	107	3.5	0.01
		0.10	103, 106, 107	105	2.0	
		0.30	100, 101	101	-	

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
		1.0	93, 95	94	-	
		Overall Recovery (n = 10)		103	5.5	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-5-hydroxy-desthio, determined as JAU 6476-5-hydroxy-desthio and calculated as JAU 6476-desthio, \* the Fortification Level for this value is 0.009 mg/kg

**Table A 48: 17-2076: Concurrent recoveries for the determination of 6-hydroxy-prothioconazole-desthio in barley**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
Alpha-hydroxy-prothio-conazole-desthio	Barley green material	0.009 / 0.01	97*, 99, 102	99	2.5	0.01
		0.10	101, 103, 105	103	1.9	
		Overall Recovery (n = 6)		101	2.8	
	Barley grain	0.01	90, 93, 93	92	1.9	0.01
		0.10	93, 94, 99	95	3.4	
		Overall Recovery (n = 6)		94	3.1	
	Barley straw	0.01	102, 105, 105	104	1.7	0.01
		0.10	104, 105, 107	105	1.5	
		0.30	97, 104	101	-	
		1.0	85, 86	86	-	
		Overall Recovery (n = 10)		100	8.1	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-6-hydroxy-desthio, determined as JAU 6476-6-hydroxy-desthio and calculated as JAU 6476-desthio

\* the Fortification Level for this value is 0.009 mg/kg

**Table A 49: 17-2076: Concurrent recoveries for the determination of 1, 2, 4-Triazole in barley**

Analyte	Sample Material	Fortification n level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
1, 2,4-T	Barley green material	0.01	90, 94, 109	98	10.3	0.01
		0.10	101, 112, 118	110	7.8	
		Overall Recovery (n = 6)		104	10.4	
	Barley green material	0.01	86, 94, 100	93	7.5	0.01
		0.10	83, 91, 108, 111	98	13.7	
		Overall Recovery (n = 7)		96	11.1	
	Barley straw	0.01	93, 104, 111	103	8.8	0.01
		0.10	96, 104, 106	102	5.2	
		Overall Recovery (n = 6)		102	6.5	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with 1,2,4-triazole, determined as 1,2,4-triazole and calculated as 1,2,4-triazole

**Table A 50: 17-2076: Concurrent recoveries for the determination of Triazole Alanine in barley**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
TA	Barley green material	0.01	97, 108, 119	108	10.2	0.01
		0.10	81, 88, 94	88	7.4	
		Overall Recovery (n = 6)		98	14.1	
	Barley green material	0.01	70 (90) <sup>a</sup> , 81 (102) <sup>a</sup> , 93 (113) <sup>a</sup>	81	14.1	0.01
		0.10	91, 98, 104 (105) <sup>b</sup> , 111, 114, 119 (120) <sup>a</sup>	106	9.9	
		Overall Recovery (n = 9)		98	16.3	
	Barley straw	0.01	86, 88, 102	92	9.5	0.01
		0.10	82, 92, 95	90	7.6	
		Overall Recovery (n = 6)		91	7.8	

RSD = Relative standard deviation, LOQ = Practical limit of quantification.

a These recoveries were background-corrected since the control sample used for spiking (17-2076-04-0023E) was found to contain (apparent) residues at a level of 0.00203 mg/kg. The uncorrected recovery is shown in brackets.

b These recoveries were background-corrected since the control sample used for spiking (17-2076-04-0023E) was found to contain (apparent) residues at a level of 0.00160 mg/kg. The uncorrected recovery is shown in brackets.  
Fortified with triazole alanine, determined as triazole alanine and calculated as triazole alanine

**Table A 51: 17-2076: Concurrent recoveries for the determination of Triazole Acetic Acid in barley**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
TAA	Barley green material	0.01	88, 96, 98	94	5.6	0.01
		0.10	76, 82, 93	84	10.3	
		<b>Overall Recovery (n = 6)</b>		<b>89</b>	<b>9.6</b>	
	Barley green material	0.01	85, 86, 95	89	6.2	0.01
		0.10	93, 103, 105	100	6.4	
		<b>Overall Recovery (n = 6)</b>		<b>95</b>	<b>8.8</b>	
	Barley straw	0.01	88, 99, 99	95	6.7	0.01
		0.10	93, 100, 103	99	5.2	
		<b>Overall Recovery (n = 6)</b>		<b>97</b>	<b>5.6</b>	

RSD = Relative standard deviation, LOQ = Practical limit of quantification.

Fortified with triazole acetic acid, determined as triazole acetic acid and calculated as triazole acetic acid.

**Table A 52: 17-2076: Concurrent recoveries for the determination of Triazole Lactic acid in barley**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
TLA	Barley green material	0.01	90, 96, 113	100	12.0	0.01
		0.10	81, 91, 95	89	8.1	
		<b>Overall Recovery (n = 6)</b>		<b>94</b>	<b>11.2</b>	
	Barley green material	0.01	68, 72, 80	73	8.3	0.01
		0.10	77, 85, 104	89	15.6	
		<b>Overall Recovery (n = 6)</b>		<b>81</b>	<b>15.7</b>	
	Barley straw	0.01	90 (103) <sup>a</sup> , 107 (120) <sup>a</sup> , 107 (120) <sup>a</sup>	101	9.7	0.01
		0.10	96 (98) <sup>a</sup> , 98 (99) <sup>a</sup> , 98 (100) <sup>a</sup>	97	1.2	
		<b>Overall Recovery (n = 6)</b>		<b>99</b>	<b>6.7</b>	

RSD = Relative standard deviation, LOQ = Practical limit of quantification.

a These recoveries were background-corrected since the control sample used for spiking (17-2076-04-0024E) was found to contain (apparent) residues at a level of 0.00126 mg/kg.

The uncorrected recovery is shown in brackets. Fortified with triazole lactic acid, determined as triazole lactic acid and calculated as triazole lactic acid.

#### - Residue results:

The residue results are summarised in the tables in the following pages.

### Conclusion

Four barley residue trials were conducted with Prothioconazole & Spiroxamine & Trifloxystrobin EC280.3 in northern and southern Europe. The product application corresponded to a prothioconazole rate of 2x140 g a.s./ha.

Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in barley grain at harvest were <0.01 mg/kg.

Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in straw at harvest ranged between <0.06 mg/kg and 2.44 mg/kg.

The results for the TDMs are summarised in the table below.

**Table A 53: 17-2076 - Residues of prothioconazole-desthio and metabolites in/on spring and winter barley applied with Prothioconazole & Spiroxamine & Trifloxystrobin EC280.3**

[illegible]

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplantin g	Application						Residues (mg/kg)							Total (PTZ- desthio+hydrox y =RD-RA1)*	
				FL	N o	kg/h a (a.s.)	kg/hL (a.s.)	G S	Dates of treatment / Application interval	Portion analyse d	DAL T (d)	JAU 6476- desthi o	JAU 6476- alpha- OH- desthi o	JAU 6476- 3-OH- desthi o	JAU 6476- 4-OH- desthi o	JAU 6476- 5-OH- desthi o		JAU 6476- 6-OH- desthi o
17-2076-04 17-2076-04-T* GLP: yes 2017		(VT) Europe, South	1) 12.12.2016 2) 26.04.2017 - 05.05.2017 3) 01.06.2017 - 30.06.2017							straw	42	1.4	0.031	0.030	0.68	0.24	0.061	2.44

\* for the sum, values <0.01 mg/kg were considered to be equal to 0.01 mg/kg, unless all the values were <0.01 mg/kg.

**Table A 54: 17-2076 - Residues of 1,2,4-T and TAA in/on spring and winter barley applied with Prothioconazole & Spiroxamine & Trifloxystrobin EC280.3**

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application					Dates of treatment / Application interval	Residues (mg/kg)			
				FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS		Portion analysed	DALT (d)	1,2,4,-T	TAA
17-2076MAN 17-2076-01 17-2076-01-T* GLP: yes 2017	Barley Kwsirina	Netherlands 1681 ND Zwaagdijk Europe, North	1) 06.04.2017 2) 27.06.2017 - 11.07.2017 3) 10.08.2017 - 20.08.2017	280.3 EC	2	0.140	0.0350	61	08.06.2017/0 27.06.2017/19	green material	0	<0.01	0.011/0.010**
										grain	48	<0.01	0.078/0.019**
										straw	48	<0.01	0.026/0.023**
17-2076MAN 17-2076-02 17-2076-02-T* GLP: yes 2017	Barley Milford	Belgium 6221 Saint- Amand Europe, North	1) 16.03.2017 2) 02.06.2017 - 07.06.2017 3) 28.07.2017 - 07.08.2017	280.3 EC	2	0.140	0.0560	61	26.05.2017/0 02.06.2017/7	green material	0	<0.01	<0.01
										grain	56	<0.01	0.024
										straw	56	<0.01	0.010
17-2076MAN 17-2076-03 17-2076-03-T* GLP: yes 2017	Barley Platine	France 13103 St Etienne du Gres Europe, South	1) 15.12.2016 2) 03.05.2017 - 10.05.2017 3) 13.06.2017 - 20.06.2017	280.3 EC	2	0.140	0.0467	61	12.04.2017/0 03.05.2017/21	green material	0	<0.01	<0.01
										grain	43	<0.01	0.077/0.012**
										straw	43	<0.01	0.017
17-2076MAN 17-2076-04 17-2076-04-T* GLP: yes 2017	Barley Mercur	Italy 01016 Tarquinia (VT) Europe, South	1) 12.12.2016 2) 26.04.2017 - 05.05.2017 3) 01.06.2017 - 30.06.2017	280.3 EC	2	0.140	0.0467	61	05.04.2017/0 26.04.2017/21	green material	0	<0.01	<0.01
										grain	42	<0.01	0.036
										straw	42	<0.01	0.014

\*\* residue in control.

Residues for 1,2,4-triazole (determined as 1,2,4-triazole and calculated as 1,2,4-triazole). Residues for triazole acetic acid (determined as triazole acetic acid and calculated as triazole acetic acid).

**Table A 55: 17-2076 - Residues of TA and TLA in/on spring and winter barley applied with Prothioconazole & Spiroxamine & Trifloxystrobin EC280.3**

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting	Application					Dates of treatment / Application interval	Residues (mg/kg)			
				FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS		Portion analysed	DALT (d)	TA	TLA
17-2076MAN 17-2076-01 17-2076-01-T* GLP: yes 2017	Barley Kwsirina	Netherlands 1681 ND Zwaagdijk Europe, North	1) 06.04.2017 2) 27.06.2017 - 11.07.2017 3) 10.08.2017 - 20.08.2017	280.3 EC	2	0.140	0.0350	61	08.06.2017/0 27.06.2017/19	green material	0	0.021/0.019**	0.022/0.022**
										grain	48	0.13/0.020**	<0.01
										straw	48	0.030/0.017**	0.028/0.014**
17-2076MAN 17-2076-02 17-2076-02-T* GLP: yes 2017	Barley Milford	Belgium 6221 Saint- Amand Europe, North	1) 16.03.2017 2) 02.06.2017 - 07.06.2017 3) 28.07.2017 - 07.08.2017	280.3 EC	2	0.140	0.0560	61	26.05.2017/0 02.06.2017/7	green material	0	0.021	0.018
										grain	56	0.052/0.010**	<0.01
										straw	56	<0.01	0.013
17-2076MAN 17-2076-03 17-2076-03-T* GLP: yes 2017	Barley Platine	France 13103 St Etienne du Gres Europe, South	1) 15.12.2016 2) 03.05.2017 - 10.05.2017 3) 13.06.2017 - 20.06.2017	280.3 EC	2	0.140	0.0467	61	12.04.2017/0 03.05.2017/21	green material	0	0.026	0.019
										grain	43	0.099/0.016**	<0.01
										straw	43	<0.01	0.039
17-2076MAN 17-2076-04 17-2076-04-T* GLP: yes 2017	Barley Mercur	Italy 01016 Tarquinia (VT) Europe, South	1) 12.12.2016 2) 26.04.2017 - 05.05.2017 3) 01.06.2017 - 30.06.2017	280.3 EC	2	0.140	0.0467	61	05.04.2017/0 26.04.2017/21	green material	0	0.017	0.013
										grain	42	0.041	<0.01
										straw	42	<0.01	0.050

\*\* residue in control.

Residues for triazole alanine (determined as triazole alanine and calculated as triazole alanine). Residues for triazole lactic acid (determined as triazole lactic acid and calculated as triazole lactic acid).

#### A 2.1.3.1.4 Barley residue trials analysing TDMs

The following tables were extracted from the “Triazole Derivate Metabolites addendum – confirmatory data prepared by the rapporteur Member State, the United Kingdom” Appendix C (UK, 2018). Only trials performed with prothioconazole were considered and presented hereafter.

**Table A 56: Application summary of residue trials conducted on barley with EC formulations containing prothioconazole**

Study Trial No. Year	Crop Variety	Country	Application of prothioconazole				
			FL	No	g as/ha	g as/hL	GS
Northern Europe							
RA-2328/06 R 2006 0457/2 2006	Spring barley Carafe	France 95510 St Cyr en Arthies (Ile-de-France)	EC 150 g/L	2	150	50	61
RA-2328/06 R 2006 0458/0 2006	Spring barley Prestige	Sweden 245 93 Staffanstorp (Scania)	EC 150 g/L	2	150	50	61
RA-2328/06 R 2006 0459/9 2006	Winter barley Sequel	United Kingdom IP21 5DB Hoxne/ Nr Eye (Suffolk)	EC 150 g/L	2	150	50	61
RA-2328/06 R 2006 0460/2 2006	Winter barley Duet	Germany 59514 Welter-Flerke (Nordrhein-Westfalen)	EC 150 g/L	2	150	50	61
RA-3669/07 * R 2007 0751/7 2007	Winter barley Cervoise	France 80560 Varennes (Picardie)	EC 250 g/L	2	200	66.8	61
RA-3669/07 * R 2007 0752/5 2007	Spring barley Scarlett	France 80700 Cremery (Picardie)	EC 250 g/L	2	200	66.8	61
RA-3669/07 * R 2007 0781/9 2007	Winter barley Vanessa	France 37210 Chambourg sur Indre (Centre)	EC 250 g/L	2	200	66.8	61
RA-3669/07 * R 2007 0782/7 2007	Spring barley Scarlett	France 37210 Chambourg sur Indre (Centre)	EC 250 g/L	2	200	66.8	61



**Table A 57: Results of residue trials conducted on barley with EC formulations containing prothioconazole**

Report No	Country Trial No	DALT (days)	Com-mo-dity	Residue in Treated Samples				Residue in Control Samples			
				Residue (mg/kg) 1,2,4-T <sup>a</sup>	TA <sup>b</sup>	TAA <sup>c</sup>	TLA <sup>d</sup>	Residue (mg/kg) 1,2,4-T <sup>a</sup>	TA <sup>b</sup>	TAA <sup>c</sup>	TLA <sup>d</sup>
Northern Europe											
RA-2328/06 MR-09/110	France R 2006 0457/2	0	plant	< 0.050	0.061	< 0.050	NA	< 0.050	0.075	0.068	NA
		34	straw	< 0.050	< 0.050	0.055	NA	< 0.050	< 0.050	0.134	NA
		34	grain	< 0.010	0.192	0.162	NA	< 0.010	0.230	0.217	NA
RA-2328/06 MR-09/110	Sweden R 2006 0458/0	0	plant	< 0.050	< 0.050	< 0.050	NA	< 0.050	< 0.050	< 0.050	NA
		7	plant	< 0.050	< 0.050	< 0.050	NA	NA	NA	NA	NA
		14	plant	< 0.050	< 0.050	< 0.050	NA	NA	NA	NA	NA
		28	plant	< 0.050	< 0.050	< 0.050	NA	NA	NA	NA	NA
		40	straw	< 0.050	< 0.050	< 0.050	NA	< 0.050	< 0.050	< 0.050	NA
		40	grain	< 0.010	0.043	0.057	NA	< 0.010	0.027	0.041	NA
RA-2328/06 MR-09/110	United Kingdom R 2006 0459/9	0	plant	< 0.050	< 0.050	< 0.050	NA	< 0.050	< 0.050	< 0.050	NA
		62	straw	< 0.050	< 0.050	< 0.050	NA	< 0.050	< 0.050	< 0.050	NA
		62	grain	< 0.010	0.190	0.057	NA	< 0.010	0.128	0.048	NA
RA-2328/06 MR-09/110	Germany R 2006 0460/2	0	plant	< 0.050	0.085	< 0.050	NA	< 0.050	0.060	< 0.050	NA
		7	plant	< 0.050	0.069	< 0.050	NA	NA	NA	NA	NA
		14	plant	< 0.050	0.084	< 0.050	NA	NA	NA	NA	NA
		28	plant	< 0.050	0.158	< 0.050	NA	NA	NA	NA	NA
		51	straw	< 0.050	< 0.050	0.083	NA	< 0.050	< 0.050	0.136	NA
		51	grain	0.011	0.440	0.157	NA	< 0.010	0.254	0.142	NA
RA-3669/07 P 1747 G	France R 2007 0751/7	63	grain	< 0.010	0.226	0.033	< 0.010	< 0.010	0.126	0.032	< 0.010
RA-3669/07 P 1747 G	France R 2007 0752/5	58	grain	< 0.010	0.184	0.067	< 0.010	< 0.010	0.054	0.027	< 0.010
RA-3669/07 P 1747 G	France R 2007 0781/9	63	grain	< 0.010	0.250	0.172	< 0.010	< 0.010	0.199	0.156	< 0.010
RA-3669/07 P 1747 G	France R 2007 0782/7	53	grain	< 0.010	0.405	0.320	0.012	< 0.010	0.279	0.290	< 0.010

DALT : Days after last treatment

NA : not analysed

In study MR-09/110:

a 1,2,4-T = Residues determined as 1,2,4-triazole derivative, calculated as 1,2,4-triazole.

b TA = Residues determined as triazole alanine derivative, calculated as triazole alanine.

c TAA = Residues determined as triazole acetic acid derivative, calculated as triazole acetic acid.

d TLA = Triazole lactic acid not analysed.

In study P 1747 G:

a 1,2,4-T = Residues determined and calculated as 1,2,4-triazole.

b TA = Residues determined and calculated as triazole alanine.

c TAA = Residues determined and calculated as triazole acetic acid.

d TLA = Residues determined and calculated as triazole lactic acid.

**Table A 58: Application summary of residue trials conducted in/on barley with an EC formulation containing 250 g/L of prothioconazole, after seed treatment with an FS formulation containing 100 g/L of prothioconazole**

Study Trial No. Year	Crop Variety	Country	Application of prothioconazole				
			FL	No	g as/ha	g as/hL	GS
Northern Europe							
09-2116 09-2116-01 2009	Winter barley Wendy	Germany 59457 Werl- Niederbergstrasse Nordrhein-Westfalen	FS 100 g/L EC 250 g/L	ST 2	27* 200	- 66.7	- 61
09-2116 09-2116-02 2009	Winter barley Wendy	The Netherlands 1681 ND, Zwaagdijk Noord-Holland	FS 100 g/L EC 250 g/L	ST 2	27* 200	- 66.7	- 61

**Table A 59: Results of residue trials conducted in/on barley with an EC formulation containing 250 g/L of prothioconazole, after seed treatment with an FS formulation containing 100 g/L of prothioconazole**

Report No	Country Trial No	DALT (days)	Commodity	Residue in Treated Samples				Residue in Control Samples			
				1,2,4-T <sup>a</sup>	TA <sup>b</sup>	TAA <sup>c</sup>	TLA <sup>d</sup>	1,2,4-T <sup>a</sup>	TA <sup>b</sup>	TAA <sup>c</sup>	TLA <sup>d</sup>
Northern Europe											
09-2116	Germany 09-2116-01	0	plant	< 0.01	0.075	< 0.01	0.039	< 0.01	0.042	< 0.01	0.027
		49	grain	< 0.01	0.382	0.050	< 0.01	< 0.01	0.123	0.021	< 0.01
		49	straw	< 0.01	0.017	0.013	0.157	< 0.01	0.013	< 0.01	0.114
09-2116	Netherlands 09-2116-02	0	plant	< 0.01	0.029	< 0.01	0.018	< 0.01	< 0.01	< 0.01	< 0.01
		55	grain	< 0.01	0.169	0.022	< 0.01	< 0.01	0.017	< 0.01	< 0.01
		55	straw	< 0.01	0.015	< 0.01	0.076	< 0.01	0.010	< 0.01	0.085

DALT = Days after last treatment

a 1,2,4-T = Residues determined as 1,2,4-triazole, calculated as 1,2,4-triazole.

b TA = Residues determined as triazole alanine, calculated as triazole alanine.

c TAA = Residues determined as triazole acetic acid, calculated as triazole acetic acid.

d TLA = Residues determined as triazole lactic acid, calculated as triazole lactic acid.

## A 2.1.3.2 Wheat, Rye

**Table A 60: Comparison of intended and critical EU GAPs – Wheat & Rye**

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP NEU (DAR, UK, 2007)	3	200	14-21	BBCH 26-69	35
cGAP NEU (Art. 12, EFSA, 2020) <i>Wheat &amp; Rye</i>	3	200	14-21	BBCH 29-69	35
Intended cGAP CEU	2	210	14-21	BBCH 30-69	35

### A 2.1.3.2.1 Study 17-2015 – NEU

Comments of zRMS:	<p>The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application. The conclusions of the assessment are presented below:</p> <p><i>Four residue trials on spring and winter wheat were conducted in northern Europe to determine residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio and the triazole-derived metabolites (1,2,4-triazole, triazole alanine, triazole acetic acid, triazole lactic acid). Wheat was treated twice at application rate of 0.200 kg a.s./ha of prothioconazole with 21 day interval between applications. The time of application was:</i></p> <ol style="list-style-type: none"> <li><i>1. at BBCH 45,</i></li> <li><i>2. at BBCH 69.</i></li> </ol> <p><i>Samples were taken at harvest.</i></p> <p><i>Analytical method for determination of prothioconazole-desthio - method 01013.</i></p> <p><i>Analytical method for determination of prothioconazole-alpha-hydroxy-desthio, -3-hydroxy-desthio, -4-hydroxy-desthio, -5-hydroxy-desthio and -6-hydroxy-desthio – method 00979/M02.</i></p> <p><i>The residues of 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in/on plant material were analysed according to the method 01062/M004.</i></p> <p><i>Limit of quantitation of 0.01 mg/kg for grain, green material and straw.</i></p> <p><i>The average recoveries were within the acceptable range of 70 – 110%, except for prothioconazole-desthio (112%) in sample material wheat, green material at LOQ level. The RSD values were below 20%.</i></p> <p><i>Maximum storage period – 524 days.</i></p> <p><i>Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in wheat grain at harvest were &lt;0.01 mg/kg.</i></p> <p><i>Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest were &lt;0.06 mg/kg.</i></p> <p><i>Residues of 1,2,4-triazole and triazole lactic acid, in wheat grain at harvest were &lt;0.01 mg/kg.</i></p> <p><i>Residues of triazole alanine, in wheat grain at harvest ranged between 0.21 and 0.65 mg/kg.</i></p> <p><i>Residues of triazole acetic acid, in wheat grain at harvest ranged between 0.085 and 0.14 mg/kg.</i></p> <p><i>The study is acceptable.</i></p>
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Reference: KCA 6.3.2/01

Report Determination of the residues of prothioconazole and spiroxamine in/on wheat after spray application of JAU 6476 & KWG 4168 EC 460 in Germany, northern France and the Netherlands  
Meklat, N.; Kerkerling, S., 24.05.2019

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	Report No: M-659920-01-1 Reference No: 17-2015
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) US EPA OCSPP 860.1500, Crop Field Trial
Deviations:	None
GLP:	Yes
Owner:	Bayer CropScience AG (Nufarm has a letter of access)
Acceptability:	Yes

**Text from Bayer: This study has never been submitted to any authority and therefore, no OECD summary is available. Nevertheless, all the relevant information is available / summarised in the following tables.**

**Table A 61: GAP Summary of the 17-2015MAN trials**

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Date of 1. Sowing or planting 2. Flowering 3. Harvest 4. Transplanting (b)	Application rate per treatment			Dates of treatment / Application interval (c)	Growth stage at last treatment (d)	Details on trial (f)
			g a.s./ha	Water (L/ha)	g a.s./hL			
17-2015-01 17-2015-01-T Germany 51399 Burscheid Europe, North 2017	Wheat, winter Potential	1) 04.10.2016 2) 30.05.2017 - 06.06.2017 3) 15.07.2017 - 15.08.2017	200 200	300 300	66.7 66.7	17.05.2017/0 07.06.2017/21	69	(g) 17-2015MAN (h) EC (prothioconazole 160 g/L ,spiroxamine 300 g/L) (i) Application method: Spraying
17-2015-02 17-2015-02-T Germany 78166 Donaueschingen OT Aasen Europe, North 2017	Wheat, spring KWS Chamsin	1) 28.03.2017 2) 01.07.2017 - 15.07.2017 3) 01.08.2017 - 19.08.2017	200 200	300 300	66.7 66.7	21.06.2017/0 12.07.2017/21	69	(g) 17-2015MAN (h) EC (prothioconazole 160 g/L ,spiroxamine 300 g/L) (i) Application method: Spraying
17-2015-03 17-2015-03-T France, north 37310 Chambourg sur Indre Europe, North 2017	Wheat, winter Venezio	1) 12.10.2016 2) 17.05.2017 - 25.05.2017 3) 01.07.2017 - 15.07.2017	200 200	300 300	66.7 66.7	02.05.2017/0 23.05.2017/21	69	(g) 17-2015MAN (h) EC (prothioconazole 160 g/L ,spiroxamine 300 g/L) (i) Application method: Spraying
17-2015-04 17-2015-04-T Netherlands 1681 ND Zwaagdijk Europe, North 2017	Wheat, spring Tybalt	1) 06.04.2017 2) 26.06.2017 - 06.07.2017 3) 10.08.2017 - 20.08.2017	200 200	400 400	50.0 50.0	15.06.2017/0 06.07.2017/21	69	(g) 17-2015MAN (h) EC (prothioconazole 160 g/L ,spiroxamine 300 g/L) (i) Application method: Spraying

**Table A 62: Analytical part of the 17-2015MAN trials – Part 1**

Analyte 1: JAU 6476-desthio (determined as JAU 6476-desthio, calculated as JAU 6476-desthio), Analyte 2: JAU 6476-4-hydroxy-desthio (determined as JAU 6476-4-hydroxy-desthio, calculated as JAU 6476-desthio), Analyte 3: JAU 6476-3-hydroxy-desthio (determined as JAU 6476-3-hydroxy-desthio, calculated as JAU 6476-desthio), Analyte 4: JAU 6476-alpha-hydroxy-desthio (determined as JAU 6476-alpha-hydroxy-desthio, calculated as JAU 6476-desthio), Analyte 5: JAU 6476-6-hydroxy-desthio (determined as JAU 6476-6-hydroxy-desthio, calculated as JAU 6476-desthio), Analyte 6: JAU 6476-5-hydroxy-desthio (determined as JAU 6476-5-hydroxy-desthio, calculated as JAU 6476-desthio)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)						Total (PTZ- desthio+hydroxy=RD- RA1)*	PHI (days) (e)	Details on trial (f)
				Analyte 1  JAU 6476- desthio as JAU 6476- desthio	Analyte 2  JAU 6476-4- hydroxy- desthio as JAU 6476- desthio	Analyte 3  JAU 6476-3- hydroxy- desthio as JAU 6476- desthio	Analyte 4  JAU 6476- alpha- hydroxy- desthio as JAU 6476- desthio	Analyte 5  JAU 6476-6- hydroxy- desthio as JAU 6476- desthio	Analyte 6  JAU 6476-5- hydroxy- desthio as JAU 6476- desthio			
17-2015-01 17-2015-01-T Germany 51399 Burscheid Europe, North F 2017	Wheat, winter Potential	green material	69	1.5	0.11	0.13	0.092	0.024	0.14	0.50	0	(g) 17-2015MAN (j) Analytical method: Analyte 1: 01013 Analyte 2,3,4,5,6: 00979/M002 (k) LOQ: 00979/M002 Analyte 2,3,4,5,6,: 0.01 mg/kg 01013 Analyte 1,: 0.01 mg/kg (l) Method Validation Data: in methods 01013 and 00979/M002 and in study 17-2015 (m) Storage: Analyte 1 straw: 394 days Analyte 2, 3, 4, 5, 6 straw: 402 days Analyte 1 green material: 454 days Analyte 2, 3, 4, 5, 6 green material: 462 days Analyte 1 grain: 394 days Analyte 2, 3, 4, 5, 6 grain: 402 days
			69								0	
		grain	89	<u>&lt;0.01</u>	<0.01	<0.01	<0.01	<0.01	<0.01	<u>&lt;0.06</u>	61	
			89								61	
			89	<u>0.089</u>	0.056	0.056	0.027	<0.01	0.064	<u>0.30</u>	61	
			89								61	
		green material  grain	69	1.5	0.11	0.15	0.16	0.029	0.087	0.54	0	
			69								0	
			89	<u>&lt;0.01</u>	<0.01	<0.01	<0.01	<0.01	<0.01	<u>&lt;0.06</u>	26	
			89								26	

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)						Total (PTZ- desthio+hydroxy=RD- RA1)*	PHI (days) (e)	Details on trial (f)
				Analyte 1  JAU 6476- desthio as JAU 6476- desthio	Analyte 2  JAU 6476-4- hydroxy- desthio as JAU 6476- desthio	Analyte 3  JAU 6476-3- hydroxy- desthio as JAU 6476- desthio	Analyte 4  JAU 6476- alpha- hydroxy- desthio as JAU 6476- desthio	Analyte 5  JAU 6476-6- hydroxy- desthio as JAU 6476- desthio	Analyte 6  JAU 6476-5- hydroxy- desthio as JAU 6476- desthio			
17-2015-02 17-2015-02-T Germany 78166 Donaueschingen OT Aasen Europe, North F 2017	Wheat, spring KWS Chamsin	straw	89 89	<u>0.15</u>	0.11	0.16	0.095	0.028	0.097	<u>0.64</u>	26 26	(g) 17-2015MAN (j) Analytical method: Analyte 1: 01013 Analyte 2,3,4,5,6: 00979/M002 (k) LOQ: 00979/M002 Analyte 2,3,4,5,6,: 0.01 mg/kg 01013 Analyte 1,: 0.01 mg/kg (l) Method Validation Data: in methods 01013 and 00979/M002 and in study 17-2015 (m) Storage: Analyte 1 straw: 394 days Analyte 2, 3, 4, 5, 6 straw: 402 days Analyte 1 green material: 419 days Analyte 2, 3, 4, 5, 6 green material: 427 days Analyte 1 grain: 394 days Analyte 2, 3, 4, 5, 6 grain: 402 days
		green material grain	69 69 89 89	1.3  <u>&lt;0.01</u>	0.051  <0.01	0.055  <0.01	0.030  <0.01	<0.01  <0.01	0.034  <0.01	0.18  <u>&lt;0.06</u>	0 0 43 43	

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)						Total (PTZ- desthio+hydroxy=RD- RA1)*	PHI (days) (e)	Details on trial (f)
				Analyte 1  JAU 6476- desthio as JAU 6476- desthio	Analyte 2  JAU 6476-4- hydroxy- desthio as JAU 6476- desthio	Analyte 3  JAU 6476-3- hydroxy- desthio as JAU 6476- desthio	Analyte 4  JAU 6476- alpha- hydroxy- desthio as JAU 6476- desthio	Analyte 5  JAU 6476-6- hydroxy- desthio as JAU 6476- desthio	Analyte 6  JAU 6476-5- hydroxy- desthio as JAU 6476- desthio			
17-2015-03 17-2015-03-T France, north 37310 Chambourg sur Indre Europe, North F 2017	Wheat, winter Venezio	straw	89 89	<u>0.18</u>	0.22	0.22	0.19	0.029	0.17	<u>1.01</u>	43 43	(g) 17-2015MAN (j) Analytical method: Analyte 1: 01013 Analyte 2,3,4,5,6: 00979/M002 (k) LOQ: 00979/M002 Analyte 2,3,4,5,6,: 0.01 mg/kg 01013 Analyte 1,: 0.01 mg/kg (l) Method Validation Data: in methods 01013 and 00979/M002 and in study 17-2015 (m) Storage: Analyte 1 straw: 427 days Analyte 2, 3, 4, 5, 6 straw: 435 days Analyte 1 green material: 469 days Analyte 2, 3, 4, 5, 6 green material: 477 days Analyte 1 grain: 427 days Analyte 2, 3, 4, 5, 6 grain: 435 days
		green material grain	69 69 89 89	1.8  <u>&lt;0.01</u>	0.085  <0.01	0.11  <0.01	0.053  <0.01	0.015  <0.01	0.077  <0.01	0.34  <u>&lt;0.06</u>	0 0 39 39	



Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)						Total (PTZ- desthio+hydroxy=RD- RA1)*	PHI (days) (e)	Details on trial (f)
				Analyte 1  JAU 6476- desthio as JAU 6476- desthio	Analyte 2  JAU 6476-4- hydroxy- desthio as JAU 6476- desthio	Analyte 3  JAU 6476-3- hydroxy- desthio as JAU 6476- desthio	Analyte 4  JAU 6476- alpha- hydroxy- desthio as JAU 6476- desthio	Analyte 5  JAU 6476-6- hydroxy- desthio as JAU 6476- desthio	Analyte 6  JAU 6476-5- hydroxy- desthio as JAU 6476- desthio			
17-2015-04 17-2015-04-T Netherlands 1681 ND Zwaagdijk Europe, North F 2017	Wheat, spring Tybalt	straw	89 89	<u>0.041</u>	0.064	0.076	0.022	0.010	0.063	<u>0.28</u>	39 39	(g) 17-2015MAN (j) Analytical method: Analyte 1: 01013 Analyte 2,3,4,5,6: 00979/M002 (k) LOQ: 00979/M002 Analyte 2,3,4,5,6,: 0.01 mg/kg 01013 Analyte 1,: 0.01 mg/kg (l) Method Validation Data: in methods 01013 and 00979/M002 and in study 17-2015 (m) Storage: Analyte 1 straw: 387 days Analyte 2, 3, 4, 5, 6 straw: 395 days Analyte 1 green material: 425 days Analyte 2, 3, 4, 5, 6 green material: 433 days Analyte 1 grain: 387 days Analyte 2, 3, 4, 5, 6 grain: 395 days

\* for the sum, values <0.01 mg/kg were considered to be equal to 0.01 mg/kg, unless all the values were <0.01 mg/kg.

**Table A 63: Analytical part of the 17-2015MAN trials (Part 2)**

Analyte 1: 1,2,4-triazole (determined as 1,2,4-triazole, calculated as 1,2,4-triazole), Analyte 2: triazole alanine (determined as triazole alanine, calculated as triazole alanine), Analyte 3: triazole acetic acid (determined as triazole acetic acid, calculated as triazole acetic acid), Analyte 4: triazole lactic acid (determined as triazole lactic acid, calculated as triazole lactic acid)

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 1,2,4- triazole as 1,2,4- triazole	Analyte 2 triazole alanine as triazole alanine	Analyte 3 triazole acetic acid as triazole acetic acid	Analyte 4 triazole lactic acid as triazole lactic acid		
17-2015-01 17-2015-01-T Germany 51399 Burscheid Europe, North F 2017	Wheat, winter Potential	green material  grain  straw	69	<0.01	0.073/0.011**	0.036	0.029	0	(g) 17-2015MAN (j) Analytical method: 01062/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: in method 01062/M004 and in appendix 5 of study 17-2015 (m) Storage: Analyte 1, 2, 3, 4 straw: 448 days Analyte 1, 2, 3, 4 green material: 509 days Analyte 1, 2, 3, 4 grain: 456 days **residue in control
			89	<0.01	0.21/0.051**	0.085/0.027**	<0.01	61	
			89	<0.01	<0.01	0.010	<0.01	61	
17-2015-02 17-2015-02-T Germany 78166 Donaueschingen OT Aasen Europe, North F 2017	Wheat, spring KWS Chamsin	green material  grain  straw	69	<0.01	0.16	0.020	0.034	0	(g) 17-2015MAN (j) Analytical method: 01062/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: in method 01062/M004 and in appendix 5 of study 17-2015 (m) Storage: Analyte 1, 2, 3, 4 straw: 448 days Analyte 1, 2, 3, 4 green material: 474 days Analyte 1, 2, 3, 4 grain: 458 days **residue in control
			89	<0.01	0.65/0.035**	0.092/0.010**	<0.01	26	
			89	<0.01	0.10	0.048	0.065	26	
17-2015-03 17-2015-03-T France, north 37310 Chambourg sur Indre Europe, North F 2017	Wheat, winter Venezio	green material  grain  straw	69	<0.01	0.052/0.11**	0.023/0.085**	0.028/0.095**	0	(g) 17-2015MAN (j) Analytical method: 01062/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: in method 01062/M004 and in appendix 5 of study 17-2015 (m) Storage: Analyte 1, 2, 3, 4 straw: 481 days Analyte 1, 2, 3, 4 green material: 524 days Analyte 1, 2, 3, 4 grain: 491 days **residue in control
			89	<0.01	0.42/0.53**	0.14/0.23**	<0.01	43	
			89	<0.01	0.016/0.014**	0.096/0.26**	0.066/0.11**	43	

Trial No. / Location / EU zone / Year	Commodity / Variety (a)	Portion analyzed	Growth stage at sampling (d)	Residues (mg/kg)				PHI (days) (e)	Details on trial (f)
				Analyte 1 1,2,4- triazole as 1,2,4- triazole	Analyte 2 triazole alanine as triazole alanine	Analyte 3 triazole acetic acid as triazole acetic acid	Analyte 4 triazole lactic acid as triazole lactic acid		
17-2015-04 17-2015-04-T Netherlands 1681 ND Zwaagdijk Europe, North F 2017	Wheat, spring Tybalt	green material	69	<0.01	0.071	0.019	0.018	0	(g) 17-2015MAN (j) Analytical method: 01062/M004 (k) LOQ: 0.01 mg/kg (l) Method Validation Data: in method 01062/M004 and in appendix 5 of study 17-2015 (m) Storage: Analyte 1, 2, 3, 4 straw: 441 days Analyte 1, 2, 3, 4 green material: 480 days Analyte 1, 2, 3, 4 grain: 449 days **residue in control
		grain	89	<u>&lt;0.01</u>	<u>0.37/0.054**</u>	<u>0.087/0.020**</u>	<u>&lt;0.01</u>	39	
		straw	89	<u>&lt;0.01</u>	<u>0.010</u>	<u>0.014</u>	<u>0.033</u>	39	

## A 2.1.3.2.2 Study S19-01268 – NEU + SEU

Comments of zRMS:	<p>The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application. The conclusions of the assessment are presented below:</p> <p><i>Four residue trials on wheat were conducted in northern Europe to determine residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio and the triazole-derived metabolites (1,2,4-triazole, triazole alanine, triazole acetic acid, triazole lactic acid).</i></p> <p><i>Wheat was treated twice at application rate of 0.200 kg a.s./ha of prothioconazole with 14 days interval between applications. Samples were taken at harvest, 35 days after last application.</i></p> <p><i>The analytical methods were validated for the determination of all analytes in wheat (whole plant, grain, straw, ears and rest of plant) according to SANCO/3029/99, rev.4 during analysis.</i></p> <p><i>The limit of quantitation for the method is set at 0.01 mg/kg for each analyte for grain, green material and straw.</i></p> <p><i>All mean recovery values were within the acceptable range of 70 – 110% in all matrix of wheat with RS&lt;20%.</i></p> <p><i>Maximum storage period – 326 days.</i></p> <p><i>Residues of prothioconazole-desthio, in wheat grain at harvest were between &lt;0.003 and 0.01 mg/kg.</i></p> <p><i>Residues of hydroxy- derivatives of prothioconazole-desthio, in wheat grain at harvest were &lt;0.01 mg/kg.</i></p> <p><i>Residues of 1,2,4-triazole and triazole lactic acid, in wheat grain at harvest were between &lt;0.003 and 0.01 mg/kg.</i></p> <p><i>Residues of triazole alanine, in wheat grain at harvest ranged between 0.49 and 1.1 mg/kg.</i></p> <p><i>Residues of triazole acetic acid, in wheat grain at harvest ranged between 0.16 and 0.48 mg/kg.</i></p> <p><i>The study is acceptable.</i></p>
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Reference:	KCA 6.3.2/02
Report	<p>Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole in Wheat (outdoor) at 4 sites in Northern Europe and 4 sites in Southern Europe 2019</p> <p>North, L., 2020</p> <p>Report No: S19-01268</p>
Guideline(s):	<p>OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32)</p> <p>OECD Test Guideline 509: Crop field trials</p> <p>OECD (2016) Guidance Document ENV/JM/MONO (2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)</p> <p>EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials</p> <p>European Community Guideline SANCO 7525/VI/95, Rev. 10.3, 13/06/17: Comparability, extrapolation, group tolerances and data requirements for setting MRLs)</p>
Deviations:	None
GLP:	Yes

Owner: Nufarm Crop Products UK  
Acceptability: Yes

### Materials and Methods

Eight residue trials were conducted on wheat during 2019, one in the United Kingdom (S19-01268-01), one in Germany (S19-01268-02), one in Northern France (S19-01268-03), one in Hungary (S19-01268-04), one in Spain (S19-01268-05), two in Italy (S19-01268-06 and 08) and one in Southern France (S19-01268-07).

Two application(s) of NUL 3390 Prothioconazole 250 EC (250 g/L prothioconazole) were applied at 200 g ai/ha, diluted with water immediately prior to application to a spray volume of 100-400 L/ha.

Samples of wheat (whole plants) from the untreated and treated plots were taken by hand 0, 7, 14 and 28-29 days after the final application. Samples of wheat (grain and straw) from the untreated and treated plots were taken either by hand or using a plot combine 30-35 days (NCH) after the final application. For trial S19-01268-07 an additional sampling was taken, at 35 days after application ears and rest of plant with a further sampling of grain and straw at normal commercial harvest.

Wheat samples were analysed for residues of prothioconazole (PTZ)-desthio according to the multi-residue QuEChERS method that was previously validated according to SANCO/30299/99, rev.4 and SANCO/825/00 rev. 8.1 for wheat (grain), grapes, oilseed rape (seed), bean (dry) and cucumber in Eurofins Agrosience Services study S16-04434. The quantitation is done using liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The limit of quantitation for the method is set at 0.01 mg/kg.

Wheat samples were analysed for residues of PTZ- $\alpha$ -hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxydesthio according to the analytical method described in Eurofins Agrosience Services study S16-04435 that was previously validated according to SANCO/30299/99, rev.4 and SANCO/825/00 rev. 8.1 for wheat (whole plant, grain and straw) and oilseed rape (seed). The quantitation is done using liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The limit of quantitation for the method is set at 0.01 mg/kg for each analyte. For PTZ- $\alpha$ -hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio the LOQ is expressed as PTZ-desthio.

Wheat samples were analysed for residues of triazole derivative metabolites (TDMs) 1,2,4-Triazole, triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) according to the analytical method described in S15-03542 that was previously validated according to SANCO/825/00 rev. 8.1 for wheat (grain and straw), barley (grain and straw), grape (bunches) and oilseed rape. The quantitation was done using liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The limit of quantitation for the method is set at 0.01 mg/kg for each analyte.

The maximum storage interval from sampling to extraction was 326 days for wheat (whole plant), 296 days for wheat (grain), 303 days for wheat (straw) and 267 days for wheat (ears and rest of plant). Storage at the Analytical Test Site from sample receipt until lab sample preparation was at  $\leq -18^{\circ}\text{C}$ .

The maximum interval from extraction to analysis at typically  $1^{\circ}\text{C}$  to  $10^{\circ}\text{C}$  with given exceptions (e.g. periods during sample extraction/work-up, periods during transfer to detection instrument and possible minor fluctuations of refrigerator temperatures) was eight days for wheat (whole plant), six days for wheat (straw), and one day for wheat (grain, ears and rest of plant).

The analytical methods were validated for the determination of all analytes in wheat (whole plant, grain, straw, ears and rest of plant) according to SANCO/3029/99, rev.4 during analysis. All mean recovery values (corrected for apparent blank residues, if necessary) at fortification levels of LOQ and 10x LOQ comply with the standard acceptance criteria of the guidance document with evaluation of one (1) mass transition. Procedural recoveries run concurrently with test sample are summarized in the table below:

**Table A 64: Summary of procedural recoveries**

Analyte	Matrix	Fortification Levels (mg/kg)	Overall Mean Recovery (%)
Prothioconazole-desthio	Whole plant	0.01, 0.1, 1.2	97
	Grain	0.01, 0.1	93
	Straw	0.01, 0.1, 2.0	102
	Ears	0.01, 0.1	85
	Rest of plant	0.01, 0.1, 0.2	97
Prothioconazole- $\alpha$ -hydroxy-desthio	Whole plant	0.01, 0.1, 0.2, 1.0	102
	Grain	0.01, 0.1	89
	Straw	0.01, 0.1, 1.0	99
	Ears	0.01, 0.1	106
	Rest of plant	0.01, 0.1	101
Prothioconazole-3-hydroxy-desthio	Whole plant	0.01, 0.1, 0.2, 1.0	93
	Grain	0.01, 0.1	89
	Straw	0.01, 0.1, 1.0	89
	Ears	0.01, 0.1	101
	Rest of plant	0.01, 0.1	93
Prothioconazole-4-hydroxy-desthio	Whole plant	0.01, 0.1, 0.2, 1.0	92
	Grain	0.01, 0.1	92
	Straw	0.01, 0.1, 1.0	88
	Ears	0.01, 0.1	101
	Rest of plant	0.01, 0.1	92
Prothioconazole-5-hydroxy-desthio	Whole plant	0.01, 0.1, 0.2, 1.0	87
	Grain	0.01, 0.1	86
	Straw	0.01, 0.1, 1.0	95
	Ears	0.01, 0.1	94
	Rest of plant	0.01, 0.1	99
Prothioconazole-6-hydroxy-desthio	Whole plant	0.01, 0.1, 0.2, 1.0	85
	Grain	0.01, 0.1	83
	Straw	0.01, 0.1	87
	Ears	0.01, 0.1	93
	Rest of plant	0.01, 0.1	84
1,2,4-Triazole	Whole plant	0.01, 0.1	107
	Grain	0.01, 0.1	103
	Straw	0.01, 0.1	103
	Ears	0.01, 0.1	105
	Rest of plant	0.01, 0.1	106
Triazole alanine	Whole plant	0.01, 0.1, 1.2	97
	Grain	0.01, 0.1, 1.2	85
	Straw	0.01, 0.1, 1.2	83
	Ears	0.01, 0.1, 1.2	82
	Rest of plant	0.01, 0.1	82
Triazole acetic acid	Whole plant	0.01, 0.1, 0.6	101
	Grain	0.01, 0.1, 0.6	85
	Straw	0.01, 0.1, 0.6	96
	Ears	0.01, 0.1, 0.6	91
	Rest of plant	0.01, 0.1	101
Triazole lactic acid	Whole plant	0.01, 0.1, 0.4	93
	Grain	0.01, 0.1, 0.4	76
	Straw	0.01, 0.1, 0.4	90
	Ears	0.01, 0.1, 0.4	89
	Rest of plant	0.01, 0.1	105

## Findings

The residue levels found in wheat are summarised in the table below.

Table A 65: Summary of the S19-01268 trials

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	PROTHIOCONAZOLE	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	Winter wheat	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	United Kingdom	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)	10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-desthio		
S19-01268-01  L390HJ, Lancashire, UK	Winter wheat / TRZAW / Gleam	1)20 Oct 18 2) na 3) 15 Aug 19	Overall spray using a boom sprayer	67	300	200	27 Jun 19 11 Jul 19	71	Whole plant	0.90	0	No residues >LOQ were found in any untreated samples, except whole plant at 28DAA and straw with a residue of 0.01 mg/kg (LOQ)
				67	306	204			Whole plant	0.70	7	
									Whole plant	0.44	14	
									Whole plant	0.16 / 0.01**	28	
									Grain	≤0.01	35	
									Straw	0.15 / 0.01**	35	

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

\*\* Residue in control samples

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting (name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/kg or g/L):

PROTHIOCONAZOLE  
Winter wheat  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
United Kingdom  
250

Commercial Product (name):  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common name and content):

NUL 3390 PROTHIOCONAZOLE 250 EC  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Outdoor  
none

Formulation (e.g. WP):		EC		Residues calculated as:				Prothioconazole-desthio (mg/kg)									
1	2	3	4	5			6	7	8	9						10	11
Report No. Location (region)	Commodity/Variety  (a)	Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	Method of Treatment  (c)	Application rate per treatment			Dates of treatment(s) or no. of treatment(s) and last date (d)	Growth stage at last treatment or date (e) BBCH	Portion analysed  (a)	Residues (mg/kg) (*)						PHI (days)  (f)	Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- α-OH- desthio	PTZ- 3-OH- desthio	PTZ- 4-OH- desthio	PTZ- 5-OH- desthio	PTZ- 6-OH- desthio	Total desthio+hydroxy=RD- RA1)*		
S19-01268-01  L390HJ, Lancashire, UK	Winter wheat / TRZAW / Gleam	1)20 Oct 18 2) na 3) 15 Aug 19	Overall spray using a boom sprayer	67 67	300 306	200 204	27 Jun 19 11 Jul 19	71	Whole plant Whole plant Whole plant Whole plant Grain Straw	0.09 0.17 0.16 0.08 <0.01 0.06	0.06 0.13 0.12 0.07 <0.003 0.10	0.05 0.07 0.06 0.03 <0.003 0.04	0.04 0.05 0.05 0.03 <0.003 0.03	0.01 0.02 0.01 <0.01 <0.003 <0.01	    <u>&lt;0.06</u> <u>0.39</u>	0 7 14 28 35 35	No residues >LOQ were found in any untreated samples, except whole plant PTZ-3, - 4, & -5 with a residue of 0.01-0.02 mg/kg

(a) According to EPPO codes  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e)  
(f)  
  
(g)  
(\*)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application  
  
Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg



## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Winter wheat</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	United Kingdom	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)				10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4- Triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid		
S19-01268-01  L390HJ, Lancashire, UK	Winter wheat / TRZAW / Gleam	1)20 Oct 18 2) na 3) 15 Aug 19	Overall spray using a boom sprayer	67	300	200	27 Jun 19 11 Jul 19	71	Whole plant	<0.003	0.30	0.19	0.14	0	No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.47 mg/kg in all other untreateds
				67	306	204			Whole plant	<0.003	0.42	0.23	0.13	7	
									Whole plant	<0.003	0.49	0.31	0.11	14	
									Whole plant	<0.003	0.70	0.35	0.02	28	
									Grain	<0.003	1.10/0.47**	0.48/0.34**	<0.01	35	
									Straw	<0.003	<0.01	0.05/0.03**	<0.01	35	

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e)

(f)

(g)

(\*)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/kg or g/L):  
  
Formulation (e.g. WP):

PROTHIOCONAZOLE  
Winter wheat  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
Germany  
250  
EC

Commercial Product (name):  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

PROTIOCONAZOLE 250 EC  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Outdoor  
none  
Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)	10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-desthio		
S19-01268-02 71706 Markgroningen, Baden Wurttemberg, Germany	Winter wheat / TRZAW / Spontan	1) 20 Oct 18	Overall spray using a boom sprayer	67	289	193	07 Jun 19 21 Jun 19	61 73	Whole plant	0.59	0	No residues >LOQ were found in any untreated samples
		2) 01-21 Jun 19		67	313	209			Whole plant	0.19	7	
		3) 26 Jul 19							Whole plant	0.18	14	
									Whole plant	0.15	28	
									Grain	0.01	35	
									Straw	0.28	35	

(a) According to EPPO codes  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application  
  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting (name, address):  
  
Country (of trial sites):  
Content of active substance nominal (g/kg or g/L):

PROTHIOCONAZOLE  
Winter wheat  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
Germany  
250

Commercial Product (name):  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common name and content):  
Residues calculated as:

NUL 3390 PROTHIOCONAZOLE 250 EC  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Outdoor  
none  
  
Prothioconazole-desthio (mg/kg)

Formulation (e.g. WP):				EC		Residues calculated as:			Prothioconazole-desthio (mg/kg)						10	11	
1	2	3	4	5			6	7	8	9					10	11	
Report No. Location (region)	Commodity/Variety  (a)	Date of 1) Sowing or Planting  2) Flowering 3) Harvest (b)	Method of Treatment  (c)	Application rate per treatment			Dates of treatment(s) or no. of treatment(s) and last date (d)	Growth stage at last treatment or date (e) BBCH	Portion analysed  (a)	Residues (mg/kg) (*)					PHI (days)  (f)	Remarks  (g)	
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- α-OH- desthio	PTZ- 3-OH- desthio	PTZ- 4-OH- desthio	PTZ- 5-OH- desthio	PTZ- 6-OH- desthio			Total (PTZ- desthio+hydroxy=RD- RA1)*
S19-01268-02 71706 Markgroningen, Baden Wurttemberg, Germany	Winter wheat / TRZAW / Spontan	1) 20 Oct 18 2) 01-21 Jun 19 3) 26 Jul 19	Overall spray using a boom sprayer	67 67	289 313	193 209	07 Jun 19 21 Jun 19	61 73	Whole plant Whole plant Whole plant Whole plant Grain Straw	0.08 0.21 0.16 0.28 <0.01 0.28	0.05 0.10 0.09 0.11 <0.003 0.22	0.04 0.08 0.06 0.07 <0.003 0.13	0.05 0.10 0.07 0.11 <0.003 0.23	0.01 0.03 0.02 0.03 <0.003 0.05	   <		

(a) According to EPPO codes  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e)  
(f)  
  
(g)  
(\*)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application  
  
Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	PROTHIOCONAZOLE	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	Winter wheat	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)				10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4- Triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid		
S19-01268-02 71706 Markgroningen, Baden Wurtemberg, Germany	Winter wheat / TRZAW / Spontan	1) 20 Oct 18 2) 01-21 Jun 19 3) 26 Jul 19	Overall spray using a boom sprayer	67	289	193	07 Jun 19	61	Whole plant	<0.003	0.14	0.06	0.05	0	No residues
				67	313	209	21 Jun 19	73	Whole plant	<0.003	0.24	0.07	0.06	7	>LOQ were
									Whole plant	<0.003	0.29	0.08	0.05	14	found in any
									Whole plant	<0.003	0.37	0.15	0.03	28	1,2,4 triazole
									Grain	<0.01	0.74/0.05**	0.23/0.03**	<0.01	35	untreated
									Straw	<0.003	0.01	0.12/0.02**	0.11/0.02**	35	samples, Residues ranged from <0.003-0.05 mg/kg in all other untreateds

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)

Active substance (common name):	PROTHIOCONAZOLE	Commercial Product (name):	PROTHIOCONAZOLE 250 EC
Crop/crop group:	Winter wheat	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	Prothioconazole-desthio (sum of isomers) (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)	10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-desthio		
S19-01268-03  91150 Mespuits-91, Essonne, France N-EU	Winter wheat / TRZAW / LG Absalom	1) 26 Oct 18 2) 27 May – 02 Jun 19 3) 17 Jul 19	Overall spray using a boom sprayer	134	146	195	29 May 19 14 Jun 19	56	Whole plant	0.51	0	No residues >LOQ were found in any untreated samples
				133	152	202		71	Whole plant	0.37	7	
									Whole plant	0.19	14	
									Whole plant	0.14	28	
									Grain	<0.003	35	
									Straw	0.42	35	

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/kg or g/L):

PROTHIOCONAZOLE  
Winter wheat  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
France  
250

Commercial Product (name):  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the  
formulation (common name and  
content):  
Residues calculated as:

NUL 3390 PROTHIOCONAZOLE 250 EC  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Outdoor  
none  
  
Prothioconazole-desthio (mg/kg)

Formulation (e.g. WP):		EC		Residues calculated as:		Prothioconazole-desthio (mg/kg)											
1	2	3	4	5			6	7	8	9					10	11	
Report No. Location (region)	Commodity/Variety  (a)	Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	Method of Treatment  (c)	Application rate per treatment			Dates of treatment(s) or no. of treatment(s) and last date  (d)	Growth stage at last treatment or date  (e) BBCH	Portion analysed  (a)	Residues (mg/kg) (*)					PHI (days)  (f)	Remarks  (g)	
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- α-OH- desthio	PTZ- 3-OH- desthio	PTZ- 4-OH- desthio	PTZ- 5-OH- desthio	PTZ- 6-OH- desthio			Total (PTZ- desthio+hydroxy=RD- RA1)*
S19-01268-03	Winter wheat / TRZAW / LG Absalom	1) 26 Oct 18 2) 27 May – 02 Jun 19 3) 17 Jul 19	Overall spray using a boom sprayer	134	146	195	29 May 19 14 Jun 19	56 71	Whole plant Whole plant Whole plant Whole plant Grain Straw	0.06	0.06	0.05	0.04	<0.01	<u>&lt;0.06</u> <u>1.4</u>	0	No residues >LOQ were found in any untreated samples
				133	152	202				0.15	0.12	0.10	0.09	0.02		7	
										0.13	0.11	0.08	0.07	0.01		14	
										0.14	0.13	0.10	0.08	0.02		28	
										<0.003	<0.003	<0.003	<0.003	<0.003		35	
										0.23	0.30	0.22	0.18	0.05		35	

(a) According to EPPO codes  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of  
equipment used must be indicated  
(d) Year must be indicated

(e)  
(f)  
  
(g)  
(\*)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA  
= days before last application, DALA = days after last application  
  
Remarks may include: climatic conditions; reference to analytical method; Information concerning  
the metabolites included, the method of storage, storage stability, analysis date  
Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Winter wheat</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address):	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)				10 PHI (days) (f)	11 Remarks (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4- Triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid		
S19-01268-03  91150 Mespuits- 91, Essonne, France N-EU	Winter wheat / TRZAW / LG Absalom	1) 26 Oct 18 2) 27 May – 02 Jun 19 3) 17 Jul 19	Overall spray using a boom sprayer	134	146	195	29 May 19	56	Whole plant	<0.003	0.07	0.04	0.05	0	No residues
				133	152	202	14 Jun 19	71	Whole plant	<0.003	0.12	0.04	0.05	7	>LOQ were
									Whole plant	<0.003	0.18	0.05	0.06	14	found in any
									Whole plant	<0.003	0.17	0.09	0.07	28	1,2,4 triazole
									Grain	<0.003	0.49/0.48**	0.18/0.35**	<0.01	35	untreated
									Straw	<0.003	0.01	0.06/0.04**	0.21/0.12**	35	samples, Residues ranged from <0.003-0.48 mg/kg in all other untreateds

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e)

(f)

(g)

(\*)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

Minimum number of days after last application (Label pre-harvest interval, PHI, underline);

DBLA = days before last application, DALA = days after last application

Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/kg or g/L):  
  
Formulation (e.g. WP):

PROTHIOCONAZOLE  
Winter wheat  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
Hungary  
250  
EC

Commercial Product (name):  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

PROTIOCONAZOLE 250 EC  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Outdoor  
none  
Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)	10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-desthio		
S19-01268-04  H-2476, Pazmand, Fejer, Hungary N-EU	Winter wheat / TRZAW / MV Lucilla	1) 31 Oct 18 2) 22 May – 03 Jun 19 3) 14 Jul 19	Overall spray using a boom sprayer	67	309	206	26 May 19 09 Jun 19	63	Whole plant	1.1	0	No residues >LOQ were found in any untreated samples
				67	310	207		73	Whole plant	1.1	7	
									Whole plant	0.35	14	
									Whole plant	0.85	28	
									Grain	<0.003	35	
									Straw	0.98	35	

(a) According to EPPO codes  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used  
must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline);  
DBLA = days before last application, DALA = days after last application  
  
(g) Remarks may include: climatic conditions; reference to analytical method; Information  
concerning the metabolites included, the method of storage, storage stability, analysis date  
(\* ) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg



RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting (name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/kg or g/L):

PROTHIOCONAZOLE  
Winter wheat  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Hungary  
250

Commercial Product (name):  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common name and content):

NUL 3390 PROTHIOCONAZOLE 250 EC  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Outdoor  
none

Formulation (e.g. WP):			EC	Residues calculated as:			Prothioconazole-desthio (mg/kg)									
1	2	3	4	5			6	7	8	9					10	11
Report No. Location (region)	Commodity/Variety  (a)	Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	Method of Treatment  (c)	Application rate per treatment			Dates of treatment(s) or no. of treatment(s) and last date  (d)	Growth stage at last treatment or date  (e) BBCH	Portion analysed  (a)	Residues (mg/kg) (*)					PHI (days)  (f)	Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- α-OH- desthio	PTZ- 3-OH- desthio	PTZ- 4-OH- desthio	PTZ- 5-OH- desthio	PTZ- 6-OH- desthio		
S19-01268-04	Winter wheat / TRZAW / MV Lucilla	1) 31 Oct 18	Overall spray using a boom sprayer	67	309	206	26 May 19	63	Whole	0.11	0.07	0.07	0.07	0.01	0 7 14 28 35 35	No residues >LOQ were found in any untreated samples
		2) 22 May – 03 Jun 19		67	310	207	09 Jun 19	73	plant	0.39	0.20	0.19	0.16	0.03		
									Whole	0.28	0.15	0.13	0.11	0.02		
		3) 14 Jul 19							plant	0.55	0.28	0.23	0.24	0.05		
									Whole	<0.01	<0.003	<0.003	<0.003	<0.003		
									plant	0.66	0.45	0.34	0.41	0.09		
H-2476, Pazmand, Fejer, Hungary								Whole								
								Whole								
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(a) According to EPPO codes  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e)  
(f)  
  
(g)  
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BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application  
  
Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Winter wheat</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	Hungary	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)				10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4- Triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid		
S19-01268-04  H-2476, Pazmand, Fejer, Hungary N-EU	Winter wheat / TRZAW / MV Lucilla	1) 31 Oct 18 2) 22 May – 03 Jun 19 3) 14 Jul 19	Overall spray using a boom sprayer	67	309	206	26 May 19	63	Whole plant	<0.003	0.12	0.02	0.03	0	No residues
				67	310	207	09 Jun 19	73	Whole plant	<0.003	0.35	0.04	0.04	7	>LOQ were
									Whole plant	<0.003	0.33	0.05	0.03	14	found in any
									Whole plant	<0.003	0.17	0.06	0.09	28	1,2,4 triazole
									Grain	<u>&lt;0.01</u>	<u>0.71/0.05**</u>	<u>0.16/0.03**</u>	<u>0.01</u>	35	untreated
									Straw	<u>&lt;0.003</u>	<u>0.02</u>	<u>0.04</u>	<u>0.18/0.01**</u>	35	samples, Residues ranged from <0.003-0.05 mg/kg in all other untreateds

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e)

(f)

(g)

(\*)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

Minimum number of days after last application (Label pre-harvest interval, PHI, underline);

DBLA = days before last application, DALA = days after last application

Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/kg or g/L):  
  
Formulation (e.g. WP):

PROTHIOCONAZOLE  
Winter wheat  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
Spain  
250  
EC

Commercial Product (name):  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

PROTIOCONAZOLE 250 EC  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Outdoor  
none  
Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)	10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-desthio		
S19-01268-05  41420, Fuentes de Andalucia, Andalucia, Spain	Winter wheat / TRZAW / Conil	1) 04 Jan 19 2) Apr to May 3) 29 May 19	Overall spray using a boom sprayer	50	378	189	15 Apr 19 29 Apr 19	61 61	Whole plant	1.0	0 7 14 28 35 35	No residues >LOQ were found in any untreated samples
				50	398	199			Whole plant	0.68		
									Whole plant	0.50		
									Whole plant	0.63		
									Grain	<0.01		
									Straw	0.25		

(a) According to EPPO codes  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used  
must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline);  
DBLA = days before last application, DALA = days after last application  
  
(g) Remarks may include: climatic conditions; reference to analytical method; Information  
concerning the metabolites included, the method of storage, storage stability, analysis date  
(\* ) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/kg or g/L):

PROTHIOCONAZOLE  
Winter wheat  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
Spain  
250

Commercial Product (name):  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the  
formulation (common name and  
content):  
Residues calculated as:

NUL 3390 PROTHIOCONAZOLE 250 EC  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Outdoor  
none  
  
Prothioconazole-desthio (mg/kg)

Formulation (e.g. WP):			EC	Residues calculated as:			Prothioconazole-desthio (mg/kg)										
1	2	3	4	5			6	7	8	9					10	11	
Report No. Location (region)	Commodity/Variety  (a)	Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	Method of Treatment  (c)	Application rate per treatment			Dates of treatment(s) or no. of treatment(s) and last date (d)	Growth stage at last treatment or date (e) BBCH	Portion analysed  (a)	Residues (mg/kg) (*)					PHI (days)  (f)	Remarks  (g)	
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- α-OH- desthio	PTZ- 3-OH- desthio	PTZ- 4-OH- desthio	PTZ- 5-OH- desthio	PTZ- 6-OH- desthio			Total desthio+hydroxy=RD- RA1)*
S19-01268-05	Winter wheat / TRZAW / Conil	1) 04 Jan 19 2) Apr to May 3) 29 May 19	Overall spray using a boom sprayer	50 50	378 398	189 199	15 Apr 19 29 Apr 19	61 61	Whole plant Whole plant Whole plant Whole plant Grain Straw	0.15 0.24 0.32 0.37 <0.01 0.08	0.11 0.15 0.21 0.28 <0.003 0.13	0.08 0.12 0.15 0.19 <0.003 0.11	0.07 0.10 0.11 0.14 <0.003 0.07	0.01 0.03 0.03 0.05 <0.003 0.03	<0.06 0.67	0 7 14 28 35	No residues >LOQ were found in any untreated samples

(a) According to EPPO codes  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of  
equipment used must be indicated  
(d) Year must be indicated

(e)  
(f)  
  
(g)  
(\*)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA =  
days before last application, DALA = days after last application  
  
Remarks may include: climatic conditions; reference to analytical method; Information concerning  
the metabolites included, the method of storage, storage stability, analysis date  
Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/kg or g/L):  
  
Formulation (e.g. WP):

PROTHIOCONAZOLE  
Winter wheat  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
Spain  
250  
EC

Commercial Product (name):  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation  
(common name and content):  
Residues calculated as:

NUL 3390 PROTHIOCONAZOLE 250 EC  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Outdoor  
none  
  
1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid  
(mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)				10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4- Triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid		
S19-01268-05  41420, Fuentes de Andalucia, Andalucia, Spain	Winter wheat / TRZAW / Conil	1) 04 Jan 19 2) Apr to May 3) 29 May 19	Overall spray using a boom sprayer	50	378	189	15 Apr 19	61	Whole plant	<0.003	0.11	0.02	0.04	0	No residues
				50	398	199	29 Apr 19	61	Whole plant	<0.003	0.20	0.03	0.05	7	>LOQ were
									Whole plant	<0.003	0.25	0.05	0.06	14	found in any
									Whole plant	<0.003	0.26	0.11	0.09	28	1,2,4 triazole
									Grain	<0.003	0.53/0.06**	0.14/0.03**	<0.01	35	untreated
									Straw	<0.003	0.02	0.03/0.01**	0.11/0.03**	35	samples, Residues ranged from <0.003-0.06 mg/kg in all other untreateds

(a) According to EPPO codes  
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated  
\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline);  
DBLA = days before last application, DALA = days after last application

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/kg or g/L):  
  
Formulation (e.g. WP):

**PROTHIOCONAZOLE**  
**Winter wheat**  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Italy  
250  
  
EC

Commercial Product (name):  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

PROTIOCONAZOLE 250 EC  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Outdoor  
none  
  
Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)  PTZ-desthio	10 PHI (days)  (f)	11 Remarks  (g)	
S19-01268-06  40026 Sesto Imolese, Bologna, Italy	Winter wheat / TRZAW / Bologna	1) 09 Nov 18	Overall spray using a boom sprayer	67	293	196	03 May 19 17 May 19	51 65	Whole plant	1.0	0	No residues >LOQ were found in any untreated samples	
		2) 14-24 May		67	284	190			Whole plant	0.44	7		
		19							Whole plant	0.12	14		
		3) 21 Jun 19							Whole plant	0.07	28		
									Grain	<0.003	35		

(a) According to EPPO codes  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used  
must be indicated  
(d) Year must be indicated

(e)  
(f)  
  
(g)  
(\*)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
Minimum number of days after last application (Label pre-harvest interval, PHI, underline);  
DBLA = days before last application, DALA = days after last application  
  
Remarks may include: climatic conditions; reference to analytical method; Information  
concerning the metabolites included, the method of storage, storage stability, analysis date  
Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/kg or g/L):

PROTHIOCONAZOLE  
Winter wheat  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
Italy  
250

Commercial Product (name):  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the  
formulation (common name and  
content):  
Residues calculated as:

NUL 3390 PROTHIOCONAZOLE 250 EC  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Outdoor  
none  
  
Prothioconazole-desthio (mg/kg)

Formulation (e.g. WP):				EC		Residues calculated as:			Prothioconazole-desthio (mg/kg)						10 PHI (days)	11 Remarks		
1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)							(f)	(g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- α-OH- desthio	PTZ- 3-OH- desthio	PTZ- 4-OH- desthio	PTZ- 5-OH- desthio	PTZ- 6-OH- desthio				
S19-01268-06  40026 Sesto Imolese, Bologna, Italy	Winter wheat / TRZAW / Bologna	1) 09 Nov 18 2) 14-24 May 19 3) 21 Jun 19	Overall spray using a boom sprayer	67 67	293 284	196 190	03 May 19 17 May 19	51 65	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw	<0.003 <0.01 <0.01 <0.01 <0.003 <0.01	0.03 0.06 0.06 0.07 <0.003 0.10	0.04 0.07 0.07 0.10 <0.003 0.08	0.08 0.13 0.10 0.11 <0.003 0.13	<0.01 0.02 0.02 0.02 <0.003 0.02	<0.06 0.45	0 7 14 28 35 35	No residues >LOQ were found in any untreated samples	

(a) According to EPPO codes  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e)  
(f)  
  
(g)  
(\*)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application  
  
Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	PROTHIOCONAZOLE	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	Winter wheat	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	Italy	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)				10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4- Triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid		
S19-01268-06  40026 Sesto Imolese, Bologna, Italy	Winter wheat / TRZAW / Bologna	1) 09 Nov 18	Overall spray using a boom sprayer	67	293	196	03 May 19	51	Whole plant	<0.003	<0.01	<0.003	<0.003	0	No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.07 mg/kg in all other untreateds
		2) 14-24 May 19		67	284	190	17 May 19	65	Whole plant	<0.003	0.01	<0.01	<0.01	7	
		3) 21 Jun 19							Whole plant	<0.003	0.01	<0.01	<0.01	14	
									Whole plant	<0.003	0.04	0.01	0.01	28	
									Grain	<0.003	0.16/0.07**	0.03/0.03**	<0.003	35	
									Straw	<0.003	0.06/0.03**	0.03/0.02**	0.03/0.02**	35	

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg



RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/kg or g/L):  
  
Formulation (e.g. WP):

PROTHIOCONAZOLE  
Winter wheat  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
France  
250  
EC

Commercial Product (name):  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

PROTIOCONAZOLE 250 EC  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Outdoor  
none  
Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)	10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-desthio		
S19-01268-07  82130, Lafrancaise, Tarn et Garonne, France SEU	Winter wheat / TRZAW / Nemo	1) 24 Oct 19 2) na 3) 03 Jul 19	Overall spray using a boom sprayer	100	215	215	10 May 19 23 May 19	59 73	Whole plant	0.69	0	No residues >LOQ were found in any untreated samples
				100	201	201			Whole plant	0.24	7	
									Whole plant	0.13	14	
									Whole plant	0.10	28	
									Ears	0.06	35	
									Rest of plant	0.11	35	
									Grain	<0.003	41	
									Straw	0.19	41	

(a) According to EPPO codes  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used  
must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline);  
DBLA = days before last application, DALA = days after last application  
  
(g) Remarks may include: climatic conditions; reference to analytical method; Information  
concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/kg or g/L):

PROTHIOCONAZOLE  
Winter wheat  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
France  
250

Commercial Product (name):  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the  
formulation (common name and  
content):  
Residues calculated as:

NUL 3390 PROTHIOCONAZOLE 250 EC  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Outdoor  
none  
  
Prothioconazole-desthio (mg/kg)

Formulation (e.g. WP):			EC		Residues calculated as:			Prothioconazole-desthio (mg/kg)									
1	2	3	4	5			6	7	8	9						10	11
Report No. Location (region)	Commodity/Variety  (a)	Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	Method of Treatment  (c)	Application rate per treatment			Dates of treatment(s) or no. of treatment(s) and last date  (d)	Growth stage at last treatment or date  (e) BBCH	Portion analysed  (a)	Residues (mg/kg) (*)						PHI (days)  (f)	Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- α-OH- desthio	PTZ- 3-OH- desthio	PTZ- 4-OH- desthio	PTZ- 5-OH- desthio	PTZ- 6-OH- desthio	Total desthio+hydroxy=RD- RA1)*		
S19-01268-07  82130, Lafrancaise, Tarn et Garonne, France SEU	Winter wheat / TRZAW / Nemo	1) 24 Oct 19 2) na 3) 03 Jul 19	Overall spray using a boom sprayer	100 100	215 201	215 201	10 May 19 23 May 19	59 73	Whole plant Whole plant Whole plant Whole plant Ears Rest of plant Grain Straw	0.06 0.11 0.09 0.09 0.05 0.10 <0.003 0.14	0.05 0.09 0.08 0.08 0.05 0.07 <0.003 0.11	0.04 0.09 0.07 0.07 0.03 0.06 <0.003 0.07	0.04 0.07 0.07 0.06 0.04 0.06 <0.003 0.07	<0.01 0.02 0.02 0.01 <0.01 0.01 <0.003 0.02	  		

(a) According to EPPO codes  
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of  
equipment used must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA  
= days before last application, DALA = days after last application  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning  
the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Winter wheat</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)				10 PHI (days) (f)	11 Remarks (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4- Triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid		
S19-01268-07  82130, Lafrancaise, Tarn et Garonne, France	Winter wheat / TRZAW / Nemo	1) 24 Oct 19 2) na 3) 03 Jul 19	Overall spray using a boom sprayer	100	215	215	10 May 19	59	Whole plant	<0.003	0.03	0.01	0.02	0	No residues
				100	201	201	23 May 19	73	Whole plant	<0.003	0.08	0.01	0.02	7	>LOQ were
									Whole plant	<0.003	0.07	0.01	0.02	14	found in any
									Whole plant	<0.003	0.13	0.03	0.03	28	1,2,4 triazole
									Ears	<0.003	0.33	0.08	0.02	35	untreated
									Rest of plant	<0.003	<0.01	0.02	0.04	35	samples,
									Grain	<0.003	0.41/0.01**	0.10/0.01**	<0.01	41	Residues
									Straw	<0.003	0.04	0.04	0.05	41	ranged from <0.003-0.01 mg/kg in all other untreateds

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e)

(f)

(g)

(\*)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

Minimum number of days after last application (Label pre-harvest interval, PHI, underline);

DBLA = days before last application, DALA = days after last application

Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/kg or g/L):  
  
Formulation (e.g. WP):

PROTHIOCONAZOLE  
Winter wheat  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
Italy  
250  
EC

Commercial Product (name):  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

PROTIOCONAZOLE 250 EC  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Outdoor  
none  
Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)	10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-desthio		
S19-01268-08  40016 San Giorgio Di Piano, Bologna, Italy	Winter wheat / TRZAW / Ideo	1) 11 Nov 18 2) 12-25 May 3) 26 Jun 19	Overall spray using a boom sprayer	66	316	210	08 May 19 22 May 19	59 69	Whole plant	0.84	0	No residues >LOQ were found in any untreated samples
				67	300	200			Whole plant	0.05	7	
									Whole plant	0.04	14	
									Whole plant	0.06	25	
									Grain	<0.003	35	
									Straw	0.08	35	

(a) According to EPPO codes  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used  
must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline);  
DBLA = days before last application, DALA = days after last application  
  
(g) Remarks may include: climatic conditions; reference to analytical method; Information  
concerning the metabolites included, the method of storage, storage stability, analysis date  
(\* ) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/kg or g/L):

PROTHIOCONAZOLE  
Winter wheat  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
Italy  
250

Commercial Product (name):  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the  
formulation (common name and  
content):  
Residues calculated as:

NUL 3390 PROTHIOCONAZOLE 250 EC  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Outdoor  
none  
  
Prothioconazole-desthio (mg/kg)

Formulation (e.g. WP):		EC		Residues calculated as:		Prothioconazole-desthio (mg/kg)											
1	2	3	4	5			6	7	8	9					10	11	
Report No. Location (region)	Commodity/Variety  (a)	Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	Method of Treatment  (c)	Application rate per treatment			Dates of treatment(s) or no. of treatment(s) and last date (d)	Growth stage at last treatment or date (e) BBCH	Portion analysed  (a)	Residues (mg/kg) (*)					PHI (days)  (f)	Remarks  (g)	
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- α-OH- desthio	PTZ- 3-OH- desthio	PTZ- 4-OH- desthio	PTZ- 5-OH- desthio	PTZ- 6-OH- desthio			Total (PTZ- desthio+hydroxy=RD- RA1)*
S19-01268-08	Winter wheat / TRZAW / Ideo	1) 11 Nov 18 2) 12-25 May 3) 26 Jun 19	Overall spray using a boom sprayer	66 67	316 300	210 200	08 May 19 22 May 19	59 69	Whole plant Whole plant Whole plant Whole plant Whole plant Grain Straw	0.04 0.06 0.05 0.05 0.06 0.06	0.03 0.06 0.05 0.03 0.06 0.06	0.03 0.05 0.04 0.02 0.03 0.04	0.03 0.05 0.04 0.03 0.06 0.02	<0.01 0.02 0.01 0.01 0.02 0.02	<0.06 0.32	0 7 14 28 35 35	No residues >LOQ were found in any untreated samples

(a) According to EPPO codes  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e)  
(f)  
  
(g)  
(\*)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application  
  
Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Winter wheat</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	Italy	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)				10 PHI (days) (f)	11 Remarks (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4- Triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid		
S19-01268-08  40016 San Giorgio Di Piano, Bologna, Italy	Winter wheat / TRZAW / Ideo	1) 11 Nov 18 2) 12-25 May 3) 26 Jun 19	Overall spray using a boom sprayer	66	316	210	08 May 19 22 May 19	59 69	Whole plant	<0.003	0.03	<0.01	<0.01	0	No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.08 mg/kg in all other untreateds
				67	300	200			Whole plant	<0.003	0.10	0.01	0.03	7	
									Whole plant	<0.003	0.11	0.02	0.03	14	
									Whole plant	<0.003	0.14	0.06	0.03	28	
									Grain	<0.01	0.42/0.08**	0.14/0.04**	<0.01	35	
									Straw	<0.003	0.02	0.05	0.07/0.03**	35	

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e)

(f)

(g)

(\*)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

Minimum number of days after last application (Label pre-harvest interval, PHI, underline);

DBLA = days before last application, DALA = days after last application

Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

### A 2.1.3.2.1 Study 16-2046 – NEU

Comments of zRMS:	<p>It should be noted that the study of Meklat, Kerkerling (16-2046) is currently under review in the EU approval renewal process for prothioconazole.</p> <p>The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application. The conclusions of the assessment are presented below:</p> <p><i>Four residue trials on spring and winter wheat were conducted in northern Europe to determine residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio and TDMs. Wheat was treated twice at application rate of 0.200 kg a.s./ha of prothioconazole with 20-24 days interval between applications. The time of application was</i></p> <ol style="list-style-type: none"> <li><i>1. at BBCH 37-51,</i></li> <li><i>2. at BBCH 65-69.</i></li> </ol> <p><i>Samples were taken at harvest.</i></p> <p><i>Analytical method for determination of prothioconazole-desthio - method 01013.</i></p> <p><i>Analytical method for determination of prothioconazole -alpha-hydroxy-desthio, -3-hydroxy-desthio, -4-hydroxy-desthio, -5-hydroxy-desthio and -6-hydroxy-desthio – method 00979/M02.</i></p> <p><i>The residues of 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in/on plant material were analysed according to the method 01062/M004.</i></p> <p><i>Limit of quantitation was 0.01 mg/kg for grain, green material and straw for all substances. Mean recoveries in acceptable range (70 - 110%), RSD &lt;20%.</i></p> <p><i>Maximum storage period – 17.5 months.</i></p> <p><i>Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in wheat grain at harvest were &lt;0.01 mg/kg.</i></p> <p><i>Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest was &lt;0.06 mg/kg.</i></p> <p><i>Residues of 1,2,4-triazole and triazole lactic acid, in wheat grain at harvest were &lt; 0.01 mg/kg.</i></p> <p><i>Residues of triazole alanine, in wheat grain at harvest ranged between 0.11 and 0.26 mg/kg.</i></p> <p><i>Residues of triazole acetic acid, in wheat grain at harvest ranged between 0.23 and 0.88 mg/kg.</i></p> <p><i>The study is acceptable.</i></p>
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Reference:	KCA 6.3.2/03
Report	<p>Determination of the residues of prothioconazole and spiroxamine in/on spring wheat and winter wheat after spray application of JAU 6476 &amp; KWG 4168 EC 460 in the United Kingdom, Germany and the Netherlands</p> <p>Meklat, N.; Kerkerling, S., 06.06.2018</p> <p>Report No: M-626175-01-1</p> <p>Reference No: 16-2046</p>
Guideline(s):	<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</p> <p>OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009)</p> <p>US EPA OCSPP 860.1500, Crop Field Trial</p>
Deviations:	None

GLP:	Yes
Owner:	Bayer CropScience AG (Nufarm Europe has a letter of access)
Acceptability:	Yes

**The following study is currently under review in the EU approval renewal process for prothioconazole.**

### Materials and Methods

Field trials were conducted in/on winter and spring wheat during the 2016 growing season. The trials were located in Germany (2 trials), the Netherlands, and the United Kingdom.

In each trial the emulsifiable concentrate (EC) formulation was applied twice at a nominal rate of prothioconazole of 200 g as/ha. The applications were carried out at the growth stages BBCH 37-51 and BBCH 65-69, respectively, using 200-400 L/ha of water. The spray intervals ranged between 20 and 24 days.

Samples of green material were taken for analysis on the day of the last application (day 0) while samples of grain and straw were taken at harvest.

Residues of prothioconazole-desthio were determined according to method 01013 with a limit of quantitation of 0.01 mg/kg for grain, green material and straw. Residues of prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio were determined according to method 00979/M002 with a limit of quantitation of 0.01 mg/kg for grain, green material and straw (cf. methods part).

The residues of 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in/on plant material were analysed according to the method 01062/M004 (cf. methods part of this summary).

### Findings

#### - Storage stability:

The maximum storage periods for prothioconazole-desthio and TDMs in barley samples from the supplementary residue field trials are presented in the table below.

**Table A 66: Maximum storage periods of field samples from supplementary residue trials**

Crop	Substance	Sample Material	Storage period (days)	Storage period (months)
Wheat	prothioconazole-desthio	grain	319	10.6
		green material	365	12.2
		straw	333	11.1
	prothioconazole-alpha-hydroxy-desthio prothioconazole-3-hydroxy-desthio prothioconazole-4-hydroxy-desthio prothioconazole-5-hydroxy-desthio prothioconazole-6-hydroxy-desthio	grain	476	15.9
		green material	524	17.5
		straw	476	15.9
	TAA; 1,2,4-T, TA	grain	326	10.9
		green material	372	12.4
		straw	326	10.9

\* the storage stability of TLA was not investigated in straw, but there is no need, as its stability has been shown for 48 months in representative commodities covering the five categories described in the OECD guideline 506 for the testing of chemicals.



Sample extracts were measured within 24 hours, or if not, acceptable recoveries measured concurrently with each set of samples ensured integrity of the sample extracts during the period of time between extraction and analysis.

No residues above the LOQ were found in the control samples with the following exceptions:

**16-2046:** Triazole alanine: green material in 2 trials (up to 0.079 mg/kg) and in grain, all trials (up to 0.26 mg/kg); Triazole acetic acid: green material, in 2 trials (up to 0.061 mg/kg) and in grain, in 3 trials (up to 0.14 mg/kg) and in straw, in 2 trials (up to 0.062 mg/kg); Triazole lactic acid: green material, in 2 trials (up to 0.063 mg/kg), in straw, one trial (0.079 mg/kg).

- Method performance:

**16-2046:** The average recoveries were within the acceptable range of 70 – 110% and the RSD values were below 20%.

**Table A 67: 16-2046: Concurrent recoveries for the determination of prothioconazole-desthio in wheat**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
Prothioconazole-desthio	Wheat grain	0.01	104	-	-	0.01
		Overall Recovery (n = 1)		-	-	
		0.01	99	-	-	
	Wheat green material	0.10	100	-	-	0.01
		3.0	102	-	-	
		Overall Recovery (n = 3)		100	1.5	
		0.01	108	-	-	
	Wheat straw	0.50	94	-	-	0.01
		Overall Recovery (n = 2)		101	-	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-desthio, determined as JAU 6476-desthio and calculated as JAU 6476-desthio

**Table A 68: 16-2046: Concurrent recoveries for the determination of alpha-hydroxy-prothioconazole-desthio in wheat**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
alpha-hydroxy-prothioconazole-desthio	Wheat grain	0.01	84, 93	89	-	0.01
		0.09	86, 89	88	-	
		Overall Recovery (n = 4)		88	4.4	
		0.01	96, 104	100	-	
	Wheat green material	0.10	92, 96	94	-	0.01
		0.20	101, 104	103	-	
		Overall Recovery (n = 6)		99	5.0	
		0.01	106, 110	108	-	
	Wheat straw	0.10	87, 103	95	-	0.01
		0.20	102, 116	109	-	
		Overall Recovery (n = 6)		104	9.4	

RSD = Relative standard deviation, LOQ = Practical limit of quantification.

Fortified with JAU 6476-alpha-hydroxy-desthio, determined as JAU 6476-alpha-hydroxy-desthio and calculated as JAU 6476-desthio

**Table A 69: 16-2046: Concurrent recoveries for the determination of 3-hydroxy-prothioconazole-desthio in wheat**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
3-hydroxy-prothioconazole-desthio	Wheat grain	0.01	86, 88	87	-	0.01
		0.09	75, 86	81	-	
		Overall Recovery (n = 4)		84	7.1	
	Wheat green material	0.01	104, 106	105	-	0.01
		0.10	85, 93	89	-	
		0.20	95, 97	96	-	
		Overall Recovery (n = 6)		97	7.9	
	Wheat straw	0.01	102, 116	109	-	0.01
		0.10	79, 100	90	-	
		0.20	99, 104	102	-	

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
		Overall Recovery (n = 6)			100	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-3-hydroxy-desthio, determined as JAU 6476-3-hydroxy-desthio and calculated as JAU 6476-desthio

**Table A 70: 16-2046: Concurrent recoveries for the determination of 4-hydroxy-prothioconazole-desthio in wheat**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
3-hydroxy-prothio-conazole-desthio	Wheat grain	0.01	84, 84	84	-	0.01
		0.09	80, 86	83	-	
		Overall Recovery (n = 4)		84	3.0	
	Wheat green material	0.01	92, 100	96	-	0.01
		0.10	96, 99	98	-	
		0.20	77, 81	79	-	
		Overall Recovery (n = 6)		91	10.6	
	Wheat straw	0.01	97, 109	103	-	0.01
		0.10	87, 89	88	-	
		0.20	87, 90	89	-	
		Overall Recovery (n = 6)		93	9.2	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-4-hydroxy-desthio, determined as JAU 6476-4-hydroxy-desthio and calculated as JAU 6476-desthio.

**Table A 71: 16-2046: Concurrent recoveries for the determination of 5-hydroxy-prothioconazole-desthio in wheat**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
3-hydroxy-prothio-conazole-desthio	Wheat grain	0.01	91, 97	94	-	0.01
		0.09	90, 92	91	-	
		Overall Recovery (n = 4)		93	3.4	
	Wheat green material	0.01	106, 111	109	-	0.01
		0.10	87, 91	89	-	
		0.20	92, 94	93	-	
		Overall Recovery (n = 6)		97	9.9	
	Wheat straw	0.01	104, 115	110	-	0.01
		0.10	93, 97	95	-	
		0.20	99, 100	100	-	
		Overall Recovery (n = 6)		101	7.5	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-5-hydroxy-desthio, determined as JAU 6476-5-hydroxy-desthio and calculated as JAU 6476-desthio

**Table A 72: 16-2046: Concurrent recoveries for the determination of 6-hydroxy-prothioconazole-desthio in wheat**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
3-hydroxy-prothio-conazole-desthio	Wheat grain	0.01	96, 100	98	-	0.01
		0.09	90, 93	92	-	
		Overall Recovery (n = 4)		95	4.5	
	Wheat green material	0.01	95, 109	102	-	0.01
		0.10	96, 100	98	-	
		0.20	74, 85	80	-	
		Overall Recovery (n = 6)		93	13.1	
	Wheat straw	0.01	101, 118	110	-	0.01
		0.10	89, 101	95	-	
		0.20	92, 93	93	-	
		Overall Recovery (n = 6)		99	10.6	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with JAU 6476-6-hydroxy-desthio, determined as JAU 6476-6-hydroxy-desthio and calculated as JAU 6476-desthio,

**Table A 73: 16-2046: Concurrent recoveries for the determination of 1, 2, 4-Triazole in wheat**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
1, 2,4-T	Wheat grain	0.01	97, 98	98	-	0.01
		0.10	99	-	-	
		0.30	102	-	-	
		Overall Recovery (n = 4)		99	2.2	
	Wheat green material	0.01	91, 93, 97	94	3.3	0.01
		0.10	104	-	-	
		0.30	95	-	-	
		Overall Recovery (n = 5)		96	5.2	
	Wheat straw	0.01	103	-	-	0.01
		0.10	105	-	-	
		0.30	102	-	-	
		Overall Recovery (n = 3)		103	1.5	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with 1,2,4-triazole, determined as 1,2,4-triazole and calculated as 1,2,4-triazole

**Table A 74: 16-2046: Concurrent recoveries for the determination of Triazole Alanine in wheat**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
TA	Wheat grain	0.01	72 (234) <sup>a</sup> , 118 (281) <sup>a</sup>	95	-	0.01
		0.10	95 (112) <sup>a</sup>	-	-	
		0.30	91 (97) <sup>a</sup>	-	-	
		1.0	86 (87) <sup>a</sup> , 87 (89) <sup>a</sup>	87	-	
		Overall Recovery (n = 6)		92	16.5	
	Wheat green material	0.01	96, 98, 113	102	9.1	0.01
		0.10	99	-	-	
		0.30	95	-	-	
		Overall Recovery (n = 5)		100	7.3	
	Wheat straw	0.01	100, 109	105	-	0.01
		0.10	87	-	-	
		0.30	86	-	-	
		Overall Recovery (n = 4)		96	11.6	

RSD = Relative standard deviation, LOQ = Practical limit of quantification.

Fortified with triazole alanine, determined as triazole alanine and calculated as triazole alanine. a These recoveries were background-corrected since the control sample used for spiking (16-2046-03-0017E) was found to contain (apparent) residues at a level of 0.0161 mg/kg. The uncorrected recovery is shown in brackets.

**Table A 75: 16-2046: Concurrent recoveries for the determination of Triazole Acetic acid in wheat**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
TAA	Wheat grain	0.01	88 (138) <sup>a</sup> , 97 (148) <sup>a</sup>	93	-	0.01
		0.10	84 (90) <sup>a</sup>	-	-	
		0.30	96 (98) <sup>a</sup>	-	-	
		Overall Recovery (n = 4)		91	6.9	
	Wheat green material	0.01	97, 97, 106	100	5.2	0.01
		0.10	100	-	-	
		0.30	97	-	-	
		Overall Recovery (n = 5)		99	3.9	
	Wheat straw	0.01	107, 111	109	-	0.01
		0.10	93	-	-	
		0.30	97	-	-	
		Overall Recovery (n = 4)		102	8.2	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

. Fortified with triazole acetic acid, determined as triazole acetic acid and calculated as triazole acetic acid. a These recoveries were background-corrected since the control sample used for spiking (16-2046-03-0017E) was found to contain (apparent) residues at a level of 0.00491 mg/kg. The uncorrected recovery is shown in brackets.

**Table A 76: 16-2046: Concurrent recoveries for the determination of Triazole Lactic acid in wheat**

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
TLA	Wheat grain	0.01	81, 89	85	-	0.01
		0.10	87	-	-	

Analyte	Sample Material	Fortification level [mg/kg]	Recovery rates [%]		RSD [%]	LOQ [mg/kg]
			Single Values	Mean		
		0.30	91	-	-	
		<b>Overall Recovery (n = 4)</b>		<b>87</b>	<b>5.0</b>	0.01
		0.01	94, 97, 111	101	9.0	
		0.10	106	-	-	
		0.30	96	-	-	
	Wheat green material	<b>Overall Recovery (n = 5)</b>		<b>101</b>	<b>7.3</b>	0.01
		0.01	96, 108	102	-	
		0.10	93	-	-	
		0.30	96	-	-	
	Wheat straw	<b>Overall Recovery (n = 4)</b>		<b>98</b>	<b>6.8</b>	0.01
		0.01	96, 108	102	-	
		0.10	93	-	-	
		0.30	96	-	-	

RSD = Relative standard deviation, LOQ = Practical limit of quantification

Fortified with triazole lactic acid, determined as triazole lactic acid and calculated as triazole lactic acid

#### - Residue results:

The residue results are summarised in the tables below.

#### Conclusion

Wheat residue trials were conducted with Prothioconazole & Spiroxamine EC 460 in northern Europe. The product application corresponded to a prothioconazole rate of 2x200 g a.s./ha.

Residues of hydroxy- derivatives of prothioconazole-desthio and prothioconazole-desthio, in wheat grain at harvest were <0.01 mg/kg.

Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in straw at harvest ranged between 0.11 mg/kg and 0.60 mg/kg.

The results for the TDMs are summarised in the table below.

**Table A 77: 16-2046 - Residues of prothioconazole-desthio and metabolites in/on spring and winter barley applied with Prothioconazole & Spiroxamine EC 460**

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Residues (mg/kg)								Total (PTZ-desthio+hydroxy=RD-RA1)*
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALT (d)	JAU 6476-desthio	JAU 6476-alpha-OH-desthio	JAU 6476-3-OH-desthio	JAU 6476-4-OH-desthio	JAU 6476-5-OH-desthio	JAU 6476-6-OH-desthio	
16-2046MAN 16-2046-01 16-2046-01-T GLP: yes 2016	Wheat, winter Cougar	United Kingdom SG8 8SS Great Chishill, Royston Europe, North	460 EC	2	0.200	0.100	69	green material	0	1.2	0.038	0.076	0.081	0.11	<0.01	1.52
								grain	50	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.06
								straw	50	0.083	0.049	0.13	0.16	0.15	0.031	0.60
16-2046MAN 16-2046-04 16-2046-04-T GLP: yes 2016	Wheat, spring Thasos	Germany 59609 Anröchte- Berge Europe, North	460 EC	2	0.200	0.0667	69	green material	0	1.1	0.050	0.078	0.062	0.059	<0.01	1.36
								grain	53	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.06
								straw	53	0.094	0.071	0.070	0.073	0.065	<0.01	0.38
16-2046MAN 16-2046-03 16-2046-03-T GLP: yes 2016	Wheat, spring Tybalt	Netherlands 1606 MG Venhuizen Europe, North	460 EC	2	0.200	0.0500	65	green material	0	1.1	0.025	0.063	0.046	0.047	<0.01	1.52
								grain	54	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.06
								straw	54	0.046	0.013	0.012	0.024	0.019	<0.01	0.12
16-2046MAN 16-2046-02 16-2046-02-T GLP: yes 2016	Wheat, winter Dekan	Germany 51399 Burscheid Europe, North	460 EC	2	0.200	0.0667	69	green material	0	0.78	0.032	0.037	0.043	0.035	0.012	0.94
								grain	62	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.06
								straw	62	0.040	0.017	<0.01	0.023	<0.01	<0.01	0.11

\* for the sum, values <0.01 mg/kg were considered to be equal to 0.01 mg/kg, unless all the values were <0.01 mg/kg.

\*\* residue in control. Residues for JAU 6476 -desthio (determined as JAU 6476-desthio and calculated as JAU 6476-desthio). Residues for JAU 6476-alpha-hydroxy-desthio (determined as JAU 6476-alpha-hydroxy-desthio and calculated as JAU 6476-desthio). Residues for JAU 6476-3-hydroxy-desthio (determined as JAU 6476-3-hydroxy-desthio and calculated as JAU 6476-desthio).

\*\* residue in control. Residues for JAU 6476-4-hydroxy-desthio (determined as JAU 6476-4-hydroxy-desthio and calculated as JAU 6476-desthio). Residues for JAU 6476-5-hydroxy-desthio (determined as JAU 6476-5-hydroxy-desthio and calculated as JAU 6476-desthio). Residues for JAU 6476-6-hydroxy-desthio (determined as JAU 6476-6-hydroxy-desthio and calculated as JAU 6476-desthio).

**Table A 78: 16-2046 - Residues of 1,2,4-T and TAA in/on spring and winter wheat applied with Prothioconazole & Spiroxamine EC 460**

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Residues (mg/kg)			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALT (d)	1,2,4,-T	TAA
16-2046MAN 16-2046-01 16-2046-01-T GLP: yes 2016	Wheat, winter Cougar	United Kingdom SG8 8SS Great Chishill, Royston Europe, North	460 EC	2	0.200	0.100	69	green material	0	<0.01	0.088/0.061**
								grain	50	<0.01	0.26/0.14**
								straw	50	<0.01	0.097/0.062**
16-2046MAN 16-2046-04 16-2046-04-T GLP: yes 2016	Wheat, spring Thasos	Germany 59609 Anröchte- Berge Europe, North	460 EC	2	0.200	0.0667	69	green material	0	<0.01	0.037/0.015**
								grain	53	<0.01	0.13/0.039**
								straw	53	<0.01	0.031/0.013**
16-2046MAN 16-2046-03 16-2046-03-T GLP: yes 2016	Wheat, spring Tybalt	Netherlands 1606 MG Venhuizen Europe, North	460 EC	2	0.200	0.0500	65	green material	0	<0.01	0.013
								grain	54	<0.01	0.11
								straw	54	<0.01	0.018
16-2046MAN 16-2046-02 16-2046-02-T GLP: yes 2016	Wheat, winter Dekan	Germany 51399 Burscheid Europe, North	460 EC	2	0.200	0.0667	69	green material	0	<0.01	0.042
								grain	62	<0.01	0.22/0.027**
								straw	62	<0.01	0.036

\*\* residue in control.

Residues for 1,2,4-triazole (determined as 1,2,4-triazole and calculated as 1,2,4-triazole). Residues for triazole acetic acid (determined as triazole acetic acid and calculated as triazole acetic acid).

**Table A 79: 16-2046 - Residues of TA and TLA in/on spring and winter wheat applied with Prothioconazole & Spiroxamine EC 460**

Study Trial No. Plot No. GLP Year	Crop Variety	Country	Application					Residues (mg/kg)			
			FL	No	kg/ha (a.s.)	kg/hL (a.s.)	GS	Portion analysed	DALT (d)	TA	TLA
16-2046MAN 16-2046-01 16-2046-01-T GLP: yes 2016	Wheat, winter Cougar	United Kingdom SG8 8SS Great Chishill, Royston Europe, North	460 EC	2	0.200	0.100	69	green material	0	0.14/0.079**	0.094/0.063**
								grain	50	0.88/0.26**	<0.01
								straw	50	0.019	0.14/0.079**
16-2046MAN 16-2046-04 16-2046-04-T GLP: yes 2016	Wheat, spring Thasos	Germany 59609 Anröchte- Berge Europe, North	460 EC	2	0.200	0.0667	69	green material	0	0.050/0.018**	0.033/0.016**
								grain	53	0.23/0.079**	<0.01
								straw	53	0.011	0.015
16-2046MAN 16-2046-03 16-2046-03-T GLP: yes 2016	Wheat, spring Tybalt	Netherlands 1606 MG Venhuizen Europe, North	460 EC	2	0.200	0.0500	65	green material	0	0.023	0.011
								grain	54	0.36/0.015**	<0.01
								straw	54	0.011	0.019
16-2046MAN 16-2046-02 16-2046-02-T GLP: yes 2016	Wheat, winter Dekan	Germany 51399 Burscheid Europe, North	460 EC	2	0.200	0.0667	69	green material	0	0.11	0.045
								grain	62	0.77/0.042**	<0.01
								straw	62	0.063	0.021

\*\* residue in control.

Residues for triazole alanine (determined as triazole alanine and calculated as triazole alanine). Residues for triazole lactic acid (determined as triazole lactic acid and calculated as triazole lactic acid).

### A 2.1.3.2.2 Wheat residue trials analysing TDMs

The following tables were extracted from the “Triazole Derivate Metabolites addendum – confirmatory data prepared by the rapporteur Member State, the United Kingdom” Appendix C (UK, 2018). Only trials performed with prothioconazole were considered and presented hereafter.

**Table A 80: Application summary of residue trials conducted with an EC formulation containing 150 g/L of prothioconazole**

prothioconazole							
Study Trial No. Year	Crop Variety	Country	Application of prothioconazole				
			FL	No	g as/ha	g as/hL	GS
Northern Europe							
RA-2326/06 R 2006 0448/3 2006	Spring wheat Vinjett	Sweden 245 93 Staffanstorp (Scania)	EC 150 g/L	3	187.5	62.5	69
RA-2326/06 R 2006 0449/1 2006	Spring wheat Tecnico	France 37210 Chambourg sur Indre (Centre)	EC 150 g/L	3	187.5	62.5	69
RA-23 26/06 R 2006 0450/5 2006	Winter wheat Einstein	United Kingdom IP29 5LH Bury St Edmunds (Suffolk)	EC 150 g/L	3	187.5	62.5	69
RA-2326/06 R 2006 0451/3 2006	Winter wheat Batis	Germany 51377 Leverkusen (Nordrhein-Westfalen)	EC 150 g/L	3	187.5	62.5	69

**Table A 81: Results of residue trials conducted on wheat with an EC formulation containing 150 g/L of prothioconazole**

Report No	Country Trial No	DALT (days)	Commodity	Residue in Treated Samples				Residue in Control Samples			
				1,2,4-T <sup>a</sup>	TA <sup>b</sup>	TAA <sup>c</sup>	TLA <sup>d</sup>	1,2,4-T <sup>a</sup>	TA <sup>b</sup>	TAA <sup>c</sup>	TLA <sup>d</sup>
Northern Europe											
RA-2326/06 MR-09/109	Sweden R 2006 0448/3	0	Plant	< 0.050	0.105	0.060	NA	< 0.050	< 0.050	0.050	NA
		47	Straw	< 0.050	< 0.050	< 0.050	NA	< 0.050	< 0.050	0.050	NA
		47	Grain	< 0.010	0.586	0.230	NA	< 0.010	0.038	0.014	NA
RA-2326/06 MR-09/109	France R 2006 0449/1	0	Plant	< 0.050	0.392	0.262	NA	< 0.050	0.132	0.097	NA
		7	Plant	< 0.050	0.468	0.281	NA	NA	NA	NA	NA
		14	Plant	< 0.050	0.518	0.368	NA	NA	NA	NA	NA
		28	Plant	< 0.050	0.524	0.434	NA	NA	NA	NA	NA
		34	Straw	< 0.050	0.079	0.307	NA	< 0.050	< 0.050	0.085	NA
		34	Grain	< 0.010	1.069	0.517	NA	< 0.010	0.237	0.112	NA
RA-2326/06 MR-09/109	United Kingdom R 2006 0450/5	0	Plant	< 0.050	0.052	< 0.050	NA	< 0.050	< 0.050	< 0.050	NA
		39	Straw	< 0.050	< 0.050	0.067	NA	< 0.050	< 0.050	< 0.050	NA
		39	Grain	< 0.010	0.332	0.138	NA	< 0.010	0.024	0.016	NA
RA-2326/06 MR-09/109	Germany R 2006 0451/3	0	Plant	< 0.050	0.097	0.100	NA	< 0.050	< 0.050	< 0.050	NA
		7	Plant	< 0.050	0.224	0.094	NA	NA	NA	NA	NA
		14	Plant	< 0.050	0.237	0.089	NA	NA	NA	NA	NA
		28	Plant	< 0.050	0.315	0.132	NA	NA	NA	NA	NA
		38	Straw	< 0.050	< 0.050	0.078	NA	< 0.050	< 0.050	< 0.050	NA
		38	Grain	< 0.010	0.684	0.243	NA	< 0.010	0.150	0.010	NA

NA : not analysed

a 1,2,4-T = Residues determined as 1,2,4-triazole derivative, calculated as 1,2,4-triazole.

b TA = Residues determined as triazole alanine derivative, calculated as triazole alanine.

c TAA = Residues determined as triazole acetic acid derivative, calculated as triazole acetic acid.



d TLA = Triazole lactic acid not analysed.

**Table A 82: Application summary of residue trials conducted in/on wheat with an EC formulation containing 250 g/L of prothioconazole, after seed treatment with an FS formulation containing 100 g/L of prothioconazole**

Study Trial No. Year	Crop Variety	Country	Application of prothioconazole				
			FL	No	g as/ha	g as/hL	GS
Northern Europe							
09-2058 09-2058-01 2009	Spring wheat Triso	Germany 51399 Burscheid Nordrhein-Westfalen	FS 100 g/L EC 250 g/L	ST 3	30* 200	- 66.7	- 69
09-2058 09-2058-02 2009	Spring wheat Triso	The Netherlands 1681 ND, Zwaagdijk Noord-Holland	FS 100 g/L EC 250 g/L	ST 3	30* 200	- 66.7	- 69

FL = Formulation; GS = BBCH growth stage at last application; ST = Seed Treatment

\* = based on a nominal seed treatment rate of 0.15 g as/kg and a seed rate of 200 kg/ha

# = last treatment done at BBCH 65 instead of 69 due to bad weather conditions

**Table A 83: Results of residue trials conducted in/on wheat with an EC formulation containing 250 g/L of prothioconazole, after seed treatment with an FS formulation containing 100 g/L of prothioconazole**

Prothioconazole, after seed treatment with an FS formulation containing 160 g/L of prothioconazole											
Report No	Country Trial No	DALT (days)	Com-mo-dity	Residue in Treated Samples				Residue in Control Sample			
				1,2,4-T <sup>a</sup>	TA <sup>b</sup>	TAA <sup>c</sup>	TLA <sup>d</sup>	1,2,4-T <sup>a</sup>	TA <sup>b</sup>	TAA <sup>c</sup>	TLA <sup>d</sup>
Northern Europe											
09-2058	Germany 09-2058-01	0	Plant	< 0.01	0.127	0.104	0.067	< 0.01	0.023	0.015	0.021
		43	Grain	< 0.01	0.952	0.377	< 0.01	< 0.01	0.143	0.065	< 0.01
		43	Straw	< 0.01	0.019	0.047	0.160	< 0.01	0.012	0.010	0.023
09-2058	Netherlands 09-2058-02	0	Plant	< 0.01	0.045	0.021	0.018	< 0.01	< 0.01	< 0.01	< 0.01
		49	Grain	< 0.01	0.486	0.193	< 0.01	< 0.01	0.012	0.069	< 0.01
		49	Straw	< 0.01	0.028	0.020	0.048	< 0.01	< 0.01	< 0.01	< 0.01

DALT = Days after last treatment

Note: If duplicate samples were taken on the same day only the higher residue levels are shown in the table.

a 1,2,4-T = Residues determined as 1,2,4-triazole, calculated as 1,2,4-triazole.

b TA = Residues determined as triazole alanine, calculated as triazole alanine.

c TAA = Residues determined as triazole acetic acid, calculated as triazole acetic acid.

d TLA = Residues determined as triazole lactic acid, calculated as triazole lactic acid.

### A 2.1.3.3 Oilseed rape and other oilseeds

**Table A 84: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP NEU (DAR, UK, 2007)	2	175	14-28	Start BBCH 53	56
cGAP NEU (Art. 12, EFSA, 2020) <i>Oilseed rape, Linseeds, Poppy seeds, Mustard seeds</i>	2	120	14	-	28
cGAP NEU (Art. 12, EFSA, 2020) <i>Gold of pleasure</i>	2	175	14	-	56
Intended cGAP CEU	1	180	-	BBCH 69	56

#### A 2.1.3.3.1 Study S19-01269 – NEU + SEU

Comments of zRMS:	<p>The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application. The conclusions of the assessment are presented below:</p> <p><i>Six residue trials on oilseed rape were conducted in northern Europe to determine residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio and TDMs.</i></p> <p><i>Oilseed rape was treated twice at application rate of 0.175 kg a.s./ha of prothioconazole with 14 days interval between applications. The time of application was</i></p> <ol style="list-style-type: none"> <li><i>1. at BBCH 65,</i></li> <li><i>2. at BBCH 69.</i></li> </ol> <p><i>Samples were taken 56 days after the final application at normal commercial harvest.</i></p> <p><i>The limit of quantification (LOQ) of the analytical methods were 0.01 mg/kg for each analyte/matrix with a limit of detection (LOD) set at 0.003 mg/kg.</i></p> <p><i>The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev. 1.</i></p> <p><i>Maximum storage period – 454 days.</i></p> <p><i>Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in oilseed rape grain at harvest were between &lt;0.003 and 0.03 mg/kg.</i></p> <p><i>Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest ranged between &lt;0.06 and 0.08 mg/kg.</i></p> <p><i>Residues of 1,2,4-triazole in oilseed rape grain at harvest were &lt; 0.003 mg/kg.</i></p> <p><i>Residues of triazole alanine in oilseed rape grain at harvest ranged 1.2 – 2.1 mg/kg.</i></p> <p><i>Residues of triazole acetic acid in oilseed rape grain at harvest ranged between &lt;0.01 and 0.1 mg/kg.</i></p> <p><i>Residues of triazole lactic acid in oilseed rape grain at harvest were between 0.02 and 0.12 mg/kg.</i></p> <p><i>The study is acceptable.</i></p>
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Reference: KCA 6.3.3/01

Report Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole 250EC in Oilseed rape (outdoor) at 4 sites in Northern Europe and 4 sites in Southern Europe 2019 North, L., 2021

Report No: S19-01269

Guideline(s):	OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32) OECD Test Guideline 509: Crop field trials OECD (2016) Guidance Document ENV/JM/MONO (2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66) EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials European Community Guideline SANCO 7525/VI/95, Rev. 10.3, 13/06/17: Comparability, extrapolation, group tolerances and data requirements for setting MRLs)
Deviations:	None
GLP:	Yes
Owner:	Nufarm Crop Products UK
Acceptability:	Yes

### Materials and Methods

Eight residue trials were conducted on oilseed rape during 2019, three in France (S19-01269-03, 07 and 08), one in the United Kingdom (S19-01269-01), one in Germany S19-01269-02, one in Hungary S19-01269-04, one in Spain S19-01269-05, and one in Italy S19-01269-06.

Two applications of NUL3390 Prothioconazole 250 EC (250g/L, prothioconazole) were applied at 175 g ai/ha, diluted with water immediately prior to application to a spray volume of 100-400 L/ha. Samples of oilseed rape from the untreated and treated plots were taken by hand at 0, 7, 14, 35 and 56 days after the final application.

Oilseed rape samples were analysed for residues of prothioconazole (PTZ)-desthio according to the multi-residue QuEChERS method that was previously validated according to SANCO/30299/99, rev.4 and SANCO/825/00 rev. 8.1 for wheat (grain), grapes, oilseed rape (seed), bean (dry) and cucumber in Eurofins Agrosience Services study S16-04434. The quantitation is done using liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The limit of quantitation for the method is set at 0.01 mg/kg.

Oilseed rape samples were analysed for residues of PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio according to the analytical method described in Eurofins Agrosience Services study S16-04435 that was previously validated according to SANCO/30299/99, rev.4 and SANCO/825/00 rev. 8.1 for wheat (whole plant, grain and straw) and oilseed rape (seed). The quantitation is done using liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The limit of quantitation for the method is set at 0.01 mg/kg for each analyte. The analytes were fortified jointly and quantified separately. For PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio the LOQ is expressed as PTZ-desthio.

Oilseed rape samples were analysed for residues of triazole derivative metabolites (TDMs) 1,2,4-Triazole, triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) according to the analytical method described in S15-03542 that was previously validated according to SANCO/825/00 rev. 8.1 for wheat (grain and straw), barley (grain and straw), grape (bunches) and oilseed rape. The quantitation was done using liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The limit of quantitation for the method is set at 0.01 mg/kg for each analyte. The analytes were fortified jointly and quantified separately.

The maximum storage interval from sampling to extraction was 326 days for oilseed rape (whole plant) and 454 days for oilseed rape (seed). Storage at the Analytical Test Site from sample receipt until lab sample preparation was at  $\leq -18^{\circ}\text{C}$ .

The maximum interval from extraction to analysis at typically  $1^{\circ}\text{C}$  to  $10^{\circ}\text{C}$  with given exceptions (e.g. periods during sample extraction/work-up, periods during transfer to detection instrument and possible minor fluctuations of refrigerator temperatures) was six days for oilseed rape (whole plant) and one day for oilseed rape (seed).

The analytical methods were validated for the determination of all analytes in oilseed rape (whole plant and seed) according to SANCO/3029/99, rev.4 during analysis. All mean recovery values (corrected for apparent blank residues, if necessary) at fortification levels of LOQ and 10x LOQ comply with the standard acceptance criteria of the guidance document with evaluation of one (1) mass transition.

Procedural recoveries run concurrently with test sample are summarized in the table below:

**Table A 85: Summary of procedural recoveries**

Analyte	Matrix	Fortification Levels (mg/kg)	Overall Mean Recovery (%)
Prothioconazole-desthio	Whole plant	0.01, 0.1, 4.0	91
	Seed	0.01, 0.1	90
Prothioconazole- $\alpha$ -hydroxy-desthio	Whole plant	0.01, 0.1, 0.25	109
	Seed	0.01, 0.1	102
Prothioconazole-3-hydroxy-desthio	Whole plant	0.01, 0.1, 0.25	107
	Seed	0.01, 0.1	96
Prothioconazole-4-hydroxy-desthio	Whole plant	0.01, 0.1, 0.25	108
	Seed	0.01, 0.1	93
Prothioconazole-5-hydroxy-desthio	Whole plant	0.01, 0.1, 0.25	109
	Seed	0.01, 0.1	97
Prothioconazole-6-hydroxy-desthio	Whole plant	0.01, 0.1, 0.25	97
	Seed	0.01, 0.1	85
1,2,4-Triazole	Whole plant	0.01, 0.1	106
	Seed	0.01, 0.1	86
Triazole alanine	Whole plant	0.01, 0.1, 1.2	105
	Seed	0.01, 0.05, 0.1, 0.5, 1.2, 4.0	91
Triazole acetic acid	Whole plant	0.01, 0.1, 0.6	104
	Grain	0.01, 0.1, 0.6	99
Triazole lactic acid	Whole plant	0.01, 0.1, 0.4	100
	Grain	0.01, 0.1, 0.4	92

## Findings

The residue levels found in oilseed rape are summarised in the table below.

In trial S19-01269-01 residues of **prothioconazole-desthio** above the LOQ were found in seeds from the control plot (0.03 mg/kg). However, no deviations were reported, either for the field phase or for the analytical phase. Therefore, there is no reason to exclude this trial and as a worst case the result in the control sample, which is higher than the one in the treated sample, was considered for MRL compliance and risk assessment.

**Table A 86: Summary of the study S19-01269 trials**

**RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)**

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Oilseed rape</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	UK	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)	10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-desthio		
S19-01269-01 Ashill, Suffolk, UK, IP257BS	Oilseed rape / BRSNN / DK Expansion	1) 15 Aug 18 2) na 3) 12 Jul 19	Overall spray using a plot sprayer	87.7	203	178	2 17 May 19	69	Whole plant Whole plant Whole plant Whole plant Seeds	0.72 0.21 0.13 0.04 0.02 / <u>0.03</u> **	0 7 14 35 56	No residues >LOQ were found in any untreated samples, except seed at 56DAA with a residue of 0.03 mg/kg

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
Crop/crop group:

PROTHIOCONAZOLE  
Oilseed rape

Commercial Product (name):  
Producer of commercial product:

NUL 3390 PROTHIOCONAZOLE 250 EC  
Nufarm UK Limited

Responsible body for reporting  
(name, address)

Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK

Country (of trial sites):  
Content of active substance nominal (g/kg or g/L):

United Kingdom  
250

Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common name and content):

Outdoor  
none

Formulation (e.g. WP):  
EC

Residues calculated as:  
Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)						10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- $\alpha$ -OH-desthio	PTZ-3-OH-desthio	PTZ-4-OH-desthio	PTZ-5-OH-desthio	PTZ-6-OH-desthio	Total (PTZ-desthio+hydroxy=RD-RA1)*		
S19-01269-01 Ashill, Suffolk, UK, IP257BS	Oilseed rape / BRSNN / DK Expansion	1) 15 Aug 18 2) na 3) 12 Jul 19	Overall spray using a plot sprayer	87.7	203	178	2 17 May 19	69	Whole plant	<0.003	0.03	0.01	<0.003	<0.003	0.77	0	No
									Whole plant	<0.01	0.06	0.02	<0.01	<0.003	0.31	7	residues
									Whole plant	<0.01	0.08	0.03	<0.01	<0.003	0.26	14	>LOQ
									Whole plant	<0.01	0.09	0.03	<0.01	<0.003	0.18	35	were found in
									Whole plant	<0.01	0.02	0.01	<0.01	<0.003	<u>0.08</u>	56	any untreated samples

(a) According to EPPO codes  
(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e)  
(f)  
(g)  
(\*)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application  
Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg,

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Oilseed rape</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address):	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	United Kingdom	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)				10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4- Triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid		
S19-01269-01 Ashill, Suffolk, UK, IP257BS	Oilseed rape / BRSNN / DK Expansion	1) 15 Aug 18	Overall spray using a plot sprayer	87.7	203	178	2 17 May 19	69	Whole plant	<0.003	0.30	0.01	0.01	0	No residues >LOQ were found in any 1,2,4 triazole untreated samples. Residues ranged from <0.01-0.80 mg/kg in all other untreateds
		2) na							Whole plant	<0.003	0.25	0.01	0.01	7	
		3) 12 Jul 19							Whole plant	<0.003	0.25	<0.01	0.01	14	
									Whole plant	<0.003	0.37	0.01	0.02	35	
									Seeds	<0.003	1.4/0.80**	0.01	0.04/0.04**	56	

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Oilseed rape</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)	10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-desthio		
S19-01269-02 21737, Wischnafen, Lower Saxony, Germany	Oilseed rape / BRSNN / Exception	1) 03 Sep 18 2) 27 Apr – 20 May 19 3) 24 Jul 19	Overall spray using a plot sprayer	58	296	173	2 16 May 19	68	Whole plant Whole plant Whole plant Whole plant Seeds	0.70 0.20 0.12 0.01 <u>&lt;0.01</u>	0 7 14 35 69	No residues >LOQ were found in any untreated samples

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

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BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg



## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **PROTHIOCONAZOLE** Commercial Product (name): **NUL 3390 PROTHIOCONAZOLE 250 EC**  
Crop/crop group: **Oilseed rape** Producer of commercial product: **Nufarm UK Limited**  
Responsible body for reporting (name, address): **Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK**  
Country (of trial sites): **Germany** Indoor/Glasshouse/Outdoor: **Outdoor**  
Content of active substance nominal (g/kg or g/L): **250** Other active substance in the formulation (common name and content): **none**

Formulation (e.g. WP): **EC** Residues calculated as: **Prothioconazole-desthio (mg/kg)**

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)						10 PHI (days) (f)	11 Remarks (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- $\alpha$ - OH- desthio	PTZ- 3-OH- desthio	PTZ- 4-OH- desthio	PTZ-5- OH- desthio	PTZ- 6-OH- desthio	Total desthio+hydroxy=RD- RA1)*		
S19-01269- 02 21737, Wisehnafen, Lower Saxony, Germany	Oilseed rape / BRSNN / Exception	1) 03 Sep 18 2) 27 Apr – 20 May 19 3) 24 Jul 19	Overall spray using a plot sprayer	58	296	173	2 16 May 19	68	Whole plant	<0.003	0.03	0.01	<0.003	<0.003	0.75	0	No
									Whole plant	<0.01	0.06	0.02	<0.01	<0.003	0.30	7	residues
									Whole plant	<0.003	0.06	0.02	<0.01	<0.003	0.22	14	>LOQ
									Whole plant	<0.003	0.04	0.01	<0.003	<0.003	0.07	35	were
									Whole plant Seeds	<0.003	<0.01	<0.003	<0.003	<0.003	<0.06	69	found in any untreated samples

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

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Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Oilseed rape</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address):	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)				10 PHI (days) (f)	11 Remarks (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4- Triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid		
S19-01269-02 21737, Wischnafen, Lower Saxony, Germany	Oilseed rape / BRSNN / Exception	1) 03 Sep 18 2) 27 Apr – 20 May 19 3) 24 Jul 19	Overall spray using a plot sprayer	58	296	173	2 16 May 19	68	Whole plant	<0.003	0.09	<0.003	<0.01	0	No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.39 mg/kg in all other untreateds
									Whole plant	<0.003	0.15	<0.01	<0.01	7	
									Whole plant	<0.003	0.23	<0.01	<0.01	14	
									Whole plant	<0.003	0.15	<0.01	0.01	35	
									Seeds	<0.003	1.2/0.39**	0.01	0.05/0.03**	69	

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

# RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Oilseed rape</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)	10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-desthio		
S19-01269-03 67140 Statzheim, Bas- Rhin, Alsace, France	Oilseed rape / BRSNN / Hillier	1) 25 Aug 19 2) 05 Apr – 10 May 3) 05 Jul 19	Overall spray using a plot sprayer	58.3	302	176	2 10 May 2018	67-69	Whole plant	0.71	0	No residues >LOQ were found in any untreated samples
									Whole plant	0.29	7	
									Whole plant	0.12	14	
									Whole plant	0.02	35	
									Seeds	<u>0.01</u>	56	

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

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BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	PROTHIOCONAZOLE	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	Oilseed rape	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none

Formulation (e.g. WP):			EC		Residues calculated as:			Prothioconazole-desthio (mg/kg)							10	11		
1	2	3	4	5			6	7	8	9						10	11	
Report No.	Commodity/Variety	Date of	Method of	Application rate per			Dates of	Growth	Portion	Residues (mg/kg)						PHI	Remarks	
Location	(a)	1) Sowing or	Treatment	treatment			or no. of	stage at	(a)	(*)						(f)	(g)	
(region)		Planting		g	Water	g	treatment(s)	last		PTZ-α-	PTZ-	PTZ-	PTZ-	PTZ-6-	Total			
		3) Harvest	(c)	as/hL	(L/ha)	a.s./ha	and last	or date		OH-	3-OH-	4-OH-	5-OH-	OH-	(PTZ-			
		(b)					date	(e)		desthio	desthio	desthio	desthio	desthio	RA1)*			
							(d)	BBCH										
S19-01269-03	Oilseed rape / BRSNN / Hillier	1) 25 Aug 19	Overall spray using a plot sprayer	58.3	302	176	2	10 May 2018	67-69	Whole plant	<0.003	0.02	<0.01	<0.003	<0.003	0.75	0	No
67140		2) 05 Apr –								Whole plant	<0.01	0.07	0.03	<0.01	<0.003	0.41	7	residues
Statzheim,		10 May								Whole plant	<0.01	0.08	0.03	<0.01	<0.003	0.25	14	>LOQ
Bas-Rhin,		3) 05 Jul 19								Whole plant	<0.01	0.06	0.01	<0.01	<0.003	0.11	35	were
Alsace, France										Whole plant	<0.01	0.02	<0.01	<0.003	<0.003	0.06	56	found in
									Seeds								any untreated samples	

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

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BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Oilseed rape</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)				10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4- Triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid		
S19-01269-03 67140 Statzheim, Bas-Rhin, Alsace, France	Oilseed rape / BRSNN / Hillier	1) 25 Aug 19	Overall spray using a plot sprayer	58.3	302	176	2 10 May 2018	67-69	Whole plant	<0.003	0.07	<0.003	<0.003	0	>LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.74 mg/kg in all other untreateds
		2) 05 Apr – 10 May							Whole plant	<0.003	0.11	<0.01	<0.01	7	
		3) 05 Jul 19							Whole plant	<0.003	0.12	<0.01	<0.01	14	
									Whole plant	<0.003	0.24	<0.01	0.02	35	
									Seeds	<0.003	1.2/0.74**	0.01	0.09/0.06**	56	

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Oilseed rape</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	Hungary	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)	10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-desthio		
S19-01269-04 H-5440 Kunszentmarton, Jasz-Nagykun- Szolnok, Hungary	Oilseed rape / BRSNN / KWS Gordon	1)04 Sep 19 2) 16 Apr – 10 May 19 3) 27 Jun 19	Overall spray using a plot sprayer	58.3	312	182	2 02 May 19	69	Whole plant Whole plant Whole plant Whole plant Seeds	2.9 0.62 0.16 0.02 <u>&lt;0.01</u>	0 7 14 35 56	No residues >LOQ were found in any untreated samples

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

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BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **PROTHIOCONAZOLE** Commercial Product (name): NUL 3390 PROTHIOCONAZOLE 250 EC  
Crop/crop group: **Oilseed rape** Producer of commercial product: Nufarm UK Limited  
Responsible body for reporting (name, address): Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
Country (of trial sites): Hungary Indoor/Glasshouse/Outdoor: Outdoor  
Content of active substance nominal (g/kg or g/L): 250 Other active substance in the formulation (common name and content): none

Formulation (e.g. WP):

EC

Residues calculated as:

Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)						10 PHI (days) (f)	11 Remarks (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- α-OH- desthio	PTZ- 3-OH- desthio	PTZ- 4-OH- desthio	PTZ- 5-OH- desthio	PTZ- 6-OH- desthio	Total desthio+hydroxy=RD- RA1)*		
S19-01269-04 H-5440 Kunszentmarton, Jasz-Nagykun- Szolnok, Hungary	Oilseed rape / BRSNN / KWS Gordon	1)04 Sep 19 2) 16 Apr – 10 May 19 3) 27 Jun 19	Overall spray using a plot sprayer	58.3	312	182	2 02 May 19	69	Whole plant Whole plant Whole plant Whole plant Seeds	<0.01 0.01 <0.01 <0.01 <0.01	0.14 0.21 0.15 0.12 <0.01	0.06 0.07 0.06 0.04 <0.003	0.02 0.02 0.02 <0.01 <0.003	<0.003 <0.003 <0.003 <0.003 <0.003	3.13 0.93 0.40 0.20 <u>≤0.06</u>	0 7 14 35 56	No residues >LOQ were found in any untreated samples

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

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BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

# RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Oilseed rape</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address):	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	Hungary	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg)

1	2	3	4	5			6	7	8	(mg/kg) 9				10	11
Report No. Location (region)	Commodity/Variety  (a)	1) Sowing or Planting 2) Flowering 3) Harvest (b)	Method of Treatment  (c)	Application rate per treatment			Dates of treatment(s) or no. of treatment(s) and last date  (d)	Growth stage at last treatment or date  (e) BBCH	Portion analysed  (a)	Residues (mg/kg) (*)				PHI (days)  (f)	Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4- Triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid		
S19-01269-04 H-5440 Kunszentmarton, Jasz-Nagykun- Szolnok, Hungary	Oilseed rape / BRSNN / KWS Gordon	1)04 Sep 19 2) 16 Apr – 10 May 19 3) 27 Jun 19	Overall spray using a plot sprayer	58.3	312	182	2 02 May 19	69	Whole plant Whole plant Whole plant Whole plant Seeds	<0.003 <0.003 <0.003 <0.003 <0.003	0.07 0.07 0.13 0.35 2.1/2.1**	<0.003 <0.003 <0.003 <0.01 0.02/0.03**	<0.01 <0.003 <0.003 0.01 0.12/0.16**	0 7 14 35 56	No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-2.1 mg/kg in all other untreateds

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg



# RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Oilseed rape</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	Spain	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)	10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-desthio		
S19-01269-05 49510 Fonfria, Aragon, Spain	Oilseed rape / BRSNN / Expression	1) 05 Sep 18 2) Apr-May 3) 11 Jul 19	Overall spray using a plot sprayer	58	314	183	2 16 May 19	69-71	Whole plant	0.21	0	No residues >LOQ were found in any untreated samples
									Whole plant	0.14	7	
									Whole plant	0.08	14	
									Whole plant	0.02	35	
									Seeds	<0.01	56	

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

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Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **PROTHIOCONAZOLE** Commercial Product (name): NUL 3390 PROTHIOCONAZOLE 250 EC  
Crop/crop group: **Oilseed rape** Producer of commercial product: Nufarm UK Limited  
Responsible body for reporting Nufarm UK Limited Wyke Lane  
(name, address) Wyke, Bradford  
BD12 9EJ, UK  
Country (of trial sites): Spain Indoor/Glasshouse/Outdoor: Outdoor  
Content of active substance nominal (g/kg or g/L): 250 Other active substance in the formulation (common name and content): none

Formulation (e.g. WP): EC Residues calculated as: Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)						10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- $\alpha$ - OH- desthio	PTZ- 3-OH- desthio	PTZ- 4-OH- desthio	PTZ- 5-OH- desthio	PTZ- 6-OH- desthio	Total desthio+hydroxy=RD- RA1)*		
S19- 01269-05 49510 Fonfria, Aragon, Spain	Oilseed rape / BRSNN / Expression	1) 05 Sep 18 2) Apr-May 3) 11 Jul 19	Overall spray using a plot sprayer	58	314	183	2 16 May 19	69-71	Whole plant	<0.003	0.06	0.02	<0.01	<0.003	0.31	0	No
									Whole plant	<0.003	0.06	0.02	<0.01	<0.003	0.24	7	residues
									Whole plant	<0.003	0.09	0.03	<0.01	<0.003	0.22	14	>LOQ
									Whole plant	<0.003	0.08	0.02	<0.01	<0.003	0.14	35	were
									Whole plant Seeds	<0.003	0.01	<0.003	<0.003	<0.003	0.03	56	found in any untreated samples

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

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Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Oilseed rape</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address):	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	Spain	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)				10 PHI (days) (f)	11 Remarks (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4- Triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid		
S19-01269-05 49510 Fonfria, Aragon, Spain	Oilseed rape / BRSNN / Expression	1) 05 Sep 18 2) Apr-May 3) 11 Jul 19	Overall spray using a plot sprayer	58	314	183	2 16 May 19	69-71	Whole plant	<0.003	0.02	<0.003	<0.003	0	No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.12 mg/kg in all other untreateds
									Whole plant	<0.003	0.03	<0.003	<0.003	7	
									Whole plant	<0.003	0.05	<0.003	<0.01	14	
									Whole plant	<0.003	0.04	<0.003	0.01	35	
									Seeds	<0.003	0.47/0.12**	<0.01	0.02/0.01**	56	

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Oilseed rape</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	Italy	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)	10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-desthio		
S19-01269-06 40068 Idice, Emilia Romagna, Italy	Oilseed rape / BRSNN / Dariot	1) 20 Oct 18 2) 02 Apr – 03 May 19 3) 14 Jun 19	Overall spray using a plot sprayer	46.7	410	179	2 19 Apr 19	65	Whole plant Whole plant Whole plant Whole plant Seeds	0.58 0.66 0.32 0.10 <0.003 n.d.	0 7 14 35 56	No residues >LOQ were found in any untreated samples

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

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Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg, n.d. = not detected

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **PROTHIOCONAZOLE** Commercial Product (name): NUL 3390 PROTHIOCONAZOLE 250 EC  
Crop/crop group: **Oilseed rape** Producer of commercial product: Nufarm UK Limited  
Responsible body for reporting (name, address): Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
Country (of trial sites): Italy Indoor/Glasshouse/Outdoor: Outdoor  
Content of active substance nominal (g/kg or g/L): 250 Other active substance in the formulation (common name and content): none

Formulation (e.g. WP): EC Residues calculated as: Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)						10 PHI (days) (f)	11 Remarks (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- $\alpha$ - OH- desthio	PTZ- 3-OH- desthio	PTZ- 4-OH- desthio	PTZ- 5-OH- desthio	PTZ- 6-OH- desthio	Total desthio+hydroxy=RD- RA1)*		
S19- 01269-06 40068 Idice, Emilia Romagna, Italy	Oilseed rape / BRSNN / Dariot	1) 20 Oct 18 2) 02 Apr – 03 May 19 3) 14 Jun 19	Overall spray using a plot sprayer	46.7	410	179	2 19 Apr 19	65	Whole plant	<0.01	0.04	0.01	<0.01	<0.003	0.65	0	No
									Whole plant	0.01	0.11	0.04	<0.01	<0.003	0.83	7	residues
									Whole plant	<0.01	0.12	0.04	0.01	<0.003	0.50	14	>LOQ
									Whole plant	<0.01	0.12	0.04	<0.01	<0.003	0.28	35	were
									Whole plant Seeds	<0.003	<0.01	<0.003	<0.003	<0.003	<0.06	56	found in any untreated samples

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

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Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	PROTHIOCONAZOLE	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	Oilseed rape	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address):	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	Italy	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)				10 PHI (days) (f)	11 Remarks (g)
	(a)			g as/hL	Water (L/ha)	g a.s./ha				1,2,4- Triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid		
S19-01269-06 40068 Idice, Emilia Romagna, Italy	Oilseed rape / BRSNN / Dariot	1) 20 Oct 18	Overall spray using a plot sprayer	46.7	410	179	2 19 Apr 19	65	Whole plant	<0.003	0.10	<0.01	<0.01	0	No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-1.9 mg/kg in all other untreateds
		2) 02 Apr – 03 May 19							Whole plant	<0.01	0.39	<0.01	0.02	7	
		3) 14 Jun 19							Whole plant	<0.003	0.13	<0.01	<0.01	14	
									Whole plant	<0.003	0.15	<0.01	<0.01	35	
									Seeds	<0.003	3.3/1.9**	0.04/0.03**	0.14/0.11**	56	

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)

Active substance (common name):	PROTHIOCONAZOLE	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	Oilseed rape	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)	10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-desthio		
S19-01269-07 82700 St Porquier, Tarn et Garonne, France	Oilseed rape / BRSNN / Trezzor	1) 26 Sep 18 2) 05-20 Apr 19 3) 25 Jun 19	Overall spray using a plot sprayer	87.2	203	177	2 02 May 19	69-72	Whole plant Whole plant Whole plant Whole plant Seeds	0.41 0.38 0.14 0.03 <0.01	0 7 14 35 54	No residues >LOQ were found in any untreated samples

- (a) According to EPPO codes
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
- (f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application
- (g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
- (\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **PROTHIOCONAZOLE** Commercial Product (name): **NUL 3390 PROTHIOCONAZOLE 250 EC**  
Crop/crop group: **Oilseed rape** Producer of commercial product: **Nufarm UK Limited**  
Responsible body for reporting (name, address): **Nufarm UK Limited**  
**Wyke Lane**  
**Wyke, Bradford**  
**BD12 9EJ, UK**  
Country (of trial sites): **France** Indoor/Glasshouse/Outdoor: **Outdoor**  
Content of active substance nominal (g/kg or g/L): **250** Other active substance in the formulation (common name and content): **none**

Formulation (e.g. WP): **EC** Residues calculated as: **Prothioconazole-desthio (mg/kg)**

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)						10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- $\alpha$ - OH- desthio	PTZ- 3-OH- desthio	PTZ- 4-OH- desthio	PTZ- 5-OH- desthio	PTZ- 6-OH- desthio	Total desthio+hydroxy=RD- RA1)*		
S19- 01269-07 82700 St Porquier, Tarn et Garonne, France	Oilseed rape / BRSNN / Trezzor	1) 26 Sep 18 2) 05-20 Apr 19 3) 25 Jun 19	Overall spray using a plot sprayer	87.2	203	177	2 02 May 19	69-72	Whole plant	<0.01	0.05	0.02	<0.01	<0.003	0.50	0	No
									Whole plant	<0.01	0.05	0.02	<0.01	<0.003	0.47	7	residues
									Whole plant	<0.01	0.07	0.02	<0.01	<0.003	0.25	14	>LOQ
									Whole plant	<0.003	0.08	0.02	<0.003	<0.003	0.14	35	were
									Whole plant Seeds	<0.01	<0.01	<0.003	<0.003	<0.003	<0.06	54	found in any untreated samples

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e)

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Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg



RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	PROTHIOCONAZOLE	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	Oilseed rape	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address):	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)				10 PHI (days)  (f)	11 Remarks  (g)
	(a)			g as/hL	Water (L/ha)	g a.s./ha				1,2,4- Triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid		
S19-01269-07 82700 St Porquier, Tarn et Garonne, France	Oilseed rape / BRSNN / Trezzor	1) 26 Sep 18	Overall spray using a plot sprayer	87.2	203	177	2 02 May 19	69-72	Whole plant	<0.003	0.28	<0.01	0.01	0	No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-1.2 mg/kg in all other untreateds
		2) 05-20 Apr 19							Whole plant	<0.003	0.36	<0.01	0.02	7	
		3) 25 Jun 19							Whole plant	<0.003	0.34	<0.01	0.02	14	
									Whole plant	<0.003	0.41	0.01	0.04	35	
									Seeds	<0.003	1.6/1.2**	0.02/0.01**	0.09/0.07**	54	

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

# RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY) (CONTINUED)

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Oilseed rape</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address)	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	Prothioconazole-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)  PTZ-desthio	10 PHI (days)  (f)	11 Remarks  (g)
S19-01269-08 82200 Moissac, Tarn et Garonne, France	Oilseed rape / BRSNN / Attletick	1) 04 Sep 18 2) 05-25 Apr 19 3) 24 Jun 19	Overall spray using a plot sprayer	87.7	203	178	2  02 May 19	78-80	Whole plant Whole plant Whole plant Whole plant Seeds	0.49 0.22 0.10 0.04 0.01	0 7 14 35 53	No residues >LOQ were found in any untreated samples

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e)

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Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting (name, address):  
  
Country (of trial sites):  
Content of active substance nominal (g/kg or g/L):

PROTHIOCONAZOLE  
Oilseed rape  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
France  
250

Commercial Product (name):  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common name and content):

NUL 3390 PROTHIOCONAZOLE 250 EC  
Nufarm UK Limited  
Wyke Lane  
Wyke, Bradford  
BD12 9EJ, UK  
  
Outdoor  
none

Formulation (e.g. WP):			EC		Residues calculated as:			Prothioconazole-desthio (mg/kg)										
1	2	3	4	5			6	7	8	9						10	11	
Report No.	Commodity/Variety	Date of	Method	Application rate per			Dates of	Growth	Portion	Residues (mg/kg)						PHI	Remarks	
Location		1) Sowing or	of				treatment(s)	stage at								(days)		
(region)	(a)	2) Flowering	Treatment	g	Water	g	or no. of	last								(f)	(g)	
		3) Harvest	(c)	as/hL	(L/ha)	a.s./ha	treatment(s)	treatment	(a)	PTZ-α-	PTZ-	PTZ-	PTZ-	PTZ-	Total			
		(b)					and last date	or date		OH-	3-OH-	4-OH-	5-OH-	6-OH-	desthio+hydroxy=RD-			
							(d)	(e)		desthio	desthio	desthio	desthio	desthio	RA1)*			
S19-01269-08	Oilseed rape / BRSNN / Attletick	1) 04 Sep 18	Overall spray using a plot sprayer	87.7	203	178	2	78-80	Whole plant	<0.003	0.05	0.02	<0.01	<0.003	0.58	0	No	
82200		2) 05-25 Apr 19					02 May 19		Whole plant	<0.01	0.06	0.02	<0.01	<0.003	0.32	7	residues	
Moissac,		3) 24 Jun 19							Whole plant	<0.003	0.09	0.02	<0.01	<0.003	0.23	14	>LOQ	
Tarn et									Whole plant	<0.003	0.09	0.02	<0.01	<0.003	0.17	35	were	
Garonne, France									Whole plant	<0.01	<0.01	<0.003	<0.003	<0.003	<0.06	53	found in any untreated samples	
									Seeds									

(a) According to EPPO codes  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e)  
(f)  
  
(g)  
(\*)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application  
  
Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

# RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	<b>PROTHIOCONAZOLE</b>	Commercial Product (name):	NUL 3390 PROTHIOCONAZOLE 250 EC
Crop/crop group:	<b>Oilseed rape</b>	Producer of commercial product:	Nufarm UK Limited
Responsible body for reporting (name, address):	Nufarm UK Limited Wyke Lane Wyke, Bradford BD12 9EJ, UK		Wyke Lane Wyke, Bradford BD12 9EJ, UK
Country (of trial sites):	France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/kg or g/L):	250	Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	EC	Residues calculated as:	1,2,4-Triazole, triazole alanine, triazole acetic acid, triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg) (*)				10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4- Triazole	Triazole alanine	Triazole acetic acid	Triazole lactic acid		
S19-01269-08 82200 Moissac, Tarn et Garonne, France	Oilseed rape / BRSNN / Attletick	1) 04 Sep 18	Overall spray using a plot sprayer	87.7	203	178	2 02 May 19	78-80	Whole plant	<0.003	0.10	<0.01	<0.01	0	No residues >LOQ were found in any 1,2,4 triazole untreated samples, Residues ranged from <0.003-0.48 mg/kg in all other untreateds
		2) 05-25 Apr 19							Whole plant	<0.003	0.05	<0.003	<0.01	7	
		3) 24 Jun 19							Whole plant	<0.003	0.07	<0.01	<0.01	14	
									Whole plant	<0.003	0.08	<0.01	0.01	35	
									Seeds	<0.003	0.41/0.48**	<0.01	0.02/0.04**	53	

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline); DBLA = days before last application, DALA = days after last application

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg

### A 2.1.3.3.2 Study S20-01046 – NEU + SEU

Comments of zRMS:	<p>The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application. The conclusions of the assessment are presented below:</p> <p><i>Four residue trials on oilseed rape were conducted in northern Europe to determine residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio and TDMs.</i></p> <p><i>Oilseed rape was treated twice at application rate of 0.175 kg a.s./ha of prothioconazole with 14 days interval between applications. The time of application was</i></p> <ol style="list-style-type: none"> <li><i>1. at BBCH 65,</i></li> <li><i>2. at BBCH 69.</i></li> </ol> <p><i>Samples were taken 56-59 days after the final application at normal commercial harvest.</i></p> <p><i>The limit of quantification (LOQ) of the analytical methods were 0.01 mg/kg for each analyte/matrix with a limit of detection (LOD) set at 0.003 mg/kg.</i></p> <p><i>The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev. 1.</i></p> <p><i>Maximum storage period – 420 days.</i></p> <p><i>Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio in oilseed rape grain at harvest were between &lt;0.003 and 0.02 mg/kg.</i></p> <p><i>Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest ranged between &lt;0.06 and 0.07 mg/kg.</i></p> <p><i>Residues of 1,2,4-triazole in oilseed rape grain at harvest were &lt; 0.003 mg/kg.</i></p> <p><i>Residues of triazole alanine in oilseed rape grain at harvest ranged between 0.43 and 1.4 mg/kg.</i></p> <p><i>Residues of triazole acetic acid in oilseed rape grain at harvest ranged between &lt;0.01 and 0.01 mg/kg.</i></p> <p><i>Residues of triazole lactic acid in oilseed rape grain at harvest were between 0.03 and 0.04 mg/kg.</i></p> <p><i>The study is acceptable.</i></p>
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Reference:	KCA 6.3.3/02
Report	<p>Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole 250EC in Oilseed rape (outdoor) at 4 sites in Northern Europe and 4 sites in Southern Europe 2020</p> <p>North, L., 2021</p> <p>Report No: S20-01046</p>
Guideline(s):	<p>OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32)</p> <p>OECD Test Guideline 509: Crop field trials</p> <p>OECD (2016) Guidance Document ENV/JM/MONO (2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)</p> <p>EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials</p> <p>European Community Guideline SANCO 7525/VI/95, Rev. 10.3, 13/06/17: Comparability, extrapolation, group tolerances and data requirements for setting MRLs)</p>
Deviations:	S20-01046-01: seed samples could not be taken as the grower had combined through the trial. Therefore no seeds samples were available for analysis. (No

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	impact on other results)
GLP:	Yes
Owner:	Nufarm Crop Products UK
Acceptability:	Yes

### Materials and Methods

Eight residue trials were conducted on oilseed rape during 2020, two in the United Kingdom (S20-01046-01, -09), one in Germany (S20-01046-02), two in France (S20-01046-03, -05), one in Spain (S20-01046-06) and two in Italy (S20-01046-07, -08). Two applications of NUL 3390 Prothioconazole 250 EC (250 g/L, Prothioconazole) were applied at 175 g ai/ha, diluted with water immediately prior to application to a spray volume of 100-400 L/ha.

Samples of oilseed rape from the untreated and treated plots were taken by hand 0 (0DAA2), 7 (7DAA2), 14 (14DAA2), 35 (35DAA2) and 56/59 (56DAA2 – NCH) days after the final application, with the exception of trial S20-01046-01, where samples at 56DAA2 were not available. Samples were frozen within a maximum of 9 hours after sampling.

Oilseed rape whole plant and seed samples were analysed for residues of prothioconazole (PTZ) and prothioconazole-desthio (PTZ-desthio) using multi-residue method QuEChERS as validated for oilseed rape (seeds) in Eurofins study S16-04434. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The maximum period between sampling and last extraction was 420 days for whole plant samples and 127 days for seed samples. The maximum period between last extraction and last analysis was 1 day for whole plant samples and 2 days for seed samples.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ). The analytes were fortified jointly and quantified separately. For prothioconazole the LOQ is expressed as PTZ-desthio.

Oilseed rape whole plant and seed samples were analysed for residues of PTZ- $\alpha$ -hydroxy-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, and PTZ-6-hydroxy-desthio using Eurofins Agrosience Services method which was validated for oilseed rape (seeds) in study S16-04435. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry (LC-MS/MS).

The maximum period between sampling and last extraction was 420 days for whole plant samples and 126 days for seed samples. The maximum period between last extraction and last analysis was 10 days for whole plant samples and 1 day for seed samples.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ). The analytes were fortified jointly and quantified separately. For PTZ- $\alpha$ -hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio the LOQ is expressed as PTZ-desthio.

Oilseed rape whole plant and seed samples were analysed for residues of 1,2,4-Triazole (T), Triazole Alanine (TA), Triazole Acetic Acid (TAA) and Triazole Lactic Acid (TLA) using Eurofins Agrosience Services method which was validated for oilseed rape (seeds) in study S15-03542. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry and SelexION Differential Mobility Separation (LC-DMS/MS/MS).

The maximum period between sampling and last extraction was 420 days for whole plant samples and 73 days for seed samples. The maximum period between last extraction and last analysis was 3 days for whole plant samples and 4 days for seed samples.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ). The analytes were fortified jointly and quantified separately.

Reduced validations of the methods were performed during analysis for oilseed rape (whole plant and seeds). Recovery levels for fortified untreated sub-samples (of each crop matrix) are reported in the table below.

#### Procedural Recoveries

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

Fortifications of prothioconazole and PTZ-desthio were performed at the level of 0.01 mg/kg, 0.1 mg/kg for oilseed rape (whole plant and seeds) and up to 4.0 mg/kg for oilseed rape (whole plant) and were thus at or above the highest residue level found in a sample.

Fortifications of PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, and -5- and -6-hydroxy-desthio were performed at the level of 0.01 mg/kg, 0.1 mg/kg for oilseed rape (whole plant and seeds) and up to 0.5 mg/kg for oilseed rape (whole plant) and were thus at or above the highest residue level found in a sample.

Fortifications of TDMs 1,2,4-Triazole, TA, TAA and TLA were performed at the level of 0.01 mg/kg, 0.1 mg/kg oilseed rape (whole plant and seeds) and up to 0.5 mg/kg for oilseed rape (whole plant) and up to 2.0 mg/kg for oilseed rape (seeds) and were thus at or above the highest residue level found in a sample.

The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 60 - 120 % and the mean recoveries at each fortification level were in the range of 70 – 110 % with relative standard deviation(s) below 20 % for all combinations of matrices and analytes.

Untreated and treated samples received a single assay. The residue levels found in oilseed rape are summarised in the table below.

Table A 87: Summary of the study S20-01046 trials

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble 11 rue West du  
92700 France  
United Kingdom  
250  
EC

Commercial Product (name):  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
Outdoor  
None  
Prothioconazole, PTZ-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*) Prothioconazole PTZ-desthio		10 PHI (days)  (f)	11 Remarks  (g)
	(a)			g as/hL	Water (L/ha)	g a.s./ha							
S20-01046-01 L40 6HE, Lathom, Lancashire, United Kingdom NEU	Oilseed rape / BRSNN / Ramses	1) 09 Sep 2019 2) 03 Apr 2020 - 25 May 2020 3) Not taken	Overall foliar with boom plot sprayer	58 59	315 299	184 175	20 May 2020 04 Jun 2020	69-73 75	Whole plant Whole plant Whole plant Whole plant	0.68 0.07 0.02 <0.01	1.0 0.36 0.19 0.06	0 7 14 35	No residues >LOQ were found in any untreated samples

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg



RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Prothioconazole	Commercial Product (name):	NUL 3390
Crop/crop group:	Oilseed rape / Oilseeds	Producer of commercial product:	Prothioconazole 250EC
Responsible body for reporting (name, address)	Nufarm Immeuble 11 rue West du 92700 France	SAS, Plaza Débarcadère Colombes	Nufarm Australia Limited
Country (of trial sites):	United Kingdom	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/L):	250	Other active substance in the formulation (common name and content):	None
Formulation (e.g. WP):	EC	Residues calculated as:	PTZ- $\alpha$ -OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)			10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- $\alpha$ -OH- desthio	PTZ-3-OH- desthio	PTZ-4-OH- desthio		
S20-01046-01 L40 6HE, Lathom, Lancashire, United Kingdom NEU	Oilseed rape / BRSNN / Ramses	1) 09 Sep 2019	Overall foliar with boom plot sprayer	58	315	184	20 May 2020 04 Jun 2020	69-73 75	Whole plant Whole plant Whole plant Whole plant	<0.01	0.06	0.03	0	No residues >LOQ were found in any untreated samples
		2) 03 Apr 2020 - 25 May 2020		59	299	175				<0.01	0.09	0.04	7	
		3) Not taken								<0.01	0.13	0.04	14	
										<0.003 n.d.	0.09	0.02	35	

- (a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Prothioconazole	Commercial Product (name):	NUL 3390
Crop/crop group:	Oilseed rape / Oilseeds	Producer of commercial product:	Prothioconazole 250EC
Responsible body for reporting (name, address)	Nufarm Immeuble 11 rue du 92700 France	SAS, Plaza Débarcadère Colombes	Nufarm Australia Limited
Country (of trial sites):	United Kingdom	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/L):	250	Other active substance in the formulation (common name and content):	None
Formulation (e.g. WP):	EC	Residues calculated as:	PTZ-5-OH-desthio, PTZ-6-OH-desthio (mg/kg)

1	2	3	4	5			6	7	8	9			10	11
Report No. Location (region)	Commodity/Variety  (a)	Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	Method of Treatment  (c)	Application rate per treatment			Dates of treatment(s) or no. of treatment(s) and last date  (d)	Growth stage at last treatment or date  (e) BBCH	Portion analysed  (a)	Residues (mg/kg)  (*)			PHI (days)  (f)	Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-5-OH-desthio	PTZ-6-OH-desthio	Total (PTZ-desthio+hydroxy=RD-RA1)*		
S20-01046-01 L40 6HE, Lathom, Lancashire, United Kingdom NEU	Oilseed rape / BRSNN / Ramses	1)09 Sep 2019 2)03 Apr 2020 - 25 May 2020 3)Not taken	Overall foliar with boom plot sprayer	58 59	315 299	184 175	20 May 2020 04 Jun 2020	69-73 75	Whole plant Whole plant Whole plant Whole plant	<0.01 0.01 0.01 <0.01	<0.003 n.d. <0.01 <0.003 n.d.	1.11 0.52 0.39 0.19	0 7 14 35	No residues >LOQ were found in any untreated samples

(a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
United Kingdom  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
SAS,  
Plaza  
Débarcadère  
Colombes  
  
Outdoor  
None  
  
1,2,4-Triazole, Triazole alanine (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)		10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4-Triazole	Triazole alanine		
S20-01046-01 L40 6HE, Lathom, Lancashire, United Kingdom NEU	Oilseed rape / BRSNN / Ramses	1) 09 Sep 2019 2) 03 Apr 2020 - 25 May 2020 3) Not taken	Overall foliar with boom plot sprayer	58	315	184	20 May 2020 04 Jun 2020	69-73 75	Whole plant	<0.003 n.d.	0.16	0	No residues >LOQ were found in any untreated 1,2,4- Triazole samples, triazole alanine samples were 0.17-0.31 mg/kg
				59	299	175			Whole plant	<0.003 n.d.	0.14	7	
									Whole plant	<0.003 n.d.	0.19	14	
									Whole plant	<0.003 n.d.	0.21	35	

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
United Kingdom  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
Outdoor  
None  
  
Triazole acetic acid, Triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)		10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				Triazole acetic acid	Triazole lactic acid		
S20-01046-01 L40 6HE, Lathom, Lancashire, United Kingdom NEU	Oilseed rape / BRSNN / Ramses	1) 09 Sep 2019	Overall foliar with boom plot sprayer	58	315	184	20 May 2020 04 Jun 2020	69-73 75	Whole plant	<0.01	<0.01	0	No residues >LOQ were found in any untreated samples except 35 DAA 0.01 mg/kg triazole lactic acid
		2) 03 Apr 2020		59	299	175			Whole plant	<0.01	<0.01	7	
		- 25 May 2020							Whole plant	<0.01	<0.01	14	
		3) Not taken							Whole plant	<0.01	<0.01	35	

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
Germany  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
Outdoor  
None  
  
Prothioconazole, PTZ-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)		10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				Prothioconazole	PTZ-desthio		
S20-01046-02 21228, Harmstorf, Niedersachsen, Germany NEU	Oilseed rape / BRSNN / Alvaro KWS	1) 11 Sep 2019 2) Not applicable 3) 27 Jul 2020	Overall foliar with boom plot sprayer	59	294	172	15 May 2020 29 May 2020	65	Whole plant	0.36	0.57	0	No residues >LOQ were found in any untreated samples
				58	293	171		69	Whole plant	0.03	0.27	7	
									Whole plant	0.02	0.10	14	
									Whole plant Seeds	<0.01 <0.003 n.d.	0.06 <u>0.02</u>	35 59	

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
Germany  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
Outdoor  
None  
  
PTZ- $\alpha$ -OH-desthio, PTZ-3-OH-desthio,  
PTZ-4-OH-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)			10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- $\alpha$ -OH- desthio	PTZ-3- OH- desthio	PTZ-4-OH- desthio		
S20-01046-02 21228, Harmstorf, Niedersachsen, Germany NEU	Oilseed rape / BRSNN / Alvaro KWS	1) 11 Sep 2019 2)Not applicable 3) 07 Jul 2020	Overall foliar with boom plot sprayer	59	294	172	15 May 2020 29 May 2020	65 69	Whole plant	<0.01	0.04	0.01	0	No residues >LOQ were found in any untreated samples
				58	293	171			Whole plant	<0.01	0.09	0.03	7	
									Whole plant	<0.01	0.09	0.03	14	
									Whole plant	<0.01	0.14	0.03	35	
									Seeds	<0.01	0.02	<0.01	59	

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Prothioconazole	Commercial Product (name):	NUL 3390
Crop/crop group:	Oilseed rape / Oilseeds	Producer of commercial product:	Prothioconazole 250EC
Responsible body for reporting (name, address)	Nufarm Immeuble West 11 rue du Débarcadère 92700 Colombes France		Nufarm Australia Limited
Country (of trial sites):	Germany	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/L):	250	Other active substance in the formulation (common name and content):	None
Formulation (e.g. WP):	EC	Residues calculated as:	PTZ-5-OH-desthio, PTZ-6-OH-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)			10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-5- OH- desthio	PTZ-6- OH- desthio	Total desthio+hydroxy=RD- RA1)*		
S20-01046-02 21228, Harmstorf, Niedersachsen, Germany NEU	Oilseed rape / BRSNN / Alvaro KWS	1)11 Sep 2019 2)Not applicable 3)27 Jul 2020	Overall foliar with boom plot sprayer	59 58	294 293	172 171	15 May 2020 29 May 2020	65 69	Whole plant	<0.01	<0.003	0.64	0	No residues >LOQ were found in any untreated samples
									Whole plant	<0.01	n.d.	0.42	7	
									Whole plant	<0.01	<0.01	0.24	14	
									Whole plant	0.01	<0.003	0.25	35	
									Seeds	<0.01	n.d.	0.07	59	
											<0.003 n.d. <0.003 n.d.			

(a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **Prothioconazole** Commercial Product (name): **NUL 3390**  
Crop/crop group: **Oilseed rape / Oilseeds** Producer of commercial product: **Prothioconazole 250EC**  
Responsible body for reporting (name, address): **Nufarm Immeuble 11 rue du Débarcadère Colombes SAS, Plaza**  
Country (of trial sites): **France Germany** Indoor/Glasshouse/Outdoor: **Outdoor**  
Content of active substance nominal (g/L): **250** Other active substance in the formulation (common name and content): **None**  
Formulation (e.g. WP): **EC** Residues calculated as: **1,2,4-Triazole, Triazole alanine (mg/kg)**

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)		10 PHI (days) (f)	11 Remarks (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4-Triazole	Triazole alanine		
S20-01046-02 21228, Harmstorf, Niedersachsen, Germany NEU	Oilseed rape / BRSNN / Alvaro KWS	1) 11 Sep 2019 2) Not applicable 3) 27 Jul 2020	Overall foliar with boom plot sprayer	59 58	294 293	172 171	15 May 2020 29 May 2020	65 69	Whole plant Whole plant Whole plant Whole plant Seeds	<0.003 n.d. <0.003 n.d. <0.003 n.d. <0.003 n.d. <0.003 n.d.	0.04 0.05 0.06 0.08 <u>0.43/0.28**</u>	0 7 14 35 59	No residues >LOQ were found in any untreated 1,2,4- Triazole samples, triazole alanine samples were 0.03-0.28 mg/kg

(a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable



RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
Germany  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
Outdoor  
None  
  
Triazole acetic acid, Triazole lactic acid  
(mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*) Triazole acetic acid Triazole lactic acid		10 PHI (days)  (f)	11 Remarks  (g)
S20-01046-02 21228, Harmstorf, Niedersachsen, Germany NEU	Oilseed rape / BRSNN / Alvaro KWS	1) 11 Sep 2019 2) Not applicable 3) 27 Jul 2020	Overall foliar with boom plot sprayer	59 58	294 293	172 171	15 May 2020 29 May 2020	65 69	Whole plant Whole plant Whole plant Whole plant Seeds	<0.003 n.d. <0.003 n.d. <0.003 n.d. <0.01 <u>&lt;0.01</u>	<0.003 n.d. <0.003 n.d. <0.01 0.01 <u>0.03/0.01**</u>	0 7 14 35 59	No residues >LOQ were found in any untreated samples except 0.01 mg/kg triazole lactic acid seed sample

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated  
\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):ProthioconazoleCommercial Product (name):NUL 3390

Crop/crop group:Oilseed rape / OilseedsProducer of commercial product:Prothioconazole 250EC

Responsible body for reporting (name, address):Nufarm Immeuble 11 rue West du Débarcadère ColombesSAS, Plaza

Country (of trial sites):FranceIndoor/Glasshouse/Outdoor:Outdoor

Content of active substance nominal (g/L):250Other active substance in the formulation (common name and content):None

Formulation (e.g. WP):ECResidues calculated as:Prothioconazole, PTZ-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*) Prothioconazole PTZ-desthio		10 PHI (days)  (f)	11 Remarks  (g)
	(a)			g as/hL	Water (L/ha)	g a.s./ha							
S20-01046-03 67140, Stotzheim, Bas-Rhin / Alsace, France NEU	Oilseed rape / BRSNN / Exclamation 90% / Ginfizz 10%	1) 20 Aug	Overall foliar with boom plot sprayer	58	307	179	23 Apr 2020 07 May 2020	67	Whole plant	0.63	0.95	0	No residues >LOQ were found in any untreated samples
		2019		70	236	165		76	Whole plant	0.05	0.32	7	
		2) 09 Apr 2020							Whole plant	0.02	0.18	14	
		- 27 Apr 2020							Whole plant	<0.01	0.06	35	
		3) 02 Jul 2020							Seeds	<0.003 n.d.	0.01	56	

(a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11  
92700  
France  
France  
250  
  
EC

West  
du

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
Outdoor  
None  
  
PTZ- $\alpha$ -OH-desthio, PTZ-3-OH-desthio,  
PTZ-4-OH-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)			10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- $\alpha$ -OH- desthio	PTZ-3-OH- desthio	PTZ-4-OH- desthio		
S20-01046-03 67140, Stotzheim, Bas-Rhin / Alsace, France NEU	Oilseed rape / BRSNN / Exclamation 90% / Ginfizz 10%	1) 20 Aug 2019 2) 09 Apr 2020 - 27 Apr 2020 3) 02 Jul 2020	Overall foliar with boom plot sprayer	58 70	307 236	179 165	23 Apr 2020 07 May 2020	67 76	Whole plant Whole plant Whole plant Whole plant Seeds	<0.01 <0.01 <0.01 <0.01 <0.01	0.04 0.08 0.11 0.14 0.02	0.02 0.03 0.04 0.05 <0.01	0 7 14 35 56	No residues >LOQ were found in any untreated samples

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
France  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation  
(common name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
  
Outdoor  
None  
  
PTZ-5-OH-desthio, PTZ-6-OH-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)			10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-5- OH- desthio	PTZ-6- OH- desthio	Total desthio+hydroxy=RD- RA1)*		
S20-01046-03 67140, Stotzheim, Bas-Rhin / Alsace, France NEU	Oilseed rape / BRSNN / Exclamation 90% / Ginfizz 10%	1) 20 Aug 2019	Overall foliar with boom plot sprayer	58 70	307 236	179 165	23 Apr 2020 07 May 2020	67 76	Whole plant	<0.01	<0.003	1.03	0	No residues >LOQ were found in any untreated samples
		2) 09 Apr 2020							Whole plant	<0.01	n.d.	0.46	7	
		- 27 Apr 2020							Whole plant	0.01	<0.01	0.36	14	
		3) 02 Jul 2020							Whole plant	0.01	<0.01	0.28	35	
									Seeds	<0.01	<0.01 <0.003	0.06	56	

- (a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated
- (e)  
(f)  
(g)  
(\*)
- BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **Prothioconazole** Commercial Product (name): **NUL 3390**  
Crop/crop group: **Oilseed rape / Oilseeds** Producer of commercial product: **Prothioconazole 250EC**  
Responsible body for reporting (name, address): **Nufarm Immeuble 11 rue du Débarcadère Colombes SAS, Plaza**  
Country (of trial sites): **France** Indoor/Glasshouse/Outdoor: **Outdoor**  
Content of active substance nominal (g/L): **250** Other active substance in the formulation (common name and content): **None**  
Formulation (e.g. WP): **EC** Residues calculated as: **1,2,4-Triazole, Triazole alanine (mg/kg)**

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)		10 PHI (days) (f)	11 Remarks (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4-Triazole	Triazole alanine		
S20-01046-03 67140, Stotzheim, Bas-Rhin / Alsace, France NEU	Oilseed rape / BRSNN / Exclamation 90% / Ginfizz 10%	1) 20 Aug 2019	Overall foliar with boom plot sprayer	58	307	179	23 Apr 2020 07 May 2020	67	Whole plant	<0.003 n.d.	0.36	0	No residues >LOQ were found in any untreated 1,2,4- Triazole samples, triazole alanine samples were 0.11-0.97 mg/kg
		2) 09 Apr 2020		70	236	165		76	Whole plant	<0.003 n.d.	0.24	7	
		- 27 Apr 2020							Whole plant	<0.003 n.d.	0.26	14	
		3) 02 Jul 2020							Whole plant Seeds	<0.003 n.d. <u>&lt;0.003 n.d.</u>	0.43 <u>1.4/0.97**</u>	35 56	

(a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Prothioconazole	Commercial Product (name):	NUL 3390
Crop/crop group:	Oilseed rape / Oilseeds	Producer of commercial product:	Prothioconazole 250EC
Responsible body for reporting (name, address)	Nufarm Immeuble 11 rue du West du Débarcadère Colombes		Nufarm Australia Limited
Country (of trial sites):	France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/L):	250	Other active substance in the formulation (common name and content):	None
Formulation (e.g. WP):	EC	Residues calculated as:	Triazole acetic acid, Triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)		10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				Triazole acetic acid	Triazole lactic acid		
S20-01046-03 67140, Stotzheim, Bas-Rhin / Alsace, France NEU	Oilseed rape / BRSNN / Exclamation 90% / Ginfizz 10%	1)20 Aug 2019 2)09 Apr 2020 - 27 Apr 2020 3)02 Jul 2020	Overall foliar with boom plot sprayer	58 70	307 236	179 165	23 Apr 2020 07 May 2020	67 76	Whole plant Whole plant Whole plant Whole plant Seeds	0.01 <0.01 0.01 0.03 <u>0.01</u>	0.02 0.01 0.02 0.08 <u>0.04/0.02**</u>	0 7 14 35 56	No residues >LOQ were found in any untreated samples except <0.01-0.02 mg/kg triazole lactic acid samples

(a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
France  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
SAS,  
Plaza  
Débarcadère  
Colombes  
  
Outdoor  
None  
  
Prothioconazole, PTZ-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)		10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				Prothioconazole	PTZ-desthio		
S20-01046-05 82700, Saint- Porquier, Tarn-et- Garonne, France SEU	Oilseed rape / BRSNN / Cadran	1) 29 Aug 2020	Overall foliar with boom plot sprayer	58	302	176	17 Apr 2020 30 Apr 2020	67-72 69-73	Whole plant Whole plant Whole plant Seeds	0.55	0.80	0	No residues >LOQ were found in any untreated samples
		2) 20 Mar 2020 - 20 Apr 2020		58	293	171				0.01	0.25	7	
		3) 25 Jun 2020								<0.01	0.09	14	
										<0.01	0.06	35	
										<0.003 n.d.	0.02	56	

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Prothioconazole	Commercial Product (name):	NUL 3390
Crop/crop group:	Oilseed rape / Oilseeds	Producer of commercial product:	Prothioconazole 250EC
Responsible body for reporting (name, address)	Nufarm Immeuble 11 rue du West du Débarcadère Colombes		Nufarm Australia Limited
Country (of trial sites):	France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/L):	250	Other active substance in the formulation (common name and content):	None
Formulation (e.g. WP):	EC	Residues calculated as:	PTZ- $\alpha$ -OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)			10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- $\alpha$ -OH- desthio	PTZ-3-OH- desthio	PTZ-4-OH- desthio		
S20-01046-05 82700, Saint- Porquier, Tarn-et- Garonne, France SEU	Oilseed rape / BRSNN / Cadran	1) 29 Aug 2020	Overall foliar with boom plot sprayer	58	302	176	17 Apr 2020 30 Apr 2020	67-72 69-73	Whole plant	<0.01	0.03	0.02	0	No residues >LOQ were found in any untreated samples
		2) 20 Mar 2020 - 20 Apr 2020		58	293	171			Whole plant	<0.01	0.12	0.05	7	
		3) 25 Jun 2020							Whole plant	<0.01	0.11	0.05	14	
									Whole plant	<0.01	0.21	0.06	35	
									Seeds	<0.01	0.03	<0.01	56	

- (a) According to EEC and Codex classifications (both) should be used
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
- (f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
- (g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
- (\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable



RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
France  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation  
(common name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
  
Outdoor  
None  
  
PTZ-5-OH-desthio, PTZ-6-OH-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)			10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-5- OH- desthio	PTZ-6- OH- desthio	Total desthio+hydroxy=RD- RA1)*		
S20-01046-05 82700, Saint-Porquier, Tarn-et-Garonne, France SEU	Oilseed rape / BRSNN / Cadran	1) 29 Aug 2020	Overall foliar with boom plot sprayer	58 58	302 293	176 171	17 Apr 2020 30 Apr 2020	67-72 69-73	Whole plant	<0.01	<0.003	0.87	0	No residues >LOQ were found in any untreated samples
		2) 20 Mar 2020 - 20 Apr 2020							Whole plant	0.02	n.d.	0.46	7	
		3) 25 Jun 2020							Whole plant	0.01	<0.01	0.28	14	
									Whole plant	0.01	<0.01	0.36	35	
									Seeds	<0.01	<0.01	0.08	56	

- (a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
France  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
Outdoor  
None  
  
1,2,4-Triazole, Triazole alanine (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date	8 Portion analysed	9 Residues (mg/kg)		10 PHI (days)	11 Remarks
(a)	(b)	(c)		g as/hL	Water (L/ha)	g a.s./ha	(d)	(e) BBCH	(a)	1,2,4-Triazole	(*) Triazole alanine	(f)	(g)
S20-01046-05 82700, Saint- Porquier, Tarn-et- Garonne, France SEU	Oilseed rape / BRSNN / Cadran	1) 29 Aug 2020	Overall foliar with boom plot sprayer	58	302	176	17 Apr 2020 30 Apr 2020	67-72 69-73	Whole plant	<0.003 n.d.	0.26	0	No residues >LOQ were found in any untreated 1,2,4- Triazole samples, triazole alanine samples were 0.29-1.6 mg/kg
		2) 20 Mar 2020 - 20 Apr 2020		58	293	171			Whole plant	<0.003 n.d.	0.46	7	
		3) 25 Jun 2020							Whole plant	<0.003 n.d.	0.29	14	
									Whole plant	<0.003 n.d.	0.34	35	
									Seeds	<0.003 n.d.	1.8/1.6**	56	

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated  
\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Prothioconazole	Commercial Product (name):	NUL 3390
Crop/crop group:	Oilseed rape / Oilseeds	Producer of commercial product:	Prothioconazole 250EC
Responsible body for reporting (name, address)	Nufarm Immeuble 11 rue West du 92700 France	SAS, Plaza Débarcadère Colombes	Nufarm Australia Limited
Country (of trial sites):	France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/L):	250	Other active substance in the formulation (common name and content):	None
Formulation (e.g. WP):	EC	Residues calculated as:	Triazole acetic acid, Triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)		10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				Triazole acetic acid	Triazole lactic acid		
S20-01046-05 82700, Saint- Porquier, Tarn-et- Garonne, France SEU	Oilseed rape / BRSNN / Cadran	1)29 Aug 2020	Overall foliar with boom plot sprayer	58	302	176	17 Apr 2020 30 Apr 2020	67-72 69-73	Whole plant	<0.01	<0.01	0	Residues in untreated samples were 0.01-0.03 mg/kg triazole acetic acid & 0.02-0.08 mg/kg triazole lactic acid
		2)20 Mar 2020		58	293	171			Whole plant	0.01	0.02	7	
		- 20 Apr 2020							Whole plant	<0.01	0.02	14	
									Whole plant	0.02	0.05	35	
		3)25 Jun 2020							Seeds	0.02/0.02**	0.08/0.08**	56	

(a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **Prothioconazole** Commercial Product (name): **NUL 3390**  
Crop/crop group: **Oilseed rape / Oilseeds** Producer of commercial product: **Prothioconazole 250EC**  
Responsible body for reporting (name, address): **Nufarm Immeuble 11 rue du West Débarcadère Colombes SAS, Plaza**  
Country (of trial sites): **France** Indoor/Glasshouse/Outdoor: **Outdoor**  
Content of active substance nominal (g/L): **Spain 250** Other active substance in the formulation (common name and content): **None**  
Formulation (e.g. WP): **EC** Residues calculated as: **Prothioconazole, PTZ-desthio (mg/kg)**

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)		10 PHI (days) (f)	11 Remarks (g)
				g as/hL	Water (L/ha)	g a.s./ha				Prothioconazole	PTZ-desthio		
S20-01046-06 44492, Fonfria, Aragon, Spain SEU	Oilseed rape / BRSNN / Expression	1) 01 Oct 2019 2) Not applicable 3) 16 Jul 2020	Overall foliar with boom plot sprayer	87	206	180	07 May 2020 21 May 2020	65-69 69-71	Whole plant Whole plant Whole plant Seeds	0.31 0.02 <0.01 <0.003 n.d. <0.003 n.d.	0.54 0.28 0.05 <0.003 n.d. 0.01	0 7 14 35 56	No residues >LOQ were found in any untreated samples except whole plant at 35 DAA <0.01- 0.01 mg/kg PTZ & 0.03-0.07 mg/kg PTZ- desthio#

(a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

# The distribution of residue results between treated and untreated samples of sampling S4 (whole plant at 35 DAA2) indicates an incorrect assignment of sample labels. In all earlier samplings, the control samples showed no residues and the residues in treated samples showed a plausible decline. For S4 (35 DAA2) the sample from the control plot showed residues above the level of the treated sample. Therefore, the retain samples S20-01046-06-007R1 and -008R1 were analysed upon request of the study director. Their analysis confirmed the first results.

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Prothioconazole	Commercial Product (name):	NUL 3390
Crop/crop group:	Oilseed rape / Oilseeds	Producer of commercial product:	Prothioconazole 250EC
Responsible body for reporting (name, address)	Nufarm Immeuble 11 rue West du 92700 France Spain	SAS, Plaza Débarcadère Colombes	Nufarm Australia Limited
Country (of trial sites):	Spain	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/L):	250	Other active substance in the formulation (common name and content):	None
Formulation (e.g. WP):	EC	Residues calculated as:	PTZ- $\alpha$ -OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)  PTZ- $\alpha$ -OH-desthio   PTZ-3-OH-desthio   PTZ-4-OH-desthio			10 PHI (days)  (f)	11 Remarks  (g)
(a)				g as/hL	Water (L/ha)	g a.s./ha								
S20-01046-06 44492, Fonfria, Aragon, Spain SEU	Oilseed rape / BRSNN / Expression	1) 01 Oct 2019	Overall foliar with boom plot sprayer	87	206	180	07 May 2020 21 May 2020	65-69 69-71	Whole plant	<0.01	0.06	0.02	0	No residues >LOQ were found in any untreated samples, except 35 DAA whole plants, 0.09- 0.11 mg/kg PTZ3 & 0.02 mg/kg PTZ 4
		2) Not applicable		87	197	172			Whole plant	<0.01	0.09	0.04	7	
		3) 16 Jul 2020							Whole plant	<0.003 n.d.	0.06	0.02	14	
									Whole plant	<0.003 n.d.	<0.003 n.d.	<0.003 n.d.	35	
									Seeds	<0.01	0.02	<0.01	56	

(a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
Spain  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation  
(common name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
Outdoor  
None  
  
PTZ-5-OH-desthio, PTZ-6-OH-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)			10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-5- OH- desthio	PTZ-6- OH- desthio	Total desthio+hydroxy=RD- RA1)*		
S20-01046-06 44492, Fonfria, Aragon, Spain SEU	Oilseed rape / BRSNN / Expression	1) 01 Oct 2019 2) Not applicable 3) 16 Jul 2020	Overall foliar with boom plot sprayer	87	206	180	07 May 2020 21 May 2020	65-69 69-71	Whole plant	<0.01	<0.003	0.64	0	No residues >LOQ were found in any untreated samples
				87	197	172			Whole plant	0.01	n.d.	0.44	7	
									Whole plant	<0.01	<0.01	0.15	14	
									Whole plant	<0.003	<0.003	<0.06	35	
									Seeds	n.d.	n.d.	0.06	56	
										<0.01	<0.003			
										n.d.	n.d.			
										<0.003				
										n.d.				

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e)  
(f)  
(g)  
(\*)

BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **Prothioconazole** Commercial Product (name): **NUL 3390**  
Crop/crop group: **Oilseed rape / Oilseeds** Producer of commercial product: **Prothioconazole 250EC**  
Responsible body for reporting (name, address): **Nufarm Immeuble 11 rue du West Débarcadère Colombes**  
Country (of trial sites): **France** Indoor/Glasshouse/Outdoor: **Outdoor**  
Content of active substance nominal (g/L): **Spain 250** Other active substance in the formulation (common name and content): **None**  
Formulation (e.g. WP): **EC** Residues calculated as: **1,2,4-Triazole, Triazole alanine (mg/kg)**

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)		10 PHI (days) (f)	11 Remarks (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4-Triazole	Triazole alanine		
S20-01046-06 44492, Fonfria, Aragon, Spain SEU	Oilseed rape / BRSNN / Expression	1) 01 Oct 2019 2) Not applicable 3) 16 Jul 2020	Overall foliar with boom plot sprayer	87	206	180	07 May 2020 21 May 2020	65-69 69-71	Whole plant	<0.003 n.d.	0.06	0	No residues >LOQ were found in any untreated 1,2, triazole samples, triazole alanine samples were 0.04-0.21 mg/kg
				87	197	172			Whole plant	<0.003 n.d.	0.05	7	
									Whole plant	<0.003 n.d.	0.10	14	
									Whole plant Seeds	<0.003 n.d. <0.003 n.d.	0.05 0.76/0.21**	35 56	

(a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):

Crop/crop group:

Responsible body for reporting  
(name, address)

Country (of trial sites):

Content of active substance nominal (g/L):

Formulation (e.g. WP):

Prothioconazole

Oilseed rape / Oilseeds

Nufarm

Immeuble

11

92700

France

Spain

250

EC

Commercial Product (name):

Producer of commercial product:

Indoor/Glasshouse/Outdoor:

Other active substance in the formulation (common name and content):

Residues calculated as:

NUL 3390

Prothioconazole 250EC

Nufarm Australia Limited

Outdoor

None

Triazole acetic acid, Triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)		10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				Triazole acetic acid	Triazole lactic acid		
S20-01046-06 44492, Fonfria, Aragon, Spain SEU	Oilseed rape / BRSNN / Expression	1) 01 Oct 2019 2) Not applicable 3) 16 Jul 2020	Overall foliar with boom plot sprayer	87	206	180	07 May 2020 21 May 2020	65-69 69-71	Whole plant	<0.003 n.d.	<0.003 n.d.	0	No residues >LOQ were found in any untreated samples
				87	197	172			Whole plant	<0.003 n.d.	<0.003 n.d.	7	
									Whole plant	<0.003 n.d.	<0.01	14	
									Whole plant	<0.01-<0.003 n.d.	<0.01	35	
									Seeds	<0.01	0.02	56	

(a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable



RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
Italy  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
SAS,  
Plaza  
Débarcadère  
Colombes  
  
Outdoor  
None  
  
Prothioconazole, PTZ-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)		10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				Prothioconazole	PTZ-desthio		
S20-01046-07 40057, Granarolo Emilia, Emilia Romagna, Italy SEU	Oilseed rape / BRSNN / Sensei	1) 19 Oct 2019 2) 01 Apr 2020 -29 Apr 2020 3) 10 Jun 2020	Overall foliar with boom plot sprayer	44	380	166	01 Apr 2020 15 Apr 2020	61	Whole plant	0.32	1.0	0	No residues >LOQ were found in any untreated samples
				44	363	159		65	Whole plant	0.03	0.76	7	
									Whole plant	0.01	0.26	14	
									Whole plant Seeds	<0.003 n.d. <0.003 n.d.	<0.01 <0.003 n.d.	35 56	

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
Italy  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
Outdoor  
None  
  
PTZ- $\alpha$ -OH-desthio, PTZ-3-OH-desthio,  
PTZ-4-OH-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)			10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- $\alpha$ -OH- desthio	PTZ-3-OH- desthio	PTZ-4-OH- desthio		
S20-01046-07 40057, Granarolo Emilia, Emilia Romagna, Italy SEU	Oilseed rape / BRSNN / Sensei	1) 19 Oct 2019	Overall foliar with boom plot sprayer	44	380	166	01 Apr 2020 15 Apr 2020	61 65	Whole plant Whole plant Whole plant Whole plant Seeds	<0.003 n.d.	0.04	0.02	0	No residues >LOQ were found in any untreated samples
		2) 01 Apr 2020 -29 Apr 2020		44	363	159				<0.01	0.10	0.04	7	
		3) 10 Jun 2020								<0.003 n.d.	0.07	0.03	14	
										<0.003 n.d.	0.04	<0.01	35	
										<0.003 n.d.	<0.003 n.d.	<0.003 n.d.	56	

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Prothioconazole	Commercial Product (name):	NUL 3390
Crop/crop group:	Oilseed rape / Oilseeds	Producer of commercial product:	Prothioconazole 250EC
Responsible body for reporting (name, address)	Nufarm Immeuble 11 rue du Débarcadère Colombes		Nufarm Australia Limited
Country (of trial sites):	Italy	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/L):	250	Other active substance in the formulation (common name and content):	None
Formulation (e.g. WP):	EC	Residues calculated as:	PTZ-5-OH-desthio, PTZ-6-OH-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)			10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-5- OH- desthio	PTZ-6- OH- desthio	Total desthio+hydroxy=RD- RA1)*		
S20-01046-07 40057, Granarolo Emilia, Emilia Romagna, Italy SEU	Oilseed rape / BRSNN / Sensei	1) 19 Oct 2019	Overall foliar with boom plot sprayer	44	380	166	01 Apr 2020 15 Apr 2020	61	Whole plant	<0.01	<0.003 n.d.	1.08	0	No residues >LOQ were found in any untreated samples
		2) 01 Apr 2020 -29 Apr 2020		44	363	159		65	Whole plant	0.01	<0.003 n.d.	0.92	7	
		3) 10 Jun 2020							Whole plant	<0.01	<0.003 n.d.	0.38	14	
									Whole plant	<0.003 n.d.	<0.003 n.d.	0.07	35	
									Seeds	<0.003 n.d.	<0.003 n.d.	<0.06	56	

(a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
Italy  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
Outdoor  
None  
  
1,2,4-Triazole, Triazole alanine (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)		10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4-Triazole	(*) Triazole alanine		
S20-01046-07 40057, Granarolo Emilia, Emilia Romagna, Italy SEU	Oilseed rape / BRSNN / Sensei	1) 19 Oct 2019 2) 01 Apr 2020 -29 Apr 2020 3) 10 Jun 2020	Overall foliar with boom plot sprayer	44	380	166	01 Apr 2020 15 Apr 2020	61	Whole plant	<0.003 n.d.	0.12	0	No residues >LOQ were found in any untreated 1,2, triazole samples, triazole alanine samples were 0.10-0.63 mg/kg
				44	363	159		65	Whole plant	<0.003 n.d.	0.15	7	
									Whole plant	<0.003 n.d.	0.10	14	
									Whole plant	<0.003 n.d.	0.11	35	
									Seeds	<0.003 n.d.	0.45/0.63**	56	

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated  
\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Prothioconazole	Commercial Product (name):	NUL 3390
Crop/crop group:	Oilseed rape / Oilseeds	Producer of commercial product:	Prothioconazole 250EC
Responsible body for reporting (name, address)	Nufarm Immeuble 11 rue du West du Débarcadère Colombes		Nufarm Australia Limited
Country (of trial sites):	France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/L):	Italy 250	Other active substance in the formulation (common name and content):	None
Formulation (e.g. WP):	EC	Residues calculated as:	Triazole acetic acid, Triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)		10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				Triazole acetic acid	Triazole lactic acid		
S20-01046-07 40057, Granarolo Emilia, Emilia Romagna, Italy SEU	Oilseed rape / BRSNN / Sensei	1) 19 Oct 2019	Overall foliar with boom plot sprayer	44	380	166	01 Apr 2020 15 Apr 2020	61	Whole plant	<0.003 n.d.	<0.01	0	No residues >LOQ were found in any untreated samples, except 0.03 mg/kg triazole lactic acid seed sample
		2) 01 Apr 2020		44	363	159		65	Whole plant	<0.01	<0.01	7	
		-29 Apr 2020							Whole plant	<0.003 n.d.	<0.01	14	
									Whole plant	<0.01	<0.01	35	
		3) 10 Jun 2020							Seeds	<0.01	0.02/0.03**	56	

(a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
Italy  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
SAS,  
Plaza  
Débarcadère  
Colombes  
  
Outdoor  
None  
  
Prothioconazole, PTZ-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)		10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				Prothioconazole	PTZ-desthio		
S20-01046-08 48124, Ravenna, Emilia Romagna, Italy SEU	Oilseed rape / BRSNN / PT 200 CL	1) 20 Sep 2019 2) 06 Apr 2020 - 30 Apr 2020 3) 16 Jun 2020	Overall foliar with boom plot sprayer	44	392	171	06 Apr 2020 21 Apr 2020	61	Whole plant	1.3	2.6	0	No residues >LOQ were found in any untreated samples
				44	433	190		65	Whole plant	0.05	1.2	7	
									Whole plant	0.03	0.51	14	
									Whole plant Seeds	<0.01 <0.003 n.d.	0.15 <0.003 n.d.	35 56	

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
Italy  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
Outdoor  
None  
  
PTZ- $\alpha$ -OH-desthio, PTZ-3-OH-desthio,  
PTZ-4-OH-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)			10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- $\alpha$ -OH- desthio	PTZ-3-OH- desthio	PTZ-4-OH- desthio		
S20-01046-08 48124, Ravenna, Emilia Romagna, Italy SEU	Oilseed rape / BRSNN / PT 200 CL	1) 20 Sep 2019	Overall foliar with boom plot sprayer	44	392	171	06 Apr 2020 21 Apr 2020	61 65	Whole plant Whole plant Whole plant Whole plant Seeds	<0.01	0.10	0.05	0	No residues >LOQ were found in any untreated samples
		2) 06 Apr 2020 - 30 Apr 2020		44	433	190				0.02	0.15	0.06	7	
										0.02	0.18	0.07	14	
										0.02	0.33	0.08	35	
		3) 16 Jun 2020								<0.003 n.d.	<0.01	<0.003 n.d.	56	

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
Italy  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation  
(common name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
Outdoor  
None  
  
PTZ-5-OH-desthio, PTZ-6-OH-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)			10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-5- OH- desthio	PTZ-6- OH- desthio	Total desthio+hydroxy=RD- RA1)*		
S20-01046-08 48124, Ravenna, Emilia Romagna, Italy SEU	Oilseed rape / BRSNN / PT 200 CL	1) 20 Sep 2019 2) 06 Apr 2020 - 30 Apr 2020 3) 16 Jun 2020	Overall foliar with boom plot sprayer	44 44	392 433	171 190	06 Apr 2020 21 Apr 2020	61 65	Whole plant	0.01	<0.003 n.d.	2.77	0	No residues >LOQ were found in any untreated samples
									Whole plant	0.02	<0.01	1.46	7	
									Whole plant	0.02	<0.01	0.81	14	
									Whole plant	0.03	<0.01	0.61	35	
									Seeds	<0.003 n.d.	<0.003 n.d.	<0.06	56	

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable



RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
Italy  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
SAS,  
Plaza  
Débarcadère  
Colombes  
  
Outdoor  
None  
  
1,2,4-Triazole, Triazole alanine (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)		10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4-Triazole	(*) Triazole alanine		
S20-01046-08 48124, Ravenna, Emilia Romagna, Italy SEU	Oilseed rape / BRSNN / PT 200 CL	1)20 Sep 2019 2)06 Apr 2020 - 30 Apr 2020 3)16 Jun 2020	Overall foliar with boom plot sprayer	44	392	171	06 Apr 2020 21 Apr 2020	61	Whole plant	<0.003 n.d.	0.06	0	No residues >LOQ were found in any untreated 1,2, triazole samples, triazole alanine samples were 0.02-0.63 mg/kg
				44	433	190		65	Whole plant	<0.003 n.d.	0.05	7	
									Whole plant	<0.003 n.d.	0.06	14	
									Whole plant	<0.003 n.d.	0.10	35	
									Seeds	<0.003 n.d.	0.47/0.63**	56	

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated  
\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Prothioconazole	Commercial Product (name):	NUL 3390
Crop/crop group:	Oilseed rape / Oilseeds	Producer of commercial product:	Prothioconazole 250EC
Responsible body for reporting (name, address)	Nufarm Immeuble 11 rue du West du Débarcadère Colombes		Nufarm Australia Limited
Country (of trial sites):	France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/L):	Italy 250	Other active substance in the formulation (common name and content):	None
Formulation (e.g. WP):	EC	Residues calculated as:	Triazole acetic acid, Triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date	8 Portion analysed	9 Residues (mg/kg)		10 PHI (days)	11 Remarks
(a)	(b)	(c)					(d)	(e) BBCH	(a)	(*)		(f)	(g)
				g as/hL	Water (L/ha)	g a.s./ha				Triazole acetic acid	Triazole lactic acid		
S20-01046-08 48124, Ravenna, Emilia Romagna, Italy SEU	Oilseed rape / BRSNN / PT 200 CL	1) 20 Sep 2019 2) 06 Apr 2020 - 30 Apr 2020 3) 16 Jun 2020	Overall foliar with boom plot sprayer	44 44	392 433	171 190	06 Apr 2020 21 Apr 2020	61 65	Whole plant Whole plant Whole plant Whole plant Seeds	<0.003 n.d. <0.003 n.d. <0.003 n.d. <0.01 <0.01	<0.003 n.d. <0.01 <0.01 0.01 0.02/0.02**	0 7 14 35 56	No residues >LOQ were found in any untreated samples, except 0.02 mg/kg triazole lactic acid seed sample

(a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):  
  
Crop/crop group:  
Responsible body for reporting  
(name, address)  
  
Country (of trial sites):  
Content of active substance nominal (g/L):  
  
Formulation (e.g. WP):

Prothioconazole  
  
Oilseed rape / Oilseeds  
Nufarm  
Immeuble  
11 rue  
92700  
France  
UK  
250  
  
EC

Commercial Product (name):  
  
Producer of commercial product:  
  
Indoor/Glasshouse/Outdoor:  
Other active substance in the formulation (common  
name and content):  
Residues calculated as:

NUL 3390  
Prothioconazole 250EC  
Nufarm Australia Limited  
  
Outdoor  
None  
  
Prothioconazole, PTZ-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)		10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				Prothioconazole <sup>(*)</sup>	PTZ-desthio		
S20-01046-09 DE73 8BH, Breedon-on- the-Hill, Leicestershire, United Kingdom NEU	Oilseed rape / BRSNN / Lumen	1)22 Apr 2020 2)Not available 3)01 Sep 2020	Overall foliar with boom plot sprayer	88	203	178	23 Jun 2020 07 Jul 2020	59-60 65-71	Whole plant Whole plant Whole plant Whole plant Seeds	0.60	1.1	0	No residues >LOQ were found in any untreated samples
				88	205	180				0.03	0.33	7	
										0.01	0.10	14	
										<0.003 n.d.	0.01	35	
										<0.003 n.d.	<0.003 n.d.	56	

(a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Prothioconazole	Commercial Product (name):	NUL 3390
Crop/crop group:	Oilseed rape / Oilseeds	Producer of commercial product:	Prothioconazole 250EC
Responsible body for reporting (name, address)	Nufarm Immeuble 11 rue 92700 France	SAS, Plaza Débarcadère Colombes	Nufarm Australia Limited
Country (of trial sites):	UK	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/L):	250	Other active substance in the formulation (common name and content):	None
Formulation (e.g. WP):	EC	Residues calculated as:	PTZ- $\alpha$ -OH-desthio, PTZ-3-OH-desthio, PTZ-4-OH-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)			10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ- $\alpha$ -OH- desthio	PTZ-3- OH- desthio	PTZ-4-OH- desthio		
S20-01046-09 DE73 8BH, Breedon-on- the-Hill, Leicestershire, United Kingdom NEU	Oilseed rape / BRSNN / Lumen	1) 22 Apr 2020 2) Not available 3) 01 Sep 2020	Overall foliar with boom plot sprayer	88 88	203 205	178 180	23 Jun 2020 07 Jul 2020	59-60 65-71	Whole plant Whole plant Whole plant Seeds	0.02 0.01 <0.01 <0.003 n.d. <0.003 n.d.	0.12 0.07 0.04 0.03 <0.003 n.d.	0.08 0.04 0.02 0.01 <0.003 n.d.	0 7 14 35 56	No residues >LOQ were found in any untreated samples

- (a) According to EEC and Codex classifications (both) should be used  
(b) Only if relevant  
(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated  
(d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4  
(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)  
(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date  
(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Prothioconazole	Commercial Product (name):	NUL 3390
Crop/crop group:	Oilseed rape / Oilseeds	Producer of commercial product:	Prothioconazole 250EC
Responsible body for reporting (name, address)	Nufarm Immeuble 11 rue West du Débarcadère Colombes 92700 France		Nufarm Australia Limited
Country (of trial sites):	UK	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/L):	250	Other active substance in the formulation (common name and content):	None
Formulation (e.g. WP):	EC	Residues calculated as:	PTZ-5-OH-desthio, PTZ-6-OH-desthio (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)			10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				PTZ-5- OH- desthio	PTZ-6- OH- desthio	Total desthio+hydroxy=RD- RA1)*		
S20-01046-09 DE73 8BH, Breedon-on- the-Hill, Leicestershire, United Kingdom NEU	Oilseed rape / BRSNN / Lumen	1) 22 Apr 2020 2) Not available 3) 01 Sep 2020	Overall foliar with boom plot sprayer	88	203	178	23 Jun 2020 07 Jul 2020	59-60 65-71	Whole plant	0.02	<0.01	1.35	0	No residues >LOQ were found in any untreated samples
				88	205	180			Whole plant	0.01	<0.01	0.47	7	
									Whole plant	<0.01	<0.003	0.18	14	
									Whole plant	<0.01	n.d.	0.07	35	
									Seeds	<0.003 n.d.	<0.003 n.d. <0.003 n.d.	<0.06	56	

- (a) According to EEC and Codex classifications (both) should be used
- (b) Only if relevant
- (c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated
- (d) Year must be indicated
- (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
- (f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)
- (g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
- (\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

## RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **Prothioconazole** Commercial Product (name): **NUL 3390**  
Crop/crop group: **Oilseed rape / Oilseeds** Producer of commercial product: **Prothioconazole 250EC**  
Responsible body for reporting (name, address): **Nufarm Immeuble 11 rue du West SAS, Plaza Débarcadère Colombes 92700 France**  
Country (of trial sites): **UK** Indoor/Glasshouse/Outdoor: **Outdoor**  
Content of active substance nominal (g/L): **250** Other active substance in the formulation (common name and content): **None**  
Formulation (e.g. WP): **EC** Residues calculated as: **1,2,4-Triazole, Triazole alanine (mg/kg)**

1 Report No. Location (region)	2 Commodity/Variety (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date (d)	7 Growth stage at last treatment or date (e) BBCH	8 Portion analysed (a)	9 Residues (mg/kg) (*)		10 PHI (days) (f)	11 Remarks (g)
				g as/hL	Water (L/ha)	g a.s./ha				1,2,4-Triazole	Triazole alanine		
S20-01046-09 DE73 8BH, Breedon-on- the-Hill, Leicestershire, United Kingdom NEU	Oilseed rape / BRSNN / Lumen	1) 22 Apr 2020 2) Not available 3) 01 Sep 2020	Overall foliar with boom plot sprayer	88	203	178	23 Jun 2020 07 Jul 2020	59-60 65-71	Whole plant Whole plant Whole plant Whole plant Seeds	<0.003 n.d.	0.17	0	No residues >LOQ were found in any untreated 1,2, triazole samples, triazole alanine samples were 0.18-1.1 mg/kg
				88	205	180				<0.003 n.d.	0.14	7	
										<0.003 n.d.	0.17	14	
										<0.003 n.d.	0.26	35	
										<0.003 n.d.	0.84/1.1**	56	

(a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

\*\* Residue level in control samples.

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):	Prothioconazole	Commercial Product (name):	NUL 3390
Crop/crop group:	Oilseed rape / Oilseeds	Producer of commercial product:	Prothioconazole 250EC
Responsible body for reporting (name, address)	Nufarm Immeuble 11 rue du West du Débarcadère Colombes		Nufarm Australia Limited
Country (of trial sites):	UK	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance nominal (g/L):	250	Other active substance in the formulation (common name and content):	None
Formulation (e.g. WP):	EC	Residues calculated as:	Triazole acetic acid, Triazole lactic acid (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety  (a)	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b)	4 Method of Treatment  (c)	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date  (d)	7 Growth stage at last treatment or date  (e) BBCH	8 Portion analysed  (a)	9 Residues (mg/kg)  (*)		10 PHI (days)  (f)	11 Remarks  (g)
				g as/hL	Water (L/ha)	g a.s./ha				Triazole acetic acid	Triazole lactic acid		
S20-01046-09 DE73 8BH, Breedon-on- the-Hill, Leicestershire, United Kingdom NEU	Oilseed rape / BRSNN / Lumen	1) 22 Apr 2020 2) Not available 3) 01 Sep 2020	Overall foliar with boom plot sprayer	88	203	178	23 Jun 2020 07 Jul 2020	59-60 65-71	Whole plant	<0.003 n.d.	<0.01	0	No residues >LOQ were found in any untreated samples, except 0.01 mg/kg triazole acetic acid seed sample and 0.01 mg/kg 35 DAA2 whole plant triazole lactic acid and 0.05 mg/kg triazole lactic acid seed sample
				88	205	180			Whole plant	<0.01	<0.01	7	
									Whole plant	<0.01	<0.01	14	
									Whole plant	<0.01	0.01	35	
									Seeds	<0.01/0.01**	0.04/0.05**	56	

(a) According to EEC and Codex classifications (both) should be used

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(\*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg; n.d. = not detectable

### A 2.1.3.3.3 Study S21-00259 – NEU

Comments of zRMS:	<p>The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application. The conclusions of the assessment are presented below:</p> <p><i>One residue trial on oilseed rape were conducted in northern Europe to determine residue of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-alpha-hydroxy-desthio and TDMs.</i></p> <p><i>Oilseed rape was treated twice at application rate of 0.175 kg a.s./ha of prothioconazole with 14 days interval between applications. The time of application was:</i></p> <ol style="list-style-type: none"> <li><i>1. at BBCH 65,</i></li> <li><i>2. at BBCH 69.</i></li> </ol> <p><i>Samples of oilseed rape from the untreated and treated plots were taken by hand 56 days after the final application at normal commercial harvest.</i></p> <p><i>The limit of quantification (LOQ) of the analytical methods were 0.01 mg/kg for each analyte/matrix with a limit of detection (LOD) set at 0.003 mg/kg.</i></p> <p><i>The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev. 1.</i></p> <p><i>Maximum storage period – 49 days.</i></p> <p><i>Residues of prothioconazole-desthio and hydroxy- derivatives of prothioconazole-desthio, in oilseed rape grain at harvest were &lt;0.01 mg/kg.</i></p> <p><i>Residues of 1,2,4-triazole in oilseed rape grain at harvest were &lt; 0.003 mg/kg.</i></p> <p><i>Residues of triazole lactic acid in oilseed rape grain at harvest were 0.1 mg/kg.</i></p> <p><i>Residues of triazole alanine in oilseed rape grain at harvest were 2.3 mg/kg.</i></p> <p><i>Residues of triazole acetic acid in oilseed rape grain at harvest were 0.01 mg/kg.</i></p> <p><i>The study is acceptable.</i></p>
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Reference: KCA 6.3.3/03

Report Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole in Oilseed rape (outdoor) at 1 site in Northern Europe in 2021  
North, L., 2021  
Report No: S21-00259

Guideline(s): OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32)  
OECD Test Guideline 509: Crop field trials  
OECD (2016) Guidance Document ENV/JM/MONO (2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)  
EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials  
European Community Guideline SANCO 7525/VI/95, Rev. 10.3, 13/06/17: Comparability, extrapolation, group tolerances and data requirements for setting MRLs)

Deviations: Trial S21-00259-02 was cancelled due to oversprayed applications.  
Trial S21-00259-03 was cancelled due to samples arrived unfrosted to the laboratory.  
A new trial was set up for the next season (2022). Report S22-00257 will be available by Q2 2023.  
No impact on the current results.



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GLP:	Yes
Owner:	Nufarm Crop Products UK
Acceptability:	Yes

### Materials and Methods

One residue trial was conducted on oilseed rape during 2021 in the United Kingdom (S21-00259-01). Trial S21-00259-02 was cancelled due to both the applications being over dosed, Trial S21-00259-03 was cancelled due to the samples arriving at the analytical test site unfrozen.

Two applications of NUL 3390 Prothioconazole 250 EC (250 g/L, Prothioconazole) were applied at 175 g ai/ha, diluted with water immediately prior to application to a spray volume of 100-400 L/ha.

Samples of oilseed rape from the untreated and treated plots were taken by hand 56 days after the final application (Normal Commercial Harvest – NCH). Samples were frozen within 24 hours after sampling.

The analytes were fortified jointly and quantified separately.

Oilseed rape straw and seed samples were analysed for residues of prothioconazole (PTZ) and prothioconazole-desthio (PTZ-desthio) using multi-residue method QuEChERS as validated for oilseed rape (seeds) in Eurofins study S16-04434. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry (LC-MS/MS).

Oilseed rape straw and seed samples were analysed for residues of PTZ- $\alpha$ -hydroxy-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, and PTZ-6-hydroxy-desthio using Eurofins Agrosience Services method which was validated for oilseed rape (seeds) in study S16-04435. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry (LC-MS/MS).

Oilseed rape whole plant and seed samples were analysed for residues of 1,2,4-Triazole (T), Triazole Alanine (TA), Triazole Acetic Acid (TAA) and Triazole Lactic Acid (TLA) using Eurofins Agrosience Services method which was validated for oilseed rape (seeds) in study S15-03542. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry and SelexION Differential Mobility Separation (LC-DMS/MS/MS).

For all analytes and all matrices, the limit of quantification (LOQ) of the analytical method was 0.01 mg/kg with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ). The analytes were fortified jointly and quantified separately. For prothioconazole the LOQ is expressed as PTZ-desthio.

For PTZ- $\alpha$ -hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio the LOQ is expressed as PTZ-desthio.

### Procedural Recoveries

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

Fortifications of all analytes were performed for all matrices at or above the highest residue level found in a sample.

The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 60 - 120 % and the mean recoveries at each fortification level were in the range of 70 – 110 % with relative standard deviation(s) below 20 % for all combinations of matrices and analytes.

### Findings

No residue of prothioconazole-desthio,  $\alpha$ -OH, 3-OH, 4-OH 5-OH and 6-OH was found in any untreated samples of all trials.

For triazole derivative metabolites, residues above the LOQ was found in some untreated samples. Triazoles are a common ingredient of numerous pesticides which were widely used by farmers as fungicides in

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various field crops. Triazole metabolites show a great persistence in the soils and can be uptaken by plants. The residue findings for TA, TAA and TLA were at a similar level in the control and treated samples and most likely origin in former usage of pesticides containing triazoles on the sampling sites or nearby. The residue levels found in oilseed rape are summarised in the table below.

Table A 88: Summary of the study S21-00259 trials - Prothioconazole-desthio and its hydroxies

Trial number	Country	Variety	Application date	Application rates (g a.s./ha)	BBCH at application	Timing	Matrix	Residue of PTZ-Desthio (mg/kg)	Residue of alpha-OH (mg/kg)	Residue of 3-OH (mg/kg)	Residue of 4-OH (mg/kg)	Residue of 5-OH (mg/kg)	Residue of 6-OH (mg/kg)	Total (PTZ-desthio+hydroxy=RD-RA1)*
S21-00259-01	Cheshire, CH3 7BF, Waverton, UK	Oilseed Rape, Click CL	21 Jun 2021 05 Jul 2021	200.28 196.39	65 69	56 DAA2 (NCH)	Grain	<u>&lt; 0.003 n.d.</u>	<0.01	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	<u>&lt;0.03</u>
							Straw	0.07	<0.01	0.09	0.02	<0.01	< 0.003 n.d.	0.20

The limit of quantitation for the method is set at 0.01 mg/kg for each analyte and matrix.

Table A 89: Summary of the study S21-00259 trials - TDMs

Trial number	Country	Variety	Application date	Application rates (g a.s./ha)	BBCH at application	Timing	Matrix	Residue in treated samples				Residue in control samples			
								Residue of Tz (mg/kg)	Residue of TA (mg/kg)	Residue of TAA (mg/kg)	Residue of TLA (mg/kg)	Residue of Tz (mg/kg)	Residue of TA (mg/kg)	Residue of TAA (mg/kg)	Residue of TLA (mg/kg)
S21-00259-01	Cheshire, CH3 7BF, Waverton, UK	Oilseed Rape, Click CL	21 Jun 2021 05 Jul 2021	200.28 196.39	65 69	56 DAA2 (NCH)	Grain	<u>&lt; 0.003 n.d.</u>	<u>2.3</u>	<u>0.01</u>	<u>0.1</u>	< 0.003 n.d.	2.2	0.01	0.1
							Straw	< 0.003 n.d.	0.07	0.03	0.05	< 0.003 n.d.	0.05	0.02	0.04

The limit of quantitation for the method is set at 0.01 mg/kg for each analyte and matrix.

### A 2.1.3.3.1 Oilseed rape residue trials analysing TDMs

The following tables were extracted from the “Triazole Derivate Metabolites addendum – confirmatory data prepared by the rapporteur Member State, the United Kingdom” Appendix C (UK, 2018). Only trials performed with prothioconazole were considered and presented hereafter.

### B.7.3.13.8 Oilseed Rape (Prothioconazole)

**Table A 90: Application summary of residue trials conducted in/on oilseed rape with an EC formulation containing 150 g/L of prothioconazole**

Study Trial No. Year	Crop Variety	Country	Application of prothioconazole				
			FL	No	g as/ha	g as/hL	GS
Northern Europe							
09-2053 09-2053-02 2009	Winter rape -	The Netherlands 9687 Nieuw Beerta Groningen	EC 150 g/L	2	150	50	77
09-2053 09-2053-03 2009	Winter rape Monalisa	Belgium 1450 Cortil-Noirmont Brabant Wallon	EC 150 g/L	2	150	75	73
09-2053 09-2053-04 2009	Winter rape Kador	France 80500 Lignieres les Roye Picardie	EC 150 g/L	2	150	50	79
09-2244 09-2244-01 2009	Winter rape Castille	United Kingdom HU17 8QY Bishop Burton, East Yorkshire	EC 150 g/L	2	150	75	69

**Table A 91: Results of residue trials conducted in/on oilseed rape with an EC formulation containing 150 g/L of prothioconazole**

Report No	Country Trial No	DALT (days)	Com-modity	Residue in Treated Samples (mg/kg)				Residue in Control Samples (mg/kg)			
				1,2,4-T <sup>a</sup>	TA <sup>b</sup>	TAA <sup>c</sup>	TLA <sup>d</sup>	1,2,4-T <sup>a</sup>	TA <sup>b</sup>	TAA <sup>c</sup>	TLA <sup>d</sup>
Northern Europe											
09-2053	Netherlands 09-2053-02	0	plant	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010
		49	seed	< 0.010	0.160	< 0.010	< 0.010	< 0.010	0.120	< 0.010	< 0.010
09-2053	Belgium 09-2053-03	0	plant	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010
		30	plant	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010
		30	pod	< 0.010	0.040	< 0.010	< 0.010	< 0.010	0.050	< 0.010	< 0.010
		42	plant	< 0.010	< 0.010	< 0.010	< 0.010	NA	NA	NA	NA
		42	pod	< 0.010	0.060	< 0.010	< 0.010	NA	NA	NA	NA
09-2053	France 09-2053-04	0	plant	< 0.010	0.030	< 0.010	< 0.010	< 0.010	0.030	< 0.010	< 0.010
		55	seed	< 0.010	0.550	< 0.010	0.020	< 0.010	0.700	< 0.010	0.030
09-2244	United Kingdom 09-2244-01	0	plant	< 0.010	0.040	< 0.010	< 0.010	< 0.010	0.060	< 0.010	< 0.010
		30	plant	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010	< 0.010
		30	pod	< 0.010	0.140	< 0.010	0.010	< 0.010	0.070	< 0.010	< 0.010
		42	plant	< 0.010	< 0.010	< 0.010	< 0.010	NA	NA	NA	NA
		42	pod	< 0.010	0.100	< 0.010	0.010	NA	NA	NA	NA
		56	seed	< 0.010	0.340	< 0.010	0.010	< 0.010	0.270	< 0.010	0.010

### A 2.1.3.3.2 New study S22-00257 – NEU

Comments of zRMS:	The study was conducted to determine residue levels of prothioconazole-desthio (sum of
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	<p>isomers) in oilseed rape. Three residue trials were conducted in N-EU on oilseed rape during 2022. Two applications of NUL 3390 (250 g/L, prothioconazole) were applied at 175 g ai/ha (target) at an interval of 14 days with the final application 56 days before harvest.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte/matrix</p> <p>The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev. 1.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>Residue results in seed of oilseed rape:</p> <p>Residues of prothioconazole-desthio, PTZ-alpha-hydroxy-desthio and PTZ-4-hydroxy-desthio were below LOQ (0.01 mg/kg) in treated oilseed rape grain samples of all trials.</p> <p>Residues of PTZ-3-hydroxy-desthio were between &lt; 0.01 mg/kg and 0.02 mg/kg.</p> <p>No residues of PTZ-5-hydroxy-desthio and PTZ-6-hydroxy-desthio were found in treated oilseed rape grain samples of all trials.</p> <p>1,2,4-T: 3x &lt;0.003 mg/kg</p> <p>TAA: 3x 0.01 mg/kg</p> <p>TA: 0.95, 1.2, 1.5 mg/kg</p> <p>TLA: 0.04, 0.06, 0.07 mg/kg.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.3/06
Report	<p>Determination of residues of Prothioconazole-desthio (sum of isomers) after two applications of Prothioconazole in Oilseed rape (outdoor) at 3 sites in Northern Europe in 2022</p> <p>North, L., 2023</p> <p>Report No: S22-00257</p>
Guideline(s):	<p>OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32)</p> <p>OECD Test Guideline 509: Crop field trials</p> <p>OECD (2016) Guidance Document ENV/JM/MONO (2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)</p> <p>EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials</p> <p>SANTE/2019/12752 Technical Guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trial and Extrapolation of Residue Data on Products from Plant and Animal Origin (Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3)</p> <p>SANTE/2020/12830, Rev.1 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (Supersedes Guidance Documents SANCO/3029/99 and SANCO/825/00)</p>
Deviations:	Some minor deviations during the field phase without impact on the study
GLP:	Yes
Owner:	Nufarm Crop Products UK
Acceptability:	Yes

## Materials and Methods

Three residue trials were conducted on oilseed rape during 2022, one in Germany (S22-00257-01), one in Poland (S22-00257-02) and one in Northern France (S22-00257-03). Two applications of NUL 3390 (250

g/L, prothioconazole) were applied at 175 g ai/ha (target) at an interval of 14 days with the final application 56 days before harvest (target), diluted with water immediately prior to application to a spray volume of 100-400 L/ha (target).

Samples of oilseed rape grain and straw from the untreated and treated plots were taken 56 days after the final application at BBCH 89. Samples were frozen within 24 hours after sampling.

The analytes were fortified jointly and quantified separately.

Oilseed rape straw and seed samples were analysed for residues of prothioconazole (PTZ) and prothioconazole-desthio (PTZ-desthio) using multi-residue method QuEChERS as validated for oilseed rape (seeds) in Eurofins study S16-04434. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry (LC-MS/MS).

Oilseed rape straw and seed samples were analysed for residues of PTZ-alpha-hydroxy-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, and PTZ-6-hydroxy-desthio using Eurofins Agrosience Services method which was validated for oilseed rape (seeds) in study S16-04435. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry (LC-MS/MS).

Oilseed rape whole plant and seed samples were analysed for residues of 1,2,4-Triazole (T), Triazole Alanine (TA), Triazole Acetic Acid (TAA) and Triazole Lactic Acid (TLA) using Eurofins Agrosience Services method which was validated for oilseed rape (seeds) in study S15-03542. Quantitation was performed by use of liquid chromatography with tandem mass spectrometry and SelexION Differential Mobility Separation (LC-DMS/MS/MS).

For all analytes and all matrices, the limit of quantification (LOQ) of the analytical method was 0.01 mg/kg with a limit of detection (LOD) set at 0.003 mg/kg (30% of the LOQ). The analytes were fortified jointly and quantified separately. For prothioconazole the LOQ is expressed as PTZ-desthio.

For PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio the LOQ is expressed as PTZ-desthio.

#### Procedural Recoveries

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

For PTZ-desthio, PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio fortifications were performed at the level of 0.01 mg/kg, and 0.1 mg/kg with additional fortifications for oilseed rape (straw) at 0.2 mg/kg for PTZ-desthio and 0.5 mg/kg for PTZ-3-hydroxy-desthio and were thus at or above the highest residue level found in a sample.

For the triazole metabolites 1,2,4-Triazole, TA, TAA and TLA fortifications were performed at the level of 0.01 mg/kg and 0.1 mg/kg with additional fortifications at 2.0 mg/kg for TA in oilseed rape (grain) and were thus at or above the highest residue level found in a sample.

No residues above 30 % of the LOQ were detected in the control (untreated) test portions used for recovery determinations of PTZ-desthio, PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio.

For the triazole metabolites blank values were unavoidable. Control samples with the lowest residues were used for recovery determinations. They were either taken from the current study but also from different origin (e.g. material of the Test Site formerly taken under GLP). The recoveries were corrected by background subtraction and even if they were  $\leq 30$  % of the LOQ.

The accuracy and precision of all three methods during sample analysis were considered to be acceptable since the following criteria were fulfilled.

For all combinations of analytes and matrices, single recoveries were in the range of 60 % - 120 %.

The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance

document SANTE/2020/12830, rev. 1.

The applicability of all methods for matrices of oilseed rape (grain and straw) was demonstrated by concurrent recoveries at LOQ and higher levels.

For PTZ-desthio the maximum storage interval from sampling to extraction was 45 days and the maximum storage period from extraction to analysis was 3 days.

For PTZ-alpha-hydroxy-desthio, PTZ-3-, -4-, -5- and -6-hydroxy-desthio the maximum storage interval from sampling to extraction was 45 days and the maximum storage period from extraction to analysis was 1 day.

For 1,2,4-Triazole, TA, TAA and TLA the maximum storage interval from sampling to extraction was 50 days and the maximum storage period from extraction to analysis was 1 day.

## Results

No residue of prothioconazole-desbio, alpha-OH, 3-OH, 4-OH 5-OH and 6-OH was found in any untreated samples of all trials.

For triazole derivative metabolites, residues above the LOQ was found in some untreated samples. Triazoles are a common ingredient of numerous pesticides which were widely used by farmers as fungicides in various field crops. Triazole metabolites show a great persistence in the soils and can be uptaken by plants. The residue findings for TA, TAA and TLA were at a similar level in the control and treated samples and most likely origin in former usage of pesticides containing triazoles on the sampling sites or nearby.

Details on residue trials are presented in the table thereafter.

Report No. Location (region)	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Method of Treatment	Application rate per treatment			Dates of treatment(s)	Growth stage at last treatment BBCH
				g as/hL	Water (L/ha)	g as/ha		
S22-00257-01 16356 Blumberg, Brandenburg, Germany NEU	Oilseed rape / Ludger	1) 07/09/2021 2) 19/04/2022 – 22/03/2022 3) 14/07/2022	Foliar with plot sprayer	58 58	324 306	189 178	06/05/2022 20/05/2022	65 69
S22-00257-02 Ordzin, Wielkopolski Poland NEU	Oilseed rape / Derrick	1) 25/05/2022 2) 7-27/05/2022 3) 21/07/2022	Foliar with plot sprayer	44 44	432 414	189 181	12/05/2022 26/05/2022	65 69
S22-00257-03 St Hilaine, St Mesmin, Loiret, France NEU	Oilseed rape / Alessandro	1) 18/08/2021 2) 05/04/2022– 04/05/2022 3) 28/06/2022	Foliar with plot sprayer	58 58	304 310	177 180	19/04/2022 03/05/2022	65 69

The residue levels found in oilseed rape are summarised in the table below.

**Table A 92: Summary of the study S22-00257 trials - Prothioconazole-desthio and its hydroxies**

Report No. Location (region)	Commodity /Variety	Application date	Application rates (g a.s./ha)	BBCH at application	PHI (days)	Matrix	Residue of PTZ- Desthio (mg/kg)	Residue of alpha- OH (mg/kg)	Residue of 3- OH (mg/kg)	Residue of 4- OH (mg/kg)	Residue of 5- OH (mg/kg)	Residue of 6- OH (mg/kg)	Total (PTZ- desthio+hydroxy=RD- RA1)*
S22-00257-01 Blumberg, Brandenburg, Germany NEU	Oilseed rape / Ludger	06/05/2022 20/05/2022	189 178	65 69	56 DAA2 (NCH)	Grain	<0.01	<0.01	<0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	<0.04
						Straw	0.14	0.02	0.25	0.09	0.03	<0.01	0.54
S22-00257-02 Ordzin, Wielkopolski Poland NEU	Oilseed rape / Derrick	12/05/2022 26/05/2022	189 181	65 69	56 DAA2 (NCH)	Grain	<0.01	< 0.003 n.d.	0.01	< 0.003 n.d.	< 0.003 n.d.	< 0.003 n.d.	0.03
						Straw	0.05	<0.01	0.08	0.03	0.01	<0.01	0.19
S22-00257-03 St Hilaine, St Mesmin, France NEU	Oilseed rape / Alessandro	19/04/2022 03/05/2022	177 180	65 69	56 DAA2 (NCH)	Grain	<0.01	<0.01	0.02	<0.01	< 0.003 n.d.	< 0.003 n.d.	0.06
						Straw	0.15	0.01	0.14	0.05	0.02	<0.01	0.38

The limit of quantitation for the method is set at 0.01 mg/kg for each analyte and matrix and the limit of detection is 0.003 mg/kg.  
NCH = Normal Commercial Harvest

**Table A 93: Summary of the study S22-00257 trials - TDMs**

Report No. Location (region)	Variety	Applica tion date	Applica tion rates (g a.s./ha)	BBCH at applicat ion	Timi ng	Mat rix	Residue in treated samples				Residue in control samples			
							Resid ue of Tz (mg/ kg)	Resid ue of TA (mg/ kg)	Resid ue of TAA (mg/ kg)	Resid ue of TLA (mg/ kg)	Residue of Tz (mg/kg)	Residue of TA (mg/kg)	Residue of TAA (mg/kg)	Residue of TLA (mg/kg)
S22- 00257-01 Blumber g, Brandenb urg, Germany NEU	Oilseed rape / Ludger	06/05/2 022 20/05/20 22	189 178	65 69	56 DAA 2 (NC H)	Grai n	≤ 0.003 n.d.	1.1	0.01	0.06	< 0.003 n.d.	1.5	0.01	0.07
						Stra w	< 0.003 n.d.	0.02	0.03	0.03	< 0.003 n.d.	0.04	0.03	0.04
S22- 00257-02	Oilseed rape / Derrick	12/05/2 022	189 181	65 69	56 DAA 2	Grai n	≤ 0.003 n.d.	1.1	0.01	0.04	< 0.003 n.d.	1.2	0.01	0.06



Report No. Location (region)	Variety	Applicat ion date	Applica tion rates (g a.s./ha)	BBCH at applicat ion	Timi ng	Mat rix	Residue in treated samples				Residue in control samples			
							Resid ue of Tz (mg/kg)	Resid ue of TA (mg/kg)	Resid ue of TAA (mg/kg)	Resid ue of TLA (mg/kg)	Residue of Tz (mg/kg)	Residue of TA (mg/kg)	Residue of TAA (mg/kg)	Residue of TLA (mg/kg)
Ordzin, Wielkopo lski Poland NEU		26/05/20 22			(NC H)	Stra w	< 0.003 n.d.	0.02	0.02	0.02	< 0.003 n.d.	0.03	0.01	0.01
S22-00257-03 St Hilaine, St Mesmin, France NEU	Oilseed rape / Alessan dro	19/04/2 022 03/05/20 22	177 180	65 69	56 DAA 2 (NC H)	Grai n	<u>≤ 0.003 n.d.</u>	0.48	< 0.01	0.03	< 0.003 n.d.	<u>0.95</u>	<u>0.01</u>	<u>0.04</u>
						Stra w	< 0.003 n.d.	0.05	< 0.01	< 0.01	< 0.003 n.d.	0.07	0.03	0.02

The limit of quantitation for the method is set at 0.01 mg/kg for each analyte and matrix.

#### A 2.1.4 Magnitude of residues in livestock

No new data submitted.

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

No new data submitted.

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

No new data submitted.

#### A 2.1.7 Other/Special Studies

##### A 2.1.7.1 Study 1 (S21-00428)

Comments of zRMS:	<p>The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for CA3301/ Joust (January 2023). This study has not been reassessed in the framework of this application. The conclusions of the assessment are presented below:</p> <p><i>The study was conducted to determine residues of prothioconazole in nectar, pollen and honey collected from honey bees from winter oilseed rape plants after two applications of CA3301 (175 g prothioconazole/ha) under semi-field conditions.</i></p> <p><i>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix.</i></p> <p><i>Sufficient stability data are available to support the residue data presented in this study.</i></p> <p><u>Honey</u></p> <p><i>No residues of prothioconazole-desthio, alpha-OH, 3-OH, 4-OH 5-OH, 6-OH and 1,2,4-triazole were found in treated honey samples of all trials.</i></p> <p><i>Residues of triazole alanine (TA) ranged from 0.0131 mg/kg to 0.0298 mg/kg. The highest residues of triazole acetic acid (TAA) was 0.0330 mg/kg in one sample. Residues of triazole lactic acid (TLA) were not detectable in treated honey samples of all trials except trial -04 with values below LOQ.</i></p> <p><i>This study complies with the requirements of SANTE / 11956/2016 rev. 9, so the study is acceptable.</i></p>
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Reference:	KCA 6.10/01
Report	<p>Determination of Residues of Prothioconazole in Nectar, Pollen and Honey of Winter Oilseed Rape after Two Applications of CA3642 in a Semi-Field Residue Study in Central and Southern Europe in 2021</p> <p>Knoll, M., 2021</p> <p>Report No S21-00428</p>
Guideline(s):	<p>Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009</p> <p>SANTE/11956/2016 rev. 9</p>
Deviations:	None
GLP:	Yes
Owner:	Nufarm Crop Products UK
Acceptability:	Yes

#### Materials and methods

Five residue trials, located in Germany (S21-00428-01, -02 and -03), Southern France (S21-00428-04) and Spain (S21-00428-05) were conducted in 2021 with winter oilseed rape as a melliferous source. Trial -01

comprised two plots/tunnels, one control tunnel (C) and one test item treatment tunnel (Ta). Trials -02 to -05 comprised three plots/tunnels, one control tunnel (C) and two test item treatment tunnels (Ta and Tb).

Prothioconazole 250 g/L EC (CA3642) was applied twice, at a nominal application rate of 700 mL product/ha, equivalent to 175 g a.s./ha for each application. The first application (A1) was conducted before flowering and 14 days before the second application (A2) which was conducted at BBCH 61-63.

Forager bees and pollen from pollen traps were collected once in the untreated control (C) and five times in the test item treatment (tunnel Ta) during the study period starting after application A2 (0DAA2) with sampling S1 and up to 8 days after application A2. In trials -02 to -05 honey from combs was sampled from the untreated control (C) tunnel and from the test item treated tunnel Tb. Samples were taken by hand using a spoon. Empty combs were inserted to the bee hive before application and honey was collected from these combs.

For nectar samples, on every sampling day approximately 450 forager bees were tried to collect for the preparation of nectar from their honey stomachs. In addition, forager bees were sampled for the determination of sugar content (at least 50 forager bees) at each sampling day. For pollen samples, on every sampling day a pooled sample of at least 0.6 g was tried to collect using pollen traps or by preparation of the pollen directly from the forager bees.

All samples ((except the honey samples which were transported ambient or on blue ice) for drying in the compartment drier) were transported on dry ice to the test facility/test site and were stored deep frozen ( $\leq -18^{\circ}\text{C}$ ) until shipment and/or honey stomach preparation and/or residue analysis.

In the analytical phase of this study, samples of pollen and nectar were analysed for residues of prothioconazole, prothioconazole-desthio (Group 1), prothioconazole-alpha-hydroxy-desthio, -3-hydroxy-desthio, -4-hydroxy-desthio, -5-hydroxy-desthio and -6-hydroxy-desthio (Group 2), as well as 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid (Group 3), with an intended limit of quantification of 0.01 mg/kg. Residues of honey were analysed for residues of prothioconazole-desthio only and analytes of Group 2 and Group 3 for risk assessment with an intended limit of quantification of 0.01 mg/kg.

Quantification was performed by use of LC-MS/MS (group 1 and 2) and LC-DMS-MS/MS (group 3) detection using matrix matched calibration.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ). For group 2 analytes the LOQ is expressed as prothioconazole-desthio equivalent.

Due to insufficient sample size few samples could not be used for sample preparation and analysis. This includes trial -02 pollen treated samples of sampling 1 and 2.

#### *Maximum storage period of pollen samples*

The maximum storage interval for pollen tested on residues of Group 1 was 134 days from sampling until extraction and applies only for the sample L21-00428-04-C-S1-P-A. The majority of samples were analysed after 50 days from sampling and the remaining under 78 days from sampling. The maximum storage interval from extraction to analysis was three days.

The maximum storage interval for pollen tested on residues of Group 2 was 134 days from sampling until extraction. The maximum storage interval from extraction to analysis was one day.

The maximum storage interval for pollen tested on residues of Group 3 was 79 days from sampling until extraction. The maximum storage interval from extraction to analysis was five days.

#### *Maximum storage period of nectar samples*

The maximum storage interval for nectar tested on residues of Group 1 was 77 days from sampling until extraction. The maximum storage interval from extraction to analysis was one day.

The maximum storage interval for nectar tested on residues of Group 2 was 133 days from sampling until extraction. The maximum storage interval from extraction to analysis was one day.

The maximum storage interval for nectar tested on residues of Group 3 was 74 days from sampling until extraction. The maximum storage interval from extraction to analysis was one day.

#### *Maximum storage period of honey samples*

The maximum storage interval for honey tested on residues of Group 1 was 54 days from sampling until extraction. The maximum storage interval from extraction to analysis was five days.

The maximum storage interval for honey tested on residues of Group 2 was 115 days from sampling until extraction. The maximum storage interval from extraction to analysis was one day.

The maximum storage interval for honey tested on residues of Group 3 was 62 days from sampling until extraction. The maximum storage interval from extraction to analysis was one day.

### **Results and discussions**

No residues of prothioconazole, prothioconazole-desthio, alpha-OH, 3-OH, 4-OH 5-OH, 6-OH and 1,2,4-triazole were found in any untreated samples for any matrix of all trials.

For the metabolite triazole alanine (TA) residues were found in untreated control samples of honey for trial -02, -03 and -04. For untreated nectar samples residues of TA were found for trial -03 and -04 and for pollen residues were found in the control samples of all trials.

Residues of the metabolite triazole acetic acid (TAA) were found in untreated control samples of honey, nectar and pollen of trial -04.

For the metabolite triazole lactic acid (TLA) residues were found in untreated control samples of honey for trial -04 and also in the untreated pollen sample of trial -04.

Triazoles are a common ingredient of numerous pesticides which were widely used by farmers as fungicides in various field crops. Triazole metabolites show a great persistence in the soils and can be uptaken by plants. The residue findings for TA, TAA and TLA were at a similar level in the control and treated samples and most likely origin in former usage of pesticides containing triazoles on the sampling sites or nearby.

#### Honey

No residues of prothioconazole-desthio, alpha-OH, 3-OH, 4-OH 5-OH, 6-OH and 1,2,4-triazole were found in honey samples of all trials.

Residues of the metabolite triazole alanine (TA) were found in the untreated and treated honey samples of trial -02 and trial -04. The values found ranged from 0.0131 mg/kg to 0.0298 mg/kg. Residues of triazole acetic acid (TAA) were also detected in untreated and treated honey samples of trial -04 with values from 0.0330 mg/kg to 0.0646 mg/kg. Residues of the metabolite triazole lactic acid (TLA) were not quantified in treated honey samples of all trials, but was quantified (0.0179 - 0.0194 mg/kg) in untreated honey samples of trial -04.

#### Nectar

Residues of prothioconazole were found in treated nectar samples within a range between not detectable and 0.0649 mg/kg in the nectar samples over all trials at the first two samplings (0DAA2 and 1DAA2). Afterwards prothioconazole was not detectable anymore. The residues of prothioconazole-desthio detected in treated nectar samples ranged from not detectable to 0.0633 mg/kg over all trials and samplings with no clear pattern. Residues of the metabolite alpha-OH found in treated nectar samples ranged from not detectable to 0.0136 mg/kg over all trials and samplings with no clear pattern. Residues of TA were found in samples of trial -01 to trial -04 of treated nectar and ranged from not detectable to 0.0286 mg/kg. In Trial -05 all samples were below LOD for TA.

No residues of 3-OH, 4-OH, 5-OH and 6-OH, 1,2,4-triazole, triazole lactic acid (TLA) and triazole acetic acid (TAA) were found in nectar samples from treated plots, except trial -04 with findings of TAA in a range from not detectable to 0.0105 mg/kg over all samplings.

#### Pollen

Residues of prothioconazole were detected in treated pollen samples of all trials and were highest at the first sampling with a range of 14.9 to 47.1 mg/kg. Afterwards the residues declined and are within a range from below LOQ to 0.0417 mg/kg at the last sampling (6 – 8DAA2). Residues of prothioconazole-desthio were found also in pollen of all trials and the maximum residue values were found at the first sampling (except for trial 05) and ranged between 0.755 mg/kg to 3.65 mg/kg. At the last sampling residues were

down to a range of 0.156 mg/kg to 0.672 mg/kg. The residues of the metabolite alpha-OH found in treated pollen sampled ranged between 0.0124 mg/kg and 0.0402 mg/kg over all trials and samplings with no clear increase or decline pattern of the course of the sampling period. Residues of 3-OH found in pollen samples from the treated plots ranged from below LOQ to 0.0121 mg/kg over all trials and samplings with no clear increase or decline pattern of the course of the sampling period. Residues of 4-OH found in pollen samples from the treated plots ranged from not detectable to 0.0123 mg/kg and residues of triazole alanine found in treated pollen samples ranged between 0.0730 mg/kg to 2.22 mg/kg over all trials and samplings with no clear increase or decline pattern of the course of the sampling period.

No residues of 5-OH and 6-OH, 1,2,4-triazole, triazole acetic acid and triazole lactic acid were found in the treated pollen samples of all trials, except the findings in trial -04 of TAA within a range between below LOQ and 0.0143 mg/kg and TLA with findings in trial -04 at below LOQ.

The residue levels of all analytes found in honey, nectar and pollen are summarised in the tables below.

**Table A 94: Summary of the study S21-00428 trials – Prothioconazole and metabolites - Honey**

Trial number	Country	Variety	Application date	Application rates (g a.s./ha)	BBCH at application	Timing	Matrix	Residue of PTZ-Desthio (mg/kg)	Residue of alpha-OH (mg/kg)	Residue of 3-OH (mg/kg)	Residue of 4-OH (mg/kg)	Residue of 5-OH (mg/kg)	Residue of 6-OH (mg/kg)
S21-00428-02	75117, Pforzheim, Baden-Württemberg, Germany	Winter Oilseed Rape, Pioneer PX 128	13 Apr 2021 08 May 2021	177.1 176.7	55 63	3DAA2	Honey	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
S21-00428-03	75438, Knittlingen, Baden-Württemberg, Germany	Winter Oilseed Rape, Raps Ludger	09 Apr 2021 23 Apr 2021	174.0 177.6	53 62	4DAA2	Honey	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
S21-00428-04	32100, Gers, Larroque-sur-I'Osse, France	Winter Oilseed Rape, DK exception	05 Mar 2021 22 Mar 2021	171.3 172.4	57 - 59 61 - 63	18DAA2	Honey	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
								n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
S21-00428-05	02640, Almansa, Albacete, Spain	Winter Oilseed Rape, SY Florida	31 Mar 2021 14 Apr 2021	183.4 170.8	57 - 59 63	16DAA2	Honey	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
								n.d.	n.d.	n.d.	n.d.	n.d.	n.d.

DAA2 Days after application 2 (last application)

n.d. Not detected (<0.003 mg/kg)

< LOQ < 0.01 mg/kg

**Table A 95: Summary of the study S21-00428 trials – Prothioconazole and metabolites – Nectar**

Trial number	Country	Variety	Application date	Application rates (g a.s./ha)	BBCH at application	Timing	Matrix	Residue of PTZ (mg/kg)	Residue of PTZ-Desthio (mg/kg)	Residue of alpha-OH (mg/kg)	Residue of 3-OH (mg/kg)	Residue of 4-OH (mg/kg)	Residue of 5-OH (mg/kg)	Residue of 6-OH (mg/kg)
S21-00428-01	76703, Kraichtal, Baden-Württemberg, Germany	Winter Oilseed Rape, LG Architect	09 Apr 2021 23 Apr 2021	180.3 175.1	55 63	0DAA <sub>2</sub>	Nectar	0.0386	0.0118	< LOQ (0.00385)	n.d.	n.d.	n.d.	n.d.
						1DAA <sub>2</sub>	Nectar	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
						2DAA <sub>2</sub>	Nectar	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
						4DAA <sub>2</sub>	Nectar	n.d.	n.d.	< LOQ (0.00356)	n.d.	n.d.	n.d.	n.d.
						6DAA <sub>2</sub>	Nectar	n.d.	< LOQ (0.00362)	n.d.	n.d.	n.d.	n.d.	n.d.
S21-00428-02	75117, Pforzheim, Baden-Württemberg, Germany	Winter Oilseed Rape, Pionier PX 128	13 Apr 2021 08 May 2021	177.4 159.2	55 63	0DAA <sub>2</sub>	Nectar	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
						1DAA <sub>2</sub>	Nectar	< LOQ (0.00534)	< LOQ (0.00498)	< LOQ (0.00460)	n.d.	n.d.	n.d.	n.d.
						2DAA <sub>2</sub>	Nectar	n.d.	n.d.	< LOQ (0.00460)	n.d.	n.d.	n.d.	n.d.
						5DAA <sub>2</sub>	Nectar	n.d.	< LOQ (0.00596)	< LOQ (0.00412)	n.d.	n.d.	n.d.	n.d.
						6DAA <sub>2</sub>	Nectar	n.d.	< LOQ (0.00397)	< LOQ (0.00404)	n.d.	n.d.	n.d.	n.d.
S21-00428-03	75438, Knittlingen, Baden-Württemberg, Germany	Winter Oilseed Rape, Raps Ludger	09 Apr 2021 23 Apr 2021	175.9 176.7	53 62	0DAA <sub>2</sub>	Nectar	0.042	0.0243	< LOQ (0.00560)	n.d.	n.d.	n.d.	n.d.
						1DAA <sub>2</sub>	Nectar	0.0206	0.0633	< LOQ (0.00572)	n.d.	n.d.	n.d.	n.d.
						2DAA <sub>2</sub>	Nectar	n.d.	< LOQ (0.00821)	< LOQ (0.00700)	n.d.	n.d.	n.d.	n.d.

Trial number	Country	Variety	Application date	Application rates (g a.s./ha)	BBCH at application	Timing	Matrix	Residue of PTZ (mg/kg)	Residue of PTZ-Desthio (mg/kg)	Residue of alpha-OH (mg/kg)	Residue of 3-OH (mg/kg)	Residue of 4-OH (mg/kg)	Residue of 5-OH (mg/kg)	Residue of 6-OH (mg/kg)
						4DAA <sub>2</sub>	Nectar	n.d.	< LOQ (0.00901)	0.0103	n.d.	n.d.	n.d.	n.d.
						6DAA <sub>2</sub>	Nectar	n.d.	< LOQ (0.00757)	n.d.	n.d.	n.d.	n.d.	n.d.
S21-00428-04	32100, Gers, Larroque-sur-l'Osse, France	Winter Oilseed Rape, DK exception	05 Mar 2021 22 Mar 2021	169.1 168.2	57 - 59 61 - 63	0DAA <sub>2</sub>	Nectar	0.0649	< LOQ (0.00671)	n.d.	n.d.	n.d.	n.d.	n.d.
						1DAA <sub>2</sub>	Nectar	< LOQ (0.00397)	n.d.	< LOQ (0.00307)	n.d.	n.d.	n.d.	n.d.
						2DAA <sub>2</sub>	Nectar	n.d.	< LOQ (0.00858)	< LOQ (0.00460)	n.d.	n.d.	n.d.	n.d.
						4DAA <sub>2</sub>	Nectar	n.d.	< LOQ (0.00610)	< LOQ (0.00748)	n.d.	n.d.	n.d.	n.d.
						8DAA <sub>2</sub>	Nectar	n.d.	< LOQ (0.00405)	n.d.	< LOQ (0.00468)	n.d.	n.d.	n.d.
S21-00428-05	02640, Almansa, Albacete, Spain	Winter Oilseed Rape, SY Florida	31 Mar 2021 14 Apr 2021	169.5 172.2	57 - 59 63	0DAA <sub>2</sub>	Nectar	0.0598	0.0218	n.d.	n.d.	n.d.	n.d.	n.d.
						2DAA <sub>2</sub>	Nectar	< LOQ (0.00442)	0.0103	n.d.	n.d.	n.d.	n.d.	n.d.
						3DAA <sub>2</sub>	Nectar	n.d.	< LOQ (0.00459)	n.d.	n.d.	n.d.	n.d.	n.d.
						4DAA <sub>2</sub>	Nectar	n.d.	< LOQ (0.00958)	0.0136	n.d.	n.d.	n.d.	n.d.
						7DAA <sub>2</sub>	Nectar	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.

DAA2 Days after application 2 (last application)

n.d. Not detected (<0.003 mg/kg)

< LOQ < 0.01 mg/kg



**Table A 96: Summary of the study S21-00428 trials – Prothioconazole and metabolites – Pollen**

Trial number	Country	Variety	Application date	Application rates (g a.s./ha)	BBCH at application	Timing	Matrix	Residue of PTZ (mg/kg)	Residue of PTZ-Desthio (mg/kg)	Residue of alpha-OH (mg/kg)	Residue of 3-OH (mg/kg)	Residue of 4-OH (mg/kg)	Residue of 5-OH (mg/kg)	Residue of 6-OH (mg/kg)
S21-00428-01	76703, Kraichtal, Baden-Württemberg, Germany	Winter Oilseed Rape, LG Architekt	09 Apr 2021 23 Apr 2021	180.3 175.1	55 63	0DAA <sub>2</sub>	Pollen	47.1	2.19	0.0306	< LOQ (0.00648)	< LOQ (0.00507)	n.d.	n.d.
						1DAA <sub>2</sub>	Pollen	1.53	0.825	0.0273	< LOQ (0.00624)	< LOQ (0.00711)	n.d.	n.d.
						2DAA <sub>2</sub>	Pollen	0.42	0.429	0.0214	< LOQ (0.00528)	< LOQ (0.00570)	n.d.	n.d.
						4DAA <sub>2</sub>	Pollen	0.0609	0.378	0.0212	< LOQ (0.00768)	< LOQ (0.00837)	n.d.	n.d.
						6DAA <sub>2</sub>	Pollen	0.0287	0.303	0.0144	< LOQ (0.00612)	< LOQ (0.00606)	n.d.	n.d.
S21-00428-02	75117, Pforzheim, Baden-Württemberg, Germany	Winter Oilseed Rape, Pionier PX 128	13 Apr 2021 08 May 2021	177.4 159.2	55 63	2DAA <sub>2</sub>	Pollen	0.248	0.435	0.0206	< LOQ (0.00492)	< LOQ (0.00558)	n.d.	n.d.
						5DAA <sub>2</sub>	Pollen	0.0202	0.256	0.0187	< LOQ (0.00618)	< LOQ (0.00303)	n.d.	n.d.
						6DAA <sub>2</sub>	Pollen	0.0219	0.221	0.017	< LOQ (0.00498)	n.d.	n.d.	n.d.
S21-00428-03	75438, Knittlingen, Baden-Württemberg, Germany	Winter Oilseed Rape, Raps Ludger	09 Apr 2021 23 Apr 2021	175.9 176.7	53 62	0DAA <sub>2</sub>	Pollen	45.8	3.65	0.0399	0.0107	< LOQ (0.00921)	n.d.	n.d.
						1DAA <sub>2</sub>	Pollen	3.35	1.73	0.036	0.0123	0.0108	n.d.	n.d.
						2DAA <sub>2</sub>	Pollen	0.402	0.69	0.0402	0.0115	< LOQ (0.00654)	n.d.	n.d.
						4DAA <sub>2</sub>	Pollen	0.393	0.717	0.0384	0.012	< LOQ (0.00855)	n.d.	n.d.

Trial number	Country	Variety	Application date	Application rates (g a.s./ha)	BBCH at application	Timing	Matrix	Residue of PTZ (mg/kg)	Residue of PTZ-Desthio (mg/kg)	Residue of alpha-OH (mg/kg)	Residue of 3-OH (mg/kg)	Residue of 4-OH (mg/kg)	Residue of 5-OH (mg/kg)	Residue of 6-OH (mg/kg)
						6DAA <sub>2</sub>	Pollen	0.0417	0.459	0.0233	0.0121	< LOQ (0.00657)	n.d.	n.d.
S21-00428-04	32100, Gers, Larroque-sur-I'Osse, France	Winter Oilseed Rape, DK exception	05 Mar 2021 22 Mar 2021	169.1 168.2	57 - 59 61 - 63	0DAA <sub>2</sub>	Pollen	14.9	1.7	0.0254	< LOQ (0.00630)	< LOQ (0.00909)	n.d.	n.d.
						1DAA <sub>2</sub>	Pollen	1.23	1.12	0.0241	< LOQ (0.00603)	< LOQ (0.00927)	n.d.	n.d.
						2DAA <sub>2</sub>	Pollen	0.298	0.744	0.0315	< LOQ (0.00672)	< LOQ (0.00960)	n.d.	n.d.
						4DAA <sub>2</sub>	Pollen	0.0822	0.687	0.0354	< LOQ (0.00783)	0.0103	n.d.	n.d.
						8DAA <sub>2</sub>	Pollen	0.0217	0.672	0.0241	< LOQ (0.00849)	0.0123	n.d.	n.d.
S21-00428-05	02640, Almansa, Albacete, Spain	Winter Oilseed Rape, SY Florida	31 Mar 2021 14 Apr 2021	169.5 172.2	57 - 59 63	0DAA <sub>2</sub>	Pollen	17.7	0.755	0.0176	< LOQ (0.00315)	< LOQ (0.00375)	n.d.	n.d.
						2DAA <sub>2</sub>	Pollen	2.19	1.21	0.0124	n.d.	n.d.	n.d.	n.d.
						3DAA <sub>2</sub>	Pollen	0.315	0.375	0.0227	n.d.	< LOQ (0.00468)	n.d.	n.d.
						4DAA <sub>2</sub>	Pollen	0.0615	0.29	0.0345	< LOQ (0.00450)	< LOQ (0.00438)	n.d.	n.d.
						7DAA <sub>2</sub>	Pollen	< LOQ (0.00783)	0.156	0.0235	< LOQ (0.00414)	< LOQ (0.00369)	n.d.	n.d.

DAA2 Days after application 2 (last application)

n.d. Not detected (<0.003 mg/kg)

< LOQ < 0.01 mg/kg

**Table A 97: Summary of the study S21-00428 trials – TDMs - Honey**

Trial number	Country	Variety	Application date	Application rates (g a.s./ha)	BBCH at application	Treatment	Timing	Matrix	Residue of Tz (mg/kg)	Residue of TA (mg/kg)	Residue of TAA (mg/kg)	Residue of TLA (mg/kg)
S21-00428-02	75117, Pforzheim, Baden-Württemberg, Germany	Winter Oilseed Rape, Pionier PX 128	-	-	-	C	3DAA2	Honey	n.d.	0.02	n.d.	n.d.
			-	-	-	C	3DAA2	Honey	n.d.	0.0198	n.d.	n.d.
			13 Apr 2021 08 May 2021	177.1 176.7	55 63	Tb	3DAA2	Honey	n.d.	0.0131	n.d.	n.d.
S21-00428-03	75438, Knittlingen, Baden-Württemberg, Germany	Winter Oilseed Rape, Raps Ludger	-	-	-	C	4DAA2	Honey	n.d.	0.0192	n.d.	n.d.
			09 Apr 2021 23 Apr 2021	174.0 177.6	53 62	Tb	4DAA2	Honey	n.d.	n.d.	n.d.	n.d.
S21-00428-04	32100, Gers, Larroque-sur-I'Osse, France	Winter Oilseed Rape, DK exception	-	-	-	C	18DAA2	Honey	n.d.	0.033	0.0638	0.0194
			-	-	-	C	18DAA2	Honey	n.d.	0.0298	0.0646	0.0179
			05 Mar 2021 22 Mar 2021	171.3 172.4	57 - 59 61 - 63	Tb	18DAA2	Honey	n.d.	0.0256	0.033	< LOQ (0.00692)
			05 Mar 2021 22 Mar 2021	171.3 172.4	57 - 59 61 - 63	Tb	18DAA2	Honey	n.d.	0.023	0.033	< LOQ (0.00738)
S21-00428-05	02640, Almansa, Albacete, Spain	Winter Oilseed Rape, SY Florida	-	-	-	C	19DAA2	Honey	n.d.	n.d.	n.d.	n.d.
			-	-	-	C	19DAA2	Honey	n.d.	n.d.	n.d.	n.d.
			31 Mar 2021 14 Apr 2021	183.4 170.8	57 - 59 63	Tb	16DAA2	Honey	n.d.	n.d.	n.d.	n.d.
			31 Mar 2021 14 Apr 2021	183.4 170.8	57 - 59 63	Tb	16DAA2	Honey	n.d.	n.d.	n.d.	n.d.

DAA2 Days after application 2 (last application)  
n.d. Not detected (<0.003 mg/kg)  
< LOQ < 0.01 mg/kg  
Tz 1,2,4-triazole  
TA Triazole alanine

TAA	Triazole acetic acid
TLA	Triazole lactic acid

**Table A 98: Summary of the study S21-00428 trials – TDMs – Nectar**

Trial number	Country	Variety	Application date	Application rates (g a.s./ha)	BBCH at application	Treatment	Timing	Matrix	Residue of Tz (mg/kg)	Residue of TA (mg/kg)	Residue of TAA (mg/kg)	Residue of TLA (mg/kg)
S21-00428-01	76703, Kraichtal, Baden-Württemberg, Germany	Winter Oilseed Rape, LG Architekt	-	-	-	C	0DAA2	Nectar	n.d.	n.d.	n.d.	n.d.
			09 Apr 2021 23 Apr 2021	180.3 175.1	55 63	Ta	0DAA2	Nectar	n.d.	< LOQ (0.00496)	n.d.	n.d.
							1DAA2	Nectar	n.d.	n.d.	n.d.	n.d.
							2DAA2	Nectar	n.d.	< LOQ (0.00504)	n.d.	n.d.
							4DAA2	Nectar	n.d.	< LOQ (0.00354)	n.d.	n.d.
							6DAA2	Nectar	n.d.	< LOQ (0.00400)	n.d.	n.d.
S21-00428-02	75117, Pforzheim, Baden-Württemberg, Germany	Winter Oilseed Rape, Pionier PX 128	-	-	-	C	0DAA2	Nectar	n.d.	n.d.	n.d.	n.d.
			13 Apr 2021 08 May 2021	177.4 159.2	55 63	Ta	0DAA2	Nectar	n.d.	n.d.	n.d.	n.d.
							1DAA2	Nectar	n.d.	< LOQ (0.00976)	n.d.	n.d.
							2DAA2	Nectar	n.d.	n.d.	n.d.	n.d.
							5DAA2	Nectar	n.d.	n.d.	n.d.	n.d.
							6DAA2	Nectar	n.d.	n.d.	n.d.	n.d.
S21-00428-03	75438, Knittlingen, Baden-Württemberg, Germany	Winter Oilseed Rape, Raps Ludger	-	-	-	C	0DAA2-1DAA2-2DAA2	Nectar	n.d.	< LOQ (0.00892)	n.d.	n.d.
			09 Apr 2021 23 Apr 2021	175.9 176.7	53 62	Ta	0DAA2	Nectar	n.d.	0.0134	n.d.	n.d.
							1DAA2	Nectar	n.d.	< LOQ (0.00812)	n.d.	n.d.
							2DAA2	Nectar	n.d.	< LOQ (0.00604)	n.d.	n.d.
							4DAA2	Nectar	n.d.	< LOQ (0.00848)	n.d.	n.d.
							6DAA2	Nectar	n.d.	< LOQ (0.00464)	n.d.	n.d.
S21-00428-04	32100, Gers, Larroque-sur-I'Osse, France	Winter Oilseed Rape, DK exception	-	-	-	C	0DAA2	Nectar	n.d.	< LOQ (0.00992)	< LOQ (0.00568)	n.d.
			05 Mar 2021	169.1 168.2	57 - 59 61 - 63	Ta	0DAA2	Nectar	n.d.	0.015	< LOQ (0.00452)	n.d.
							1DAA2	Nectar	n.d.	0.0103	0.0105	n.d.

Trial number	Country	Variety	Application date	Application rates (g a.s./ha)	BBCH at application	Treatment	Timing	Matrix	Residue of Tz (mg/kg)	Residue of TA (mg/kg)	Residue of TAA (mg/kg)	Residue of TLA (mg/kg)
			22 Mar 2021				2DAA2	Nectar	n.d.	0.0286	< LOQ (0.00896)	n.d.
							4DAA2	Nectar	n.d.	0.014	< LOQ (0.00624)	n.d.
							8DAA2	Nectar	n.d.	0.0142	n.d.	n.d.
S21-00428-05	02640, Almansa, Albacete, Spain	Winter Oilseed Rape, SY Florida	-	-	-	C	0DAA2	Nectar	n.d.	n.d.	n.d.	n.d.
			31 Mar 2021 14 Apr 2021	169.5 172.2	57 - 59 63	Ta	0DAA2	Nectar	n.d.	n.d.	n.d.	n.d.
							2DAA2	Nectar	n.d.	n.d.	n.d.	n.d.
							3DAA2	Nectar	n.d.	n.d.	n.d.	n.d.
							4DAA2	Nectar	n.d.	n.d.	n.d.	n.d.
							7DAA2	Nectar	n.d.	n.d.	n.d.	n.d.

DAA2 Days after application 2 (last application)

n.d. Not detected (<0.003 mg/kg)

< LOQ < 0.01 mg/kg

Tz 1,2,4-triazole

TA Triazole alanine

TAA Triazole acetic acid

TLA Triazole lactic acid

**Table A 99: Summary of the study S21-00428 trials – TDMs – Pollen**

Trial number	Country	Variety	Application date	Application rates (g a.s./ha)	BBCH at application	Treatment	Timing	Matrix	Residue of Tz (mg/kg)	Residue of TA (mg/kg)	Residue of TAA (mg/kg)	Residue of TLA (mg/kg)
S21-00428-01	76703, Kraichtal, Baden-Württemberg, Germany	Winter Oilseed Rape, LG Architekt	-	-	-	C	0DAA2	Pollen	n.d.	0.246	n.d.	n.d.
			09 Apr 2021 23 Apr 2021	180.3 175.1	55 63	Ta	0DAA2	Pollen	n.d.	0.61	n.d.	n.d.
							1DAA2	Pollen	n.d.	0.727	n.d.	n.d.
							2DAA2	Pollen	n.d.	0.773	n.d.	n.d.
							4DAA2	Pollen	n.d.	0.987	n.d.	n.d.
							6DAA2	Pollen	n.d.	1.02	n.d.	n.d.
S21-00428-02	75117, Pforzheim, Baden-Württemberg, Germany	Winter Oilseed Rape, Pionier PX 128	-	-	-	C	0DAA2	Pollen	n.d.	0.182	n.d.	n.d.
			13 Apr 2021 08 May 2021	177.4 159.2	55 63	Ta	2DAA2	Pollen	n.d.	0.37	n.d.	n.d.
							5DAA2	Pollen	n.d.	0.24	n.d.	n.d.
							6DAA2	Pollen	n.d.	0.251	n.d.	n.d.
S21-00428-03	75438, Knittlingen, Baden-Württemberg, Germany	Winter Oilseed Rape, Raps Ludger	-	-	-	C	0DAA2-1DAA2-2DAA2	Pollen	n.d.	0.55	n.d.	n.d.
			09 Apr 2021 23 Apr 2021	175.9 176.7	53 62	Ta	0DAA2	Pollen	n.d.	0.477	n.d.	n.d.
							1DAA2	Pollen	n.d.	0.463	n.d.	n.d.
							2DAA2	Pollen	n.d.	0.553	n.d.	n.d.
							4DAA2	Pollen	n.d.	0.673	n.d.	n.d.
							6DAA2	Pollen	n.d.	0.63	n.d.	n.d.
S21-00428-04	32100, Gers, Larroque-sur-l'Osse, France	Winter Oilseed Rape, DK exception	-	-	-	C	0DAA2	Pollen	n.d.	1.57	0.0111	< LOQ (0.00530)
			05 Mar 2021 22 Mar 2021	169.1 168.2	57 - 59 61 - 63	Ta	0DAA2	Pollen	n.d.	1.7	0.01	< LOQ (0.00503)
							1DAA2	Pollen	n.d.	1.73	0.0143	< LOQ (0.00767)
							2DAA2	Pollen	n.d.	1.7	0.0133	< LOQ (0.00810)
							4DAA2	Pollen	n.d.	2	0.0115	< LOQ (0.00787)
							8DAA2	Pollen	n.d.	2.22	< LOQ (0.00800)	< LOQ (0.00407)
S21-00428-05	02640, Almansa, Albacete, Spain	Winter Oilseed Rape, SY Florida	-	-	-	C	0DAA2	Pollen	n.d.	0.0623	n.d.	n.d.
			31 Mar 2021 14 Apr 2021 31 Mar 2021 14 Apr 2021	169.5 172.2 169.5 172.2	57 - 59 63 57 - 59 63	Ta Ta	0DAA2	Pollen	n.d.	0.066	n.d.	n.d.
							2DAA2	Pollen	n.d.	0.067	n.d.	n.d.
							3DAA2	Pollen	n.d.	0.0697	n.d.	n.d.

Trial number	Country	Variety	Application date	Application rates (g a.s./ha)	BBCH at application	Treatment	Timing	Matrix	Residue of Tz (mg/kg)	Residue of TA (mg/kg)	Residue of TAA (mg/kg)	Residue of TLA (mg/kg)
							4DAA2	Pollen	n.d.	0.067	n.d.	n.d.
							7DAA2	Pollen	n.d.	0.073	n.d.	n.d.

DAA2    Days after application 2 (last application)  
n.d.    Not detected (<0.003 mg/kg)  
< LOQ    < 0.01 mg/kg  
Tz    1,2,4-triazole  
TA    Triazole alanine  
TAA    Triazole acetic acid  
TLA    Triazole lactic acid



## A 2.2 Azoxystrobin

### A 2.2.1 Stability of residues

No new data submitted.

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

No new data submitted.

#### A 2.2.2.1 Nature of residues in livestock

No new data submitted.

### A 2.2.3 Magnitude of residues in plants

#### A 2.2.3.1 Barley, Oat

**Table A 100: Comparison of intended and critical EU GAPs – Barley & Oat**

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP NEU (DAR, UK, 2009) <i>Barley</i>	2	250	14	BBCH 31-59	35
cGAP NEU (Art. 12, EFSA, 2013) <i>Barley</i>	3	250	-	BBCH 71	35
cGAP NEU (Art. 12, EFSA, 2020) <i>Oat</i>	2	250	-	BBCH 71	35
Intended cGAP CEU <i>Barley, Oat</i>	2	150	14-21	BBCH 30-61	35

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

#### A 2.2.3.1.1 Study ChR-10-8230 – NEU

Comments of zRMS:	<p>The study was conducted to determine residues of azoxystrobin in barley raw agricultural commodity (RAC grain and straw) and processed fractions specimens of summer barley after two applications of NUL 2206. Four residues trials were performed in Poland during 2010.</p> <p>T1 plot was intended for residue at harvest, treated twice with NUL 2206 at the rate of 1 L/ha. T2 plot was intended for residue in processing fractions, treated at 3 L/ha, representing 750 g/ha of azoxystrobin at each application.</p> <p>In each trial, two foliar applications were made on T1 and T2 plots. Applications were placed at late stem elongation (BBCH 39 – flag leaf stage) and at end of heading (BBCH 59).</p> <p>One sampling was taken at harvest in each plot, between 34 to 40 days after last application.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix. Sufficient stability data are available to support the residue data presented in this study.</p> <p><u>Barley</u></p> <p>Untreated specimens were not contaminated with azoxystrobin or z-isomer. Two trials (PL01 and PL03) were slightly contaminated in the straw specimens (0.019 and 0.038 mg/kg). This contamination was impossible to trace but it may have occurred during field activities. It had no major impact on the study since the grains were not contaminated in both trials concerned.</p> <p>Residues of azoxystrobin in barley grain ranged from 0.042 mg/kg to 0.13 mg/kg.</p> <p>In straw, azoxystrobin residues were found up to an average of 2.46 mg/kg, ranging from 1.72 to 3.64 mg/kg.</p> <p>The study is acceptable.</p>
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	<p><b>Remark:</b></p> <p>According to the SANTE/2019/12752 four trials from study ChR-10-8230 are not considered independent.</p> <p>The distance between:</p> <p>Chwalecin – Chrzan is ~14 km, Kruczynek – Chrzan is ~15 km, Michalow – Chrzan is ~13 km, Kruczynek – Chwalecin is ~ 5 km, Kruczynek – Michalow is ~ 4 km, Chwalecin – Michalow is ~ 2 km.</p> <p>Dates of planting and treatments between trials are close to each other.</p> <p>According to OECD (2016), the following factors should be considered separately to decide whether supervised residue trials are independent:</p> <ul style="list-style-type: none"> <li>- Geographical location and site – Trials at different geographic locations are considered independent. The different sites must be at least 20 km far from one another unless sufficient evidence is available to demonstrate that in shorter-distance sites significant variations occur in relevant conditions e.g. soil types, weather conditions, etc.</li> <li>- Dates of planting (annual crops) and treatments – Trials involving significantly different planting dates or treatment dates (&gt; 30 days apart) are considered independent.</li> </ul> <p>For those trials being considered as not independent the measured residues should be treated as being replicates.</p>
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Reference:	KCA 6.3.1/08
Report	<p>Magnitude Of The Residues Of Azoxystrobin In Summer Barley (RAC Grain And Straw) And Processed Fractions Following Two Applications Of NUL 2206, Poland, 2010</p> <p>Roussel, C-H., 2011</p> <p>Report No.: ChR-10-8230</p>
Guideline(s):	<p>-Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2).</p> <p>-General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5)</p> <p>-Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000.</p> <p>-Guidance document on residue analytical methods. Document SANCO 825/00, 2004.</p> <p>-Method validation and quality control procedures for pesticide residues analysis in food and feed. Document SANCO/10684/2009, 2010.</p>
Deviations:	None
GLP:	Yes
Acceptability:	Yes

## Materials and Methods

Four residue trials were conducted in Poland on barley during 2010.

### Field phase

Three plots were established in each trial: U plot was left untreated. T1 plot was intended for residue at harvest, treated twice with NUL 2206 at the rate of 1 L/ha. T2 plot was intended for residue in processing fractions, treated at 3 L/ha, representing 750 g/ha of azoxystrobin at each application.

In each trial, two foliar applications were made on T1 and T2 plots. Applications were placed at late stem

elongation (BBCH 39 – flag leaf stage) and at end of heading (BBCH 59).

One sampling was taken at harvest in each plot, between 34 to 40 days after last application. In plots U and T1, grain and straw specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen within 2 hours after sampling and shipped on freezer truck. In plots U and T2, grain specimens for processing were collected and stored under ambient conditions before being shipped in cool conditions (about 8°C) to the processing site.

#### *Processing phase*

Please refer to A 2.2.5.2.

#### *Analytical phase*

Analysis of specimens were performed at Food Safety Laboratory (FSL). The analytical method was described and validated in FSL report PBBZ-2011/07/DPL separately from this study. For details, please refer to dRR B5.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for azoxystrobin. Limit of determination (LOD) was calculated from analytical procedure. They found to be between 0.001 and 0.004 mg/kg according to the matrices. The determinations of azoxystrobin were performed by LC/MS/MS.

The maximum storage intervals were 343 days for all barley samples between sampling and analysis, and 1 day between extraction and analysis.

### **Findings**

The azoxystrobin levels found in barley are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg), except on two specimens of straw in trials PL01 and PL03 in which slight contaminations were observed.

#### **Please note that:**

- Trial ChR-10-8233 PL01 at PBI 2 months and trial ChR-10-8230 PL02 (study on primary crops) were performed in similar conditions (location, variety, date and similar application rate on the primary crop barley). The residue level measured in barley grain is the same in both trials (0.058 mg/kg). For straw, the residue level is higher in primary crops ChR-10-8230 PL02 (1.72 mg/kg) compared to rotational crop ChR-10-8233 PL01 (1.64 mg/kg).
- Trial ChR-10-8233 PL02 at PBI 2 months and trial ChR-10-8230 PL04 (study on primary crops) were also performed in similar conditions (location, variety, date and similar application rate on the primary crop barley). The residue level measured in barley grain is higher in primary crops (0.10 mg/kg) compared to rotational crop (0.089 mg/kg). For straw, it is the opposite: the residue level is lower in primary crops (1.93 mg/kg) compared to rotational crop (3.18 mg/kg).

The highest value was considered for the risk assessment.

**Table A 101: Summary of the study ChR-10-8230 trials**

Active substance (common name): **AZOXSYTROBIN**  
Crop/crop group: **Barley**  
Responsible body for reporting (name, address): **STAPHYT**  
**62860 Inchy en Artois**

Commercial Product (name): **NUL 2206**  
Producer of commercial product: **Nufarm S.A.S**

Content of active substance nominal (g/kg or 250 g/L g/L):

Formulation (e.g. WP): **SC**

Indoor/Glasshouse/Outdoor: **Outdoor**  
Other active substance in the formulation (common name and content): **none**

Residues calculated as: **Azoxystrobin**

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
Poland Wielkopolska 63-210 Chrzan Trial number	Summer barley Enawa	1- 15/04/10 2- 18/06/10 3- 25/07/10	Foliar broadcast application	0.266	307	0.087	08/06/10	39	Grain	U: <0.01 T: <u>0.042</u>	39	Analytical validation report FSL PBBZ- 2011/07/DPL LOQ: 0.01 mg/kg
				0.263	303	0.087	16/06/10	57		U: 0.038 T: <u>2.54</u>		

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
ChR-10-8230 PL01				0.785	302	0.260	08/06/10	39	Grain	U: <0.01 T: 0.38	39	Max. Storage Interval between sampling and analysis: 340 days
				0.785	302	0.260	16/06/10	59	Cleaned grain	U: <0.001 T: 0.069		
									De-germinated Malt	U: <0.01 T: 0.11		
									Germes	U: <0.004 T: 0.15		
									Spent grain	U: <0.001 T: 0.047		
									Wort	U: <0.001 T: <0.01		
									Flocs	U: <0.001 T: 0.015		
									Young beer	U: <0.001 T: <0.01		
									Spent yeast	U: <0.01 T: 0.019		
									Beer	U: <0.001 T: <0.01		
									Pot barley	U: <0.001 T: 0.10		
									Hull	U: <0.01 T: 3.15		

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
Poland Wielkopolska 63-040 Chwalecin Trial number ChR-10-8230 PL02	Summer barley Granal	1- 31/03/10 2- 18/06/10 3- 27/07/10	Foliar broadcast application	0.260	300	0.087	08/06/10 16/06/10	39 59	Grain	U: <0.001 T: <u>0.058</u>	40	Analytical validation report FSL PBBZ- 2011/07/DPL LOQ: 0.01 mg/kg
				0.266	307	0.087			Straw	U: <0.004 T: <u>1.72</u>		
				0.787	303	0.260	08/06/10 16/06/10	39 59	Grain	U: <0.001 T: 0.17	40	Max. Storage Interval between sampling and analysis: 339 days
				0.785	302	0.260			De-germinated Malt	U: <0.001 T: 0.068		
									Wort	U: <0.001 T: <0.01		
									Beer	U: <0.001 T: <0.01		
Poland Wielkopolska 63-040 Kruczynek Trial number ChR-10-8230	Summer barley Nadek	1- 07/04/10 2- 19/06/10 3- 22/07/10	Foliar broadcast application	0.266	307	0.087	08/06/10 18/06/10	39 59	Grain	U: <0.01 T: <u>0.13</u>	34	Analytical validation report FSL PBBZ- 2011/07/DPL LOQ: 0.01 mg/kg  Max. Storage
				0.251	290	0.087			Straw	U: 0.019 T: <u>3.64</u>		

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
PL03				0.777	299	0.260	08/06/10	39	Grain	U: <0.01 T: 0.29	34	Interval between sampling and analysis: 343 days
				0.780	300	0.260	18/06/10	59	De-germinated Malt	U: <0.001 T: 0.076		
									Spent grain	U: <0.001 T: 0.031		
									Wort	U: <0.001 T: <0.01		
									Beer	U: <0.001 T: <0.01		
									Pot barley	U: <0.001 T: 0.023		
Poland Wielkopolska 63-040 Michalow Trial number ChR-10-8230	Summer barley Johan	1- 02/04/10 2- 18/06/10 3- 24/07/10	Foliar broadcast application	0.266 0.260	307 300	0.087 0.087	08/06/10 16/06/10	39 59	Grain  Straw	U: <0.001 T: <u>0.10</u>  U: <0.004 T: 1.93 <sup>(a)</sup>	37	Analytical validation report FSL PBBZ- 2011/07/DPL LOQ: 0.01 mg/kg

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
PL04				0.780	300	0.260	08/06/10	39	Grain	U: <0.001 T: 0.81	37	Max. Storage Interval between sampling and analysis: 342 days
				0.789	303	0.260	16/06/10	59	De-germinated Malt	U: <0.001 T: 0.14		
									Spent grain	U: <0.001 T: 0.050		
									Wort	U: <0.001 T: 0.010		
									Beer	U: <0.001 T: <0.01		
									Pot barley	U: <0.001 T: 0.082		

U: Untreated, T: Treated

(a): Please refer to the note above in “Findings”.



### A 2.2.3.1.2 Study JCB-11-10126 – NEU + SEU

Comments of zRMS:	<p>The study was conducted to determine residues of azoxystrobin in barley raw agricultural commodity (RAC whole plant, grain and straw) after two applications of NUL 2206. Twelve trials (4 decline and 8 harvest) were performed in Northern France (2 trials), Germany (2 trials), Italy (2 trials), Spain (4 trials), Southern France (1 trial) and Greece (1 trial) in 2011.</p> <p>CA2702 (NUL 2206) was applied twice at 1 L/ha on plot T, at BBCH39 and BBCH59. Whole plant specimens were collected on the decline trials at -0, +0, 7 and 21±1 days after application 2. Grain and straw specimens were sampled at commercial harvest, 50 days in average after last application.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix. Sufficient stability data are available to support the residue data presented in this study.</p> <p><u>Barley</u></p> <p>All untreated specimens were found below the LOQ.</p> <p>Residues of azoxystrobin in barley grain ranged from &lt;0.01 mg/kg to 0.016 mg/kg in N-EU (&lt;0.01, 0.011, 0.015, 0.016 mg/kg).</p> <p>In straw, azoxystrobin residues ranged from 0.23 to 1.5 mg/kg in N-EU.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.1/09
Report	<p>Residues Of Azoxystrobin In Barley (RAC Whole Plant, Grain And Straw) Following Two Applications Of CA 2702 (NUL 2206), Northern &amp; Southern Europe – 2011</p> <p>Boissinot, J-C., 2011</p> <p>Report No.: JCB-11-10126</p>
Guideline(s):	<p>-Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2).</p> <p>-General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5)</p> <p>-Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000.</p> <p>-Guidance document on residue analytical methods. Document SANCO 825/00, 2004.</p> <p>-Method validation and quality control procedures for pesticide residues analysis in food and feed. Document SANCO/10684/2009, 2010.</p>
Deviations:	None
GLP:	Yes
Acceptability:	Yes

#### Materials and Methods

Twelve trials (4 decline and 8 harvest) were performed in Northern France, Germany, Italy, Spain, Southern France and Greece in 2011.

#### Field phase

Two plots were established in each trial: U plot was left untreated; T plot was treated twice with CA 2702 (NUL 2206) at the rate of 1.0 L /ha, representing 250 g/ha of azoxystrobin (nominal rate)

at each application..

Applications were made at flag leaf and end of heading stages (respectively BBCH 39 and BBCH 59 (BBCH 39-49 and 55-69/71 on one occasion)).

For the harvest trials, one sample was taken at harvest (straw and grain) in each plot, between 28 and 62 days after last application. For the decline trials, samples were collected at +/- 0, +7 and +21+/-1 days (whole plant) after last application and at harvest (straw and grain), between 42 and 71 days after application.

In plots U and T, whole plant, grain and straw specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen within 7 hours after sampling and shipped on freezer truck/with dry ice.

#### *Analytical phase*

Analyses of specimens were performed at GIRPA. The analytical method was described and validated in GIRPA report NUFARM/AZO/11.01 and GIR/MET/AZOXYSTR/03V1 separately from this study.

Fortification procedures were conducted to confirm the validity of the analytical method during analysis of the specimens. Recoveries were all in the requested range of 70% to 110 %, RSD <20%.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for azoxystrobin. The determinations of azoxystrobin were performed by LC/MS/MS.

The maximum storage interval was 139 days for barley grain and straw samples between sampling and analysis. The maximum interval was 1 day for barley grain and 18 days for barley straw between extraction and analysis.

#### **Findings**

The azoxystrobin levels found in barley are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg).

**Table A 102: Summary of the study JCB-11-10126 trials**

Active substance (common name): **AZOSYTROBIN**  
Crop/crop group: **Barley**  
Responsible body for reporting (name, address): **STAPHYT**  
**62860 Inchy en Artois**

Commercial Product (name): **NUL 2206**  
Producer of commercial product: **Nufarm S.A.S**

Content of active substance nominal (g/kg or g/L): **250 g/L**

Indoor/Glasshouse/Outdoor: **Outdoor**  
Other active substance in the formulation (common name and content): **none**

Formulation (e.g. WP): **SC**

Residues calculated as: **Azoxystrobin**

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
France North Champagne Ardenne 08190 Houdilcourt Trial number JCB-11-10126 FR01	Spring Barley Sebastian	1- 22/03/11 2- 02/06/11 3- 25/07/11	Foliar broadcast application	0.246	189	0.130	12/05/11 01/06/11	39 59	Whole Plant	U: <0.01 T: 1.5 U: <0.01 T: 4.2 T: 2.2 T :0.82	-0	Analytical report GIRPA analytical Phase STAPH/AZO/11.02 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 130 days
				0.263	202	0.130			Grain	U: <0.01 T: <u>0.016</u>	+0 7 22 54	
									Straw	U: <0.01 T: <u>0.93</u>	54	

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
Germany Herzogtum Lauenberg 23847 Kastorf Trial number JCB-11-10126 DE02	Spring Barley Simba	1- 08/04/11 2- 13/06/11 3- 24/08/11	Foliar broadcast application	0.262	302	0.087	25/05/11 09/06/11	39 59	Whole Plant	U: <0.01 T: 0.26 U: <0.01 T: 3.9 T: 3.2 T :0.34	-0	Analytical report GIRPA analytical Phase STAPH/AZO/11.02 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 118 days
				0.264	303	0.087			Grain	U: <0.01 T: <u>&lt;0.01</u>	+0	
									Straw	U: <0.01 T: <u>0.23</u>	7 21	
Germany Thüringen 04603 Taupadel Trial number JCB-11-10126 DE03	Spring Barley Tocada	1- 01/04/11 2- 13/06/11 3- 25/07/11	Foliar broadcast application	0.269	310	0.087	24/05/11 10/06/11	39 59	Grain	U: <0.01 T: <u>0.015</u>	45	Analytical report GIRPA analytical phase STAPH/AZO/11.02 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 74 days
				0.258	297	0.087			Straw	U: <0.01 T: <u>0.29</u>		
France Nord Pas-de- Calais 62147 Hermies Trial number JCB-11-10126 FR04	Spring Barley Sebastian	1- 23/03/11 2- 15/06/11 3- 03/08/11	Foliar broadcast application	0.249	239	0.104	20/05/11 01/06/11	39 59	Grain	U: <0.01 T: <u>0.011</u>	62	Analytical report GIRPA analytical phase STAPH/AZO/11.02 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 66 days
				0.256	246	0.104			Straw	U: <0.01 T: <u>1.5</u>		

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
Italy Lombardia 26900 Lodi Trial number JCB-11-10126 IT05	Spring Barley Otis	1- 24/02/11 2- 30/05/11 3- 24/06/11	Foliar broadcast application	0.265	407	0.065	10/05/11 27/05/11	39	Grain	U: <0.01 T: <0.01	28	Analytical report GIRPA analytical phase STAPH/AZO/11.02 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 105 days
				0.254	390	0.065		59	Straw	U: <0.01 T: 0.42		
Italy Lombardia 20090 Caleppio di Settala Trial number JCB-11-10126 IT06	Spring Barley Tunika	1- 28/02/11 2- 30/05/11 3- 05/07/11	Foliar broadcast application	0.254	390	0.065	11/05/11 19/05/11	39	Whole Plant	U: <0.01 T: <0.01 U: <0.01 T: 2.1 T: 3.9 T : <0.01	-0	Analytical report GIRPA analytical phase STAPH/AZO/11.02 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 139 days
				0.259	398	0.065		59			+0	
									Grain	U: <0.01 T: <0.01	7 21	
									Straw	U: <0.01 T: <0.01	47	
	Spring Barley Flika	1- 15/02/11 2- May 2011 3- July 2011	Foliar broadcast application	0.268	360	0.074	06/05/11 20/05/11	39	Grain	U: <0.01 T: 0.13	42	Analytical report GIRPA analytical phase STAPH/AZO/11.02 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 98 days
				0.273	367	0.074		59	Straw	U: <0.01 T: 1.3		

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
Spain Pais Vasco 01423 Valdegobia Trial number JCB-11-10126 ES08	Spring Barley Mane	1- 10/02/11 2- May/June 2011 3- July 2011	Foliar broadcast application	0.273	367	0.074	06/05/11 20/05/11	39 59	Grain	U: <0.01 T: 0.016	46	Analytical report GIRPA analytical phase STAPH/AZO/11.02 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 94 days
				0.261	350	0.075			Straw	U: <0.01 T: 1.2		
Spain Valencia 46317 Villargordo del Cabriel Trial number JCB-11-10126 ES09	Spring Barley Voley	1- 20/02/11 2- 31/05/11 3- July 2011	Foliar broadcast application	0.269	413	0.065	05/05/11 20/05/11	39 59	Grain	U: <0.01 T: 0.015	46	Analytical report GIRPA analytical phase STAPH/AZO/11.02 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 94 days
				0.274	420	0.065			Straw	U: <0.01 T: 0.43		
Spain Valencia 46330 Camporrobles Trial number JCB-11-10126 ES10	Spring Barley Beca	1- 05/03/11 2- 31/05/11 3- July 2011	Foliar broadcast application	0.267	410	0.065	05/05/11 24/05/11	39 59	Whole plant	U: <0.01 T: 0.25 U: <0.01 T: 4.2 T: 4.5 T: 1.1	-0	Analytical report GIRPA analytical phase STAPH/AZO/11.02 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 134 days
				0.267	410	0.065					+0	
											7	
									Grain	U: <0.01 T: 0.019	21	
									Straw	U: <0.01 T: 0.53	42	

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
France South Rhône-Alpes 01560 Vernoux Trial number JCB-11-10126 FR11	Spring Barley Sebastian	1- 09/03/11 2- 15/06/11 3- 17/08/11	Foliar broadcast application	0.274	210	0.130	18/05/11 10/06/11	39-49 55-69/71	Grain	U: <0.01 T: 0.057	62	Analytical report GIRPA analytical phase STAPH/AZO/11.02 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 57 days
				0.265	204	0.130			Straw	U: <0.01 T: 0.13		
Greece West Macedonia 50100 Polymilos Trial number JCB-11-10126 GR12	Spring Barley Mutso	1- 20/04/11 2- 25/06/11 3- 18/08/11	Foliar broadcast application	0.261	400	0.065	10/06/11 23/06/11	39 59	Grain	U: <0.01 T: 0.11	55	Analytical report GIRPA analytical phase STAPH/AZO/11.02 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 51 days
				0.264	406	0.065			Straw	U: <0.01 T: 2.5		

U: Untreated, T: Treated

## A 2.2.3.2 Wheat, Rye

**Table A 103: Comparison of intended and critical EU GAPs – Wheat & Rye**

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP NEU (Art. 12, EFSA, 2013) <i>Wheat</i>	3	250	-	BBCH 71	35
cGAP NEU (Art. 12, EFSA, 2013) <i>Rye</i>	2	250	-	BBCH 71	35
Intended cGAP CEU <i>Wheat, Rye</i>	2	210	14-21	BBCH 30-69	35

### A 2.2.3.2.1 Study ChR-10-8231 – NEU

Comments of zRMS:	<p>The study was conducted to determine residues of azoxystrobin in wheat raw agricultural commodity (RAC grain and straw) and processed fractions specimens of winter wheat after two applications of NUL 2206. Four residues trials were performed in Poland during 2010. T1 plot was intended for residue at harvest, treated twice with NUL 2206 at the rate of 1 L/ha. T2 plot was intended for residue in processing fractions, treated twice at 3 L/ha. In each trial, two foliar applications were made on T1 and T2 plots. Applications were placed at late stem elongation (BBCH 39 – flag leaf stage) and at end of flowering (BBCH 69).</p> <p>One sampling was taken at harvest in each plot, between 40 to 46 days after last application.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg. Sufficient stability data are available to support the residue data presented in this study.</p> <p><u>Wheat</u> The residue found was below LOQ (&lt;0.01 mg/kg) for all untreated specimens. Residues of azoxystrobin in wheat grain ranged from &lt;0.01 mg/kg to 0.013 mg/kg. In straw, azoxystrobin residues ranged from 1.50 to 2.29 mg/kg. The study is acceptable.</p> <p><u>Remark:</u> According to the SANTE/2019/12752 four trials from study ChR-10-8231 are not considered independent. The distance between: Dabrowa – Potarzyca is ~6 km, Dabrowa – Wojciechowo is ~10 km, Dabrowa – Katy is ~14 km, Katy – Potarzyca is ~18 km, Katy – Wojciechowo is ~20 km, Potarzyca – Wojciechowo – ~10 km. Dates of planting and treatments between trials are close to each other.</p> <p>According to OECD (2016), the following factors should be considered separately to decide whether supervised residue trials are independent: - Geographical location and site – Trials at different geographic locations are considered independent. The different sites must be at least 20 km far from one another unless sufficient evidence is available to demonstrate that in shorter-distance sites significant variations occur in relevant conditions e.g. soil types, weather conditions, etc. - Dates of planting (annual crops) and treatments – Trials involving significantly different planting dates or treatment dates (&gt; 30 days apart) are considered independent. For those trials being considered as not independent the measured residues should be treated as being replicates.</p>
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Report	Magnitude Of The Residues Of Azoxystrobin In Winter Wheat (RAC Grain And Straw) And Processed Fractions Following Two Applications Of NUL 2206, Poland, 2010 Roussel, C-H., 2011 Report No.: ChR-10-8231
Guideline(s):	-Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2). -General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5) -Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000. -Guidance document on residue analytical methods. Document SANCO 825/00, 2010.
Deviations:	None
GLP:	Yes
Acceptability:	Yes

## Materials and Methods

Four residue trials were conducted in Poland on wheat during 2010.

### *Field phase*

Three plots were established in each trial: U plot was left untreated. T1 plot was intended for residue at harvest, treated twice with NUL 2206 at the rate of 1 L/ha. T2 plot was intended for residue in processing fractions, treated twice at 3 L/ha.

In each trial, two applications were made on T1 and T2 plots. Applications were placed at late stem elongation (BBCH 39 – flag leaf stage) and at end of flowering (BBCH 69).

One sampling was taken at harvest in each plot, between 40 and 46 days after last application.

In plots U and T1, grain and straw specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen within 2 hours after sampling and shipped on freezer truck.

In plots U and T2, grain specimens for processing were collected and stored under ambient conditions before being shipped in cool conditions (about 8°C) to the processing site.

### *Processing phase*

Please refer to A 2.2.5.2.

### *Analytical phase*

Analysis of specimens were performed at Food Safety Laboratory (FSL). The analytical method was described and validated in FSL report PBBZ-2011/07/DPL separately from this study.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for azoxystrobin. Limit of determination (LOD) was calculated from analytical procedure. They found to be between 0.001 and 0.004 mg/kg according to the matrices. The determinations of azoxystrobin were performed by LC/MS/MS.

The maximum storage intervals were 344 days for all wheat samples between sampling and analysis, and 1 day between extraction and analysis.

## Findings

The azoxystrobin levels found in wheat are summarised in the table below.

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In all untreated specimens, the residue was below LOQ (<0.01 mg/kg).

**Table A 104: Summary of the study ChR-10-8231 trials**

Active substance (common name): **AZOXSYTROBIN**  
Crop/crop group: **Wheat**  
Responsible body for reporting  
(name, address) **STAPHYT**  
**62860 Inchy en Artois**

Commercial Product (name): **NUL 2206**  
Producer of commercial product: **Nufarm S.A.S**

Content of active substance nominal (g/kg or 250 g/L  
g/L):

Indoor/Glasshouse/Outdoor: **Outdoor**  
Other active substance in the formulation  
(common name and content): **none**

Formulation (e.g. WP): **SC**

Residues calculated as: **Azoxystrobin**

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
Poland Wielkopolska 63-233 Dabrowa Trial number	Winter wheat Nowalis	1- 10/11/09 2- 11/06/10 3- 29/07/10	Foliar broadcast application	0.271	313	0.087	26/05/10	39	Grain	U: <0.001 T: <u>0.013</u>	41	Analytical validation report FSL PBBZ-2011/07/DPL LOQ: 0.01 mg/kg
				0.257	297	0.087	15/06/10	69		U: <0.01 T: <u>2.29</u>		

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
ChR-10-8231 PL01				0.785	302	0.260	26/05/10	39	Grain	U: <0.001 T: 0.074	41	Max. Storage Interval between sampling and analysis: 343 days
				0.783	301	0.260	15/06/10	69	Cleaned Grain	U: <0.001 T: 0.021		
									Steeped Grain	U: <0.001 T: < 0.01		
									Steeping Water	U: <0.001 T: < 0.01		
									Germes	U: <0.001 T: 0.024		
									Middlings	U: <0.004 T: 0.01		
									White flour	U: <0.001 T: < 0.01		
									Bran	U: <0.01 T: 0.050		
									Wholemeal Flour	U: <0.01 T: 0.021		
									Wholemeal Dough	U: <0.001 T: 0.011		
									Wholemeal bread	U: <0.001 T: 0.013		

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
Poland Wielkopolska 63-233 Wojciechowo Trial number ChR-10-8231 PL02	Winter wheat Nadodna	1- 26/10/09 2- 12/06/10 3- 28/07/10	Foliar broadcast application	0.266	307	0.087	26/05/10 15/06/10	39 69	Grain	U: <0.001 T: <u>0.01</u>	40	Analytical validation report FSL PBBZ-2011/07/DPL LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 344 days
				0.266	307	0.087			Straw	U: <0.01 T: <u>2.02</u>		
				0.785	302	0.260	26/05/10 15/06/10	39 69	Grain	U: <0.001 T: 0.051	40	
				0.777	299	0.260			Germes	U: <0.001 T: 0.065		
									White flour	U: <0.001 T: < 0.01		
									Bran	U: <0.001 T: 0.19		
			Whole meal flour	U: <0.001 T: 0.040								
			Whole meal bread	U: <0.001 T: 0.032								
Poland Wielkopolska 63-200 Potarzyca Trial number ChR-10-8231	Winter wheat Ostka	1- 31/10/09 2- 12/06/10 3- 31/07/10	Foliar broadcast application	0.266	307	0.087	01/06/10 15/06/10	39 69	Grain	U: <0.001 T: <u>&lt; 0.01</u>	46	Analytical validation report FSL PBBZ-2011/07/DPL LOQ: 0.01 mg/kg  Max. Storage
				0.266	307	0.087			Straw	U: <0.002 T: <u>1.50</u>		

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
PL03				0.777	299	0.260	01/06/10	39	Grain	U: <0.001	46	Interval between sampling and analysis: 338 days
				0.783	301	0.260	15/06/10	69		T: 0.027		
									Germ	U: <0.001		
										T: 0.023		
									White flour	U: <0.001		
										T: < 0.01		
Poland Wielkopolska 63-200 Katy Trial number	Winter wheat Ismena	1- 20/10/09 2- 10/06/10 3- 28/07/10	Foliar broadcast application	0.266	307	0.087	28/05/10	39	Grain	U: <0.001	42	Analytical validation report FSL PBBZ-2011/07/DPL LOQ: 0.01 mg/kg
				0.269	310	0.087	15/06/10	69		T: <u>&lt; 0.01</u>		
									Straw	U: <0.002		
										T: <u>2.02</u>		

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
ChR-10-8231 PL04				0.782	301	0.260	28/05/10	39	Grain	U: <0.001 T: 0.030	42	Max. Storage Interval between sampling and analysis: 342 days
				0.789	303	0.260	15/06/10	69	Germ	U: <0.001 T: 0.023		
									White flour	U: <0.001 T: < 0.01		
									Bran	U: <0.001 T: 0.090		
									Wholemeal Flour	U: <0.001 T: 0.030		
									Wholemeal bread	U: <0.001 T: 0.015		

U: Untreated, T: Treated

### A 2.2.3.2.2 Study JCB-11-10125 – NEU + SEU

Comments of zRMS:	<p>The study was conducted to determine residues of azoxystrobin in wheat raw agricultural commodity (RAC whole plant, grain and straw) after two applications of NUL 2206. Twelve trials (4 decline and 8 harvest) were performed in Northern Europe (4 trials) and in Southern Europe (8 trials) in 2011.</p> <p>Two plots were established in each trial: U plot was left untreated; T plot was intended for residue at +/- 0, +7 and +21±1 days after last application (decline trials only) and at harvest (all trials), treated twice with CA 2702 (NUL 2206) at the rate of 1.0 L /ha.</p> <p>For the harvest trials, one sample was taken at harvest in each plot, between 27 and 58 days after last application. For the decline trials, samples were collected at +/- 0, +7 and +21±1 days after last application and at harvest, between 30 and 66 days after application.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg. Sufficient stability data are available to support the residue data presented in this study.</p> <p><u>Wheat</u></p> <p>All untreated specimens were found below the LOQ except for one untreated straw specimen, which was found contaminated at harvest with residues of azoxystrobin above the LOQ: 0.029 mg/kg for specimen n°79 (according to the Amendment 1 to final Report). Residues of azoxystrobin in barley grain ranged from &lt;0.01 mg/kg to 0.028 mg/kg in N-EU &lt;0.01, &lt;0.01, 0.022, 0.028 mg/kg).</p> <p>In straw, azoxystrobin residues ranged from 0.41 to 10.1 mg/kg in N-EU.</p> <p>The study is acceptable.</p>
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Reference:	KCA 6.3.2/05
Report	Residues Of Azoxystrobin In Wheat (RAC Whole Plant, Grain And Straw) Following Two Applications Of CA 2702 (NUL 2206), Northern & Southern Europe – 2011, Final report and Amendment 1 Boissinot, J-C. 2011, (2012 amendment) Report No.: JCB-11-10125
Guideline(s):	<p>-Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2).</p> <p>-General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5)</p> <p>-Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000.</p> <p>-Guidance document on residue analytical methods. Document SANCO 825/00, 2004.</p> <p>-Method validation and quality control procedures for pesticide residues analysis in food and feed. Document SANCO/10684/2009, 2010.</p>
Deviations:	None
GLP:	Yes
Acceptability:	Yes

#### Materials and Methods

Twelve trials (4 decline and 8 harvest) were performed in Northern France, Germany, Italy, Spain and Greece in 2011.

#### Field phase



Two plots were established in each trial: U plot was left untreated; T plot was treated twice with CA 2702 (NUL 2206) at the rate of 1.0 L /ha, representing 250 g/ha of azoxystrobin (nominal rate) at each application.

Applications were made at flag leaf and end of flowering stages (respectively BBCH39 (BBCH43 on one occasion) and BBCH 69).

For the harvest trials, one sample was taken at (straw and grain) in each plot, between 27 and 58 days after last application. For the decline trials, samples were collected at +/- 0, +7 and +21±1 days (whole plant) after last application and at harvest (straw and grain), between 30 and 66 days after application.

In plots U and T, whole plant, grain and straw specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen within 7 hours after sampling and shipped on freezer truck/with dry ice.

#### *Analytical phase*

Analyses of specimens were performed at GIRPA. The analytical method was described and validated in GIRPA report NUFARM/AZO/11.01 and GIR/MET/AZOXYSTRO/03V1 separately from this study.

Fortification procedures were conducted to confirm the validity of the analytical method during analysis of the specimens. Recoveries were all in the requested range of 70% to 110 %, RSD <20%.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for azoxystrobin. The determinations of azoxystrobin were performed by LC/MS/MS.

The maximum storage interval was 129 days for wheat grain and straw samples between sampling and analysis. The maximum interval was 6 days for wheat grain and 5 days for wheat straw between extraction and analysis.

#### **Findings**

The azoxystrobin levels found in wheat are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg), except for two untreated straw specimens in trial ES06, which were found contaminated with residues of azoxystrobin at 0.029 mg/kg.

**Table A 105: Summary of the study JCB-11-10125 trials**

Active substance (common name): **AZOXSYTROBIN**  
Crop/crop group: **Wheat**  
Responsible body for reporting (name, address): **STAPHYT**  
**62860 Inchy en Artois**

Commercial Product (name): **NUL 2206**  
Producer of commercial product: **Nufarm S.A.S**

Content of active substance nominal (g/kg or 250 g/L g/L):

Formulation (e.g. WP): **SC**

Indoor/Glasshouse/Outdoor: **Outdoor**  
Other active substance in the formulation (common name and content): **none**  
Residues calculated as: **Azoxystrobin**

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
France North Nord Pas-de- Calais 62860 Inchy en Artois Trial number JCB-11-10125 FR01	Winter Wheat Altamira	1- 15/11/10 2- 17/05/11 3- 31/07/11	Foliar broadcast application	0.265	305	0.087	09/05/11 25/05/11	39 69	Whole Plant	U: <0.01 T: 1.4 U: <0.01 T: 3.0 T: 3.3 T :0.84	-0	Analytical report GIRPA analytical phase STAPH/AZO/11.01 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 129 days
				0.264	305	0.087			Grain	U: <0.01 T: <u>&lt;0.01</u>	+0	
									Straw	U: <0.01 T: <u>1.2</u>	7 21 66	
France North Champagne Ardenne 08190 Houdilcourt Trial number JCB-11-10125 FR02	Winter Wheat Bermude	1- 12/10/10 2- 27/05/11 3- 30/07/11	Foliar broadcast application	0.262	251	0.104	10/05/11 01/06/11	39 69	Grain	U: <0.01 T: <u>&lt;0.01</u>	58	Analytical report GIRPA analytical phase STAPH/AZO/11.01 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 56 days
				0.269	258	0.104			Straw	U: <0.01 T: <u>1.7</u>		

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
France North Centre 37110 Azouer en Touraine Trial number JCB-11-10125 FR03	Winter Wheat Premio	1- 19/10/10 2- 12/05/11 3- 05/07/11	Foliar broadcast application	0.241	278	0.087	04/05/11 20/05/11	43 69	Grain	U: <0.01 T: <u>0.028</u>	47	Analytical report GIRPA analytical phase STAPH/AZO/11.01 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 73 days
				0.249	286	0.087			Straw	U: <0.01 T: <u>10.1</u>		
Germany Baden Württemberg 97990 Weikersheim / Queckbronn Trial number JCB-11-10125 DE04	Winter Wheat Mulan	1- 20/10/10 2- 01/06/11 3- 05/08/11	Foliar broadcast application	0.252	290	0.087	13/05/11 15/06/11	39 69	Whole plant	U: <0.01 T: 0.25 U: <0.01 T: 2.6 T: 1.1 T :0.27	-0	Analytical report GIRPA analytical phase STAPH/AZO/11.01 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 108 days
				0.267	307	0.087					+0	
									Grain	U: <0.01 T: <u>0.022</u>	36	
									Straw	U: <0.01 T: <u>0.41</u>	36	
Italy Lombardia 20060 Bellinzago Lombardo Trial number JCB-11-10125 IT05	Spring Wheat Accor	1- 04/03/11 2- 31/05/11 3- 30/06/11	Foliar broadcast application	0.265	407	0.065	06/05/11 03/06/11	39 69	Grain	U: <0.01 T: 0.026	27	Analytical report GIRPA analytical phase STAPH/AZO/11.01 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 79 days
				0.271	417	0.065			Straw	U: <0.01 T: 1.0		

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
Spain Teruel 44126 Frias de Albarracin Trial number JCB-11-10125 ES06	Winter Wheat Isingrein	1- 25/10/10 2- June 2011 3- 03/08/11	Foliar broadcast application	0.268	411	0.065	19/05/11 15/06/11	39 69	Whole plant	U: <0.01 T: 0.091 U: <0.01 T: 2.8 T: 0.88 T :0.33	-0  +0  7 21	Analytical report GIRPA analytical phase STAPH/AZO/11.01 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 108 days
				0.251	386	0.065			Grain	U: <0.01 T: 0.020	49	
									Straw	U: 0.029 T: 2.4	49	
Spain Pais Vasco 01213 Lantaron Trial number JCB-11-10125 ES07	Winter Wheat Aguila	1- 25/11/10 2- June 2011 3- 20/07/11	Foliar broadcast application	0.271	363	0.075	06/05/11 08/06/11	39 69	Grain	U: <0.01 T: 0.13	29	Analytical report GIRPA analytical phase STAPH/AZO/11.01 LOQ: 0.01 mg/kg Max. Storage Interval between sampling and analysis: 72 days
				0.248	333	0.074			Straw	U: <0.01 T: 6.8		
Spain Pais Vasco 01230 Iruña de Oca Trial number JCB-11-10125 ES08	Winter Wheat Berdun	1- 10/11/10 2- June 2011 3- 11/07/11	Foliar broadcast application	0.272	365	0.075	12/05/11 08/06/11	39 69	Whole plant	U: <0.01 T: 3.8 U: <0.01 T: 4.1 T: 3.6 T :2.5	-0  +0  7 22	Analytical report GIRPA analytical phase STAPH/AZO/11.01 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 115 days
				0.264	355	0.074			Grain	U: <0.01 T: 0.27	30	
									Straw	U: <0.01 T: 7.4	30	

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
Spain Teruel 44366 Orihuela del Tremedal Trial number JCB-11-10125 ES09	Winter Wheat Marius	1- 25/11/10 2- June 2011 3- 27/07/11	Foliar broadcast application	0.271 0.254	417 390	0.065 0.065	19/05/11 15/06/11	39 69	Grain  Straw	U: <0.01 T: 0.054  U: <0.01 T: 7.3	42	Analytical report GIRPA analytical phase STAPH/AZO/11.01 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 52 days
Spain Alava 01118 Lagran Trial number JCB-11-10125 ES10	Winter Wheat Berdun	1- 15/11/10 2- June 2011 3- 27/07/11	Foliar broadcast application	0.247 0.250	380 383	0.065 0.065	17/05/11 08/06/11	39 69	Grain  Straw	U: <0.01 T: 0.20  U: <0.01 T: 5.1	44	Analytical report GIRPA analytical phase STAPH/AZO/11.01 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 57 days
Greece West Macedonia 50100 Koilada Trial number JCB-11-10125 GR11	Winter Wheat Athos	1- 06/11/10 2- 15/05/11 3- 13/07/11	Foliar broadcast application	0.256 0.262	295 302	0.087 0.087	12/05/11 30/05/11	39 69	Grain  Straw	U: <0.01 T: <0.01  U: <0.01 T: 0.81	43	Analytical report GIRPA analytical phase STAPH/AZO/11.01 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 67 days

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
Greece West Macedonia 53200 Agios Panteleimonas Trial number JCB-11-10125 GR12	Winter Wheat Simeto	1- 20/01/11 2- 20/05/11 3- 31/06/11	Foliar broadcast application	0.257	296	0.087	12/05/11	39	Grain	U: <0.01	34	Analytical report GIRPA analytical phase STAPH/AZO/11.01 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 80 days
				0.260	299	0.087	26/05/11	69	Straw	T: 0.1  U: <0.01 T: 2.6		

U: Untreated, T: Treated

### A 2.2.3.3 Oilseed rape, sunflower and other minor oilseeds

**Table A 106: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment (g a.s./ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP NEU + SEU (DAR, UK, 2009)	Not a representative use				
cGAP NEU (Art. 12, EFSA, 2013) <i>Oilseed rape, Poppy seeds, Mustard seeds, Gold of pleasure</i>	2	250	-	-	21
cGAP NEU (Art. 12, EFSA, 2013) <i>Linseed</i>	Not existing use				
Intended cGAP CEU	1	180	-	BBCH 69	56

#### A 2.2.3.3.1 Study GBU-11-10127 – NEU + SEU

Comments of zRMS:	<p>The study was conducted to determine residues of azoxystrobin in oilseed rape raw agricultural commodity (RAC whole plant, pods, grain) after one application of NUL 2206 (azoxystrobin 250 SC).</p> <p>Eight trials (4 decline and 4 harvest) were performed in Northern Europe (4 trials) and in Southern Europe (4 trials) in 2011.</p> <p>Two plots were established in each trial: U plot was left untreated; T plot was intended for residue at harvest and for residue decline treated one with CA 2702 (NUL 2206) at the rate of 1.0 L /ha.</p> <p>For the harvest trials, one sample was taken at harvest in each plot, between 47 and 66 days after application.</p> <p>For the decline trials, samples were collected just after application, at +7, +13-14 and +28-29 days after application and at harvest, between 55 and 66 days after application.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p><u>Oilseed rape</u></p> <p>No residues were detected (below 0.01 mg/kg) in any untreated specimen.</p> <p>Residues of azoxystrobin in oilseed rape grain were below 0.01 mg/kg (N-EU).</p> <p>The study is acceptable.</p>
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Reference: KCA 6.3.3/04

Report Residues Of Azoxystrobin In Oilseed Rape, Following One Application Of CA 2702 (NUL 2206), Northern & Southern Europe – 2011, Final report and Amendment 1  
Boileau, G., 2011  
Report No.: GBU-11-10127

Guideline(s):  
-Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2).  
-General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5)  
-Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000.

- Guidance document on residue analytical methods. Document SANCO 825/00, 2004.
- Method validation and quality control procedures for pesticide residues analysis in food and feed. Document SANCO/10684/2009, 2010.

Deviations: None  
GLP: Yes  
Acceptability: Yes

## Materials and Methods

Eight trials were performed in Germany, Spain, Northern and Southern France in 2011.

### *Field phase*

Two plots were established in each trial: U plot was left untreated. For half of the trials, T plot was intended for residue at harvest, treated once with CA 2702 (NUL 2206) at the rate of 1.0 L/ha; and for the others, T plot was intended for residue decline treated once with CA 2702 (NUL 2206) at rate dose 1.0 L/ha, representing 250 g/ha of azoxystrobin at application.

In each trial, one application was made on plot T. Application was placed at end of flowering (BBCH 69) except in trial FR08 (BBCH 72 = 20% of pods have reached final size).

For the harvest trials, one sample was taken at harvest in each plot, between 47 and 66 days after application. For the decline trials, samples were collected just after application, at +7, +13-14 and +28-29 days after application and at harvest, between 55 and 66 days after application.

In plots U and T, whole plants, pods and/or grain specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen within 4 hours after sampling and shipped on freezer truck. They were delivered deep-frozen and in good condition to the analytical site.

### *Analytical phase*

Analyses of specimens were performed at GIRPA. The analytical method was described and validated in GIRPA reports NUFARM/AZO/11.01 (oilseed rape grain), NUFARM/AZO/11.02 (oilseed rape whole plants) and GIR/MET/AZOXYSTR/03V1 separately from this study.

Fortification procedures were conducted to confirm the validity of the analytical method during analysis of the specimens. Recoveries were all in the requested range of 70% to 110 %, RSD <20%.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for azoxystrobin. The determinations of azoxystrobin were performed by LC/MS/MS.

The maximum storage interval was 152 days for all oilseed rape samples between sampling and analysis. The maximum interval was 6 days for oilseed rape seeds, 22 days for whole plant and 9 days for pods between extraction and analysis.

Extract stability was demonstrated within a separate validation study, PBBZ-2011/07/DPL (for details, please refer to dRR B5). Following storage for 14 days at refrigerator temperature, the average recovery was above 90% for azoxystrobin and its Z-isomer.

## Findings

The azoxystrobin levels found in oilseed rape are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg).



**Table A 107: Summary of the study GBU-11-10127 trials**

Active substance (common name): **AZOXSYTROBIN**  
Crop/crop group: **Oilseed rape**  
Responsible body for reporting (name, address): **STAPHYT**  
**62860 Inchy en Artois**

Commercial Product (name): **NUL 2206**  
Producer of commercial product: **Nufarm S.A.S**

Content of active substance nominal (g/kg or 250 g/L g/L):

Formulation (e.g. WP): **SC**

Indoor/Glasshouse/Outdoor: **Outdoor**  
Other active substance in the formulation (common name and content): **none**  
Residues calculated as: **Azoxystrobin**

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
Germany Sachsen 08393 Mosel Trial number GBU-11-10127 DE01	Oilseed rape Chagall	1- 04/09/10 2- 18/04/11 3- 12/07/11	Foliar broadcast application	0.2571	296	0.087	10/05/11	69	Whole Plants	U: <0.01 T: 1.5 T: 0.27 T: 0.26	0	Analytical report GIRPA analytical phase STAPH/AZO/11.03 LOQ: 0.01 mg/kg Max. Storage Interval between sampling and analysis: 152 days
									Pods	U: <0.01 T: <0.01	7 14 28	
									Grain	U: <0.01 T: <u>&lt;0.01</u>	60	
Germany Schleswig- Holstein 23847 Kastorf Trial number GBU-11-10127 DE02	Oilseed rape Visby	1- 04/09/10 2- 10/05/11 3- 28/07/11	Foliar broadcast application	0.2636	303	0.087	25/05/11	69	Grain	U: <0.01 T: <u>&lt;0.01</u>	64	Analytical report GIRPA analytical phase STAPH/AZO/11.03 LOQ: 0.01 mg/kg Max. Storage Interval between sampling and analysis: 63 days

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
France Northern Champagne- Ardenne 08310 Juniville Trial number GBU-11-10127 FR03	Oilseed rape Alpaga	1- 01/09/10 2- 11/04/11 3- 11/07/11	Foliar broadcast application	0.2696	207	0.130	06/05/11	69	Whole Plants	U: <0.01 T: 2.1 T: 1.2 T: 1.2	0	Analytical report GIRPA analytical phase STAPH/AZO/11.03 LOQ: 0.01 mg/kg Max. Storage Interval between sampling and analysis: 132 days
									Pods	U: <0.01 T: 0.096	7 14 28	
									Grain	U: <0.01 T: <0.01	66	
France Northern Centre 41190 Santenay Trial number GBU-11-10127 FR04	Oilseed rape DK Exquisite	1- 22/08/10 2- 06/04/11 3- 03/07/11	Foliar broadcast application	0.2597	399	0.0695	29/04/11	69	Grain	U: <0.01 T: <0.01	66	Analytical report GIRPA analytical phase STAPH/AZO/11.03 LOQ: 0.01 mg/kg Max. Storage Interval between sampling and analysis: 87 days
Spain Pais Vasco 01213 Lantaron Trial number GBU-11-10127 ES05	Oilseed rape Mistral	1- 17/09/10 2- 20/04/11 3- 01/07/11	Foliar broadcast application	0.2443	375	0.065	15/05/11	69	Grain	U: <0.01 T: 0.19	47	Analytical report GIRPA analytical phase STAPH/AZO/11.03 LOQ: 0.01 mg/kg Max. Storage Interval between sampling and analysis: 95 days

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
Spain Pais Vasco 01520 Arrazua Trial number GBU-11-10127 ES06	Oilseed rape Mistral	1- 24/09/10 2- 25/04/11 3- from 01/07/11 to 10/07/11	Foliar broadcast application	0.2503	288	0.087	14/05/11	69	Whole Plants	U: <0.01 T: 3.5 T: 0.21 T: <0.01	0	Analytical report GIRPA analytical phase STAPH/AZO/11.03 LOQ: 0.01 mg/kg Max. Storage Interval between sampling and analysis: 133 days
									Pods	U: <0.01 T: 0.016	7 13 29	
									Grain	U: <0.01 T: <0.01	55	
France South Midi-Pyrénées 81630 La Sauzière Saint Jean Trial number GBU-11-10127 FR07	Oilseed rape Facile	1- 20/09/10 2- 15/04/11 3- 30/06/11	Foliar broadcast application	0.2623	302	0.087	03/05/11	69	Whole Plants	U: <0.01 T: 3.7 T: 1.9 T: 0.30	0	Analytical report GIRPA analytical phase STAPH/AZO/11.03 LOQ: 0.01 mg/kg Max. Storage Interval between sampling and analysis: 135 days
									Pods	U: <0.01 T: 0.14	7 14 28	
									Grain	U: <0.01 T: <0.01	57	
France South Midi-Pyrénées 82230 Verlhac- Tescou Trial number GBU-11-10127 FR08	Oilseed rape Albatros	1- 30/09/10 2- 03/04/11 3- 28/06/11	Foliar broadcast application	0.2644	304	0.087	03/05/11	72	Grain	U: <0.01 T: <0.01	57	Analytical report GIRPA analytical phase STAPH/AZO/11.03 LOQ: 0.01 mg/kg Max. Storage Interval between sampling and analysis: 92 days

U: Untreated, T: Treated

### A 2.2.3.3.2 Study ChR-10-8214 – NEU

Comments of zRMS:	<p>The study was conducted to determine residues of azoxystrobin in oilseed rape raw agricultural commodity (RAC grain) and processed fractions specimens of oilseed rape after one application of NUL 2206. Four residues trials were performed in Poland during 2010. T1 plot was intended for residue at harvest, treated one with NUL 2206 at the rate of 1 L/ha. T2 plot was intended for residue in processing fractions, treated at 3 L/ha. In each trial, one foliar application was made on T1 and T2 plots. Applications were placed at end of flowering (BBCH 69). One sampling was taken at harvest in each plot, between 48 to 52 days after last application.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg. Sufficient stability data are available to support the residue data presented in this study.</p> <p><u>Oilseed rape</u></p> <p>The residue found was below LOQ (&lt;0.01 mg/kg) for all untreated specimens. Residues of azoxystrobin in oilseed rape grain ranged from &lt;0.001 mg/kg to 0.13 mg/kg. The study is acceptable.</p> <p><u>Remark:</u></p> <p>According to the SANTE/2019/12752, four trials from study ChR-10-8214 are not considered independent.</p> <p>The distance between:</p> <p>Dabrowa – Chwalecin is ~10 km, Dabrowa – Jaraczewo is ~10 km, Chwalecin – Jaraczewo is ~9 km, Chwalecin – Chwalecin is ~0 km, Dates of planting and treatments between trials are close to each other.</p> <p>According to OECD (2016), the following factors should be considered separately to decide whether supervised residue trials are independent:</p> <ul style="list-style-type: none"> <li>- Geographical location and site – Trials at different geographic locations are considered independent. The different sites must be at least 20 km far from one another unless sufficient evidence is available to demonstrate that in shorter-distance sites significant variations occur in relevant conditions e.g. soil types, weather conditions, etc.</li> <li>- Dates of planting (annual crops) and treatments – Trials involving significantly different planting dates or treatment dates (&gt; 30 days apart) are considered independent.</li> </ul> <p>For those trials being considered as not independent the measured residues should be treated as being replicates.</p>
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Reference:	KCA 6.3.3/05
Report	<p>Magnitude Of The Residues Of Azoxystrobin In Oilseed Rape (RAC Grain) And Processed Fractions Following One Application Of NUL 2206, Poland, 2010</p> <p>Roussel, C-H., 2011</p> <p>Report No.: ChR-10-8214</p>
Guideline(s):	<p>-Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2).</p> <p>-General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5)</p> <p>-Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000.</p> <p>-Guidance document on residue analytical methods. Document SANCO 825/00, 2010.</p>

-Method validation and quality control procedures for pesticide residues analysis in food and feed. Document SANCO/10684/2009, 2010.

Deviations: None  
GLP: Yes  
Acceptability: Yes

## Materials and Methods

Four trials were performed in Poland in 2010.

### *Field phase*

Three plots were established in each trial: U plot was left untreated. T1 plot was intended for the determination of the residue at harvest and was treated once with NUL 2206 at the rate of 1 L/ha (250 g a.s./ha). T2 plot was intended for the determination of the residue in processed fractions and was treated at 3 L/ha (750 g a.s./ha).

In each trial, one application was made to T1 and T2 plots at end of flowering (BBCH 69).

One sampling was taken at harvest in each plot, between 48 and 52 days after last application.

In plots U and T1, grain specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen within 3 hours after sampling and shipped on freezer truck.

In plots U and T2, grain specimens for processing were collected and stored under ambient conditions before being shipped in cool conditions (about 8°C) to the processing site.

### *Processing phase*

Please refer to A 2.2.5.2.

### *Analytical phase*

Analyses of specimens were performed at Food Safety Laboratory (FSL). The analytical method was described and validated in FSL report PBBZ-2011/07/DPL separately from this study.

Residues were calculated as the mean of three independent analyses.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for azoxystrobin. Limit of determination (LOD) was found to be 0.001 mg/kg. The determination of azoxystrobin was performed by LC/MS/MS.

The maximum storage interval was 358 days for all oilseed rape samples between sampling and analysis. The maximum interval was 1 day between extraction and analysis.

Extract stability was demonstrated within a separate validation study, PBBZ-2011/07/DPL (for details, please refer to dRR B5). Following storage for 14 days at refrigerator temperature, the average recovery was above 90% for azoxystrobin and its Z-isomer.

## Findings

The azoxystrobin levels found in barley are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg).

**Table A 108: Summary of the study ChR-10-8214 trials**

Active substance (common name): **AZOXSYTROBIN**  
Crop/crop group: **Oilseed rape**  
Responsible body for reporting (name, address): **STAPHYT**  
**62860 Inchy en Artois**

Commercial Product (name): **NUL 2206**  
Producer of commercial product: **Nufarm S.A.S**

Content of active substance nominal (g/kg or 250 g/L g/L):

Formulation (e.g. WP): **SC**

Indoor/Glasshouse/Outdoor: **Outdoor**  
Other active substance in the formulation (common name and content): **none**  
Residues calculated as: **Azoxystrobin**

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
Poland Wielkopolska 63-233 Dabrowa Trial number ChR-10-8214 PL01	Rapeseed Kazoar	1- 14/09/09 2- 14/05/10 3- 20/07/10	Foliar broadcast application	0.257	297	0.087	01/06/10	69	Grain	U: <0.001 T: <u>0.13</u>	48	Analytical validation report FSL PBBZ-2011/07/DPL LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 357 days
				0.780	300	0.260	01/06/10	69	Grain	U: <0.001 T: 0.035	48	
									Cake	U: <0.001 T: 0.03		
									Raw oil	U: <0.001 T: 0.058		
									Refined oil	U: <0.001 T: 0.057		
Poland Wielkopolska 63-040 Chwalecin Trial number ChR-10-8214 PL02	Rapeseed Smart	1- 25/08/09 2- 10/05/10 3- 16/07/10	Foliar broadcast application	0.263	303	0.087	26/05/10	69	Grain	U: <0.001 T: <u>&lt; 0.001</u>	51	Analytical validation report FSL PBBZ-2011/07/DPL LOQ: 0.01 mg/kg Max. Storage Interval between sampling and analysis: 358 days
				0.784	302	0.260	26/05/10	69	Grain	U: <0.001 T: 0.1	51	
									Raw oil	U: <0.001 T: 0.036		
									Refined oil	U: <0.001 T: 0.031		

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
Poland Wielkopolska 63-040 Chwalecin Trial number ChR-10-8214 PL03	Rapeseed Nelson	1- 27/08/09 2- 12/05/10 3- 19/07/10	Foliar broadcast application	0.260	300	0.087	28/05/10	69	Grain	U: <0.001 T: < 0.01	52	Analytical validation report FSL PBBZ-2011/07/DPL LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 355 days
				0.789	303	0.260	28/05/10	69	Grain	U: <0.001 T: 0.040	52	
									Raw oil	U: <0.001 T: 0.015		
									Refined oil	U: <0.001 T: 0.016		
Poland Wielkopolska 63-233 Jaraczewo Trial number ChR-10-8214 PL04	Rapeseed Ontario	1- 31/08/09 2- 14/05/10 3- 20/07/10	Foliar broadcast application	0.266	307	0.087	01/06/10	69	Grain	U: <0.001 T: 0.032	48	Analytical validation report FSL PBBZ-2011/07/DPL LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 355 days
				0.782	301	0.260	01/06/10	69	Grain	U: <0.001 T: 0.72	48	
									Raw oil	U: <0.001 T: 0.081		
									Refined oil	U: <0.001 T: 0.083		

U: Untreated, T: Treated

### A 2.2.3.3.3 Study ongoing S23-100807 – NEU

Comments of zRMS:	<p>Four independent residue trials was conducted on oilseed rape during 2023 in N-EU to determine residue levels and behaviour of azoxystrobin in the raw agricultural commodity oilseed rape and its processed fractions treated with CA2702.</p> <p>One application of CA2702 (250 g/L azoxystrobin) was applied to plot 2 at 250 g ai/ha and to plot 3 at 750 g ai/ha at BBCH 69.</p> <p>Samples of oilseed rape seeds from the untreated and treated plot 2 were taken by hand at normal commercial harvest (BBCH 89), 49-60 days after application from trials S23-100807-01, 02, 03 &amp; 04.</p> <p>Samples of oilseed rape (whole plant, pods and rest of plants) from treated plot 2 were taken by hand at 0, 14, 21 and 35 days after application from trials S23-100807-01 &amp; 02.</p> <p>Processing samples were taken from treated plot 3 by hand at normal commercial harvest (BBCH 89), 49-60 days after application for trials S23-100807-01, 02 &amp; 03.</p> <p><u>Analytical methods</u></p> <p>Analytical method has been successfully validated to determine residues of azoxystrobin in samples of oilseed rape (whole plant, pods, rest of plant and seed) as well as its processed fractions (RAC rapeseed, press cake, crude oil, refined oil, meal and extracted oil) for residues of azoxystrobin in accordance with guidance document SANTE/2020/12830, rev. 2 for risk assessment and/or monitoring.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p><u>Oilseed rape</u></p> <p>No residues were detected (below 0.01 mg/kg) in any untreated specimen.</p> <p>Residues of azoxystrobin in oilseed rape grain were below 0.01 mg/kg (N-EU).</p> <p>The study is acceptable.</p>
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Reference: KCA 6.3.3/07

Report Determination of residues of Azoxystrobin after a single application of CA2702 in Oilseed rape (outdoor) and its processed fractions at 4 sites in Northern Europe 2023  
North, L., ongoing 2024  
Report No.: S23-100807

Guideline(s): OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32)  
OECD Test Guideline 509: Crop field trials  
OECD (2016) Guidance Document ENV/JM/MONO (2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)  
EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials  
SANTE/2019/12752 Technical Guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trial and Extrapolation of Residue Data on Products from Plant and Animal Origin (Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3)  
SANTE/2020/12830, Rev.2 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (Supersedes Guidance Documents SANCO/3029/99 and SANCO/825/00)

Deviations: Study ongoing



GLP: Yes  
Acceptability: ~~Study ongoing~~ Yes

## Materials and Methods

Four trials were performed in Northern France, Germany, Hungary and the UK in 2023 in oilseed rape (2 DCS and 2 HS).

### Field phase

In 3 trials, 3 plots were established: U plot was left untreated. T1 plot was intended for the determination of the residue at harvest or for residue decline and was treated once with CA 2702 at the rate of 1 L/ha (250 g a.s./ha). T2 plot was intended for the determination of the residue in processed fractions and was treated at 3 L/ha (750 g a.s./ha).

In the last trial, 2 plots were established: U plot was left untreated. T plot was intended for residue decline and treated once with CA 2702 at the rate of 1.0 L/ha, representing 250 g/ha of azoxystrobin at application

For all trials, 1 application was made at end of flowering (BBCH 69).

In plots U and T1, grain specimens were placed into labelled plastic bags, weighed and double bagged. Specimens were frozen within 3 hours after sampling and shipped on freezer truck.

In plots U and T2, grain specimens for processing were collected and stored under ambient conditions before being shipped in cool conditions (about 8°C) to the processing site.

### Processing phase

Please refer to A 2.2.5.2.4.

### Analytical phase

Samples of oilseed rape (whole plant, pods, rest of plant and seed) as well as its processed fractions (RAC rapeseed, press cake, crude oil, refined oil, meal and extracted oil) were analysed for residues of azoxystrobin in accordance to guidance document SANTE/2020/12830, rev. 2 for risk assessment and/or monitoring.

~~The analytical phase is ongoing.~~

A validation for the high water content matrix oilseed (whole plant) and for the high oil content matrix oilseed rape (seed) ~~will be~~ was part of this analytical phase.

For matrices oilseed rape (pods, rest of plant, RAC rapeseed, press cake, crude oil, refined oil, meal and extracted oil) the applicability/suitability of the method will be demonstrated by concurrent recoveries within this analytical phase.

Analyses of specimens were performed at Eurofins. The analytical method was described and validated in Eurofins reports Analytical Phase Report S23-100807-L1 (EAS-2311) included in this study.

The method was successfully validated for determination of oilseed rape (whole plant, seed and meal) with an LOQ of 0.01 mg/kg and up to 0.1 mg/kg according to guidance document(s) SANTE/2020/12830, rev. 2.

With regard to selectivity, accuracy and precision, the analytical method was applied successfully for each analytical set for oilseed rape (whole plant, pods, rest of plant and seed) as well as its processed fractions (RAC rapeseed, press cake, crude oil, refined oil, meal and extracted oil) when analysing the samples of the study.

Limit of quantification (LOQ) achieved was 0.01 mg/kg for azoxystrobin. Limit of determination (LOD) was found to be 0.003 mg/kg. The determination of azoxystrobin was performed by LC/MS/MS.

The maximum storage interval was 270 days for all oilseed rape samples between sampling and analysis.

The storage temperature of the samples at the analytical test site was  $\leq -18^{\circ}\text{C}$  with no exceedance.

The maximum storage interval of final sample extracts at typically 1°C to 10°C from extraction until injection to the detection system was 7 days for whole plant, 5 days for RAC rapeseed, one day for press

cake, crude oil, refined oil, meal and extracted oil and 0 days for pods, rest of plant and seed. Extract stability was demonstrated within this study: recoveries are within 70 % - 120 % in all matrix extracts for at least 2 days when considering all matrices (covering all actual storage durations) when stored at typically 1 °C to 10 °C in the dark.

## Findings

Ongoing

The azoxystrobin levels found in oilseed rape are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg).

**Table A 109: Summary of the study S23-100807 trials**

Active substance (common name):	AZOXYTROBIN	Commercial Product (name):	CA2702
Crop/crop group:	Oilseed rape	Producer of commercial product:	Nufarm S.A.S.
Responsible body for reporting (name, address)	Nufarm Crop Products UK Wyke Lane, Wyke, Bradford, BD12 9EJ, United Kingdom		
Content of active substance nominal (g/kg or g/L):	250 g/L	Indoor/Glasshouse/Outdoor:	Outdoor
		Other active substance in the formulation (common name and content):	none
Formulation (e.g. WP):	SC	Residues calculated as:	Azoxystrobin (mg/kg)

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
S23-100807-01 27478, Altenbruch, Niedersachsen, Germany	Oilseed rape / DK Exception	02 Sep 2022 20 Apr – 22 May 2023 21 Jul 2023	Foliar with plot sprayer	0.260	291	0.089	22/05/23	69	Whole plant	U: <0.01 T: 2.1	0	Analytical validation report S23-100807 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 270 days
									Whole plant	T: 0.05	14	
									Whole plant	T: 0.04	21	
									Pods	U: <0.01 T: 0.01	35	
									Rest of plant	U: <0.01 T: 0.04	35	
									seed	U: <0.01 T: <0.01	60	
				0.785	293	0.268	22/05/23	69	Seed	U: <0.01 T: 0.01/<0.01	60	
									Press cake	U: <0.01 T: 0.01		
									Crude oil	U: <0.01 T: 0.01		
									Refined oil	U: <0.01 T: 0.01		
									Meal	U: <0.01 T: 0.03		
									Extracted oil	U: <0.01 T: <0.01		

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
S23-100807-02 L39 9EN, Bickerstatte, Lancashire, UK	Oilseed rape / Ramses	15 Aug 2022 Not applicable 20 Jul 2023	Foliar with plot sprayer	0.249	200	0.125	01/06/23	69	Whole plant	U: <0.01 T: 2.2	0	Analytical validation report S23-100807 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 260 days
									Whole plant	T: 0.20	14	
									Whole plant	T: 0.07	21	
									Pods	T: 0.02	35	
									Rest of plant	T: 0.07	35	
									seed	U: <0.01 T: <0.01	49	
				0.759	202	0.376	01/06/23	69	Seed	U: <0.01 T: 0.02/0.02	49	
									Press cake	U: <0.01 T: <0.01		
									Crude oil	U: <0.01 T: < 0.01		
									Refined oil	U: <0.01 T: <0.01		
									Meal	U: <0.01 T: 0.01		
									Extracted oil	U: <0.01 T: <0.01		

1 Report No. Location (region)	2 Commodity/Variety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 PHI (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
S23-100807-03 67860, Boofzheim, Bas Rhin, Alsace, France	Oilseed rape / LG Airon	24 Aug 2022 10 Apr – 10 May 2023 28 Jun 2023	Foliar with plot sprayer	0.243	243	0.100	09/05/23	69	seed	U: <0.01 T: <b>&lt;0.01</b>	50	Analytical validation report S23-100807 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 226 days
				0.744	248	0.300	09/05/23	69	Seed	U: <0.01 T: 1.9/2.0	50	
									Press cake	U: <0.01 T: 0.05		
									Crude oil	U: <0.01 T: 0.07		
									Refined oil	U: <0.01 T: 0.07		
									Meal	U: <0.01 T: 0.05		
S23-100807-04 H-2484, Agard, Fejer, Hungary Plot 2	Oilseed rape / Dariot	07 Sep 2022 Mid Apr to start of May 29 Jun 2023	Foliar with plot sprayer	0.251	352	0.071	08/05/23	69	seed	U: <0.01 T: <b>&lt;0.01</b>	52	Analytical validation report S23-100807 LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 232 days

U: Untreated, T: Treated

#### **A 2.2.4 Magnitude of residues in livestock**

No new data submitted.

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

##### **A 2.2.5.1 Distribution of the residue in peel/pulp**

No new data submitted.

##### **A 2.2.5.2 Processing studies on a core set of representative processes**

##### **A 2.2.5.2.1 Study ChR-10-8230**

Comments of zRMS:	<p>The study was conducted to determine residues of azoxystrobin in barley raw agricultural commodity (RAC grain and straw) and processed fractions specimens of summer barley after two applications of NUL 2206. Four residues trials were performed in Poland during 2010.</p> <p>T1 plot was intended for residue at harvest, treated twice with NUL 2206 at the rate of 1 L/ha. T2 plot was intended for residue in processing fractions, treated at 3 L/ha, representing 750 g/ha of azoxystrobin at each application.</p> <p>In each trial, two foliar applications were made on T1 and T2 plots. Applications were placed at late stem elongation (BBCH 39 – flag leaf stage) and at end of heading (BBCH 59).</p> <p>One sampling was taken at harvest in each plot, between 34 to 40 days after last application. PL01 was conducted as a balance trial. PL02, PL03 and PL04 were conducted as follow up trials.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix. Sufficient stability data are available to support the residue data presented in this study.</p> <p>Grains used for processing were characterized by a higher azoxystrobin residue level (0.41 mg/kg on average).</p> <p>In processed fractions, azoxystrobin residue level was reduced in almost all fractions analyzed (cleaned grain, de-germinated malt, germs, spent grain, wort, flocs, yeast, beer and pot barley). Transfer factors were below 0.40.</p> <p>Azoxystrobin and z-isomer residues were increased in hulls. Average Transfer Factors were 9.41 for azoxystrobin and 8.61 for its Z-isomer respectively.</p> <p>The study is acceptable.</p>
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Reference: KCA 6.3.1/08

Report Magnitude Of The Residues Of Azoxystrobin In Summer Barley (RAC Grain And Straw) And Processed Fractions Following Two Applications Of NUL 2206, Poland, 2010  
Roussel, C-H., 2011  
Report No.: ChR-10-8230

Guideline(s): Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2).  
-General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5)  
-Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000.  
-Guidance document on residue analytical methods. Document SANCO

825/00, 2004.

-Method validation and quality control procedures for pesticide residues analysis in food and feed. Document SANCO/10684/2009, 2010.

Deviations: None

GLP: Yes

Acceptability: Yes

### **Materials and methods**

Please refer to summary made under A 2.2.3 Magnitude of residues in plants for further details on the field and analytical phase.

Four residue trials were conducted in Poland on barley during 2010.

#### *Processing phase*

Upon arrival, the grains received were cleaned. With clean grain, the following processing were conducted separately: beer (including malting) and pot barley processing. All specimens issued from barley processing were frozen and shipped in freezer truck with dry ice inside the shipment boxes. They were delivered to the analytical site frozen and in good condition.

#### Malting processing

The malting is composed of three different stages:

- Steeping: barley is passed successively through water (three times) and through air (two times). This at a temperature of 16°C for approximately 42 hours (summer barley).
- Germination: barley is kept at 16°C for approximately 120 hours.
- Kilning: barley passes 6 different stages between 30° and 80°C. This treatment lasts approximately 24 hours.

Germs were removed. De-germinated malt was kept at +5 to +10°C before brewing, for a minimum of eight days (malt maturation).

#### Brewing method

Malt was ground. Ground malt was mixed with water at approximately 45°C (mashing-in). Wort pH was corrected to approximately 5.5, by addition of lactic acid.

Brewing was composed of different stages: firstly at 45°C for 20 minutes, secondly at 64°C for 20 minutes and thirdly at 74°C for 30 minutes. Wort was filtered and cooked at approximately 100°C for 1h30. At the start of the cooking, hops (pellets or CO<sub>2</sub> extract) were added to the wort. At the end of the cooking, pH of the wort was corrected to approximately 5.5, by addition of lactic acid.

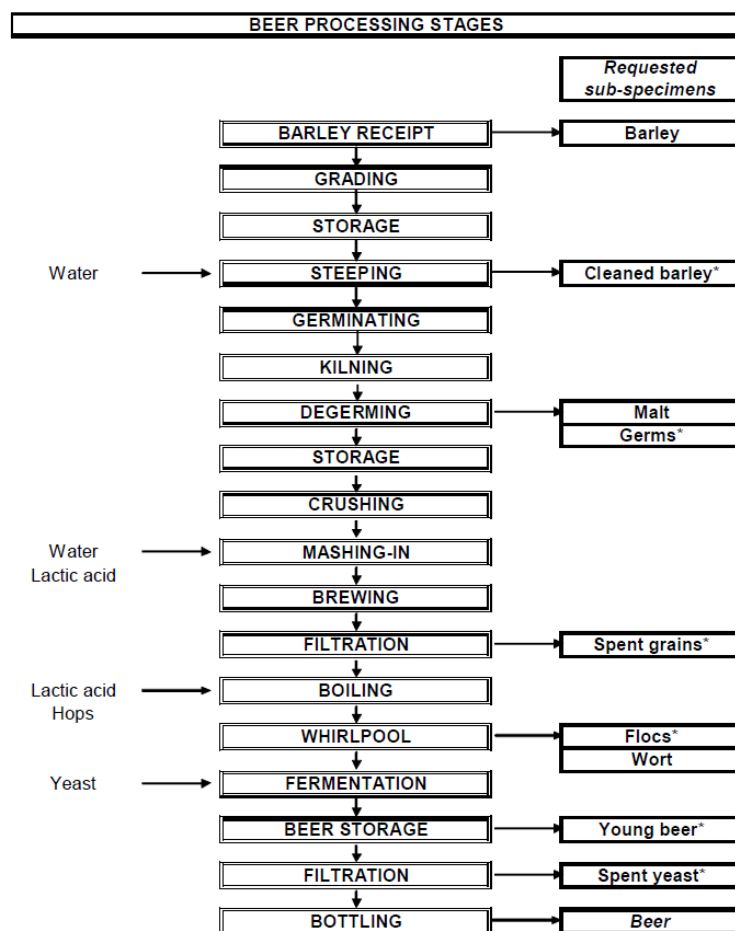
Suspension particles in the wort was removed by passing through whirlpool stages.

The wort was cooled and put in a fermentation tank thermoregulated at 12°C.

Wort was inoculated with yeast at 12°C. Beer fermentation was monitored on working days measuring the density. The fermentation was regarded as finished when density is remained stable for two consecutive days.

After fermentation, beer was stored for 15 days minimum at 0 to +5°C. Beer was filtrated using a plate filter and then bottled.

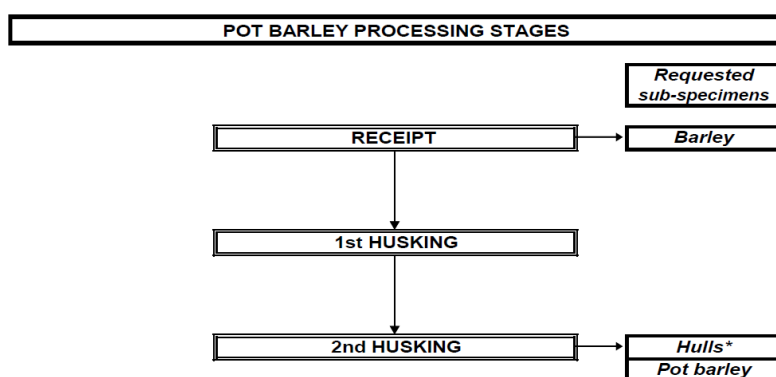




\* Only for the trial ChR-10-8230 PL01

### Pot barley processing

The barley was introduced in the husker "SATAKE" 100 g at a time until the require quantity was added. The time spent in the husker was determined for each modality. After each passage, the hulls and the pot barley were recovered in plastic bags. The waste and the pot barley was transported at ambient temperature at the STAPHYT processing laboratory to be weighed.



\* Only for the trials ChR-10-8230 PL01& ChR-10-8230 PL02

### Results

The azoxystrobin levels found in barley are summarised in the table below. In all untreated specimens, the residue was below LOQ (<0.01 mg/kg). Processing factors were calculated and presented hereafter.

**Table A 110: Residue data from Barley processing study with azoxystrobin**

Trial number	Residues in RAC (unwashed sample, mg/kg)	PHI (days)	Processed commodity	Residue (mg/kg)	PF*
PL01	0.38	39	Cleaned grain	0.069	0.18
			De-germinated malt	0.11	0.29
			Germes	0.15	0.39
			Spent grain	0.047	0.12
			Wort	<0.01	0.026**
			Flocs	0.015	0.04
			Young beer	<0.01	0.026**
			Beer	<0.01	0.026**
			Pot barley	0.1	0.26
			Hull	3.15	8.29
PL02	0.17	40	De-germinated malt	0.068	0.40
			Wort	<0.01	0.06**
			Beer	<0.01	0.06**
			Pot barley	0.031	0.18
			Hull	1.79	10.53
PL03	0.29	34	De-germinated malt	0.076	0.26
			Spent grain	0.031	0.11
			Wort	<0.01	0.03**
			Beer	<0.01	0.03**
			Pot barley	0.023	0.08
PL04	0.81	37	De-germinated malt	0.14	0.17
			Spent grain	0.05	0.06
			Wort	0.01	0.01
			Beer	<0.01	0.01**
			Pot barley	0.082	0.10

\* Processing factor

\*\* In case residues are < LOQ in the processed commodity, the LOQ value was considered instead for the calculation (worst-case assumption).

#### A 2.2.5.2.2 Study ChR-10-8231

Comments of zRMS:	The study was conducted to determine residues of azoxystrobin in wheat raw agricultural commodity (RAC grain and straw) and processed fractions specimens of winter wheat after two applications of NUL 2206. Four residues trials were performed in Poland during 2010.
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	<p>T1 plot was intended for residue at harvest, treated twice with NUL 2206 at the rate of 1 L/ha. T2 plot was intended for residue in processing fractions, treated twice at 3 L/ha. In each trial, two foliar applications were made on T1 and T2 plots. Applications were placed at late stem elongation (BBCH 39 – flag leaf stage) and at end of flowering (BBCH 69). One sampling was taken at harvest in each plot, between 40 to 46 days after last application. Four trials were processed. PL01 was conducted as a balance trial. PL02, PL03 and PL04 were conducted as follow up trials.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg. Sufficient stability data are available to support the residue data presented in this study.</p> <p>Grain used for processing were characterized by a higher azoxystrobin residue level (0.05 mg/kg in average). In processed fractions, azoxystrobin residue level was reduced in most of the fractions analyzed (white flour, whole meal bread or whole meal flour). Transfer factors were below 1. The azoxystrobin residue was maintained in germs (Transfer factor around 0.8) and increased by concentration on bran (average Transfer Factor was 2.5). Bran was obviously responsible for the higher level in whole meal flour and bread compared to white flour. The study is acceptable.</p>
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Reference:	KCA 6.3.2/04
Report	<p>Magnitude Of The Residues Of Azoxystrobin In Winter Wheat (RAC Grain And Straw) And Processed Fractions Following Two Applications Of NUL 2206, Poland, 2010</p> <p>Roussel, C-H., 2011</p> <p>Report No.: ChR-10-8231</p>
Guideline(s):	<p>-Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2).</p> <p>-General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5)</p> <p>-Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000.</p> <p>-Guidance document on residue analytical methods. Document SANCO 825/00, 2010.</p>
Deviations:	None
GLP:	Yes
Acceptability:	Yes

### Materials and Methods

Please refer to summary made under A 2.2.3 Magnitude of residues in plants for further details on the field and analytical phase.

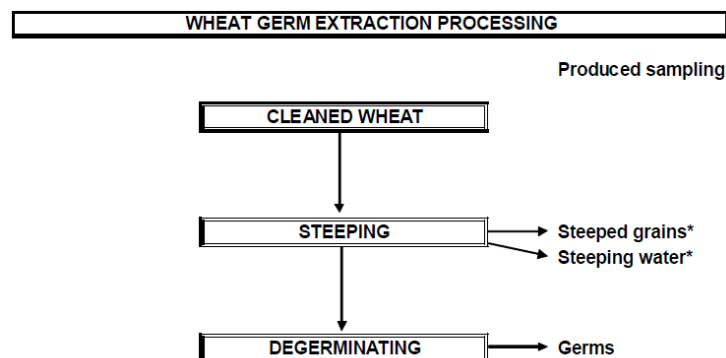
Four residue trials were conducted in Poland on wheat during 2010.

#### *Processing phase*

The grain specimens were processed under normal conditions into white flour, wholemeal flour, wholemeal bread, wheat germs and semolina (middling). Processing specimens were shipped to the analytical site on a freezer truck with dry ice added inside the shipment boxes. They were delivered to the analytical site frozen and in good condition.

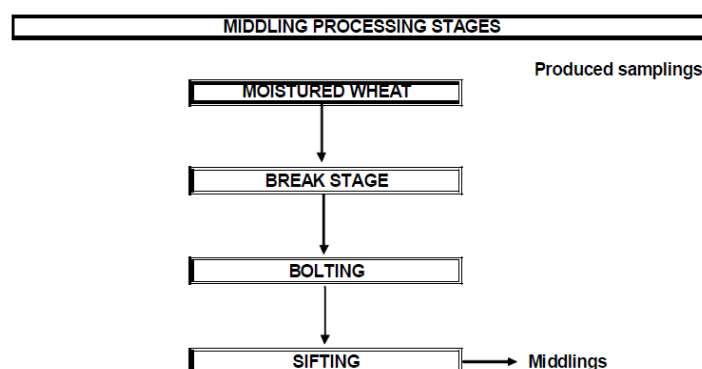
### Germ extraction

After cleaning the grains, 1 kg of cleaned grains was placed in a plastic pan filled with 1 kg of water. The steeping duration was a minimum of 12 hours. After straining, a portion of grains was placed on absorbing paper. For the balance trial, two 0.1 kg wheat steeped grain sub-specimens were taken in plastic bags and two 0.1 kg steeping water samples were taken in plastic bottles and frozen (below  $-18^{\circ}\text{C}$ ). For the other trials, steeping water was discarded. Germs were removed from wheat grains with a cutter.



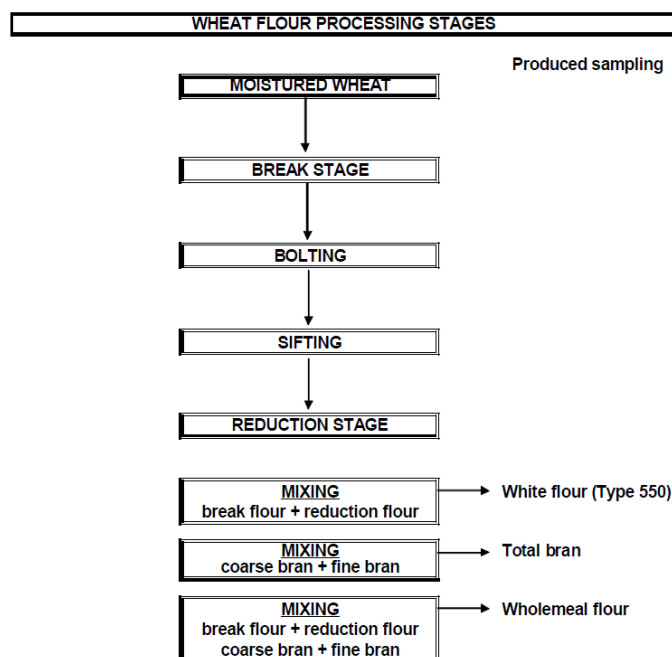
### Middling and flour processing (white flour Type 550 and wholemeal flour)

Middling: the wheat grains were stored in a wet and closed place during minimum 12 hours, to obtain a water content of about 17 %. The moisture wheat grains were placed through a mill consisting of break rolls and screened. The break flour and the bran were weighed and discarded.



White flour (Type 550) processing: The moisture wheat grains were passed through a mill consisting of break rolls and then reduction rolls and screened. After the break stage, coarse bran and break flour were recovered. After the reduction stage, fine bran and reduction flour were recovered. Coarse bran and fine bran were combined to obtain total bran. Break flours and reduction flours were combined to obtain white flour (Type 550).

Wholemeal flour processing: The remaining white flour was mixed to the total bran in proportion to the flour/bran quantity starting (before samplings) to produce wholemeal flour.

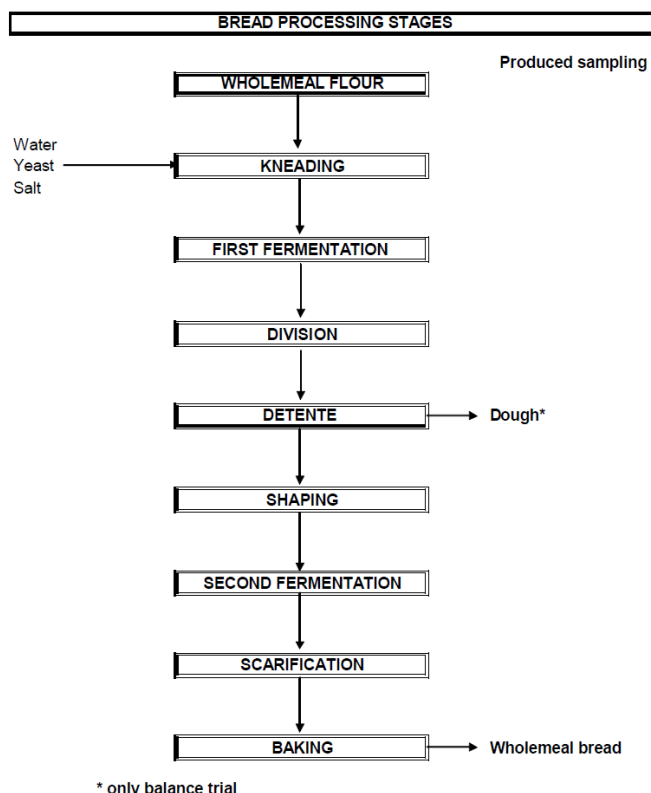


### Bread processing

The wholemeal bread was made with the wholemeal flour obtained. Before the bread processing, the flour moisture was measured. According to the flour moisture, the flour quantity was determined and weighed. The dry baker's yeast was rehydrated with sugar and water. The water quantity to add was calculated. The flour, water and yeast were put in the kneading machine. The mix was kneaded. Five minutes before the end of the kneading, salt was added.

The obtained dough was placed in a pan at ambient temperature for 45 minutes. The dough was divided into several little dough pieces of approximately 350 grammes. The divided dough was covered and kept at ambient temperature for 15 minutes. The divided dough was shaped into a baguette of approximately 35 centimetres. The baguettes were covered and kept at ambient temperature for 2 hours.

The baguette was notched with a knife three times and baked in an oven at 250°C for approximately 20 minutes. The cooked baguettes were taken out of the oven and put on a aired support for cooling.



## Results

The azoxystrobin levels found in wheat are summarised in the table below.

In all untreated specimens, the residue was below LOQ (<0.01 mg/kg).

Processing factors were calculated and presented hereafter.

**Table A 111: Residue data from Wheat processing study with azoxystrobin**

Trial number	Residues in RAC (unwashed sample, mg/kg)	PHI (days)	Processed commodity	Residue (mg/kg)	PF*
PL01	0.074	41	Cleaned grain	0.021	0.28
			Steeped grain	<0.01	0.14**
			Germes	0.024	0.32
			Middlings	0.01	0.14
			White flour	<0.01	0.14**
			Bran	0.050	0.68
			Wholemeal Flour	0.021	0.28
			Wholemeal Dough	0.011	0.15
			Wholemeal bread	0.013	0.18
PL02	0.051	40	Germes	0.065	1.27
			White flour	<0.01	0.20**
			Bran	0.19	3.73
			Wholemeal Flour	0.040	0.78
			Wholemeal bread	0.032	0.63
PL03	0.027	46	Germes	0.023	0.85
			White flour	<0.01	0.37**
			Bran	0.070	2.59

Trial number	Residues in RAC (unwashed sample, mg/kg)	PHI (days)	Processed commodity	Residue (mg/kg)	PF*
			Wholemeal Flour	0.023	0.85
PL04	0.030	42	Wholemeal bread	0.017	0.63
			Germ	0.023	0.77
			White flour	<0.01	0.33**
			Bran	0.090	3.00
			Wholemeal Flour	0.030	1.00
			Wholemeal bread	0.015	0.50

\* Processing factor

\*\* In case residues are < LOQ in the processed commodity, the LOQ value was considered instead for the calculation (worst-case assumption).

### A 2.2.5.2.3 Study ChR-10-8214

Comments of zRMS:	<p>The study was conducted to determine residues of azoxystrobin in oilseed rape raw agricultural commodity (RAC grain) and processed fractions specimens of oilseed rape after one application of NUL 2206. Four residues trials were performed in Poland during 2010. T1 plot was intended for residue at harvest, treated one with NUL 2206 at the rate of 1 L/ha. T2 plot was intended for residue in processing fractions, treated at 3 L/ha. In each trial, one foliar application was made on T1 and T2 plots. Applications were placed at end of flowering (BBCH 69). One sampling was taken at harvest in each plot, between 48 to 52 days after last application.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg. Sufficient stability data are available to support the residue data presented in this study.</p> <p>Untreated specimens from the field and from processing were not contaminated with azoxystrobin or its z-isomer.</p> <p>The grain used for processing had received a higher application rate in the field (NUL 2206 3 L/ha).</p> <p>Azoxystrobin residue level was slightly reduced in the cake taken in one occasion for the balance trial. In oil, transfer factor (TF) was below 1 for 3 trials out of 4. Average TF was 0.63 for raw oil and 0.61 for refined oil, pointing out a decrease of the residue level during processing. Very close results between raw and refined oil showed a strong reliability of the results.</p> <p>No azoxystrobin-z-isomer had been detected above 0.01 mg/kg in the specimens generated during processing phase.</p> <p>The study is acceptable.</p>
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Reference: KCA 6.3.3/05

Report Magnitude Of The Residues Of Azoxystrobin In Oilseed Rape (RAC Grain) And Processed Fractions Following One Application Of NUL 2206, Poland, 2010  
Roussel, C-H., 2011  
Report No.: ChR-10-8214

Guideline(s): -Guidelines for the generation of data concerning residues as provided in Annex II, part A, section 6 and annex III, part A, section 8 of directive 91/414/EEC concerning the placing of plant protection products on the market. (1607/VI/97 rev. 2).

- General recommendation for the design, preparation and realisation of residue trials (7029/VI/95rev.5)
- Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Document SANCO 3029/99, 2000.
- Guidance document on residue analytical methods. Document SANCO 825/00, 2010.
- Method validation and quality control procedures for pesticide residues analysis in food and feed. Document SANCO/10684/2009, 2010.

Deviations: None  
GLP: Yes  
Acceptability: Yes

### **Materials and Methods**

Please refer to summary made under A 2.2.3 Magnitude of residues in plants for further details on the field and analytical phase.

Four trials were performed in Poland in 2010.

#### *Processing phase – Oil processing*

All oilseed rape seed specimens were cleaned with a grading unit. The cleaned oilseed rape seeds were dried in an oven set at 60°C for at least 12 hours before pressing.

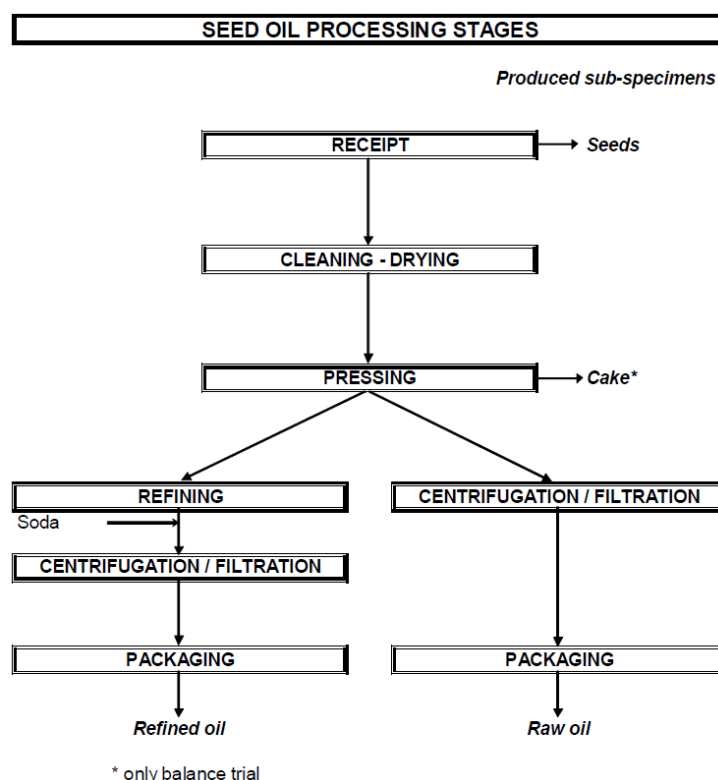
The oilseed rape seeds were introduced into the press.

The cake was collected in a plastic container placed at the press head exit and the oil was collected in a plastic bucket placed under the press head. The obtained oil was separated in two parts: one part to produce raw oil and a second part to produce refined oil.

Raw oil production: After settling for 30 minutes, the oil was centrifuged and then filtered to produce raw oil.

Refined oil production: Soda (concentration: 115 g/L) was added to the other part to produce refined oil. The mixing was maintained for approximately 30 minutes in an oven at a temperature of about 80 -90°C. After a settling period of 30 minutes, the oil was centrifuged and then filtered.





## Results

The azoxystrobin levels found in oilseed rape are summarised in the table below.  
In all untreated specimens, the residue was below LOQ (<0.01 mg/kg).  
Processing factors were calculated and presented hereafter.

**Table A 112: Residue data from Oilseed rape processing study with azoxystrobin**

Trial number	Residues in RAC (unwashed sample, mg/kg)	PHI (days)	Processed commodity	Residue (mg/kg)	PF*
PL01	0.035	48	Cake	0.03	0.86
			Raw oil	0.058	1.66
			Refined oil	0.057	1.63
PL02	0.1	51	Raw oil	0.036	0.36
			Refined oil	0.031	0.31
PL03	0.04	51	Raw oil	0.015	0.38
			Refined oil	0.016	0.40
PL04	0.72	48	Raw oil	0.081	0.11
			Refined oil	0.083	0.12

### A 2.2.5.2.4 Study ongoing S23-100807 - NEU

Comments of zRMS:	<p>Please refer to zRMS conclusion in point A 2.2.3.3.3.</p> <p>Tree residue field trials generated specimens of RAC rapeseed for the processing phase. Rapeseed specimens were sampled for each trial, with two untreated and two treated specimens.</p> <p>Results:</p>
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	<b>Overall Mean Transfer Factors</b>	S23-100807-02-011A and -012A & S23-100807-03-005A and -006A
	Press cake	<0.26
	Crude oil	<0.27
	Refined oil	<0.27
	Meal	0.26
	Extracted oil	<0.26
The study is acceptable.		

Reference:	KCA 6.3.3/07
Report	Determination of residues of Azoxystrobin after a single application of CA2702 in Oilseed rape (outdoor) and its processed fractions at 4 sites in Northern Europe 2023 North, L., <del>ongoing</del> 2024 Report No.: S23-100807
Guideline(s):	OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32) OECD Test Guideline 509: Crop field trials OECD (2016) Guidance Document ENV/JM/MONO (2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66) EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials SANTE/2019/12752 Technical Guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trial and Extrapolation of Residue Data on Products from Plant and Animal Origin (Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3) SANTE/2020/12830, Rev.1 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (Supersedes Guidance Documents SANCO/3029/99 and SANCO/825/00)
Deviations:	<del>Study ongoing</del> Some deviation during the field phase and the processing phase but without impact on the study and the residue data.
GLP:	Yes
Acceptability:	<del>Study ongoing</del> Yes

### Materials and Methods

Please refer to summary made under A 2.2.3 Magnitude of residues in plants for further details on the field and analytical phase.

Three trials were performed in Central administrative zone in 2023.

Processed fractions (RAC rapeseed, press cake, crude oil, refined oil, meal and extracted oil) were analysed for residues of azoxystrobin in accordance to guidance document SANTE/2020/12830, rev. 2 for risk assessment and/or monitoring.

~~Results and details ongoing.~~

*Processing phase – Crude oil processing*

Prior to the start of the processing phase, the sample “Rape seeds, prior to processing” was taken.

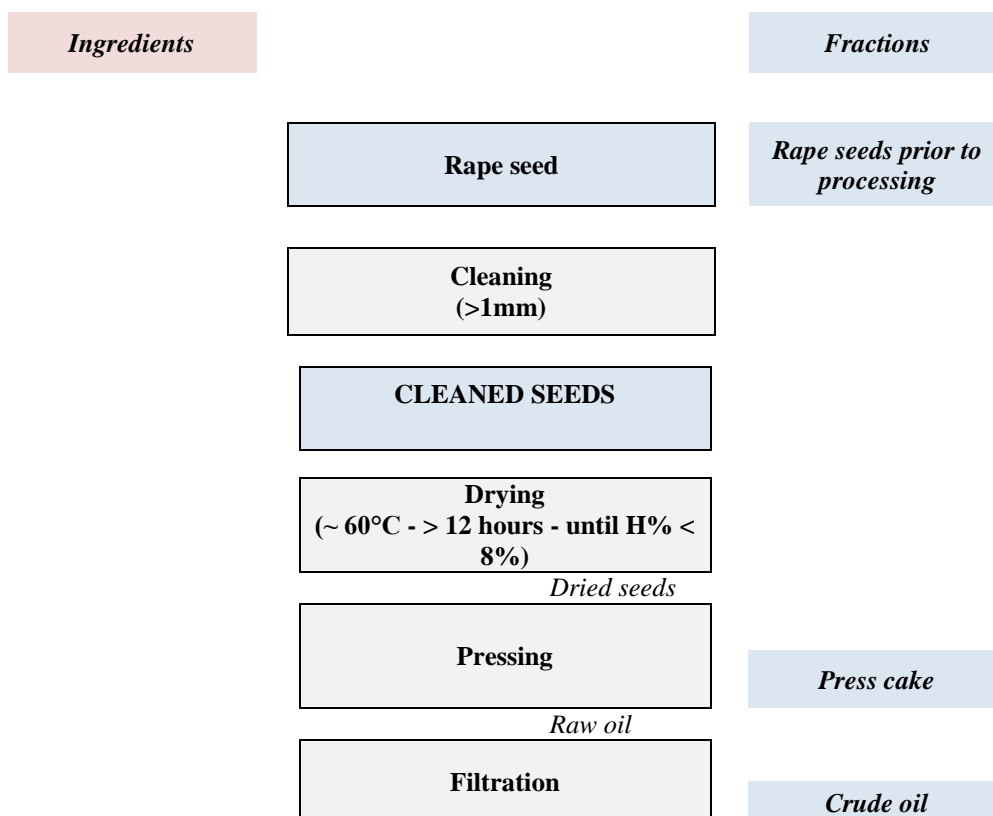
**Sorting / Cleaning:** the seeds were cleaned using suitable cleaning equipment (sample cleaner SLN3). The grains with a size > 1mm were used for the processing.

When necessary, the cleaned seeds were stored in chilled conditions (target temperature +7°C) until the next process.

**Drying:** The cleaned seeds were dried in a drying oven set at 60°C approximately for at least 12 hours. The drying is completed when the moisture of the seeds is lower than 8%.

**Pressing:** The conditioned seeds were pressed mechanically using suitable equipment - “oil extrusion press”. The sample “**Press cake**” was taken.

**Filtration:** Then the raw oil was filtered using a glass feeding bottle, a funnel, a filter sheet (Whatman) and vacuum pump, to obtain the crude oil. The sample “**Crude oil**” was taken.



#### Processing phase – Processing to refined oil

**Degumming:** About 0.4mL of citric acid solution (at 625g/L) per 100g of crude oil were added to the crude oil. The mixture was stirred continuously and heated at about 95°C, for minimum 35 minutes.

**Neutralisation:** A soda solution (NaOH at 118g/L) was added to the oil (about 1.8mL per 100g of crude oil) (still under continuous stirring, above 95°C). The mixture was stirred continuously and heated at about 95°C, for about 50 minutes.

**Centrifugation:** After cooling down, the oil was centrifuged about 3 minutes to remove the aqueous wastes.

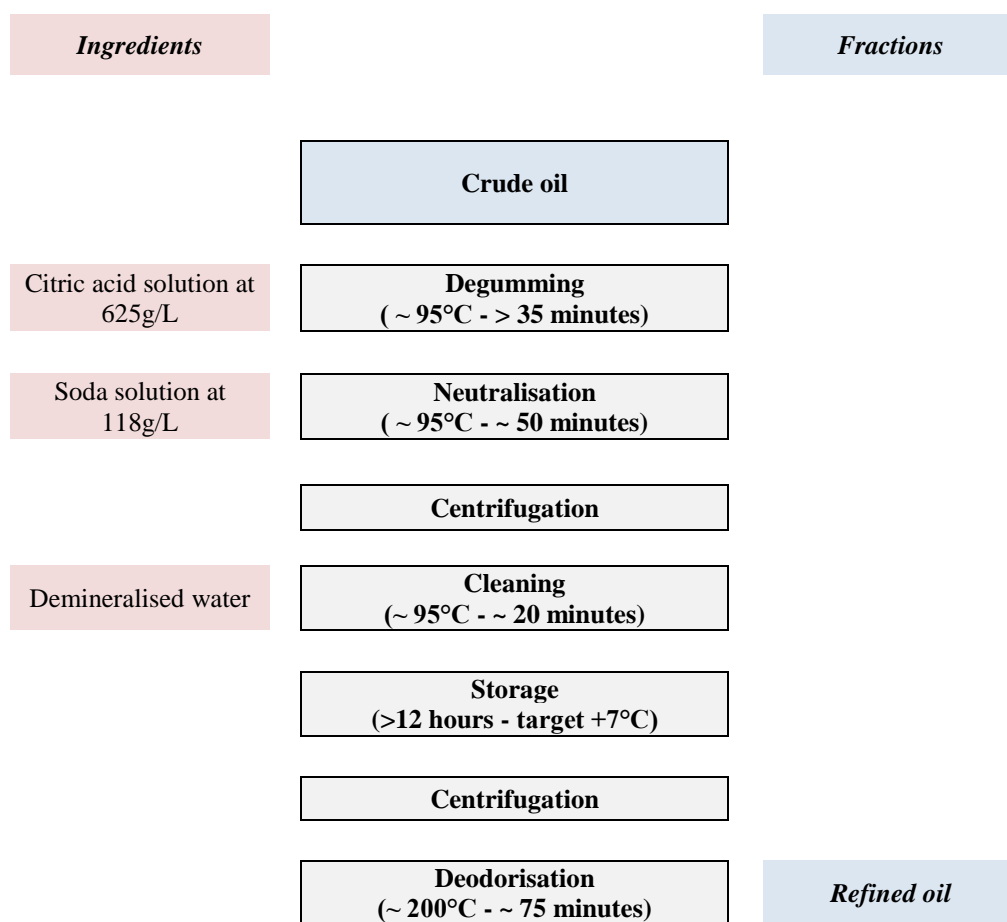
**Cleaning:** About 10% (w/w) of demineralised water was added to the oil and heated to about 95°C for 20 minutes in the oven.

Then, the aqueous wastes were removed with a separator funnel.

**Storage:** The oil was then stored in cool conditions (target +7°C) overnight (for minimum 12 hours).

**Centrifugation:** The oil was centrifuged.

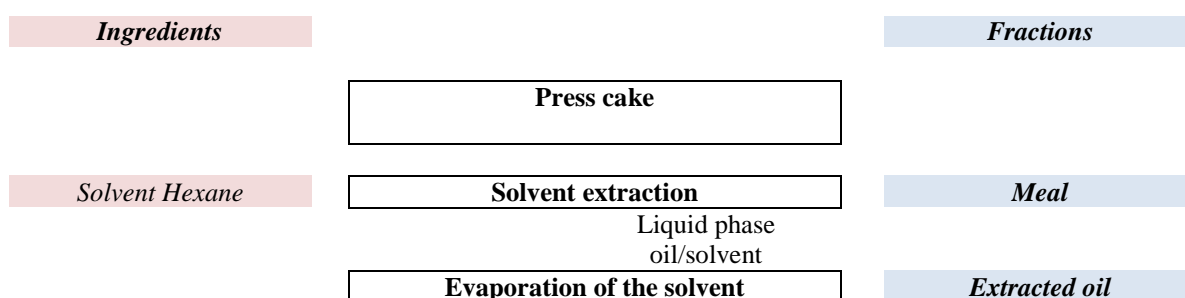
**Deodorisation:** The oil was put into the oven at about 200°C for minimum 75 minutes. The sample “**Refined oil**” was taken.



#### Processing phase –Oil after solvent extraction

**Solvent extraction:** The press cake was “washed” with the solvent (about 1L of hexane (CAS Number 110-54-3) per kg of press cake). The liquid phase was separated from the solid phase (meal) by decantation. The “Meal” was sampled.

**Evaporation:** Then the liquid phase was heated until evaporation of the solvent. The **extracted oil** was produced and sampled.



#### Results

The azoxystrobin levels found in oilseed rape are summarised in the table below. In all untreated specimens, the residue was below LOQ (<0.01 mg/kg). Processing factors were calculated and presented hereafter.

**Table A 113: Residue data from Oilseed rape processing study with azoxystrobin**

Trial number	Residues in RAC (unwashed sample, mg/kg)	PHI (days)	Processed commodity	Residue (mg/kg)	PF*
S23-100807-01	0.01 / < 0.01 (Average: <0.01)	60	Press cake	0.01	Not applicable
			Crude oil	0.01	Not applicable
			Refined oil	0.01	Not applicable
			Meal	0.03	Not applicable
			Extracted oil	<0.01	Not applicable
S23-100807-02	0.02 / 0.02 (Average: 0.02)	49	Press cake	<0.01	Not applicable
			Crude oil	< 0.01	Not applicable
			Refined oil	<0.01	Not applicable
			Meal	0.01	0.50
			Extracted oil	<0.01	Not applicable
S23-100807-03	1.9 / 2.0 (Average: 1.95)	50	Press cake	0.05	0.03
			Crude oil	0.07	0.04
			Refined oil	0.07	0.04
			Meal	0.05	0.03
			Extracted oil	0.04	0.02

\* Processing factor

## A 2.2.6 Magnitude of residues in representative succeeding crops

### A 2.2.6.1 Study ChR-10-8233

Comments of zRMS:	<p>The study was conducted to determine magnitude of residues of azoxystrobin and its z-isomer in rotational crops following two applications of NUL 2206 at 1L/ha on summer barley.</p> <p>Treated summer barley was sampled at 20 Days After Last Application as green material and at harvest (grain and straw separately), 36 to 40 days after application.</p> <p>At three different Plant Back Intervals (30 days after last application, 2 months and 10 months), three crops were settled on the trial plots. Replacement or rotational crops were radishes, lettuce and barley (summer or winter according to the season).</p> <p>PBI 1 was established 28 days after last application and 8 days after summer barley destruction.</p> <p>PBI 2 was established 2 months after last application, after normal harvest as normal succeeding crops.</p> <p>PBI 3 was established 10 months after last application as a normal following season.</p> <p>Untreated specimens were not contaminated with azoxystrobin or azoxystrobin z-isomer.</p> <p>Residues of azoxystrobin and its z-isomer found in treated summer barley were normal either in green material at 20 days after application or at harvest.</p> <p>Residues of azoxystrobin in green material were 1.75 mg/kg on average (1.37 – 2.13). Residues in grain were 0.074 mg/kg on average (0.058 – 0.089). Residues in straw were 2.41 mg/kg (1.64 – 3.18).</p> <p>Residues of z-isomer in green material were 0.071 mg/kg on average (0.061 – 0.081). Residues in straw were 0.172 mg/kg (0.083 – 0.26). No z-isomer residues were found in grain above LOQ.</p> <p>In rotational crops, neither azoxystrobin nor its z-isomer residue was found above LOQ in any specimen taken in the two trials PL01 and PL02: radishes (roots or leaves), lettuces</p>
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	heads, barley (green material, grain or straw) at any sampling interval.
	The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.

Reference:	KCA 6.6.2/01
Report	Magnitude Of The Residues Of Azoxystrobin In Rotational Crops Following Two Applications Of NUL 2206 On Summer Barley, Poland, 2010-2011 Roussel, C-H., 2011 Report No.: ChR-10-8233
Guideline(s):	OECD Guideline for the Testing of Chemicals on Residues in Rotational Crops (Limited Field Studies) (TG 504 published in January 2007) General recommendation for the testing of plant protection products in rotational crops (7524/VI/95 rev.2)
Deviations:	None
GLP:	Yes
Acceptability:	Yes

## Materials and Methods

Two trials were performed in Poland in 2010 in a summer barley field.

### *Field phase*

Two plots (6 sub-plots in total) were established in each trial: 3 untreated plots (U1, U2 and U3) were left untreated. T1, T2 and T3 plots were intended for 3 Plant Back intervals (PBI), 30 days, 2 months and 10 months respectively. Each treated plot was treated twice with NUL 2206 at the rate of 1 L/ha, representing 250 g/ha of azoxystrobin.

In each trial, two applications were made on T1, T2 and T3 plots. Applications were made at end of stem elongation (BBCH 39) and before flowering (BBCH 59).

20 days after application, summer barley was destroyed on plots PBI 1 (U1 and T1) and 28 days after last application, three types of crops were established (planted or sown) at three different Plant Back Intervals (PBI): radishes, lettuce and summer barley.

On plot U2 and T2, the summer barley was normally harvested at 36 to 40 Days After Last Application (DALA). 2 months after last application three rotational crops were established: radishes, lettuce and winter barley.

On plot U3 and T3, after normal harvest, the soil was left as such during winter and 10 months after last application, actually 300 DALA for summer barley and 314 DALA for radishes and lettuce, the same rotational crops were established.

Two samplings were taken in treated summer barley: green material before destruction in PBI 1 and barley grain and straw separately in PBI 2. In addition, one sampling was taken at normal harvest stage in each individual plot of rotational crops. Exception for summer barley in PBI 1: due to the climate specificity in Poland, this crop was not susceptible to finish its cycle before winter; the sampling was taken as green material just before winter 2010.

The BBCH at sampling for the rotational crops was the following:

- Barley green material: BBCH 59-73
- Barley grain and straw: BBCH 89
- Radish root and leaves: BBCH 49
- Lettuce head: BBCH 18-49

All specimens were placed into labelled plastic bags, weighed and double bagged, frozen within 4 hours after sampling and shipped on freezer truck. They were delivered in frozen, good condition to analytical site.

#### *Analytical phase*

Analyses of specimens were performed at Food Safety Laboratory (FSL). The analytical method was described and validated in FSL report PBBZ-2011/07/DPL, separately from this study.

The limit of quantification (LOQ) achieved was 0.01 mg/kg for azoxystrobin. Limit of determination (LOD) was found to be between 0.001 and 0.004 mg/kg according to the matrices. The LOD was estimated from the lowest calibration standard concentration used with a signal to noise ratio  $\geq 3$ . The determinations of azoxystrobin were performed by LC/MS/MS.

The maximum storage intervals were 402 days for all samples between sampling and analysis, and 1 day between extraction and analysis.

#### **Findings**

The azoxystrobin levels found in summer barley and the rotational crops radish, lettuce and barley are summarised in the table below.

In all untreated specimens, the residue was below LOQ ( $<0.01$  mg/kg).

No azoxystrobin residue above 0.01 mg/kg was found in any succeeding crops at all PBIs.

#### **Please note that:**

- Trial ChR-10-8233 PL01 at PBI 2 months and trial ChR-10-8230 PL02 (study on primary crops) were performed in similar conditions (location, variety, date and similar application rate on the primary crop barley). The residue level measured in barley grain is the same in both trials (0.058 mg/kg). For straw, the residue level is higher in primary crops ChR-10-8230 PL02 (1.72 mg/kg) compared to rotational crop ChR-10-8233 PL01 (1.64 mg/kg).
- Trial ChR-10-8233 PL02 at PBI 2 months and trial ChR-10-8230 PL04 (study on primary crops) were also performed in similar conditions (location, variety, date and similar application rate on the primary crop barley). The residue level measured in barley grain is higher in primary crops (0.10 mg/kg) compared to rotational crop (0.089 mg/kg). For straw, it is the opposite: the residue level is lower in primary crops (1.93 mg/kg) compared to rotational crop (3.18 mg/kg).

The highest value was considered for the risk assessment.

**Table A 114: Rotational trial summary for ChR-10-8233 study**

Preceding crop:	Summer Barley	Analytical method:	FSL PBBZ-2011/07/DPL
Succeeding crop:	Radish, lettuce and barley	Limit of Quantification (mg/kg):	0.001 mg/kg
Indoor/Outdoor:	Outdoor		
Formulation:	SC	Residues calculated as:	Azoxystrobin
Content of active substance (g/kg or g/L):	250 g/L		

1 Report No. Location (region)	2 Commodity/V ariety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 DALA (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
Poland Wielkopolska 63-040 Chlawecin Trial number ChR-10-8233 PL01	Summer barley Granal  (Preceding crop)	1- 31/03/10 2- 18/06/10 3- 26/07/10	Foliar broadcast application	0.260	300	0.087	09/06/10 16/06/10    <b>PBI 30 days</b>	39 59	<b>Barley green Material</b>	<b>U: &lt;0.001 T: 1.37</b>	<b>20</b>	U: Untreated T: Treated Analytical validation report FSL PBBZ-2011/07/DPL LOQ: 0.01 mg/kg  Max. Storage Interval between sampling and analysis: 402 days
				0.256	296	0.086			Radishes roots	U: <0.001 T: <0.001	68	
									Radishes leaves	U: <0.001 T: <0.001	68	
									Lettuce	U: <0.001 T: <0.01	76	
									Barley green material	U: <0.001 T: <0.01	106	



1 Report No. Location (region)	2 Commodity/V ariety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 DALA (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
				0.262 0.259	302 299	0.087 0.087						
							09/06/10 16/06/10	39 59	Barley Grain	U: <0.001 T: 0.058	40	
									Barley Straw	U: <0.004 T: 1.64	40	
									Radishes roots	U: <0.001 T: <0.001	98	
									Radishes Leaves	U: <0.001 T: <0.001	98	
									Lettuce	U: <0.001 T: <0.01	98	
									Barley grain	U: <0.001 T: <0.001	379	
									Barley straw	U: <0.004 T: <0.004	379	
							09/06/10 16/06/10	39 59	Radishes roots	U: <0.001 T: <0.001	348	
									Radishes Leaves	U: <0.001 T: <0.001	348	
									Lettuce	U: <0.001 T: <0.001	371	
									Barley grain	U: <0.001 T: <0.001	405	
									Barley straw	U: <0.004 T: <0.004	405	

1 Report No. Location (region)	2 Commodity/V ariety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 DALA (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
Poland Wielkopolska 63-040 Michalow Trial number ChR-10-8233 PL02	Summer barley Johan <b>(Preceding crop)</b>	1- 02/04/10 2- 18/06/10 3- 22/07/10	Foliar broadcast application	0.260	300	0.087	09/06/10 16/06/10  <b>PBI 30 days</b>	39 59	<b>Barley green Material</b>	<b>U: &lt;0.001 T: 2.13</b>	<b>20</b>	U: Untreated T: Treated Analytical validation report FSL PBBZ-2011/07/DPL LOQ: 0.01 mg/kg Max. Storage Interval between sampling and analysis: 402 days
				0.258	298	0.087			Radishes roots	U: <0.001 T: <0.001	68	
									Radishes leaves	U: <0.001 T: <0.01	68	
									Lettuce	U: <0.001 T: <0.01	75	
									Barley green material	U: <0.001 T: <0.001	107	
				0.258	298	0.087	09/06/10 16/06/10  <b>PBI 2 months</b>	39 59	<b>Barley Grain</b>	<b>U: &lt;0.001 T: 0.089</b>	<b>36</b>	
				0.258	298	0.087			<b>Barley Straw</b>	<b>U: &lt;0.004 T: 3.18</b>	<b>36</b>	
									Radishes roots	U: <0.001 T: <0.001	97	
									Radishes Leaves	U: <0.001 T: <0.01	97	
									Lettuce	U: <0.001 T: <0.01	97	
									Barley grain	U: <0.001 T: <0.001	386	
									Barley straw	U: <0.004 T: <0.004	386	

1 Report No. Location (region)	2 Commodity/V ariety	3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest	4 Method of Treatment	5 Application rate per treatment			6 Dates of treatment(s) or no. of treatment(s) and last date	7 Growth stage at last treatment or date  BBCH	8 Portion analysed	9 Residues (mg/kg) (*)	10 DALA (days)	11 Remarks
				kg a.s./ha	Water (L/ha)	kg as/hL				Azoxystrobin		
				0.262 0.260	303 300	0.086 0.087				U: <0.001 T: <0.001		
							09/06/10 16/06/10    <b>PBI 10 months</b>	39 59	Radishes roots  Radishes Leaves  Lettuce  Barley grain  Barley straw	U: <0.001 T: <0.01  U: <0.001 T: <0.001  U: <0.001 T: <0.001  U: <0.004 T: <0.004	348  348  371  406  406	

## A 2.2.7 Other/Special Studies

The applicant Nufarm has a letter of co-ownership by the Azoxystrobin Task Force which authorizes Nufarm to access to the studies submitted during the AIR4 renewal of azoxystrobin (process currently ongoing).

For the residue studies on bee products, the applicant kindly asks the zRMS to refer to the studies submitted for the AIR4 renewal of azoxystrobin.

It should be noted that during the AIR4 renewal process, one study (Report No S21-01128) was still ongoing. As the report is now available, the study is summarised hereafter.

### A 2.2.7.1 Study 1 (S21-01128)

Comments of zRMS:	<p>The study has been evaluated and accepted by zRMS-PL in RR – Part B7 for A22773A/Orondis Evo (June 2023). This study has not been reassessed in the framework of this application.</p> <p>The conclusions of the assessment are presented below:</p> <p><i>The study contained five field trials (four were performed successfully) on winter oilseed rape was conducted in northern/southern Europe. Azoxystrobin was applied to winter oilseed rape as A12705B, an SC formulation containing nominally 250 g azoxystrobin per litre. Two applications, (applied at growth stage 62-65 BBCH), separated by a 5-7 day interval were made at a nominal rate of 250 g ai/ha for A1 and A2.</i></p> <p><i>Treated samples were collected once at maturity (trials -01 and -04) of honey or at the end of flowering (trials -02 and -05) at 2-18 days after the last application (DALA). Untreated samples were collected once at maturity (trials -01 and -04) of honey or at the end of flowering (trials -02 and -05) at 2-18 days after the last application (DALA). In trial -03 no samples could be collected. The samples of trials -02 and -05 were dried in the laboratory to reach the requested sugar content of at least 80%. The sugar content of the honey samples was assessed by performing BRIX analysis.</i></p> <p><i>The ranges of residues of azoxystrobin were &lt;0.01 – 0.02 mg/kg and R230310 were &lt;0.01 mg/kg.</i></p> <p><i>No residues of azoxystrobin and its metabolite R230310 at or above the limit of quantification of 0.01 mg/kg were found in any of the untreated honey samples.</i></p> <p><i>Samples were stored frozen for a maximum period of 76 days from sampling to extraction. Field samples for residue analysis were analysed for azoxystrobin and its metabolite R230310 in honey using method RAM 305/03 as described in Syngenta Report Number: T011298-06-REG. The analytical method has been validated for beer, wheat flour and various crop matrices and honey.</i></p> <p><i>Limit of Quantification: 0.01 mg/kg</i></p> <p><i>The study is acceptable.</i></p>
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Reference:	KCA 6.10/02
Report	<p>Azoxystrobin - Determination of Residues of Azoxystrobin and R230310 (z-isomer) in Honey after Two Applications of A12705B to Winter Oilseed rape at 5 Sites in Northern and Southern Europe in 2021</p> <p>Appeltauer, A., 2022</p> <p>Report No S21-01128</p>
Guideline(s):	<p>OECD 509</p> <p>OECD 506</p> <p>SANTE/11956/2016 rev. 9</p> <p>SANTE/2020/12830 rev. 1</p>
Deviations:	None from guidelines
GLP:	Yes

Owner: Syngenta Ltd  
(Nufarm Crop Products UK has a letter of co-ownership by the Azoxystrobin Task Force)

Acceptability: Yes

### Materials and methods

Four residue trials, located in Germany, Austria and Spain were conducted in 2021 with winter oilseed rape as a melliferous source. A fifth residue trial on winter oilseed rape in Romania was not successfully conducted because it was not possible to sample enough honey for analysis.

A12705B 250 g/L SC was applied twice, at a nominal application rate of 250 g a.s./ha for each application. The applications were conducted during flowering between BBCH 62-65 and separated by a 5–7-day interval.

In each trial, the honeybee hives were installed in tunnel tents (5 m × 40 m with a height of 3.5 m) placed over the winter oilseed rape plots at growth stage BBCH 62. The number of honeybees at the first colony assessment were in the range from 6500 to 15912 bees per colony over all trials. For each trial, the colonies were as homogeneous as possible. The condition of the hives and the brood development were checked once prior to the set-up in the tunnels and once after the sampling of honey.

Treated samples were collected once at maturity (trials -01 and -04) of honey or at the end of flowering (trials -02 and -05) at 2-18 days after the last application (DALA). Untreated samples were collected once at maturity (trials -01 and -04) of honey or at the end of flowering (trials -02 and -05) at 2-18 days after the last application (DALA). The samples of trials -02 and -05 were dried in the laboratory to reach the requested sugar content of at least 80%. The sugar content of the honey samples was assessed by performing BRIX analysis.

All samples were transported on dry ice to the test facility/test site and were stored deep frozen ( $\leq -18^{\circ}\text{C}$ ).

Samples were analysed for azoxystrobin and R230310 (Z-isomer) using the Syngenta method RAM 305/03. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte with a limit of detection (LOD) set at 0.003 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ).

#### *Maximum storage period of honey samples and extracts*

Samples were stored frozen for a maximum period of 76 days from sampling to extraction.

The storage stability of azoxystrobin and R230310 (Z-isomer) in honey was investigated within the study. Residues of azoxystrobin and its metabolite R230310 in honey have been shown to be stable under these conditions for at least 81 days.

- Three (3) control samples at Day 0 and two (2) control samples for the end of the storage period (Day X) were fortified for each analyte. A set of pre-weighed control samples was also stored under the same conditions as the fortified samples, to be used for the control and freshly fortified recovery samples analysed with each storage interval.
- One (1) control, two (2) procedural recovery and three (3) fortified storage stability samples were analysed for residues of azoxystrobin and its metabolite R230310 immediately following preparation (i.e. Day 0).
- One (1) control, two (2) procedural recovery and two (2) fortified storage stability samples were analysed for residues of azoxystrobin and its metabolite R230310 at the end of the storage period (i.e. Day 81).
- The control, procedural recovery and fortified storage stability samples were analysed for residues of azoxystrobin and its metabolite R230310 using analytical method RAM 305/03 as described in Syngenta Report Number: T011298-06-REG.

An assessment of the storage stability samples (fortified at  $10\times$  LOQ) was made using the quantitation transition only. Samples are said to be stable if the % recovery of each individual fortified sample at the end of the storage period is within 70 - 110% of nominal and if the residue level in the stored samples (%)

of nominal) is within  $\pm 30\%$  of the initial.

**Table A 115: Storage Stability of Azoxystrobin in Honey Samples**

Interval Storage Time (Actual)	Nominal Fortification Level	Procedural Recovery		Mean Procedural Recovery	Uncorrected Stored Sample Residue	Mean Uncorrected Stored Sample Residue	Mean Corrected Stored Sample Residue <sup>2</sup>	Mean Corrected Stored Sample Recovery <sup>3</sup>
days	mg/kg	mg/kg	%	mg/kg (%)	mg/kg	mg/kg (% of nominal)	mg/kg	% of nominal
<b>Azoxystrobin</b>								
0	0.100	0.105 0.105	105 105	0.105 (105)	0.108 0.108 0.108	0.108 (108)	0.103	103
81	0.100	0.090 0.093	90 93	0.092 (92)	0.096 0.094	0.095 (95)	0.103	103
<b>R230310</b>								
0	0.100	0.105 0.103	105 103	0.104 (104)	0.108 0.105 0.106	0.106 (106)	0.102	102
81	0.100	0.087 0.091	87 91	0.089 (89)	0.096 0.090	0.093 (93)	0.104	104

% recovery and % of nominal fortification level are calculated on rounded data and are not corrected for the residue found in the control samples.

1 [Mean Procedural Recovery Sample Residue (mg/kg) / Nominal Fortification Level (mg/kg)] x 100

2 [Mean Uncorrected Stored Sample Residue (mg/kg) / Mean Procedural Recovery (%)] x 100

3 Based on nominal fortification level = [Mean Corrected Stored Sample Residue (mg/kg) / Nominal Fortification Level (mg/kg)] x 100

Extract solutions were analysed on the same day of extraction for azoxystrobin and its metabolite R230310. The stability of the analytes in the sample extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the sample extracts.

The stability of azoxystrobin and its metabolite R230310 in in final sample extracts was assessed by storing final extracts fortified at 10x LOQ refrigerated at 1 °C - 10 °C. The samples were then re-analysed by a second measurement after 12 days storage using freshly prepared calibration standards. Results show azoxystrobin and its metabolite R230310 are stable up to 12 days in in final sample extracts.

**Table A 116: Recovery Data for Extract Stability Obtained after 12 Days' Storage at 1 °C to 10 °C for Honey**

Storage interval <sup>a</sup>	Fortification level	Recoveries Single Values						No. of Analyses	Mean	Rel. Std. Dev.	Range
days	mg/kg	%							%	%	%
Azoxystrobin											
0	0.10	100	100	102	100	100	5	100	0.89	100-102	
12	0.10	97	97	95	97	97	5	97	0.93	95-97	
Difference of recoveries after storage to recoveries before storage [%] <sup>b</sup>									-3.8	-	-
R230310											
0	0.10	99	100	100	99	99	5	99	0.55	99-100	
12	0.10	96	95	96	96	96	5	96	0.47	95-96	
Difference of recoveries after storage to recoveries before storage [%] <sup>b</sup>									-3.8	-	-

a Time interval between 1st and 2nd injection

b Difference of recoveries after storage to recoveries before storage = (100 % × mean of the 2nd injection / mean of the 1st injection) – 100 %

## Results and discussions

No residues of azoxystrobin or R230310 at or above the limit of quantification (0.01 mg/kg) were found in any of the untreated honey samples.

The residue levels of all analytes found in honey are summarised in the table below.

**Table A 117: Summary of the study S21-01128 trials**

<b>Trial number</b>	<b>Country</b>	<b>Variety</b>	<b>Application date</b>	<b>Application rates (g a.s./ha)</b>	<b>BBCH at application</b>	<b>Timing</b>	<b>Matrix</b>	<b>Residue of Azoxystrobin (mg/kg)</b>	<b>Residue of R230310 (mg/kg)</b>
S21-01128-01	76646, Heidelberg, Baden-Württemberg, Germany	Winter Oilseed Rape, LG Architect	22 Apr 2021 27 Apr 2021	243.3 247.0	62 63 (5DAA1)	2 DALA	Honey	<u>0.02</u>	<0.01
S21-01128-02	8263, Großwilfersdorf, Hartberg-Fürstenfeld, Austria	Winter Oilseed Rape, PT 271	30 Apr 2021 6 May 2021	247.9 249.6	62 63 (6DAA1)	14 DALA	Honey	<u>&lt;0.01</u>	<0.01
S21-01128-03	300645, Timisoara, Timis, Romania	Winter Oilseed Rape, Expower	19 Apr 2021 26 Apr 2021	263.5 270.3	62 63 (7DAA1)	Not applicable <sup>a</sup>	Honey	-	-
S21-01128-04	02640, Almansa, Albacete, Spain	Winter Oilseed Rape, Florida	11 Apr 2021 18 Apr 2021	251.8 245.0	62 63 (7DAA1)	12 DALA	Honey	<u>&lt;0.01</u>	<0.01
S21-01128-05	02150, Valdeganga, Albacete, Spain	Winter Oilseed Rape, Florida	6 Apr 2021 12 Apr 2021	255.9 245.8	62 63-65 (6DAA1)	18 DALA	Honey	<u>&lt;0.01</u>	<0.01

<sup>a</sup> No honey could be sampled. There was no honey available on the combs entered before setup of colonies in the tunnels.

### A 3.1 TMDI calculations

## Prothioconazole-desthio

Chronic risk assessment: JMPR methodology (IEDI/TMDI)												
			No of diets exceeding the ADI: ---								Exposure resulting from commodities not under assessment (in % of ADI)	
TMDI/NED/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)		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)		
	41%	NL toddler	4.10	8%	Wheat	7%	Maize/corn	6%	Milk: Cattle	11%		
	36%	GEMS/Food G11	3.61	15%	Soyabeans	7%	Wheat	3%	Barley	3%		
	35%	GEMS/Food G10	3.49	13%	Soyabeans	8%	Wheat	2%	Barley	3%		
	34%	GEMS/Food G15	3.42	9%	Wheat	7%	Soyabeans	3%	Barley	3%		
	34%	GEMS/Food G07	3.38	8%	Wheat	7%	Soyabeans	2%	Barley	3%		
	33%	GEMS/Food G08	3.35	8%	Wheat	8%	Soyabeans	4%	Barley	3%		
	33%	GEMS/Food G06	3.32	14%	Wheat	5%	Soyabeans	2%	Peas	3%		
	25%	IE adult	2.47	6%	Peas	5%	Wheat	3%	Lentils	3%		
	24%	FR child 3 15 yr	2.37	9%	Wheat	4%	Lentils	2%	Milk: Cattle	5%		
	23%	DK child	2.35	9%	Wheat	6%	Rye	4%	Carrots	3%		
	23%	NL child	2.28	8%	Wheat	2%	Milk: Cattle	1%	Sunflower seeds	6%		
	22%	ES child	2.21	9%	Wheat	5%	Lentils	2%	Peas	3%		
	22%	RO general	2.17	10%	Wheat	3%	Sunflower seeds	3%	Head cabbages	3%		
	21%	UK infant	2.05	5%	Wheat	4%	Milk: Cattle	4%	Carrots	6%		
	20%	DE child	2.03	8%	Wheat	3%	Carrots	2%	Milk: Cattle	6%		
	19%	FR toddler 2 3 yr	1.89	6%	Wheat	3%	Milk: Cattle	2%	Lentils	5%		
	17%	UK toddler	1.69	8%	Wheat	2%	Milk: Cattle	1%	Carrots	4%		
	16%	IT toddler	1.62	13%	Wheat	0.7%	Lentils	0.5%	Carrots	1%		
	16%	SE general	1.55	6%	Wheat	2%	Carrots	1%	Milk: Cattle	3%		
	15%	PT general	1.55	8%	Wheat	2%	Carrots	1%	Soyabeans	2%		
	14%	ES adult	1.36	5%	Wheat	2%	Lentils	2%	Barley	2%		
	13%	NL general	1.31	4%	Wheat	1%	Barley	0.8%	Milk: Cattle	3%		
	13%	DE general	1.25	4%	Wheat	2%	Barley	1%	Milk: Cattle	3%		
	12%	DE women 14-50 yr	1.16	4%	Wheat	1%	Milk: Cattle	0.8%	Carrots	3%		
	11%	FR adult	1.10	4%	Wheat	1%	Lentils	0.5%	Carrots	2%		
	11%	IT adult	1.05	8%	Wheat	0.4%	Carrots	0.4%	Lentils	0.8%		
	10%	FI 3 yr	1.04	2%	Wheat	2%	Carrots	0.9%	Potatoes	2%		
	10%	FR infant	0.99	3%	Carrots	2%	Milk: Cattle	2%	Wheat	3%		
	9%	FI 6 yr	0.89	2%	Wheat	2%	Carrots	1%	Peas	1%		
	9%	UK vegetarian	0.87	4%	Wheat	0.8%	Lentils	0.6%	Carrots	1%		
	7%	FI adult	0.74	3%	Coffee beans	0.9%	Carrots	0.7%	Peas	3%		
	7%	LT adult	0.73	2%	Wheat	1%	Rye	0.7%	Head cabbages	1%		
	7%	UK adult	0.69	3%	Wheat	0.5%	Carrots	0.3%	Milk: Cattle	1%		
7%	DK adult	0.67	2%	Wheat	1%	Carrots	0.5%	Milk: Cattle	1%			
4%	PL general	0.44	0.8%	Carrots	0.7%	Potatoes	0.7%	Head cabbages	1%			
4%	IE child	0.39	2%	Wheat	0.5%	Carrots	0.4%	Milk: Cattle	0.7%			
<b>Conclusion:</b> The estimated long-term dietary intake (TMDI/NED/IEDI) was below the ADI. The long-term intake of residues of Prothioconazole-desithio (sum of isomers) (F) is unlikely to present a public health concern.												




***Triazole alanine***

Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
			No of diets exceeding the ADI: ---							Exposure resulting from commodities not under assessment	
Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)		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)
				Commodity / group of commodities							
TMDI/NED/IEDI calculation (based on average food consumption)	6%	NL toddler	18.66	1%	Maize/corn	0.8%	Wheat	0.8%	Milk: Cattle		
	4%	GEMS/Food G10	13.34	1%	Soyabeans	0.8%	Wheat	0.3%	Rice		
	4%	GEMS/Food G06	13.31	1%	Wheat	0.5%	Soyabeans	0.3%	Rice		
	4%	GEMS/Food G11	12.12	1%	Soyabeans	0.7%	Wheat	0.2%	Potatoes		
	4%	GEMS/Food G08	12.07	0.8%	Wheat	0.8%	Soyabeans	0.3%	Olives for oil production		
	4%	GEMS/Food G07	11.67	0.9%	Wheat	0.7%	Soyabeans	0.2%	Potatoes		
	4%	GEMS/Food G15	11.19	0.9%	Wheat	0.7%	Soyabeans	0.2%	Potatoes		
	4%	NL child	10.52	0.9%	Wheat	0.3%	Milk: Cattle	0.3%	Oil palm fruits		
	3%	DK child	10.20	1%	Rye	0.9%	Wheat	0.2%	Bovine: Muscle/meat		
	3%	FR child 3 15 yr	9.20	1.0%	Wheat	0.4%	Oranges	0.3%	Milk: Cattle		
	3%	DE child	8.79	0.9%	Wheat	0.4%	Oranges	0.3%	Milk: Cattle		
	3%	RO general	8.32	1%	Wheat	0.3%	Sunflower seeds	0.2%	Potatoes		
	3%	ES child	7.89	0.9%	Wheat	0.3%	Olives for oil production	0.2%	Oranges		
	3%	SE general	7.61	0.7%	Bovine: Muscle/meat	0.7%	Wheat	0.3%	Potatoes		
	2%	FR toddler 2 3 yr	7.25	0.6%	Wheat	0.4%	Milk: Cattle	0.2%	Bovine: Muscle/meat		
	2%	UK infant	7.16	0.5%	Wheat	0.5%	Milk: Cattle	0.2%	Maize/corn		
	2%	IE adult	6.90	0.5%	Wheat	0.2%	Sweet potatoes	0.1%	Potatoes		
	2%	UK toddler	6.85	0.8%	Wheat	0.3%	Milk: Cattle	0.2%	Potatoes		
	2%	IT toddler	6.43	1%	Wheat	0.3%	Other cereals	0.1%	Tomatoes		
	2%	PT general	6.39	0.8%	Wheat	0.3%	Potatoes	0.2%	Rice		
	2%	NL general	5.82	0.4%	Wheat	0.2%	Oil palm fruits	0.1%	Potatoes		
	2%	DE women 14-50 yr	4.93	0.4%	Wheat	0.2%	Oranges	0.2%	Milk: Cattle		
	2%	DE general	4.92	0.4%	Wheat	0.2%	Oranges	0.2%	Milk: Cattle		
	2%	ES adult	4.79	0.5%	Wheat	0.2%	Olives for oil production	0.1%	Oranges		
	1%	FI 3 yr	4.31	0.3%	Potatoes	0.2%	Wheat	0.1%	Rye		
	1%	IT adult	4.16	0.9%	Wheat	0.1%	Other cereals	0.1%	Tomatoes		
	1%	FR adult	3.61	0.5%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Oranges		
	1%	FI 6 yr	3.41	0.2%	Potatoes	0.2%	Wheat	0.1%	Rye		
	1%	LT adult	3.38	0.2%	Rye	0.2%	Wheat	0.2%	Potatoes		
	1%	UK vegetarian	3.07	0.4%	Wheat	0.1%	Oranges	0.1%	Potatoes		
	1.0%	FR infant	2.94	0.2%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes		
	0.9%	UK adult	2.79	0.3%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Potatoes		
	0.9%	DK adult	2.72	0.2%	Wheat	0.1%	Rye	0.1%	Bovine: Muscle/meat		
	0.6%	FI adult	1.88	0.1%	Rye	0.1%	Potatoes	0.1%	Wheat		
0.5%	IE child	1.50	0.2%	Wheat	0.1%	Rice	0.0%	Milk: Cattle			
0.5%	PL general	1.45	0.2%	Potatoes	0.1%	Onions	0.1%	Tomatoes			
<b>Conclusion:</b> The estimated long-term dietary intake (TMDI/NED/IEDI) was below the ADI. The long-term intake of residues of Triazole alanine is unlikely to present a public health concern.											

## Azoxystrobin

Chronic risk assessment: JMPR methodology (IED/TMDI)												
				No of diets exceeding the ADI : ---							Exposure resulting from	
	Calculated exposure (% of ADI)		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/NEDI calculation (based on average food consumption)	83%	NL toddler	165.46	17%	Oranges	15%	Potatoes	13%	Sugar beet roots	0.4%		
	69%	DE child	138.29	30%	Oranges	9%	Potatoes	3%	Mandarins	0.2%		
	68%	NL child	135.89	21%	Sugar beet roots	12%	Potatoes	11%	Oranges	0.2%		
	57%	FR child 3 15 yr	113.14	26%	Oranges	9%	Sugar beet roots	5%	Potatoes	0.2%		
	50%	GEMS/Food G06	99.69	7%	Oranges	7%	Potatoes	5%	Tomatoes	0.0%		
	48%	UK toddler	95.97	15%	Oranges	12%	Potatoes	8%	Sugar beet roots	0.1%		
	47%	IE adult	94.02	8%	Potatoes	8%	Oranges	5%	Grapefruits	0.1%		
	46%	GEMS/Food G07	92.39	13%	Potatoes	10%	Oranges	2%	Wine grapes	0.1%		
	45%	GEMS/Food G10	90.60	10%	Potatoes	8%	Oranges	3%	Rice	0.1%		
	44%	FR toddler 2 3 yr	88.23	11%	Oranges	7%	Sugar beet roots	7%	Potatoes	0.2%		
	44%	GEMS/Food G11	87.79	14%	Potatoes	5%	Oranges	3%	Lemons	0.1%		
	44%	DE women 14-50 yr	87.52	14%	Oranges	11%	Sugar beet roots	4%	Potatoes	0.1%		
	43%	SE general	86.92	15%	Potatoes	6%	Oranges	3%	Mandarins	0.1%		
	41%	GEMS/Food G08	82.97	14%	Potatoes	3%	Oranges	3%	Onions	0.1%		
	40%	DE general	79.76	12%	Oranges	11%	Sugar beet roots	4%	Potatoes	0.1%		
	39%	GEMS/Food G15	78.51	12%	Potatoes	5%	Oranges	3%	Onions	0.1%		
	39%	PT general	77.61	19%	Potatoes	5%	Oranges	4%	Wine grapes	0.0%		
	38%	RO general	76.13	13%	Potatoes	4%	Onions	4%	Head cabbages	0.1%		
	37%	ES child	74.30	16%	Oranges	6%	Potatoes	3%	Lettuces	0.1%		
	37%	NL general	73.14	9%	Potatoes	8%	Oranges	7%	Sugar beet roots	0.1%		
	36%	UK infant	71.27	11%	Potatoes	10%	Oranges	4%	Sugar beet roots	0.2%		
	34%	FI 3 yr	67.05	17%	Potatoes	3%	Mandarins	2%	Onions	0.0%		
	27%	FI 6 yr	54.14	14%	Potatoes	2%	Mandarins	1%	Onions	0.0%		
	27%	ES adult	53.88	10%	Oranges	4%	Lettuces	3%	Potatoes	0.1%		
	23%	UK vegetarian	46.88	6%	Oranges	5%	Potatoes	1%	Sugar beet roots	0.0%		
	23%	FR infant	46.41	7%	Potatoes	3%	Sugar beet roots	2%	Spinaches	0.1%		
	23%	DK child	45.73	9%	Potatoes	1%	Rye	1%	Oranges	0.1%		
	22%	IT toddler	44.98	4%	Oranges	3%	Potatoes	2%	Lettuces	0.0%		
	22%	FR adult	43.29	4%	Oranges	3%	Wine grapes	3%	Potatoes	0.0%		
	20%	IT adult	40.81	3%	Lettuces	3%	Oranges	2%	Potatoes	0.0%		
20%	PL general	39.56	12%	Potatoes	2%	Onions	1%	Tomatoes	0.0%			
19%	UK adult	38.51	5%	Potatoes	4%	Oranges	2%	Wine grapes	0.0%			
16%	LT adult	32.82	11%	Potatoes	1.0%	Head cabbages	0.9%	Tomatoes	0.0%			
15%	FI adult	29.68	4%	Potatoes	3%	Oranges	1%	Lettuces	0.0%			
14%	DK adult	27.40	4%	Potatoes	1%	Wine grapes	1%	Oranges	0.0%			
6%	IE child	11.34	2%	Potatoes	0.7%	Rice	0.6%	Oranges	0.0%			
<b>Conclusion:</b> The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Azoxystrobin (Reg. (EU) 2022/476) is unlikely to present a public health concern.												

<div> European Food Safety Authority EFSA PRIMo revision 3.1; 2021/01/06</div>			<b>Azoxystrobin Reg. (EU) 2024/1078</b>				Input values							
			LOQs (mg/kg) range from: 0,01 to: 0,05				<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>							
			<b>Toxicological reference values</b>											
			ADI (mg/kg bw/day): 0,2		ARID (mg/kg bw): Not necessary									
			Source of ADI: EFSA		Source of ARID:									
Year of evaluation: 2010		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	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/IEDI calculation (based on average food consumption)	82%	NL toddler	164,38	17%	Oranges		15%	Potatoes		13%	Sugar beet roots	0,4%		
	69%	DE child	137,70	30%	Oranges		9%	Potatoes		3%	Mandarins	0,2%		
	68%	NL child	135,14	21%	Sugar beet roots		12%	Potatoes		11%	Oranges	0,2%		
	56%	FR child 3 15 yr	112,53	26%	Oranges		9%	Sugar beet roots		5%	Potatoes	0,2%		
	49%	GEMS/Food G06	98,93	7%	Oranges		7%	Potatoes		5%	Tomatoes	0,0%		
	48%	UK toddler	95,87	15%	Oranges		12%	Potatoes		8%	Sugar beet roots	0,1%		
	47%	IE adult	93,60	8%	Potatoes		8%	Oranges		5%	Grapefruits	0,1%		
	46%	GEMS/Food G07	91,15	13%	Potatoes		10%	Oranges		2%	Wine grapes	0,1%		
	44%	GEMS/Food G10	88,60	10%	Potatoes		8%	Oranges		3%	Rice	0,1%		
	44%	FR toddler 2 3 yr	88,04	11%	Oranges		7%	Sugar beet roots		7%	Potatoes	0,2%		
	43%	DE women 14-50 yr	86,84	14%	Oranges		11%	Sugar beet roots		4%	Potatoes	0,1%		
	43%	GEMS/Food G11	86,73	14%	Potatoes		5%	Oranges		3%	Lemons	0,1%		
	42%	SE general	84,90	15%	Potatoes		6%	Oranges		3%	Mandarins	0,1%		
	41%	GEMS/Food G08	81,62	14%	Potatoes		3%	Oranges		3%	Onions	0,1%		
	40%	DE general	79,24	12%	Oranges		11%	Sugar beet roots		4%	Potatoes	0,1%		
	39%	GEMS/Food G15	78,00	12%	Potatoes		5%	Oranges		3%	Onions	0,1%		
	39%	PT general	77,09	19%	Potatoes		5%	Oranges		4%	Wine grapes	0,0%		
	38%	RO general	76,13	13%	Potatoes		4%	Onions		4%	Head cabbages	0,1%		
	36%	NL general	72,22	9%	Potatoes		8%	Oranges		7%	Sugar beet roots	0,1%		
	36%	ES child	72,21	16%	Oranges		6%	Potatoes		2%	Lettuces	0,1%		
	36%	UK infant	71,27	11%	Potatoes		10%	Oranges		4%	Sugar beet roots	0,2%		
	33%	FI 3 yr	66,89	17%	Potatoes		3%	Mandarins		2%	Onions	0,0%		
	27%	FI 6 yr	53,74	14%	Potatoes		2%	Mandarins		1%	Onions	0,0%		
	26%	ES adult	51,20	10%	Oranges		3%	Potatoes		3%	Lettuces	0,1%		
	23%	FR infant	46,40	7%	Potatoes		3%	Sugar beet roots		2%	Spinaches	0,1%		
	23%	UK vegetarian	46,20	6%	Oranges		5%	Potatoes		1%	Sugar beet roots	0,0%		
	23%	DK child	45,02	9%	Potatoes		1%	Rye		1%	Oranges	0,1%		
	21%	IT toddler	42,92	4%	Oranges		3%	Potatoes		2%	Tomatoes	0,0%		
	21%	FR adult	42,41	4%	Oranges		3%	Wine grapes		3%	Potatoes	0,0%		
	20%	PL general	39,50	12%	Potatoes		2%	Onions		1%	Tomatoes	0,0%		
	19%	IT adult	38,02	3%	Oranges		2%	Potatoes		2%	Lettuces	0,0%		
	19%	UK adult	37,99	5%	Potatoes		4%	Oranges		2%	Wine grapes	0,0%		
	16%	LT adult	32,50	11%	Potatoes		1,0%	Head cabbages		0,9%	Tomatoes	0,0%		
	14%	FI adult	28,97	4%	Potatoes		3%	Oranges		1%	Mandarins	0,0%		
	13%	DK adult	26,94	4%	Potatoes		1%	Wine grapes		1%	Oranges	0,0%		
	6%	IE child	11,31	2%	Potatoes		0,7%	Rice		0,6%	Oranges	0,0%		

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**IEDI calculations**

**Prothioconazole-desthio**

Not triggered.

**Azoxystrobin**

Not triggered.

## A 3.2 IESTI calculations - Raw commodities

### Prothioconazole-desthio

Unprocessed commodities	<b>Results for children</b>				<b>Results for adults</b>			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	<b>IESTI</b>				<b>IESTI</b>			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	9%	Wheat	0.06 / 0.06	0.87	5%	Wheat	0.06 / 0.06	0.50
	7%	Bovine: Liver	0.04 / 0.08	0.68	3%	Bovine: Liver	0.04 / 0.08	0.34
	6%	Milk: Cattle	0.01 / 0.01	0.62	3%	Rye	0.06 / 0.06	0.29
	4%	Bovine: Kidney	0.01 / 0.11	0.41	3%	Barley	0.06 / 0.06	0.29
	4%	Rye	0.06 / 0.06	0.38	2%	Sheep: Liver	0.04 / 0.08	0.24
	3%	Barley	0.06 / 0.06	0.34	2%	Bovine: Kidney	0.01 / 0.11	0.23
	2%	Poultry: Muscle/meat	0.01 / 0.01	0.17	2%	Milk: Cattle	0.01 / 0.01	0.19
	1%	Eggs: Chicken	0.01 / 0.01	0.12	1%	Poultry: Muscle	0.01 / 0.01	0.12
	0.6%	Mustard seeds	0.06 / 0.06	0.06	0.5%	Poultry: Liver	0.01 / 0.01	0.05
	0.6%	Equine: Muscle/meat	0.01 / 0.01	0.06	0.4%	Eggs: Chicken	0.01 / 0.01	0.04
	0.5%	Sheep: Muscle/meat	0.01 / 0.01	0.05	0.4%	Poppy seeds	0.06 / 0.06	0.04
	0.2%	Bovine: Fat tissue	0.01 / 0.01	0.02	0.4%	Poppy seeds	0.06 / 0.06	0.04
	0.2%	Milk: Sheep	0.01 / 0.01	0.02	0.4%	Oat	0.06 / 0.06	0.04
	0.2%	Swine: Fat tissue	0.01 / 0.01	0.02	0.3%	Rapeseeds/canola seeds	0.06 / 0.06	0.03
	0.1%	Swine: Kidney	0.01 / 0.01	0.01	0.3%	Linseeds	0.06 / 0.06	0.03
	0.1%	Swine: Liver	0.01 / 0.01	0.01	0.2%	Swine: Kidney	0.01 / 0.01	0.02
	0.1%	Poultry: Liver	0.01 / 0.01	0.01	0.2%	Swine: Fat tissue	0.01 / 0.01	0.02
	0.1%	Honey and other apiculture	0 / 0	0.01	0.2%	Goat: Muscle	0.01 / 0.01	0.02
	0.01%	Poultry: Fat tissue	0.01 / 0.01	0.00	0.1%	Swine: Liver	0.01 / 0.01	0.01
					0.1%	Eggs: Quail	0.01 / 0.01	0.01
					0.1%	Poultry: Kidney	0.01 / 0.01	0.01
					0.1%	Sheep: Kidney	0.01 / 0.11	0.01
					0.10%	Bovine: Fat tissue	0.01 / 0.01	0.01
					0.05%	Eggs: Goose	0.01 / 0.01	0.01
					0.04%	Honey and other apiculture	0 / 0	0.00
					0.03%	Poultry: Fat tissue	0.01 / 0.01	0.00
	Expand/collapse list							
	<b>Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)</b>							

## TDMs

### 1,2,4-triazole

Unprocessed commodities	<b>Results for children</b>				<b>Results for adults</b>			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	<b>IESTI</b>				<b>IESTI</b>			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	43%	Milk: Cattle	0.35 / 0.35	43	13%	Milk: Cattle	0.35 / 0.35	13
	9%	Milk: Goat	0.37 / 0.37	8.9	7%	Milk: Goat	0.37 / 0.37	6.8
	3%	Bovine: Liver	0.36 / 0.36	2.9	6%	Milk: Sheep	0.37 / 0.37	5.6
	2%	Bovine: Muscle/meat	0.31 / 0.31	2.2	2%	Bovine: Muscle	0.31 / 0.31	1.8
	2%	Swine: Muscle/meat	0.17 / 0.17	2.1	2%	Sheep: Muscle/meat	0.33 / 0.33	1.6
	2%	Equine: Muscle/meat	0.31 / 0.31	1.9	1%	Equine: Muscle/meat	0.31 / 0.31	1.5
	2%	Sheep: Muscle/meat	0.33 / 0.33	1.8	1%	Bovine: Liver	0.36 / 0.36	1.4
	1%	Milk: Sheep	0.37 / 0.37	1.3	1%	Sheep: Liver	0.39 / 0.39	1.1
	1%	Bovine: Kidney	0.34 / 0.34	1.3	0.8%	Swine: Muscle/meat	0.17 / 0.17	0.82
	0.7%	Poultry: Muscle/meat	0.04 / 0.04	0.68	0.7%	Bovine: Kidney	0.34 / 0.34	0.72
	0.5%	Bovine: Fat tissue	0.24 / 0.24	0.50	0.5%	Goat: Muscle	0.33 / 0.33	0.52
	0.5%	Eggs: Chicken	0.04 / 0.04	0.50	0.5%	Poultry: Muscle	0.04 / 0.04	0.47
	0.3%	Swine: Kidney	0.2 / 0.2	0.25	0.4%	Swine: Kidney	0.2 / 0.2	0.44
	0.2%	Swine: Fat tissue	0.13 / 0.13	0.22	0.3%	Swine: Fat tissue	0.13 / 0.13	0.26
	0.2%	Swine: Liver	0.17 / 0.17	0.21	0.2%	Swine: Liver	0.17 / 0.17	0.24
	0.1%	Wheat	0.01 / 0.01	0.14	0.2%	Bovine: Fat tissue	0.24 / 0.24	0.23
	0.06%	Rye	0.01 / 0.01	0.06	0.2%	Poultry: Liver	0.04 / 0.04	0.19
	0.06%	Barley	0.01 / 0.01	0.06	0.2%	Eggs: Chicken	0.04 / 0.04	0.17
	0.04%	Poultry: Liver	0.04 / 0.04	0.04	0.08%	Wheat	0.01 / 0.01	0.08
	0.01%	Oat	0.01 / 0.01	0.01	0.06%	Eggs: Quail	0.04 / 0.04	0.06
	0.01%	Honey and other apiculture	0 / 0	0.01	0.05%	Poultry: Kidney	0.04 / 0.04	0.05
	0.00%	Rapeseeds/canola seeds	0 / 0	0.00	0.05%	Rye	0.01 / 0.01	0.05
	0.00%	Poultry: Fat tissue	0.04 / 0.04	0.00	0.05%	Barley	0.01 / 0.01	0.05
	0.00%	Linseeds	0 / 0	0.00	0.04%	Sheep: Kidney	0.37 / 0.37	0.04
	0.00%	Mustard seeds	0 / 0	0.00	0.02%	Eggs: Goose	0.04 / 0.04	0.02
					0.01%	Poultry: Fat tissue	0.04 / 0.04	0.01
					0.01%	Oat	0.01 / 0.01	0.01
					0.00%	Honey and other apiculture	0 / 0	0.00
					0.00%	Poppy seeds	0 / 0	0.00
					0.00%	Mustard seeds	0 / 0	0.00
					0.00%	Rapeseeds/canola seeds	0 / 0	0.00
					0.00%	Linseeds	0 / 0	0.00
	<b>Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)</b>							

### Triazole alanine

Unprocessed commodities	<b>Results for children</b>				<b>Results for adults</b>			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	<b>IESTI</b>				<b>IESTI</b>			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	4%	Bovine: Liver	1.36 / 1.36	11	2%	Bovine: Liver	1.36 / 1.36	5.4
	3%	Wheat	0.62 / 0.62	9.0	2%	Wheat	0.62 / 0.62	5.2
	2%	Milk: Cattle	0.04 / 0.04	5.0	2%	Sheep: Liver	1.8 / 1.8	5.0
	1%	Bovine: Muscle/meat	0.62 / 0.62	4.5	1%	Bovine: Muscle	0.62 / 0.62	3.5
	1%	Rye	0.62 / 0.62	3.9	1%	Sheep: Muscle/meat	0.68 / 0.68	3.2
	1%	Equine: Muscle/meat	0.62 / 0.62	3.7	1%	Rye	0.62 / 0.62	3.0
	1%	Sheep: Muscle/meat	0.68 / 0.68	3.7	1.0%	Equine: Muscle/meat	0.62 / 0.62	3.0
	1%	Swine: Muscle/meat	0.27 / 0.27	3.3	0.5%	Milk: Cattle	0.04 / 0.04	1.5
	0.7%	Bovine: Kidney	0.58 / 0.58	2.2	0.5%	Poultry: Liver	0.31 / 0.31	1.5
	0.7%	Poultry: Muscle/meat	0.12 / 0.12	2.0	0.5%	Poultry: Muscle	0.12 / 0.12	1.4
	0.6%	Rapeseeds/canola seeds	1.3 / 1.3	1.8	0.4%	Swine: Muscle/meat	0.27 / 0.27	1.3
	0.5%	Linseeds	1.3 / 1.3	1.4	0.4%	Bovine: Kidney	0.58 / 0.58	1.2
	0.4%	Mustard seeds	1.3 / 1.3	1.3	0.4%	Goat: Muscle	0.68 / 0.68	1.1
	0.4%	Barley	0.21 / 0.21	1.2	0.3%	Barley	0.21 / 0.21	1.0
	0.3%	Milk: Goat	0.04 / 0.04	0.97	0.3%	Poppy seeds	1.3 / 1.3	0.91
	0.2%	Swine: Liver	0.61 / 0.61	0.75	0.3%	Poppy seeds	1.3 / 1.3	0.91
	0.2%	Eggs: Chicken	0.06 / 0.06	0.74	0.3%	Swine: Liver	0.61 / 0.61	0.86
	0.2%	Bovine: Fat tissue	0.34 / 0.34	0.71	0.2%	Milk: Goat	0.04 / 0.04	0.74
	0.1%	Swine: Kidney	0.27 / 0.27	0.34	0.2%	Rapeseeds/canola seeds	1.3 / 1.3	0.69
	0.1%	Poultry: Liver	0.31 / 0.31	0.34	0.2%	Linseeds	1.3 / 1.3	0.62
	0.08%	Swine: Fat tissue	0.14 / 0.14	0.24	0.2%	Milk: Sheep	0.04 / 0.04	0.60
	0.08%	Oat	0.21 / 0.21	0.23	0.2%	Swine: Kidney	0.27 / 0.27	0.59
	0.05%	Milk: Sheep	0.04 / 0.04	0.14	0.1%	Bovine: Fat tissue	0.34 / 0.34	0.33
	0.04%	Honey and other apiculture	0.03 / 0.03	0.12	0.09%	Swine: Fat tissue	0.14 / 0.14	0.28
	0.00%	Poultry: Fat tissue	0.11 / 0.11	0.01	0.09%	Eggs: Chicken	0.06 / 0.06	0.26
					0.04%	Oat	0.21 / 0.21	0.13
					0.03%	Eggs: Quail	0.06 / 0.06	0.08
					0.03%	Poultry: Kidney	0.06 / 0.06	0.08
					0.02%	Sheep: Kidney	0.65 / 0.65	0.07
					0.02%	Honey and other apiculture	0.03 / 0.03	0.05
					0.01%	Poultry: Fat tissue	0.11 / 0.11	0.03
					0.01%	Eggs: Goose	0.06 / 0.06	0.03
	Expand/collapse list							
	<b>Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)</b>							

Unprocessed commodities	<b>Results for children</b> No. of commodities for which ARfD/ADI is exceeded (IESTI):				<b>Results for adults</b> No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	0.5%	Milk: Cattle	0.04 / 0.04	5.0	0.2%	Wheat	0.23 / 0.23	1.9
	0.3%	Wheat	0.23 / 0.23	3.3	0.2%	Milk: Cattle	0.04 / 0.04	1.5
	0.1%	Rye	0.23 / 0.23	1.4	0.1%	Rye	0.23 / 0.23	1.1
	0.10%	Milk: Goat	0.04 / 0.04	0.97	0.07%	Milk: Goat	0.04 / 0.04	0.74
	0.08%	Bovine: Kidney	0.22 / 0.22	0.83	0.06%	Milk: Sheep	0.04 / 0.04	0.60
	0.07%	Poultry: Muscle/meat	0.04 / 0.04	0.68	0.05%	Poultry: Muscle	0.04 / 0.04	0.47
	0.05%	Eggs: Chicken	0.04 / 0.04	0.50	0.05%	Bovine: Kidney	0.22 / 0.22	0.46
	0.05%	Swine: Muscle/meat	0.04 / 0.04	0.48	0.04%	Barley	0.08 / 0.08	0.41
	0.05%	Barley	0.08 / 0.08	0.47	0.03%	Swine: Kidney	0.14 / 0.14	0.31
	0.04%	Bovine: Liver	0.05 / 0.05	0.40	0.02%	Poultry: Liver	0.05 / 0.05	0.24
	0.03%	Bovine: Muscle/meat	0.04 / 0.04	0.29	0.02%	Bovine: Muscle	0.04 / 0.04	0.23
	0.02%	Equine: Muscle/meat	0.04 / 0.04	0.24	0.02%	Bovine: Liver	0.05 / 0.05	0.20
	0.02%	Honey and other apiculture	0.07 / 0.07	0.23	0.02%	Swine: Muscle/meat	0.04 / 0.04	0.19
	0.02%	Sheep: Muscle/meat	0.04 / 0.04	0.22	0.02%	Equine: Muscle/meat	0.04 / 0.04	0.19
	0.02%	Swine: Kidney	0.14 / 0.14	0.18	0.02%	Sheep: Muscle/meat	0.04 / 0.04	0.19
	0.02%	Bovine: Fat tissue	0.08 / 0.08	0.17	0.02%	Eggs: Chicken	0.04 / 0.04	0.17
	0.01%	Milk: Sheep	0.04 / 0.04	0.14	0.01%	Sheep: Liver	0.05 / 0.05	0.14
	0.01%	Oat	0.08 / 0.08	0.09	0.01%	Swine: Fat tissue	0.05 / 0.05	0.10
	0.01%	Swine: Fat tissue	0.05 / 0.05	0.09	0.01%	Honey and other apiculture	0.07 / 0.07	0.09
	0.01%	Swine: Liver	0.05 / 0.05	0.06	0.01%	Bovine: Fat tissue	0.08 / 0.08	0.08
	0.01%	Poultry: Liver	0.05 / 0.05	0.06	0.01%	Swine: Liver	0.05 / 0.05	0.07
	0.00%	Rapeseeds/canola seeds	0.01 / 0.01	0.01	0.01%	Poultry: Kidney	0.05 / 0.05	0.06
	0.00%	Linseeds	0.01 / 0.01	0.01	0.01%	Goat: Muscle	0.04 / 0.04	0.06
	0.00%	Mustard seeds	0.01 / 0.01	0.01	0.01%	Eggs: Quail	0.04 / 0.04	0.06
	0.00%	Poultry: Fat tissue	0.04 / 0.04	0.00	0.01%	Oat	0.08 / 0.08	0.05
					0.00%	Sheep: Kidney	0.25 / 0.25	0.03
					0.00%	Eggs: Goose	0.04 / 0.04	0.02
					0.00%	Poultry: Fat tissue	0.04 / 0.04	0.01
					0.00%	Poppy seeds	0.01 / 0.01	0.01
					0.00%	Poppy seeds	0.01 / 0.01	0.01
					0.00%	Rapeseeds/canola seeds	0.01 / 0.01	0.01
					0.00%	Linseeds	0.01 / 0.01	0.00
	Expand/collapse list							



Unprocessed commodities	<b>Results for children</b> No. of commodities for which ARfD/ADI is exceeded (IESTI):				<b>Results for adults</b> No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	<b>IESTI</b>				<b>IESTI</b>			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	2%	Milk: Cattle	0.04 / 0.04	5.0	0.5%	Milk: Cattle	0.04 / 0.04	1.5
	0.3%	Milk: Goat	0.04 / 0.04	0.97	0.2%	Milk: Goat	0.04 / 0.04	0.74
	0.2%	Poultry: Muscle/meat	0.04 / 0.04	0.68	0.2%	Milk: Sheep	0.04 / 0.04	0.60
	0.2%	Eggs: Chicken	0.04 / 0.04	0.50	0.2%	Poultry: Muscle	0.04 / 0.04	0.47
	0.2%	Bovine: Kidney	0.13 / 0.13	0.49	0.09%	Bovine: Kidney	0.13 / 0.13	0.27
	0.2%	Swine: Muscle/meat	0.04 / 0.04	0.48	0.08%	Bovine: Muscle	0.04 / 0.04	0.23
	0.1%	Bovine: Liver	0.04 / 0.04	0.32	0.06%	Swine: Muscle/meat	0.04 / 0.04	0.19
	0.10%	Bovine: Muscle/meat	0.04 / 0.04	0.29	0.06%	Equine: Muscle/meat	0.04 / 0.04	0.19
	0.08%	Equine: Muscle/meat	0.04 / 0.04	0.24	0.06%	Sheep: Muscle/meat	0.04 / 0.04	0.19
	0.07%	Sheep: Muscle/meat	0.04 / 0.04	0.22	0.06%	Poultry: Liver	0.04 / 0.04	0.19
	0.07%	Bovine: Fat tissue	0.1 / 0.1	0.21	0.06%	Swine: Kidney	0.08 / 0.08	0.18
	0.05%	Wheat	0.01 / 0.01	0.14	0.06%	Eggs: Chicken	0.04 / 0.04	0.17
	0.05%	Milk: Sheep	0.04 / 0.04	0.14	0.05%	Swine: Fat tissue	0.08 / 0.08	0.16
	0.05%	Swine: Fat tissue	0.08 / 0.08	0.14	0.05%	Bovine: Liver	0.04 / 0.04	0.16
	0.03%	Swine: Kidney	0.08 / 0.08	0.10	0.04%	Sheep: Liver	0.04 / 0.04	0.11
	0.02%	Rapeseeds/canola seeds	0.05 / 0.05	0.07	0.03%	Bovine: Fat tissue	0.1 / 0.1	0.10
	0.02%	Honey and other apiculture	0.02 / 0.02	0.07	0.03%	Wheat	0.01 / 0.01	0.08
	0.02%	Rye	0.01 / 0.01	0.06	0.02%	Goat: Muscle	0.04 / 0.04	0.06
	0.02%	Barley	0.01 / 0.01	0.06	0.02%	Swine: Liver	0.04 / 0.04	0.06
	0.02%	Linseeds	0.05 / 0.05	0.05	0.02%	Eggs: Quail	0.04 / 0.04	0.06
	0.02%	Mustard seeds	0.05 / 0.05	0.05	0.02%	Poultry: Kidney	0.04 / 0.04	0.05
	0.02%	Swine: Liver	0.04 / 0.04	0.05	0.02%	Rye	0.01 / 0.01	0.05
	0.01%	Poultry: Liver	0.04 / 0.04	0.04	0.02%	Barley	0.01 / 0.01	0.05
	0.00%	Oat	0.01 / 0.01	0.01	0.01%	Poppy seeds	0.05 / 0.05	0.04
	0.00%	Poultry: Fat tissue	0.04 / 0.04	0.00	0.01%	Poppy seeds	0.05 / 0.05	0.04
					0.01%	Rapeseeds/canola seeds	0.05 / 0.05	0.03
					0.01%	Honey and other apiculture	0.02 / 0.02	0.03
					0.01%	Linseeds	0.05 / 0.05	0.02
					0.01%	Eggs: Goose	0.04 / 0.04	0.02
					0.00%	Sheep: Kidney	0.13 / 0.13	0.01
					0.00%	Poultry: Fat tissue	0.04 / 0.04	0.01
					0.00%	Oat	0.01 / 0.01	0.01
Expand/collapse list								

### A 3.3 IESTI calculations - Processed commodities

#### Prothioconazole-desthio

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)
	7%	Wheat / milling (flour)	0.06 / 0.06	0.73	4%	Barley / beer	0.06 / 0.01	0.43
	3%	Wheat / milling (wholemeal)-l	0.06 / 0.06	0.33	3%	Wheat / bread/pizza	0.06 / 0.06	0.26
	2%	Rye / boiled	0.06 / 0.06	0.22	2%	Wheat / pasta	0.06 / 0.06	0.23
	2%	Oat / boiled	0.06 / 0.06	0.22	2%	Wheat / bread (wholemeal)	0.06 / 0.06	0.21
	2%	Barley / cooked	0.06 / 0.06	0.22	0.9%	Oat / boiled	0.06 / 0.06	0.09
	2%	Rye / milling (wholemeal)-bal	0.06 / 0.06	0.21				
	2%	Oat / milling (flakes)	0.06 / 0.06	0.18				
	1%	Barley / milling (flour)	0.06 / 0.06	0.11				
	0.4%	Rapeseeds / oils	0.06 / 0.12	0.04				
	Expand/collapse list							

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)
	0.1%	Wheat / milling (flour)	0.01 / 0.01	0.12	0.1%	Barley / beer	0.01 / 0	0.07
	0.1%	Wheat / milling (wholemeal)-l	0.01 / 0.01	0.06	0.04%	Wheat / bread/pizza	0.01 / 0.01	0.04
	0.0%	Rye / boiled	0.01 / 0.01	0.04	0.04%	Wheat / pasta	0.01 / 0.01	0.04
	0.0%	Oat / boiled	0.01 / 0.01	0.04	0.03%	Wheat / bread (wholemeal)	0.01 / 0.01	0.03
	0.0%	Barley / cooked	0.01 / 0.01	0.04	0.02%	Oat / boiled	0.01 / 0.01	0.02
0.0%	Rye / milling (wholemeal)-bal	0.01 / 0.01	0.04	#NUM!	#NUM!	#NUM!	#NUM!	
0.0%	Oat / milling (flakes)	0.01 / 0.01	0.03	#NUM!	#NUM!	#NUM!	#NUM!	
0.0%	Barley / milling (flour)	0.01 / 0.01	0.02	#NUM!	#NUM!	#NUM!	#NUM!	
0.0%	Rapeseeds / oils	0 / 0.01	0.00	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
Expand/collapse list								

***Triazole alanine***

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	2%	Wheat / milling (flour)	0.62 / 0.62	7.5	0.9%	Wheat / bread/pizza	0.62 / 0.62	2.7
	1%	Wheat / milling (wholemeal)-l	0.62 / 0.62	3.4	0.8%	Wheat / pasta	0.62 / 0.62	2.4
	0.7%	Rye / boiled	0.62 / 0.62	2.2	0.7%	Wheat / bread (wholemeal)	0.62 / 0.62	2.2
	0.7%	Rye / milling (wholemeal)-bal	0.62 / 0.62	2.2	0.5%	Barley / beer	0.21 / 0.04	1.5
	0.3%	Rapeseeds / oils	1.3 / 2.6	0.76	0.1%	Oat / boiled	0.21 / 0.21	0.32
	0.3%	Oat / boiled	0.21 / 0.21	0.76	#NUM!	#NUM!	#NUM!	#NUM!
	0.3%	Barley / cooked	0.21 / 0.21	0.76	#NUM!	#NUM!	#NUM!	#NUM!
	0.2%	Oat / milling (flakes)	0.21 / 0.21	0.63	#NUM!	#NUM!	#NUM!	#NUM!
	0.1%	Barley / milling (flour)	0.21 / 0.21	0.38	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
Expand/collapse list								

***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)
	0.3%	Wheat / milling (flour)	0.23 / 0.23	2.7	0.1%	Wheat / bread/pizza	0.23 / 0.23	0.99
	0.1%	Wheat / milling (wholemeal)-l	0.23 / 0.23	1.2	0.09%	Wheat / pasta	0.23 / 0.23	0.86
	0.1%	Rye / boiled	0.23 / 0.23	0.82	0.08%	Wheat / bread (wholemeal)	0.23 / 0.23	0.79
	0.1%	Rye / milling (wholemeal)-bal	0.23 / 0.23	0.79	0.06%	Barley / beer	0.08 / 0.02	0.60
	0.0%	Oat / boiled	0.08 / 0.08	0.30	0.01%	Oat / boiled	0.08 / 0.08	0.13
	0.0%	Barley / cooked	0.08 / 0.08	0.30	#NUM!	#NUM!	#NUM!	#NUM!
	0.0%	Oat / milling (flakes)	0.08 / 0.08	0.25	#NUM!	#NUM!	#NUM!	#NUM!
	0.0%	Barley / milling (flour)	0.08 / 0.08	0.15	#NUM!	#NUM!	#NUM!	#NUM!
	0.0%	Rapeseeds / oils	0.01 / 0.02	0.01	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
Expand/collapse list								

***Triazole lactic acid***

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	0.0%	Wheat / milling (flour)	0.01 / 0.01	0.12	0.0%	Barley / beer	0.01 / 0	0.07
	0.0%	Wheat / milling (wholemeal)-l	0.01 / 0.01	0.06	0.01%	Wheat / bread/pizza	0.01 / 0.01	0.04
	0.0%	Rye / boiled	0.01 / 0.01	0.04	0.01%	Wheat / pasta	0.01 / 0.01	0.04
	0.0%	Oat / boiled	0.01 / 0.01	0.04	0.01%	Wheat / bread (wholemeal)	0.01 / 0.01	0.03
	0.0%	Barley / cooked	0.01 / 0.01	0.04	0.01%	Oat / boiled	0.01 / 0.01	0.02
	0.0%	Rye / milling (wholemeal)-bal	0.01 / 0.01	0.04	#NUM!	#NUM!	#NUM!	#NUM!
	0.0%	Oat / milling (flakes)	0.01 / 0.01	0.03	#NUM!	#NUM!	#NUM!	#NUM!
	0.0%	Rapeseeds / oils	0.05 / 0.1	0.03	#NUM!	#NUM!	#NUM!	#NUM!
	0.0%	Barley / milling (flour)	0.01 / 0.01	0.02	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
Expand/collapse list								

## Appendix 4 Additional information provided by the applicant

### A 4.1 Input values for the maximum dietary burden calculation of Triazole alanine considering TDMs EU data and uses under consideration

1 - Forages		STMR	HR	PF	CF	Default PF	STMR by-P	HR by-P
Alfalfa	forage (green)	0.16	0.52	-		-	0.16	0.52
Alfalfa	hay (fodder)	0.16	0.52			2.5	0.40	1.31
Alfalfa	meal	0.16	0.52			2.5	0.40	1.31
Alfalfa	silage	0.16	0.52			1.1	0.18	0.576
Barley	straw	0.12	0.65	-		-	0.12	0.65
Beet, mangel	fodder	0.18	0.239	-		-	0.18	0.239
Beet, sugar	tops	0.04	0.218	-		-	0.04	0.218
Cabbage, heads	leaves	0.17	0.500	-		-	0.17	0.50
Clover	forage	0.16	0.524	-		-	0.16	0.524
Clover	hay	0.16	0.52			3	0.48	1.57
Clover	silage	0.16	0.52			1	0.16	0.524
Corn, field	stover (fodder)	0.12	0.65	-		-	0.12	0.65
Corn, pop	stover (fodder)	0.12	0.65	-		-	0.12	0.65
Grass	forage (fresh)	0.16	0.524	-		-	0.16	0.524
Grass	hay	0.16	0.524			3.5	0.56	1.83
Grass	silage	0.16	0.524			1.6	0.26	0.838
Kale	leaves (forage)	0.17	0.500	-		-	0.17	0.50
Oat	straw	0.12	0.65	-		-	0.12	0.65
Rape	forage	0.10	0.913	-		-	0.10	0.913
Rye	straw	0.12	0.65	-		-	0.12	0.65
Triticale	straw	0.12	0.65	-		-	0.12	0.65
Turnip	tops (leaves)	0.04	0.218	-		-	0.04	0.218
Wheat	straw	0.12	0.65	-		-	0.12	0.65
2 - Roots & Tubers		STMR	HR	-	CF	-	STMR	HR
Potato	culls	0.18	0.239				0.18	0.239
3 - Cereal grains/Crop seeds		STMR	Post-h?	HR	CF	-	STMR	HR
Barley	grain	0.621	N				0.621	
Bean	seed (dry)	0.17	N				0.17	
Corn, field (Maize)	grain	0.621	N				0.621	
Corn, pop	grain	0.62	N				0.62	
Cotton	undelinted seed	1.200	N				1.200	
Cowpea	seed	0.17	N				0.17	
Lupin	seed	0.17	N				0.17	
Oat	grain	0.621	N				0.621	
Rye	grain	0.621	N				0.621	
Soybean	seed	1.200	N				1.200	
Triticale	grain	0.621	N				0.621	
Wheat	grain	0.621	N				0.621	
4 - By-products		STMR	-	PF	CF	Default PF	STMR by-P	-
Apple	pomace, wet	0.32		0.52		5	0.167	
Beet, sugar	dried pulp	0.18				18	3.30	

Beet, sugar	ensiled pulp	0.18				3	0.55	
Beet, sugar	molasses	0.18				28	5.1	
Brewer's grain	dried	0.62				3.3	2.0	
Canola (Rape seed)	meal	1.200		1.4		2	1.68	
Citrus	dried pulp	0.32		0.5		10	0.167	
Corn, field	milled by-pdts	0.62				1	0.621	
Corn, field	hominy meal	0.62				6	3.73	
Corn, field	gluten feed	0.62				2.5	1.55	
Corn, field	gluten, meal	0.62				1	0.621	
Cotton	meal	1.30		1.4		1.3	1.68	
Distiller's grain	dried	0.62				3.3	2.0	
Flaxseed/Linseed	meal	1.200		1.4		2	1.68	
Lupin seed	meal	0.17				1.1	0.187	
Potato	process waste	0.18				20	3.68	
Potato	dried pulp	0.18				38	6.99	
Rape	meal	1.200		1.4		2	1.68	
Safflower	meal	1.200		1.4		2	1.68	
Soybean	meal	1.200		1.4		1.3	1.68	
Soybean	hulls	1.200				13	15.6	
Sugarcane	molasses	0.18				32	5.89	
Sunflower	meal	1.200		1.4		2	1.68	
Wheat gluten	meal	0.62				1.8	1.12	
Wheat	milled by-pdts	0.62				7	4.35	