FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: CHR/F/PROTAZO 375 SC

Product name(s): CLARO 375 SC, KAJMAN 375 SC

Chemical active substance(s):

Prothioconazole, 175 g/L

Azoxystrobin, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: May 2020

MS Finalisation date: 28/04/2022

Version history

When	What
May 2021	Dossier sent for evaluation
December 2021	Applicant updated dRR on the zRMS request
December 2021	Applicant updated data on the zRMS request
January 2022	Applicant updated dRR on the zRMS request
January 2022	zRMS finalised evaluation
April 2022	Final version prepared by zRMS after Commenting period

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zRMS comments:
This report has been completed by the applicant.
The text highlighted in grey was provided by the evaluator.

7 Metabolism and residue data (KCA section 6)

In the following document, data for active substance azoxystrobin was described during its inclusion on Annex 1 process in 2009. Were reference to active substance data in the current risk assessment has been made, it was based on the data presented by Syngenta.
In June 9th, 2011r Amistar 250 SC product has been authorized in Poland thus according to the art. 59 reg. 1107/2009, data protection for mentioned data expired 10 years from date of first authorization of product containing that active substance (in this case June 10th, 2021)

7.1 Summary and zRMS Conclusion

Prothioconazole
Critical GAP for CHR/F/PROTAZO/CLARO 375 SC on cereals (wheat, triticale, barley, rye): 2 appl. in max. BBCH-69, max application rate per treatment: 175 g PROTIO/ha, interval 14-28 days, PHI- 35
EU GAP on wheat, rye, triticale (SANCO/3923/07-final 26 January 2021): max 3 appl., max application rate per treatment 200 g a.s./ha in max BBCB-69; interval 14-21 days, PHI-35
EU GAP on barley, oat (SANCO/3923/07-final 26 January 2021): max 2 appl., max application rate per treatment 200 g a.s./ha in max BBCB-61; interval 14-21 days, PHI-35
EU GAP on rape (SANCO/3923/07-final 26 January 2021): max 2 appl., max application rate per treatment 175 g a.s./ha in start BBCB-53; interval 14-28 days, PHI-56
EU GAP covers the uses proposed on cereals and rape for CHR/F/PROTAZO/CLARO 375 SC.

According to the SANTE/2019/12752, it is possible to extrapolate from any representatives of the oilseeds group (except peenuts) to the whole group in the case the use takes place before forming of the edible part. The proposed use in max BBCH(69) for sunflower, soya, poppy seeds and mustard seeds concerns the flowering phase, ie before the development of the edible parts of the plant.
Prothioconazole belongs to the group of triazole compounds that form metabolites(TDMs): triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA). According to the SANCO/3923/07, 26 January 2021 it has been agreed that the reference values and residue definition that includes TDMs should be used in the risk assessment for triazole active substances and their TDMs for applications for authorization of plant protection products submitted from 1 July 2020. This dossier was submitted before that date.
Stability
The storage stability study evaluated during Annex I inclusion support the residue data presented in this dossier. Taking into account the new requirements regarding TDMs, it should be considered that in this respect the stability studies presented by the Applicant are not sufficient. However, it should be taken into account that the dossier was submitted before the validity date of the assessment for TDMs.
Storage stability of residues in plants (EFSA Journal 2020;18(2):5999: *The storage stability of prothioconazole-desthio in plant samples stored under frozen conditions was investigated in the framework of the MRL review and relevant end points are summarised in Appendix B.1.1.2. In high water and high oil content commodities, relevant for the celeriacs and rapeseeds use, prothioconazole-desthio is stable for a maximum of 24 months, when stored at 18°C (EFSA, 2014). A data gap was noted by EFSA during the MRL review for the need of further storage stability data for at least one hydroxylated metabolite included in the risk assessment residue definition in the relevant commodity groups (i.e. high water, high oil content commodities and dry (high starch/high protein) commodities) (EFSA, 2014). In order to address this data gap (number 38) the EMS referred to storage stability studies submitted by the applicant in the framework of the renewal of the approval (United Kingdom, 2018). EFSA assessed the submitted studies, noting that the renewal of the approval has not been finalised yet. Freezer storage stability of prothioconazole-a-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-*

hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxydesthio 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. 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) when stored at ≤ 18°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. The data gap identified by the MRL review is considered addressed for all crops, except for dry pulses, which belong to dry (high protein content) commodity group in which the storage stability of any of the hydroxy-metabolites of prothioconazole-desthio has not been investigated. The freezer storage stability of various TDMs was investigated in the framework of the peer review of TDMs (EFSA, 2018b). In the commodity groups relevant for the current assessment the stability of all TDMs has been investigated, except that of 1,2,4-T in high protein content matrices, and of 1,2,4-T and TA in rapeseeds (see Appendix B.1.1.2).
Stability of residues in sample extracts has not been investigated in the framework of the first inclusion process. For the new studies provided by the Applicant, study of stability of residue in sample extracts is not required as the analyses were performed within 24 hours.

Nature of residues in crops
According to the EFSA Journal 2020;18(2):5999: *In the framework of the peer review under Directive 91/414/EEC and the Art.12 MRL review (EFSA, 2007b, 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, 2007a,b). In addition, the metabolism of prothioconazole-desthio labelled in the triazole moiety was investigated after foliar applications on cereals (EFSA, 2007b).* ***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. As the parent compound was only present in minor amounts and prothioconazole-desthio was shown to more toxic than the parent compound, it was concluded to define prothioconazole-desthio as the relevant residue for enforcement.*** *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 metabolism studies indicate that in root crops and oilseeds, relevant for the intended uses of prothioconazole on celeriacs and oilseed rape, the main identified TDMs are triazole alanine (TA) (29 total radioactive residue (TRR) in roots; 47.8% TRR in oilseed) and triazole lactic acid (TLA) (24.5% TRR in oilseed).*
According to soil degradation studies, investigated in the framework of the EU pesticides peer review, prothioconazole itself is of very low persistence in soil (DT90 field of 5.5 days (median)), whereas prothioconazole-desthio is of low persistence with DT90 field of 140 days (median) (EFSA, 2007b).
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).*
The effect on the nature of prothioconazole and prothioconazole-desthio in processed commodities has not been investigated in the framework of the EU pesticides peer review. The MRL review referred to studies with prothioconazole investigated by the JMPR and studies with prothioconazole-desthio reported by Germany (EFSA, 2014). Prothioconazole-desthio was reported to be stable under all standard hydrolysis steps (99.4–99.9% applied radioactivity (AR)), whereas parent prothioconazole slightly degraded to prothioconazole-desthio under sterilisation process (≤ 11% AR). The same processing study referred to in the MRL review was now submitted for the renewal of the approval (United Kingdom, 2018).
The remaining compounds included in the risk assessment residue definition were concluded to remain stable under standard hydrolysis conditions, considering their structural similarity to parent compound (EFSA, 2014). The TDMs are stable under hydrolysis studies simulating baking/brewing/boiling, pasteurisation and sterilisation (EFSA, 2018b).

The metabolism of prothioconazole in primary and rotational crops is considered sufficiently addressed (sufficient data are available in the DAR, UK 2004) for the intended uses.
Taking into account that residues of prothioconazole-desthio for the intended uses are below the trigger value of 0.1 mg/kg, no study investigating the nature of residues in processed commodities is required.

Nature of residues in livestock
According to the 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-14C-phenyl]-labelled prothioconazole and prothioconazole-desthio and one study in laying hens using [U-14C-phenyl]-labelled prothioconazole. Besides, two additional studies were assessed by the JMPR (FAO, 2008a, 2008b) on lactating goats and laying hens, using both [3,5-14C-triazole]-labelled prothioconazole.*
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)****.*
EFSA concludes that the residue definition for enforcement in commodities of animal origin is fat soluble.

TDMs

According to the EFSA Journal 2018;16(7):5376: *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 14C-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 14C-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 detected in the ruminant matrices from the feeding study conducted with TA. 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*:

RD for enforcement: Triazole parent compound only

RDs 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

The metabolism of prothioconazole in livestock is considered sufficiently addressed (sufficient data for this application are available in the DAR, UK 2004).

Magnitude of residues in plants

The Applicant did not submit any new data on the level of residues in cereals and used unprotected data assessed during the approval of prothioconazole as active substance. GAP proposed for CHR/F/PROTAZO 375 SC is covered by GAP evaluated at EU level. For the proposed use in oilseed rape, the Applicant has provided 6 trials in line with the proposed GAP for this crop. According to the SANCO 7525/VI/95 Rev. 10.3 oilseed rape is regarded as a major crop therefore 8 trials are required. Therefore, the assessment takes into account unprotected studies assessed at Community level (n=8 for NEU, EFSA 2007 Conclusion on the peer review of prothioconazole). These studies for oilseed rape cover a much more critical use than the ones proposed in this documentation:

EFSA 2007 - Trials GAP: 2 x 0.175 kg as/ha, BBCH 65-78, PHI 56-67

Use proposed for CHR/F/PROTAZO 375 SC – 1 x 0.175 kg as/ha, BBCH 59-69, PHI 56

According to the SANTE/2019/12752, it is possible to extrapolate from any representatives of the oilseeds group (except peenuts) to the whole group in the case the use takes place before forming of the edible part. The proposed use in max BBCH(69) for sunflower, soya, poppy seeds and mustard seeds concerns the flowering phase, ie before the development of the edible parts of the plant. Therefore, the proposed extrapolation of residue results from rapeseed to sunflower, soya, poppy seeds and mustard seeds is accepted. In all cases, the results show no residues above the applicable MRLs.

The proposed use of CHR/F/PROTAZO 375 SC applies to the SC formulation, while all studies supporting the evaluation, both assessed at Community level and the new ones provided by the Applicant were performed for the EC formulation. The SC formulation has not been assessed at Community level. According to the SANTE/2009/12752: *Residue trials that are performed with a formulation type that is not equivalent to the formulation type specified in the GAP under assessment are not acceptable; a complete data set performed with the formulation type defined in the GAP is required, unless comparable residue behaviour can be demonstrated with bridging studies However, experience shows that emulsifiable concentrates (EC), wettable powders (WP), dispersible granules (WG), and suspension concentrates (SC) formulations usually produce comparable residues (especially if the last application is more than seven days prior to harvest) and well-justified and documented departures from the above could be considered.* Considering the above, and the fact that the PHI for all proposed uses for edible crops is at least 35 days and that the proposed uses are less critical than those assessed at Community

level for EC formulations, it is considered that the results of the residue trials for the proposed uses will not be higher than in the studies presented in the dossier. And therefore the related studies assessed for the EC formulation may support the use proposed for the SC formulation.
Magnitude of TDMs in cereals and rapeseed was assessed at Community level (EFSA Journal 2020;18(2):5999) in evaluation confirmatory data following the Article 12 MRL review.
The data provided was considered sufficient taking into account the date of submission of the application.
Dietary burden
Dietary burden calculations performed at EU level seems to cover the uses proposed for CHR/F/PROTAZO 375 SC (EFSA Journal 2020;18(2):5999):

Relevant groups	Dietary burden expressed in				Most critical diet [a]	Most critical commodity [b]		Trigger exceeded (Yes/No) 0.10 mg/kg DM	JMPR 2017 (FAO, 2018) Max burden mg/kg DM
	mg/kg bw per day		mg/kg DM						
	Median	Maximum	Median	Maximum					
Cattle (all diets)	0.036	0.109	1.15	3.10	Dairy cattle	Barley	Straw	Y	18.42 (AUT dairy cattle)
Cattle (dairy only)	0.036	0.109	0.84	2.85	Dairy cattle	Barley	Straw	Y	21.60 (AUT beef cattle)
Sheep (all diets)	0.075	0.236	1.77	5.55	Lamb	Barley	Straw	Y	Not calculated
Sheep (ewe only)	0.059	0.185	1.77	5.55	Ram/ewe	Barley	Straw	Y	Not calculated
Swine (all diets)	0.015	0.018	0.49	0.64	Swine (finishing)	Swede	Roots	Y	Not calculated
Poultry (all diets)	0.035	0.059	0.52	0.86	Poultry layer	Wheat	Straw	Y	3.05 (EU poultry layer)
Poultry (layer only)	0.035	0.059	0.52	0.86	Poultry layer	Wheat	Straw	Y	Not calculated

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

The calculated dietary burdens for all groups of livestock exceeds the trigger value of 0.1 mg/kg DM.
The Applicant did not submit any new livestock feeding studies. The studies that have been assessed at Community level at the inclusion of prothioconazole are sufficient.
No significant residues, i.e. >0.1 mg/kg, were found in grain (both notifiers) and therefore processing studies are not required.

According to the 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*
Considering that the proposed uses are not more critical than those assessed at Community level, no risk mitigation measures need to be proposed.

The proposed uses of prothioconazole in the formulation CHR/F/PROTAZO do not represent unacceptable acute and chronic risks for the consumer.

Azoxystrobin

Critical GAP for CHR/F/PROTAZO/CLARO 375 SC on cereals (wheat, triticale, barley, rye): 2 appl. in max. BBCH-69, max application rate per treatment: 200 g AZX/ha, interval 14-28 days, PHI- 35
Critical GAP for CHR/F/PROTAZO/CLARO 375 SC on rapeseed, mustard seed, poppy seed, soya beans, sunflower seeds: 1 appl. in max. BBCH-69, max application rate per treatment: 200 g AZX/ha, PHI- 56
EU GAP on wheat (SANCO/11027/2011 rev.3): max 2 appl., max application rate per treatment 250 g a.s./ha in max BBCB-59; interval 14 days, PHI-35
EU GAP on barley (SANCO/11027/2011 rev.3): max 2 appl., max application rate per treatment 250 g a.s./ha in max BBCB-69; interval 14 days, PHI-35
EU GAP on rape (EFSA 2013): max 2 appl., max application rate per treatment 250 g a.s./ha, PHI-21
EU GAP covers the uses proposed on cereals and rape for CHR/F/PROTAZO/CLARO 375 SC
Nature of residues
Plant metabolism studies evaluated at Community level support the intended uses proposed in the GAP for CHR/F/PROTAZO 375 SC. The residue definition for enforcement and risk assessment in all plant commodities following foliar application is defined as azoxystrobin.

The nature of residues in rotational crops was evaluated at Community level. Additional studies are not required. It was concluded that metabolism of azoxystrobin in rotational crops is similar to the metabolism observed in primary crops. The relevant residue definition in rotational crops is parent azoxystrobin.
The nature of residues in processed commodities was evaluated at Community level. Addition studies are not required. It was concluded that residue pattern in processed commodities is similar to residue pattern in raw commodities.
The livestock metabolism studies were evaluated at Community level. The general metabolic pathways in rodents and ruminants were found to be comparable therefore extrapolation from ruminants to pig is possible. The residue definition for enforcement is defined as azoxystrobin. No conclusion could be drown on the toxicological profile of metabolites L1, L4 and L9 (genotoxicity of these metabolites can be ruled out), additional data at EU level are required. It is proposed on tentative basis, to define the residue definition for risk assessment as azoxystrobin. Additional studies are not required for this dossier.

Magnitude of residues
The Applicant did not submit any new data on the level of residues in cereals and used unprotected data assessed during the approval of azoxystrobin as active substance (SC formulation). GAP proposed for CHR/F/PROTAZO 375 SC is covered by GAP evaluated at EU level. For the proposed use in oilseed rape, the Applicant has provided 8 trials in line with the proposed GAP for this crop. According to the SANCO 7525/VI/95 Rev. 10.3 oilseed rape is regarded as a major crop therefore 8 trials are required.
According to the SANTE/2019/12752, it is possible to extrapolate from any representatives of the oilseeds group (except peenuts) to the whole group in the case the use takes place before forming of the edible part. The proposed use in max BBCH(69) for sunflower, soya, poppy seeds and mustard seeds concerns the flowering phase, ie before the development of the edible parts of the plant. Therefore, the proposed extrapolation of residue results from rapeseed to sunflower, soya, poppy seeds and mustard seeds is accepted. In all cases, the results show no residues above the applicable MRLs.
However, the studies submitted by the Applicant were performed for formulation SE, while the proposed formulation is SC. For this reason the Applicant has provided bridging studies showing that the residue levels will not be higher when used in the formulation proposed in the GAP for CHR/F/PROTAZO 375 SC. These studies have been approved. No additional studies are required.

According to the EFSA Journal 2020;18(8):6231: *Several rotational crop field trials were evaluated in the framework of the peer review (United Kingdom, 2009). 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 where the highest residues were expected to be 0.05 mg/kg and 0.04 mg/kg, respectively. However, no impact on the residue level in products of animal origin is expected (EFSA, 2013)*.
Based on field rotational crop studies evaluated at Community level residues in rotational and succeeding crops have no impact on the MRLs in plants and livestock commodities. Considering that the proposed

uses are not more critical than those assessed at Community level, no risk mitigation measures need to be proposed.

According to the SANTE/11956/2016 rev.9 rape seed, soya bean, sunflower seed, mustard seed have melliferous capacity. In addition proposed use in rape seed is during flowering and azoxystrobin is systemic substance. Taking into account the above, a residue trials in honey for these crops, are required and were provided by the Applicant. The provided studies were accepted and show no prothioconazole and azoxystrobin residues in the honey after CHR/F/PROTAZO 375 SC application according to the proposed GAP.

Authorization can be granted.

Upon request by the zRMS, the Applicant has provided a summary of the new studies included in this dossier:

Table Residue trial summary for oilseed rape

Trial No./ Location/ Year	*Commodity/ Variety*	*Date of 1.Sowing or planting 2.Flowering 3. Harvest*	*Application rate per treatment*			*Dates of treatment or no. of treatments and last date*	*Growth stage at last treatment or date*	*Portion analyzed*	*Residues (mg/kg)*	*PHI (days)*	*Remarks*
			g a.s./ ha	*Water (l/ha)*	*g a.s./hl*						
Azoxystrobin											
B8178/ 2921 Komarom, Central Transdanucia, Hungary/ 2018	Oilssed rape/ GK Reka	1. 18/08/2017 2.- 3.26/06/2018	260.8	313	83.3	22.05.2018	BBCH 75	5g of seeds	0.026 mg azoxystrobin/kg	35	Foliar application Date of reception: 24.07/2018 Date of extraction: 13.11.2018 Max. Interval: 175 days LOD: 0.003 mg/kg LOQ: 0.01 mg/kg
B8186/ 516 01 Synkov – Slemeno, Hradec Kralove, Czech Republic/ 2018	Oilseed rape/ Rescator	1. 28.08.2017 2.- 3. 20/07/2018	244.2	293	83.3	14.06.2018	77-79	5 g of seeds	0.032 mg azoxystroin/kg	36	Foliar application Date of reception: 24.07.2018 Latest date of extraction: 13.11.2018 Max. Interval: 152 days LOD: 0.003 mg/kg LOQ: 0.01 mg/kg
B8187/ 95-010 Strykow, Lodzkie, Poland/ 2018	Oilseed rape/ Visby	1.28.08.2017 2. – 3. 09.07.2018	253.3	304	83.3	08.06.2018	BBCH 75-76	5g of seeds	0.042 mg azoxystrobin/kg	31	Foliar application Date of reception: 24.07.2018 Latest date of extraction: 13.11.2018 Max. Interval: 158 days LOD: 0.003 mg/kg LOQ: 0.01 mg/kg

Table Residue trial summary for oilseed rape

Trial No./ Location/ Year	*Commodity/ Variety*	*Date of 1.Sowing or planting 2.Flowering 3. Harvest*	*Application rate per treatment*			*Dates of treatment or no. of treatments and last date*	*Growth stage at last treatment or date*	*Portion analyzed*	*Residues (mg/kg)*	*PHI (days)*	*Remarks*
			g a.s./ ha	*Water (l/ha)*	*g a.s./hl*						
B8188./ 79206 Breisach, Baden-Wurttemberg, Germany/2018	Oilseed rape/ Aristoteles	1. 18.09.2017 2. – 3. 26.06.2018	264.2	317	83.3	05.06.2018	BBCH 80-82	5g of seeds	0.036 mg azoxystrobin/kg	35	Foliar application Date of reception: 24.07.2018 Latest date of extraction: 13.11.2018 Max. Interval: 161 days LOD: 0.003 mg/kg LOQ: 0.01 mg/kg
B8190/ 57810 Donnelay, Grand-Est, France/ 2018	Oilseed rape/ Dariot	1. 20.08.2017 2-. 3. 02.07.2018	252.5	303	83.3	31.05.2018	BBCH 69-71	5 g of seeds	0.046 mg azoxystrobin/kg	32	Foliar application Date of reception: 24.07.2018 Latest date of extraction: 13.11.2018 Max. Interval: 166 days LOD: 0.003 mg/kg LOQ: 0.01 mg/kg

Table Residue trial summary for oilseed rape

Trial No./ Location/ Year	*Commodity/ Variety*	*Date of 1.Sowing or planting 2.Flowering 3. Harvest*	*Application rate per treatment*			*Dates of treatment or no. of treatments and last date*	*Growth stage at last treatment or date*	*Portion analyzed*	*Residues (mg/kg)*	*PHI (days)*	*Remarks*
			g a.s./ ha	*Water (l/ha)*	*g a.s./hl*						
B9215/ 51756 Slatina nad Zdobnici, Hradec Kralove, Czech Republic/ 2019	Oilseed rape/ Architect	1. 28.08.2018 2. – 3. 30.07.2019	247.5	297	83.3	25.06.2019	BBCH 79	5 g of seeds	0.098 mg azoxystrobin.kg	35	Foliar application Date of reception in analytical lab: 01.08.2019 Date of extraction: 16.09.2019 Max. Interval: 83 days LOD: 0.003 mg/kg LOQ: 0.01 mg/kg
B9216/ 95-010 Strykow, Lodzkie, Poland/ 2019	Oilseed rape/ Tajfun	1. 20.08.2018 2.- 3. 08.07.2019	261.7	314	83.3	11.06.2019	BBCH 78-79	5g of seeds	0.035 mg azoxystrobin/kg	35	Foliar application Date of reception in analytical lab: 01.08.2019 Date of extraction: 16.09.2019 Max. Interval: 97 days LOD: 0.003 mg/kg LOQ: 0.01 mg/kg
20SGS10/ 89620 Sławęcin, Pomorskie, Poland/ 2021	Oilseed rape/ Atora	1. 27.08.2019 2.- 3. 31.07.2020	238.25	286	83.3	27.05.2020	BBCH 69	5 g of seeds	<LOD for seeds <LOQ for whole plant without root	35	Foliar application Date of reception: 23.09.2020 Date of extraction: 16.12.2020 Max. Interval: 203 days LOD: 0.003 mg/kg LOQ: 0.01 mg/kg

Table Residue trial summary for oilseed rape

Trial No./ Location/ Year	*Commodity/ Variety*	*Date of 1.Sowing or planting 2.Flowering 3. Harvest*	*Application rate per treatment*			*Dates of treatment or no. of treatments and last date*	*Growth stage at last treatment or date*	*Portion analyzed*	*Residues (mg/kg)*	*PHI (days)*	*Remarks*
			g a.s./ ha	*Water (l/ha)*	*g a.s./hl*						
Prothioconazole											
B9146/56125 Rudoltice, Pardubice, Czech Republic/2020	Oilseed rape/ Pioneer PT 271	1. 29.08.2018 2. 3. 20.07.2019	213.3	320	66.6	17.05.2019	BBCH 67	5g	<LOQ ptohioconazole desthio	64	Foliar application Date of extraction: 19.08.2019 Max. Interval: 94 days LOD: 0.003 mg/kg LOQ: 0.01 mg/kg
B9147/95061 Dmosin, Lodzkie, Poland /2020	Oilssed rape/ Sherpa	1. 21.08.2018 2. 3. 12.07.2019	197.3	296	66.6	17.05.2019	BBCH 67	5 g	<LOQ prothioconazole destio for seed and whole plant	56	Foliar application Date of extraction: 09.08.2019 Max. Interval: 84 days LOD: 0.003 mg/kg LOQ: 0.01 mg/kg
B9148/67250 Ingolsheim, Grand Est, France/2020	Oilssed rape/ Attletic	1.22.08.2018 2. 3. 05.07.2019	192.1	290	66.2	07.05.2019	BBCH 65-67	5g	<LOQ prothiconazole desthio	59	Foliar application Date of extraction: 11.07.2019 Max. Interval: 65 days LOD: 0.003 mg/kg LOQ: 0.01 mg/kg

Table Residue trial summary for oilseed rape

Trial No./ Location/ Year	*Commodity/ Variety*	*Date of 1.Sowing or planting 2.Flowering 3. Harvest*	*Application rate per treatment*			*Dates of treatment or no. of treatments and last date*	*Growth stage at last treatment or date*	*Portion analyzed*	*Residues (mg/kg)*	*PHI (days)*	*Remarks*
			g a.s./ ha	*Water (l/ha)*	*g a.s./hl*						
B9149/ 57810 Donnelay, Grand Est, France/ 2020	Oilseed rape/ Mambo	1. 08.08.2018 2. – 3. 11.07.2019	206.7	310	66.6	15.05.2019	BBCH 67	5g	0.01 mg prothioconazole-dethio/kg for seeds	57	Foliar application Date of extraction: 08.08.2019 Max. Interval: 85 days LOD: 0.003 mg/kg LOQ: 0.01 mg/kg
B9150/ 79206 Breisach am Rhein, Baden-Wurttemberg, Germany/2020	Oilseed rape/ Aristoteles	1. 03.09.2018 2. 3. 18.07.2019	200	300	66.6	24.05.2019	BBCH 67	5g	<LOQ prothiconazole desthio	55	Foliar application Date of extraction: 08.08.2019 Max. Interval: 76 days LOD: 0.003 mg/kg LOQ: 0.01 mg/kg
B9151/ 51756 Slatina nad Zdobnici, Hradec Kralove/ Czech Rebuplic/ 2020	Oilseed rpe/ Architekt	1.28.08.2018 2.- 3. 18.07.2019	204.7	307	66.7	16.05.2019	BBCH 65-67	5g	<LOQ prothiconazole desthio	63	Foliar application Date of extraction: 16.09.2019 Max. Interval: 123 days LOD: 0.003 mg/kg LOQ: 0.01 mg/kg

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation CHR/F/PROTAZO 375 SC are presented in Table 7.1-1. They have been selected from the individual GAPs in the central zone for winter cereals and winter oilseed rape. A list of all intended uses within the zone is given in Part B, Section 0.
Justification for the selection of the critical GAP

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL 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 are unlikely to present a public health concern.
As far as consumer health protection is concerned, Poland as zRMS agrees with the authorization of the intended uses.

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

Data gaps

None

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

			GAP rev. , date: 19-02-2020day
PPP (product name/code):	CHR/F/PROTAZO	Formulation type:	~~EC~~ SC [a, b]
Active substance 1:	prothioconazol	Conc. of as 1:	175g [c]
Active substance 2:	azoxystrobine	Conc. of as 2:	200[c]
Safener:	n/a	Conc. of safener:	conc. [c]
Synergist:	n/a	Conc. of synergist:	conc. [c]
Applicant:	PUH Chemirol Sp. z o.o.	Professional use:	☒
Zone(s):	Central ~~northern/central/southern/interzonal~~ [d]	Non professional use:	☐
Verified by MS:	yes/no		

Field of use: fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L/kg product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat/ Pszenica ozima,, *triticum aestivum* (TRZAW), Spring barley/ Jęczmień jary *hordeum vulgare* (HORVS), Winter Triticale/	F	*diseases*	Spray	Spring BBCH 25-69	a) 1 b) 2	14-28	a) 1,0 b) 2,0	c) 0,200 AZX + 0,175 PROTIO d) 0,400 AZX + 0,350 PROTIO	200-400	35	A	

		Pszenżyto ozimy triticale (TTLWI)												
2	PL	Winter oilseed rape / Rzepak ozimy (BRSNW)	F	Diseases	Spray	Spring BBCH 59-69, the risk of infection, warning	c) 1 d) 1	N/A	e) 1,0 f) 1,0	g) 0,200 AZX + 0,175 PROTIO h) 0,200 AZX + 0,175 PROTIO	200-400	56	A	
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
3														
Minor uses according to Article 51 (field uses)														
5	PL	Spring Rye	F	*diseases*	Spray	Spring BBCH 25-69	e) 1 f) 2	14-28	i) 1,0 j) 2,0	k) 0,200 AZX + 0,175 PROTIO l) 0,400 AZX + 0,350 PROTIO	200-400	35	A	
6	PL	Spring oilseed rape	F	Diseases	Spray	Spring BBCH 59-69, the risk of infection, warning	g) 1 h) 1	N/A	m) 1,0 n) 1,0	o) 0,200 AZX + 0,175 PROTIO p) 0,200 AZX + 0,175 PROTIO	200-400	56	A	
	PL	Common Sunflower	F	Diseases	Spray	Spring BBCH 18-69, the risk of infection, warning	i) 1 j) 1	N/A	q) 1,0 r) 1,0	s) 0,200 AZX + 0,175 PROTIO t) 0,200 AZX + 0,175 PROTIO	200-400	56	A	
	PL	Soya	F	Diseases	Spray	Spring BBCH 12-69, the risk of infection, warning	k) 1 l) 1	N/A	u) 1,0 v) 1,0	w) 0,200 AZX + 0,175 PROTIO x) 0,200 AZX + 0,175 PROTIO	200-400	56	A	
	PL	Breadseed	F	Diseases	Spray	Spring	m) 1	N/A	y) 1,0	aa) 0,200 AZX	200-	56	A	

		poppy				BBCH 59-69, the risk of infection, warning	n) 1		z) 1,0	+ 0,175 PROTIO bb) 0,200 AZX + 0,175 PROTIO	400			
	PL	Mustard	F	Diseases	Spray	Spring BBCH 59-69, the risk of infection, warning	o) 1 p) 1	N/A	cc) 1,0 dd) 1,0	ee) 0,200 AZX + 0,175 PROTIO ff) 0,200 AZX + 0,175 PROTIO	200-400	56	A	
	PL	Tobacco (NIOTA)	F	*diseases*	Spray	Spring BBCH 10-89	q) 1 r) 2	14-28	gg) 1,0 hh) 2,0	ii) 0,200 AZX + 0,175 PROTIO jj) 0,400 AZX + 0,350 PROTIO	200-400	n/a	A	
	PL	Coniferous / deciduous forest nurseries, Ornamental shrubs	F	*diseases*	Spray	Spring BBCH 10-89, the risk of infection, warning	s) 1 t) 2	14-28	kk) 1,0 ll) 2,0	mm) 0,200 AZX + 0,175 PROTIO nn) 0,400 AZX + 0,350 PROTIO	200-400	n/a	A	
	PL	*Salix viminalis* (SAXVI) Wicker (1SAXG)	F	*diseases*	Spray	BBCH 10-89, the risk of infection, warning	u) 1 v) 2	14-28	oo) 1,0 pp) 2,0	qq) 0,200 AZX + 0,175 PROTIO rr) 0,400 AZX + 0,350 PROTIO	200-400	n/a	A	
	PL	*Ornamental*	F	*diseases*	Spray	BBCH 10-89, the risk of infection, warning	w) 1 x) 2	14-28	ss) 1,0 tt) 2,0	uu) 0,200 AZX + 0,175 PROTIO vv) 0,400 AZX + 0,350 PROTIO	200-400	n/a	A	
Minor uses according to Article 51 (interzonal uses)														
7														

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

Explanation for Column 11 “Conclusion”

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

7.1.2 Summary of the evaluation

The preparation CHR/F/PROTAZO is composed of prothioconazole and azoxystrobin

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

Reference value	Source	Year	Value	Study relied upon	Safety factor
Prothioconazole - Parent compound					
ADI	EFSA	2007	0.05	rat – oncogenicity	100
ARfD	EFSA	2007	0.02	original & suppl. rat developm. studies combined	100
Prothioconazole – metabolite Prothioconazole-desthio					
ADI	EFSA	2007	0.01	rat – oncogenicity	100
ARfD	EFSA	2007	0.01	Supplementary rat developmental	100
Azoxystrobin					
ADI	EFSA	2010	0.2	2-year rat	100
ARfD	Not required				

zRMS comments:
Prothioconazole belongs to the group of triazole compounds that form metabolites(TDMs): triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA). According to the SANCO/3923/07, 26 January 2021 it has been agreed that the reference values and residue definition that includes TDMs should be used in the risk assessment for triazole active substances and their TDMs for applications for authorization of plant protection products submitted from 1 July 2020. This dossier was submitted before that date, however the relevant data on toxicological reference values for dietary risk assessment are provided below.

Reference value	Source	Year	Value	Study relied upon	Safety factor
Triazole alanine (TA)					
ADI	EFSA Journal 2018; 16(7):5376	2018	0.3 mg/kg bw/day	Rabbit developmental study	100
ARfD		2018	0.3 mg/kg bw	Rabbit developmental study	100
Triazole lactic acid (TLA)					
ADI	EFSA Journal 2018; 16(7):5376	2018	0.3 mg/kg bw/day	Bridging from TA	
ARfD		2018	0.3 mg/kg bw	Bridging from TA	
Triazole acetic acid (TAA)					
ADI	EFSA Journal 2018; 16(7):5376	2018	1 mg/kg bw/day	Rat 2 generation and Rabbit developmental studies	100
ARfD		2018	1 mg/kg bw	Rat 2 generation and Rabbit developmental studies	100
1, 2, 4-triazole (1,2,4-T)					

Reference value	Source	Year	Value	Study relied upon	Safety factor
ADI	EFSA Journal 2018; 16(7):5376	2018	0.023 mg/kg bw/day	Rat 12-month study	300
ARfD		2018	0.1 mg/kg bw	Rabbit developmental study	300

7.1.2.1 Summary for 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?
	Winter wheat	Yes	Yes	Yes	Yes	Yes	~~Yes~~ No	~~Yes~~ No
	Winter oilseed rape	Yes	Yes	Yes	Yes	Yes		~~Yes~~ No
	Spring rye	Yes	Yes	Yes	Yes	Yes		~~Yes~~ No
	Spring oil seed rape	Yes	Yes	Yes	Yes	Yes		~~Yes~~ No
	Sunflower	Yes	Yes	Yes	Yes	Yes		~~Yes~~ No
	Soya	Yes	Yes	Yes	Yes	Yes		~~Yes~~ No
	Breadseed poppy	Yes	Yes	Yes	Yes	Yes		~~Yes~~ No
	Mustard	Yes	Yes	Yes	Yes	Yes		~~Yes~~ No
	Tobacco	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required		~~Yes~~ Not relevan
	Coniferous/ deciduous forest nurseries, Ornamental shrubs	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required		~~Yes~~ Not relevant
	Salix viminalis, Wicker	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required		~~Yes~~ Not relevant
	Ornamental	~~Yes~~ Not required	~~Yes~~ Not	~~Yes~~ Not required	~~Yes~~ Not	~~Yes~~ Not required		~~Yes~~ Not

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?
			required		required			relevant

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

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

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	Winter wheat	Yes	Yes	Yes	Yes	Yes	~~Yes~~ No	~~Yes~~ No
2	Winter oilseed rape	Yes	Yes	Yes	Yes	Yes		~~Yes~~ No
	Spring rye	Yes	Yes	Yes	Yes	Yes		~~Yes~~ No
	Spring oil seed rape	Yes	Yes	Yes	Yes	Yes		~~Yes~~ No
	Sunflower	Yes	Yes	Yes	Yes	Yes		~~Yes~~ No
	Soya	Yes	Yes	Yes	Yes	Yes		~~Yes~~ No
	Breadseed poppy	Yes	Yes	Yes	Yes	Yes		~~Yes~~ No
	Mustard	Yes	Yes	Yes	Yes	Yes		~~Yes~~ No
	Tobacco	~~Yes~~ Not relevant	~~Yes~~ Not relevant	~~Yes~~ Not relevant	~~Yes~~ Not relevant	~~Yes~~ Not relevant		~~Yes~~ Not relevant
	Coniferous/ deciduous forest nurseries, Ornamental shrubs	~~Yes~~ Not relevant	~~Yes~~ Not relevant	~~Yes~~ Not relevant	~~Yes~~ Not relevant	~~Yes~~ Not relevant		~~Yes~~ Not relevant
	Salix viminalis,	~~Yes~~ Not	~~Yes~~ Not	~~Yes~~ Not	~~Yes~~ Not	~~Yes~~ Not		~~Yes~~

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?
	Wicker	relevant	relevant	relevant	relevant	relevant		Not relevant
	Ornamental	~~Yes~~ Not relevant	~~Yes~~ Not relevant	~~Yes~~ Not relevant	~~Yes~~ Not relevant	~~Yes~~ Not relevant		~~Yes~~ Not relevant

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

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

7.1.2.3 Summary for CHR/F/PROTAZO

Table 7.1-5: Information on CHR/F/PROTAZO (KCP 6.8)

Crop	PHI for CHR/F/PROTIO proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CHR/F/PROTIO proposed by zRMS	zRMS Comments (if different PHI proposed)
		Prothioconazole and azoxystrobin		
Winter wheat	35 days	Yes/	35 days	
Winter oilseed rape	56 days	Yes	56 days	
Spring rye	35 days	Yes/	35 days	
Spring oil seed rape	56 days	Yes	56 days	
Sunflower	56 days	Yes	56 days	
Soya	56 days	Yes	56 days	
Breadseed poppy	56 days	Yes	56 days	
Mustard	56 days	Yes	56 days	
Tobacco	N/A	N/A	N/A	
Coniferous/ deciduous forest nurseries, Ornamental shrubs	N/A	N/A	N/A	
Salix viminalis, Wicker	N/A	N/A	N/A	

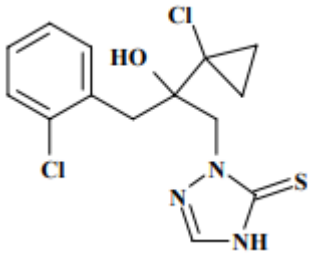
Crop	PHI for CHR/F/PROTIO proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CHR/F/PROTIO proposed by zRMS	zRMS Comments (if different PHI proposed)
		Prothioconazole and azoxystrobin		
Ornamental	N/A	N/A	N/A	

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

7.2 Prothioconazole

General data on Prothioconazole are summarized in the table below (last updated 2007/12/10)

Table 7.2-1: General information on Prothioconazole

Active substance (ISO Common Name)	Prothioconazole
IUPAC	(RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)- 2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3- thione
Chemical structure	
Molecular formula	C14H15Cl2N3OS
Molar mass	344.26
Chemical group	Triazoles
Mode of action (if available)	Sterol biosynthesis in membranes
Systemic	Yes/
Company (ies)	BAYER Cropscience AG
Rapporteur Member State (RMS)	United Kingdom
Approval status	Approved COMMISSION DIRECTIVE 2008/44/EC of 4 April 2008
Restriction	~~COMMISSION IMPLEMENTING REGULATION (EU) 2019/707 of 7 May 2019~~ Reg. (EU) No 540/2011, Only uses as fungicide may be authorised.
Review Report	SANCO/3923 /07 - final 10 December 2007
Current MRL regulation	COMMISSION REGULATION (EU) 2019/552 of 4 April 2019
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	~~No~~ Yes
EFSA Journal : Conclusion on the peer review	EFSA Scientific Report (2007) 106, 1-98
EFSA Journal: conclusion on article 12	Yes EFSA 2014; 12(5):3689
Current MRL applications on intended uses	~~EFSA-Q-2008-617 (EMS)~~ None

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

7.2.1 Stability of Residues (KCP 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat	High starch content	60 day for prothioconazole 540 days for Prothioconazole-desthio	Heinemann, O., 2001
Canola seeds	High oil content	25 months	Freitag T., 2005

Conclusion on stability of residues during storage

The storage stability evaluated during Annex I inclusion covers plant matrices for use CHR/F/PROTAZO 250 EC according to the label.

zRMS comments:
The storage stability study evaluated during Annex I inclusion support the residue data presented in this dossier. Taking into account the new requirements regarding TDMs, it should be considered that in this respect the stability studies presented by the Applicant are not sufficient. However, it should be taken into account that the dossier was submitted before the validity date of the assessment for TDMs.
Storage stability of residues in plants (EFSA Journal 2020;18(2):5999: *The storage stability of prothioconazole-desthio in plant samples stored under frozen conditions was investigated in the framework of the MRL review and relevant end points are summarised in Appendix B.1.1.2. In high water and high oil content commodities, relevant for the celeriacs and rapeseeds use, prothioconazole-desthio is stable for a maximum of 24 months, when stored at 18°C (EFSA, 2014). A data gap was noted by EFSA during the MRL review for the need of further storage stability data for at least one hydroxylated metabolite included in the risk assessment residue definition in the relevant commodity groups (i.e. high water, high oil content commodities and dry (high starch/high protein) commodities) (EFSA, 2014). In order to address this data gap (number 38) the EMS referred to storage stability studies submitted by the applicant in the framework of the renewal of the approval (United Kingdom, 2018). EFSA assessed the submitted studies, noting that the renewal of the approval has not been finalised yet. Freezer storage stability of prothioconazole-a-hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxydesthio 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. 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) when stored at ≤ 18°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. The data gap identified by the MRL review is considered addressed for all crops, except for dry pulses, which belong to dry (high protein content) commodity group in which the storage stability of any of the hydroxy-metabolites of prothioconazole-desthio has not been investigated. The freezer storage stability of various TDMs was investigated in the framework of the peer review of TDMs (EFSA, 2018b). In the commodity groups relevant for the current assessment the stability of all TDMs has been investigated, except that of 1,2,4-T in high protein content matrices, and of 1,2,4-T and TA in rapeseeds (see Appendix B.1.1.2).

7.2.1.2 Stability of residues in sample extracts (KCP 6.1)

From GLP study *Determination of Prothioconazole-desthio (sum of isomers) Residues in Oilseed rape Following One Foliar application with CHR/F/PROTIO 250 EC under Field Conditions in Northern Europe in 2019, J. Diebold, Study code: B9146 – B9151* analysis time were less than 24 hours between extraction and analysis or it was shown that study extracts are stable.

zRMS comments:
Stability of residues in sample extracts has not been investigated in the framework of the first inclusion process. For the new studies provided by the Applicant, study of stability of residue in sample extracts is not required as the analyses were performed within 24 hours.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCP 6.2.1)

Available data

No new data submitted in the framework of this application.

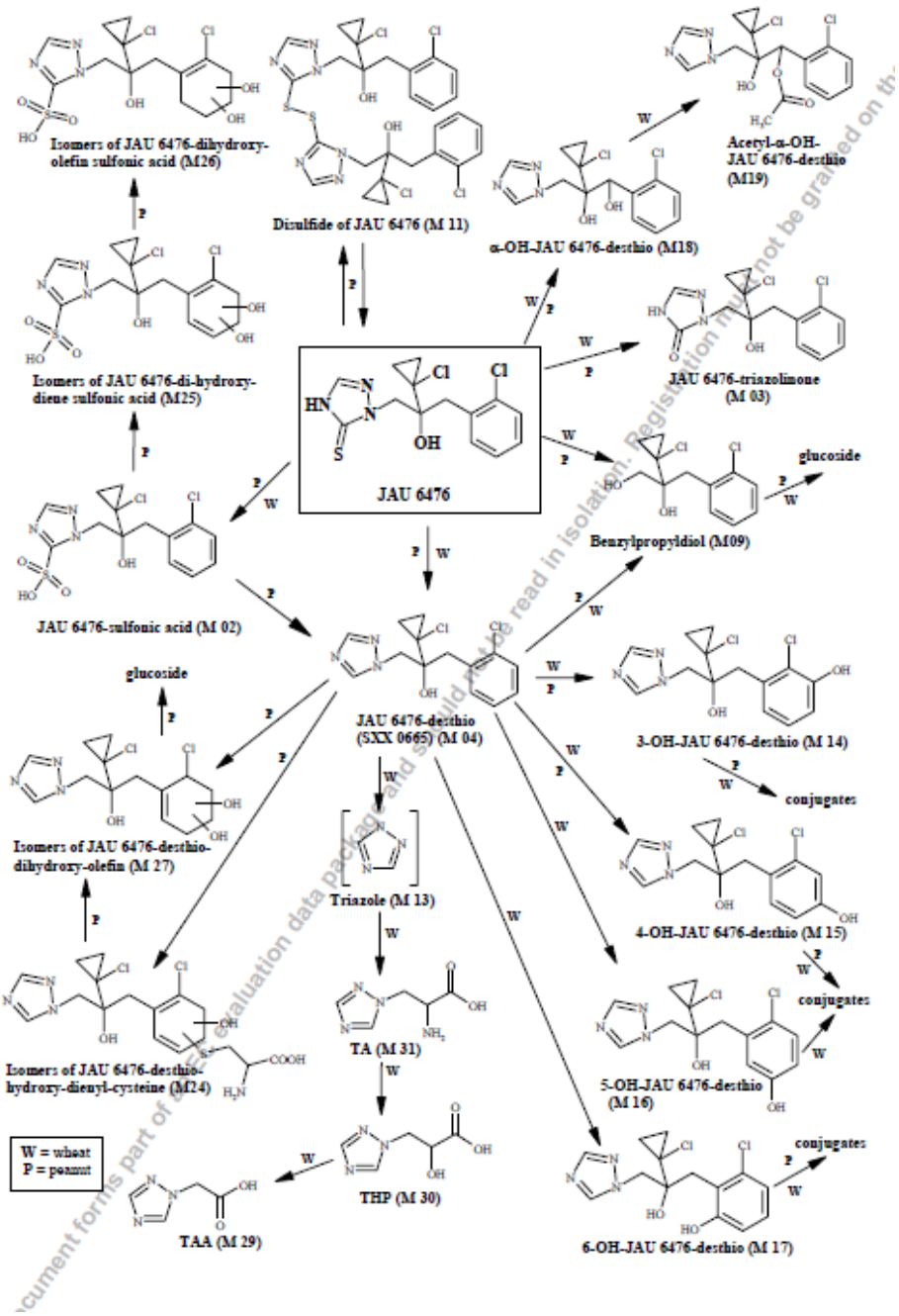
Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Pulses and oilseeds	Peanut	[phenyl-UL-14C] JAU 6476	foliar treatment, F	300 g as/ha	3	14 days	-	Haas, 2001
Cereals	Wheat	phenyl-UL-14C JAU 6476	foliar treatment, F	200 g as/ha	2	6, 26 and 48 days	-	Haas, Bornatsch, 2000) Vogeler *et al*, 1993)
		[triazole-3,5-14C]-JAU 6476-desthio		250 g as/ha		0, 14 and 48 days		

Summary of plant metabolism studies reported in the EU

JAU 6476 was intensively metabolised in spring wheat. In a first step the sulphur of the triazolinethione ring was oxidised to the corresponding sulfonic acid (M02). The subsequent elimination of the sulfonic acid moiety resulted in the main metabolite JAU 6476-desthio. This metabolite was further hydroxylated in the chlorophenyl ring to the JAU 6476-3-, 4-, 5-, and 6-hydroxy-desthio isomers (M14, M15, M16, M17), which occurred mainly as glucose conjugates. Similarly, M18 was formed by hydroxylation of the chlorobenzyl methylene group. Hence hydroxylation followed by conjugation with glucose or other sugars as well as higher conjugation was the major metabolic route in wheat. Further degradation pathways were identified from the triazole-labelled JAU 6476-desthio metabolism study, although the additional metabolites (M29 and M31) were identified in significant amounts in the grain fraction only. In peanuts, the main metabolite was again identified as JAU 6476-desthio, which was further hydroxylated in the chlorophenyl ring to its 3- or 4- monohydroxylated derivatives (M14 and M15), which were further glucosylated. Further minor metabolites were also identified, although essentially, the metabolic pathway was comparable to that found in wheat.

Figure B.7.1 Proposed metabolic pathway for JAU 6476 in plants



Conclusion on metabolism in primary crops

The metabolism in primary crops presented during Annex I inclusion, covers use of CHR/F/PROTAZO on winter cereals. No new studies were necessary.

zRMS comments:
According to the EFSA Journal 2020;18(2):5999: *In the framework of the peer review under Directive 91/414/EEC and the Art.12 MRL review (EFSA, 2007b, 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, 2007a,b). In addition, the metabolism of prothioconazole-desthio labelled in the triazole moiety was investigated after foliar applications on cereals (EFSA, 2007b).* ***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. As the parent compound was only present in minor amounts and prothioconazole-desthio was shown to more toxic than the parent compound, it was concluded to define prothioconazole-desthio as the relevant residue for enforcement. *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 metabolism studies indicate that in root crops and oilseeds, relevant for the intended uses of prothioconazole on celeriacs and oilseed rape, the main identified TDMs are triazole alanine (TA) (29 total radioactive residue (TRR) in roots; 47.8% TRR in oilseed) and triazole lactic acid (TLA) (24.5% TRR in oilseed).*
The metabolism of prothioconazole is considered sufficiently addressed (sufficient data are available in the DAR, UK 2004) for the intended uses.

7.2.2.2 Nature of residue in rotational crops (KCP 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	swisschard	[phenyl-UL-14C]-JAU 6476	F	580 g as/ha	28, 146 and 269 days	80, 188 and 348 days	-	Haas, 2001
Root and tuber vegetables	turnip	[phenyl-UL-14C]-JAU 6476	F	580 g as/ha	28, 146 and 269 days	94, 201 and 349 days	-	Haas, 2001
Cereals	wheat	[phenyl-UL-14C]-JAU 6476	F	580 g as/ha	28, 146 and 269 days	73, 111,145, 178, 231, 269, 327, 377 and 412 days	-	Haas, 2001

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

Summary of plant metabolism studies reported in the EU

There are no significant soil residues of JAU 6476 at times of sowing following crops, residues of JAU 6476-desthio are predicted to be 42% 120 days after treatment. A study of uptake and metabolism in rotational crops showed that residues in all rotational crops declined between first and third rotations. Significant residues (>0.1 mg/kg) were only found in wheat straw and hay and these were at similar or lower levels than those recorded for the directly treated crop, also with similar metabolic profiles.

Therefore, residues in rotational crops will not lead to any additional exposure to JAU 6476-desthio above that from directly treated crops.

Conclusion on metabolism in rotational crops

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

zRMS comments:
According to the EFSA Journal 2020;18(2):5999: *According to soil degradation studies, investigated in the framework of the EU pesticides peer review, prothioconazole itself is of very low persistence in soil (DT90 field of 5.5 days (median)), whereas prothioconazole-desthio is of low persistence with DT90 field of 140 days (median) (EFSA, 2007b).*
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).*
The metabolism of prothioconazole in rotational crops is considered sufficiently addressed (sufficient data are available in the DAR, UK 2004) for the intended uses.

7.2.2.3 Nature of residues in processed commodities (KCP 6.5.1)

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

zRMS comments:
According to the EFSA Journal 2020;18(2):5999: *The effect on the nature of prothioconazole and prothioconazole-desthio has not been investigated in the framework of the EU pesticides peer review. The MRL review referred to studies with prothioconazole investigated by the JMPR and studies with prothioconazole-desthio reported by Germany (EFSA, 2014). Prothioconazole-desthio was reported to be stable under all standard hydrolysis steps (99.4–99.9% applied radioactivity (AR)), whereas parent prothioconazole slightly degraded to prothioconazole-desthio under sterilisation process (≤ 11% AR). The same processing study referred to in the MRL review was now submitted for the renewal of the approval (United Kingdom, 2018).*
The remaining compounds included in the risk assessment residue definition were concluded to remain stable under standard hydrolysis conditions, considering their structural similarity to parent compound (EFSA, 2014). The TDMs are stable under hydrolysis studies simulating baking/brewing/boiling, pasteurisation and sterilisation (EFSA, 2018b).
Taking into account that residues of prothioconazole-desthio for the intended uses are below the trigger value of 0.1 mg/kg, no study investigating the nature of residues in processed commodities is required.

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

Table 7.2-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Pulses and oilseeds (Peanut) Cereals (Wheat)
Rotational crops covered	Cereals (wheat) Leafy vegetables (swisschard) Root vegetables (turnip)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not provided and not required , TDMs stable under hydrolytic conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Prothioconazole-desthio. (JAU 6476-desthio) Reg. (EU) No 2019/552: prothioconazole: prothioconazole-desthio (sum of isomers)
Plant residue definition for risk assessment	Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety) expressed as prothioconazole-desthio (sum of isomers), EFSA 2014. TDMs: with separate assessment of: - Triazole alanine (TA) and triazole lactic acid (TLA) - Triazole acetic acid (TAA) - 1,2,4-triazole (1,2,4-T), EFSA 2018
Conversion factor from enforcement to RA	2 (cereal grain and oilseeds), leafy vegetables, root and tuber vegetables), 3 (cereal straw), EFSA 2014

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

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

Available data

No new data submitted in the framework of this application.

Table 7.2-6: Summary of animal metabolism studies

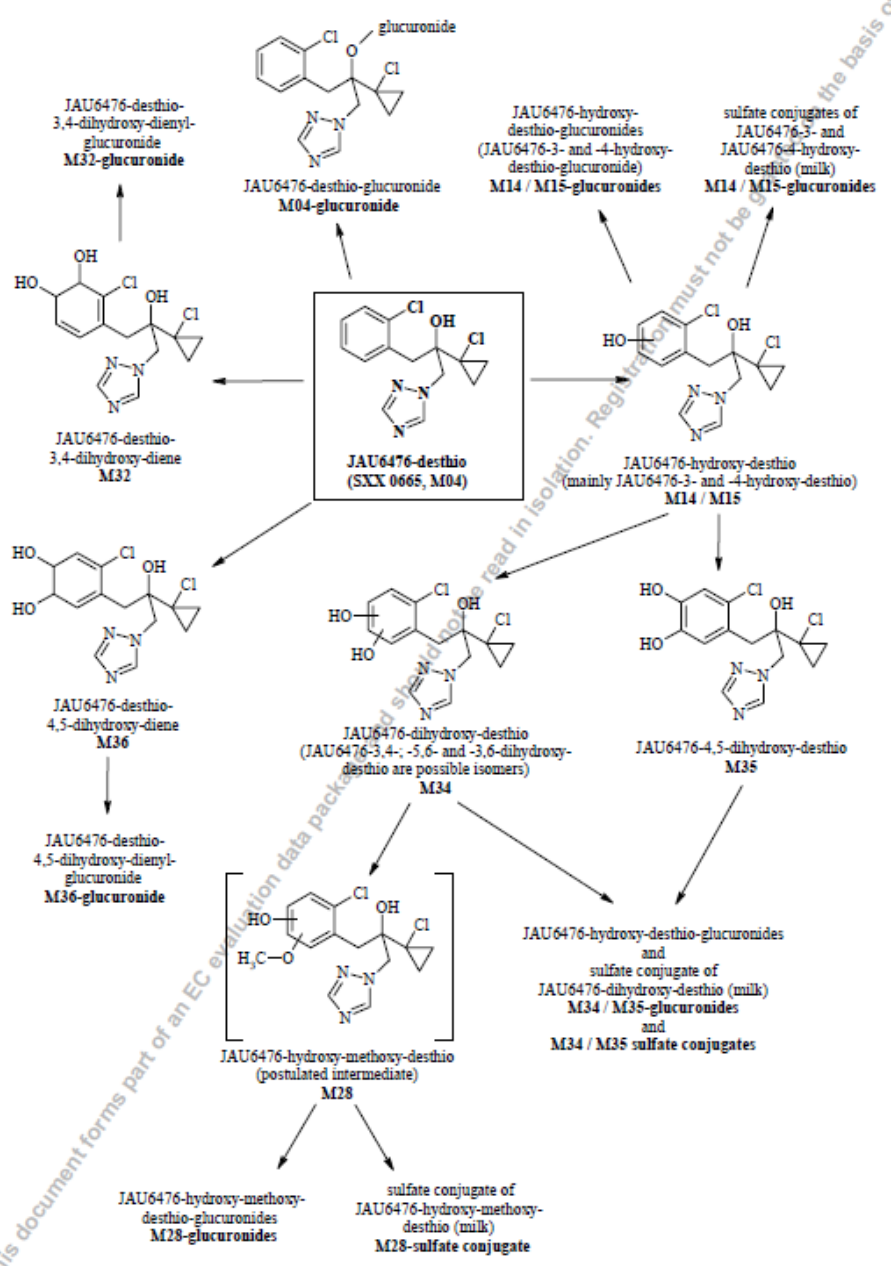
Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	[Phenyl-UL-	2	10	3	Milk		xxxxxxxxx
						Urine and faeces		

		14C]JAU 6476				Tissues	at sacrifice	
Laying poultry	Hens	[Phenyl-UL-14C]JAU 6476	6	10	3	Eggs	twice daily	xxxxxxxxx
						Excreta	regular intervals	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

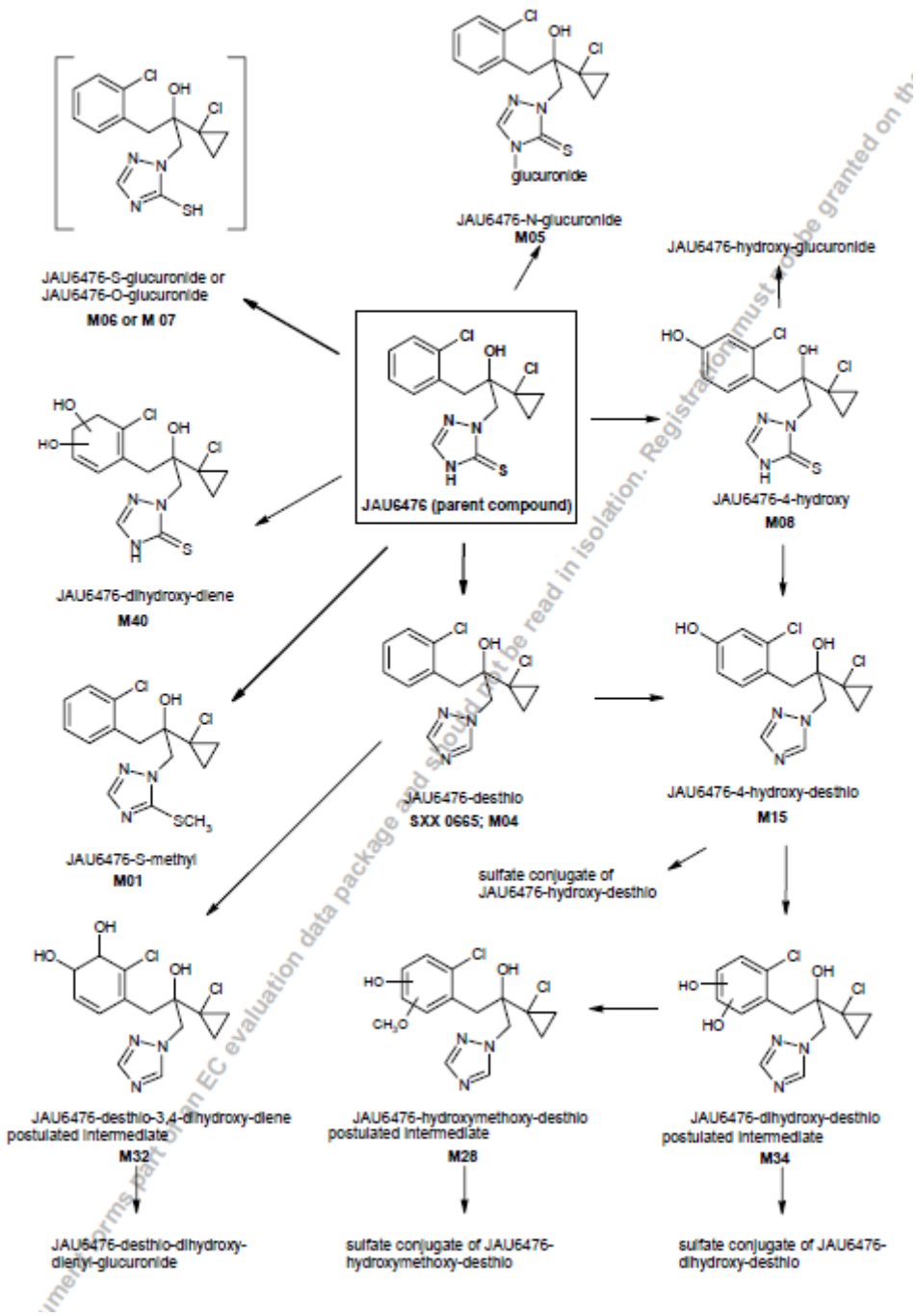
Rat and goat metabolism studies showed that JAU 6476 is rapidly adsorbed but not extensively metabolised. In the rat, JAU 6476 was almost completely excreted and in the goat it was largely excreted. In the goat, only 0.96% of the total dose was found in tissues after sacrifice and JAU 6476 was the major residue. However, as animals are more likely to be exposed to the JAU 6476-desthio metabolite, this compound was also been studied. Again in the rat and goat, JAU 6476-desthio is rapidly adsorbed, although there is more extensive metabolism. Although still largely excreted in the goat, 1.9 % of the total dose was found in tissues after sacrifice. The main metabolic reactions in the goat were hydroxylation of JAU 6476-desthio resulting in the isomers M14 and M15, followed by oxidation of the chlorophenyl moiety leading to M32 and M36. To greater or lesser extent, there was also conjugation of JAU 6476-desthio and metabolites with glucuronic acid. Although these compounds were found in tissues following dosing at very exaggerated levels, they were mainly associated with the excretory organs and are therefore unlikely to be distributed to other parts of the body.

Figure B.7.2 Proposed metabolic pathway for JAU 6476-desthio in the goat



A similar metabolic pathway was observed in poultry, although residue levels in poultry
feed are unlikely to lead to significant residues in products of poultry origin.

Figure B.7.3 Proposed metabolic pathway for JAU 6476 in the hen



Conclusion on metabolism in livestock

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

zRMS comments:
According to the EFSA Journal 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-14C-phenyl]-labelled prothioconazole and prothioconazole-desthio and one study in laying hens using [U-*

14C-phenyl]-labelled prothioconazole. Besides, two additional studies were assessed by the JMPR (FAO, 2008a, 2008b) on lactating goats and laying hens, using both [3,5-14C-triazole]-labelled prothioconazole.
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)**.*
EFSA concludes that the residue definition for enforcement in commodities of animal origin is fat soluble.
<u>TDMs</u>
According to the EFSA Journal 2018;16(7):5376: *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 14C-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 14C-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 detected in the ruminant matrices from the feeding study conducted with TA. 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*:
RD for enforcement: Triazole parent compound only
RDs 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

The metabolism of prothioconazole in livestock is considered sufficiently addressed (sufficient data for this application are available in the DAR, UK 2004).

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

Table 7.2-7: 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	4 days in milk
	6 days in eggs
Animal residue definition for monitoring	Sum of prothioconazole-desthio and its glucuronide conjugate, expressed as prothioconazole-desthio (JAU 4676-desthio) EFSA, 2014 (Reasoned opinion on Art. 12): Prothioconazole-desthio (sum of isomers) Reg. (EU) 2019/552: Prothioconazole-desthio (sum of isomers)
Animal residue definition for risk assessment	Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety) expressed as prothioconazole-desthio. EFSA, 2014 (Reasoned opinion on Art. 12): 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)
Conversion factor	10 Milk 2 Liver 10 Muscle ~~2~~ 9 Kidney 4 Fat
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes, Log Pow for JAU 6476-desthio = 3.04

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

7.2.3 Magnitude of residues in plants (KCP 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, which covers cGAP for CHR/F/PROTAZO 250 EC. Please refer to the Determination of Prothioconazole-desthio (sum of isomers) Residues in Oilseed rape Following One Foliar application with CHR/F/PROTAZO 250 EC under Field Conditions in Northern Europe in 2019, J. Diebold, Study code: B9146 – B1951. These studies are summarized in the Table below.

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of CHR/F/PROTAZO and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Wheat (Grain) extrapolation on rye and triticale	DAR Prothioconazole - Volume 3, Annex B.7: Residues (2004	N-EU	GAP on which MRL/EU a.s. assessment is based: 3 x 0.2 kg as/ha, BBCH 69, PHI 35d, outdoor E: 11 x <0.01 RA: 11 x <0.01x2	N/A				
	Overall supporting data for cGAP	N-EU	E : 11 <0.01 RA: 11 <0.01 x2	<0.01 RA:<0.02	<0.01 RA:<0.02	0.01	0.1 for wheat and 0.05 for rye	Yes
Wheat (straw) extrapolation on rye and triticale	DAR Prothioconazole - Volume 3, Annex B.7: Residues (2004	EU	GAP on which MRL/EU a.s. assessment is based: 3 x 0.2 kg as/ha, BBCH 69, PHI 35d, outdoor E: 0.08, 0.09, 0.11, 0.14, 0.15, 0.19, 020, 0.27, 0.31, 0.66, 0.72 RA (CF=3): ~~0.08, 0.09, 0.11, 0.14, 0.15, 0.19, 020, 0.27, 0.31, 0.66, 0.72~~ 0.24, 0.27, 0.33, 0.42, 0.45, 0.57, 0.6, 0.81, 0.93, 1.98, 2.16	N/A				

	Overall supporting data for cGAP	EU	E : 0.08, 0.09, 0.11, 0.14, 0.15, 0.19, 020, 0.27, 0.31, 0.66, 0.72 RA (CF=3): ~~0.08, 0.09, 0.11, 0.14, 0.15, 0.19, 020, 0.27, 0.31, 0.66, 0.72~~ 0.24, 0.27, 0.33, 0.42, 0.45, 0.57, 0.6, 0.81, 0.93, 1.98, 2.16	0.19 RA: 0.57	0.72 RA: 2.16		~~0.1~~	~~Yes/~~
Barley (grain)	DAR Prothioconazole - Volume 3, Annex B.7: Residues (2004	EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.2 kg as/ha, BBCH 61, PHI 35d, outdoor E: 9 x <0.01 RA: 9 x <0.01 x2	N/A				
	Overall supporting data for cGAP	EU	E : 9 <0.01 RA: 9 <0.01 x2	<0.01 RA:<0.02	<0.01 RA:<0.02	0.01	~~0.1~~ 0.2	Yes
Barley (straw)	DAR Prothioconazole - Volume 3, Annex B.7: Residues (2004	EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.2 kg as/ha, BBCH 61, PHI 35d, outdoor E: 0.05, 0.08, 2 x 0.10, 2x 0.13, 2 x 0.14, 0.30 RA (CF=3): ~~0.05, 0.08, 2 x 0.10, 2x 0.13, 2 x 0.14, 0.30~~ 0.15, 0.24, 2x0.3, 3x0.39, 2x0.42, 0.9	N/A				
	Overall supporting data for cGAP	EU	E : 0.05, 0.08, 2 x 0.10, 2x 0.13, 2 x 0.14, 0.30 RA (CF=3): ~~0.05, 0.08, 2 x 0.10, 2x 0.13, 2 x 0.14, 0.30~~ 0.15, 0.24, 2x0.3, 3x0.39, 2x0.42, 0.9	0.13 RA: 0.39	0.30 RA: 0.9		~~0.1~~	~~Yes~~
Oilseed rape (whole plant)	New trials Determination of Prothioconazole-desthio (sum of isomers) Residues in Oilseed rape Following One Foliar application with CHR/F/PROTIO 250 EC under Field Conditions in Northern	EU	Trials GAP: 1 x 0.2 kg as/ha, PHI 56d E: 3<0.01, 0.01, 2x 0.02 RA: 3<0.01, 0.01, 2x 0.02	N/A				

	Europe in 2019, J. Diebold, Study code: B9146 – B1951.							
	Overall supporting data for cGAP	EU	E : 3<LOQ, 0.01, 2x 0.02 RA: 3<LOQ, 0.01, 2x 0.02	0.01	0.02		~~0.15~~	~~Yes~~
Oilseed rape (Seeds) Extrapolation on sunflower, soya, poppy seeds and mustard seeds	New trials Determination of Prothioconazole-desthio (sum of isomers) Residues in Oilseed rape Following One Foliar application with CHR/F/PROTIO 250 EC under Field Conditions in Northern Europe in 2019, J. Diebold, Study code: B9146 – B1951.	EU	Trials GAP: 1 x 0.2 kg as/ha, PHI 56d, E: ~~5x <0.003, 0.01~~ E: <0.003, <0.01, 0.01 ~~RA 5x <0.003, 0.01~~ RA (CF2): <0.006, <0.02, 0.02 Only 3 out of 6 submitted by the Applicant studies have been approved	N/A				
	EFSA, 2007	NEU	Trials GAP: 2 x 0.175 kg as/ha, BBCH 65-78, PHI 56-67, outdoor E: 5x<0.01, 0.01, 2x0.02 RA(CF=2): 5x<0.02, 0.02, 2x0.04					
	Overall supporting data for cGAP	EU	~~E : 5x <0.003, 2x0.01, 2x0.02~~ E: <0.003, 6x<0.01, 2x0.01, 2x0.02 ~~RA: 5x <0.003, 0.01~~ RA (CF2): <0.006, 6x<0.02, 2x0.02, 2x0.04	~~<0.003~~ E: 0.01 ~~RA:<0.006~~ RA: 0.02	0.02 RA: 0.04	0.031	0.15 for rape, 0.2 for sunflower and soya, 0.09 for poppy and	Yes

							mustard seeds	

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

According to COMMISSION REGULATION (EU) No 283/2013 point “Magnitude of residue trials in plants” studies shall always be performed where the plant protection product is to be applied to plants or plant products that are used as food or feed. Tobacco is a crop designed for smoking, not for eating. Tobacco have no edible part therefore residues evaluation isn’t necessary according to EU 283/2013.

According to COMMISSION REGULATION (EU) No 283/2013 point “Magnitude of residue trials in plants” studies shall always be performed where the plant protection product is to be applied to plants or plant products that are used as food or feed. Coniferous / deciduous forest nurseries and Ornamental shrubs have no edible part therefore residues evaluation isn’t necessary according to EU 283/2013.

According to COMMISSION REGULATION (EU) No 283/2013 point “Magnitude of residue trials in plants” studies shall always be performed where the plant protection product is to be applied to plants or plant products that are used as food or feed. *Salix viminalis and* Wicker are used for crafting and green energy purposes and have no edible part so residues evaluation isn’t necessary according to EU 283/2013.

According to COMMISSION REGULATION (EU) No 283/2013 point “Magnitude of residue trials in plants” studies shall always be performed where the plant protection product is to be applied to plants or plant products that are used as food or feed. Ornamentals are used for crafting and green energy purposes and have no edible part so residues evaluation isn’t necessary according to EU 283/2013

According to SANCO 7525/VI/95 Rev. 10.2, 23 September 2016 guidance document, residue data set for sunflower, soya, mustard, breadseed poppy, spring oil seed rape can be obtained winter oilseed rape. According to GAP both all crop covered by winter oil seed rape is designed in end phases BBCH 66 which is “before forming the edible part” situation. The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assessment. Data/information which are source of extrapolation to sunflower, soya, mustard, breadseed poppy, spring oil seed rape on residues in winter oil seed rape were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated according to Guidance Document SANCO 7525/VI/95 Rev. 10.2.23 September 2016.

According to SANCO 7525/VI/95 Rev. 10.2, 23 September 2016 guidance document, residue data set for spring rye can be obtained wheat. According to GAP spring rye is designed in the same phases BBCH is “before forming the edible part” situation. The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assessment. Data/information which are source of extrapolation to spring rye on residues in wheat were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated according to Guidance Document SANCO 7525/VI/95 Rev. 10.2.23 September 2016

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on cereals and oilseed rape are considered acceptable, for ~~both indoor and~~ outdoor uses.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

zRMS comments:
The Applicant did not submit any new data on the level of residues in cereals and used unprotected data assessed during the approval of prothioconazole as active substance. GAP proposed for CHR/F/PROTAZO 375 SC is covered by GAP evaluated at EU level. For the proposed use in oilseed rape, the Applicant has provided 6 trials in line with the proposed GAP for this crop. According to the SANCO 7525/VI/95 Rev. 10.3 oilseed rape is regarded as a major crop therefore 8 trials are required. Therefore, the assessment takes into account unprotected studies assessed at Community level (n=8 for NEU, EFSA 2007 Conclusion on the peer review of prothioconazole). These studies for oilseed rape cover a much more critical use than the ones proposed in this documentation:
EFSA 2007 - Trials GAP: 2 x 0.175 kg as/ha, BBCH 65-78, PHI 56-67
Use proposed for CHR/F/PROTAZO 375 SC – 1 x 0.175 kg as/ha, BBCH 59-69, PHI 56
According to the SANTE/2019/12752, it is possible to extrapolate from any representatives of the oilseeds group (except peenuts) to the whole group in the case the use takes place before forming of the edible part. The proposed use in max BBCH(69) for sunflower, soya, poppy seeds and mustard seeds concerns the flowering phase, ie before the development of the edible parts of the plant. Therefore, the proposed extrapolation of residue results from rapeseed to sunflower, soya, poppy seeds and mustard seeds is accepted. In all cases, the results show no residues above the applicable MRLs.

The proposed use of CHR/F/PROTAZO 375 SC applies to the SC formulation, while all studies supporting the evaluation, both assessed at Community level and the new ones provided by the Applicant were performed for the EC formulation. The SC formulation has not been assessed at Community level. According to the SANTE/2009/12752: *Residue trials that are performed with a formulation type that is not equivalent to the formulation type specified in the GAP under assessment are not acceptable; a complete data set performed with the formulation type defined in the GAP is required, unless comparable residue behaviour can be demonstrated with bridging studies However, experience shows that emulsifiable concentrates (EC), wettable powders (WP), dispersible granules (WG), and suspension concentrates (SC) formulations usually produce comparable residues (especially if the last application is more than seven days prior to harvest) and well-justified and documented departures from the above could be considered.* Considering the above, and the fact that the PHI for all proposed uses for edible crops is at least 35 days and that the proposed uses are less critical than those assessed at Community level for EC formulations, it is considered that the results of the residue trials for the proposed uses will not be higher than in the studies presented in the dossier. And therefore the related studies assessed for the EC formulation may support the use proposed for the SC formulation.
Magnitude of TDMs in cereals and rapeseed was assessed at Community level (EFSA Journal 2020;18(2):5999) in evaluation confirmatory data following the Article 12 MRL review.
The data provided was considered sufficient taking into account the date of submission of the application.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Dietary Burden calculations were perfomed during Annex I inclusion. New calculations were presented below witth MRL-Calculator.

Table 7.2-9: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS)

Commodity	Median Residue (mg/kg)
Wheat/rye/triticale grain	0.005 (1/2 LOQ)
Wheat/rye/triticale straw	0.39
Barley/oats grain	0.01
Barley/oats straw	0.58
Rapeseed straw	0.05

A calculation of theoretical maximum acute daily intakes of JAU 6476 by domestic animals is not necessary, as metabolism and feeding studies show that residues in animal tissues do not rapidly plateau.

		mg/kg diet (DM)	mg/kg diet (AR)	mg/animal/ day	mg/kg bw/day
Dairy	*	0.1395	0.1200	2.7935	0.00508
Beef		0.3430	0.2950	5.1488	0.01465
Sheep		0.3430	0.2950	1.0291	0.01370
Goat	*	0.1395	0.1200	0.4186	0.00597
Pig	*	0.0093	0.0080	0.0279	0.00037
Chicken	*	0.0082	0.0070	0.0010	0.00051
Turkey	*	0.0058	0.0050	0.0012	0.00017

* Less than 100% of diet employed

Based on the intakes calculated in table above, residues of JAU 6476-desthio in poultry products are not expected to be significant. Based on the intakes calculated in Table B.7.23 above, and the results of the livestock feeding study, residues of JAU 6476-desthio in products of animal origin are estimated at levels given below:
Milk: <0.004 mg/kg
meat: <0.01 mg/kg
fat: <0.01 mg/kg
liver: 0.04 mg/kg
kidney: 0.02 mg/kg

zRMS comments:
Dietary burden calculations performed at EU level seems to cover the uses proposed for CHR/F/PROTAZO 375 SC (EFSA Journal 2020;18(2):5999):

Relevant groups	Dietary burden expressed in				Most critical diet [a]	Most critical commodity [b]		Trigger exceeded (Yes/No) 0.10 mg/kg DM	JMPR 2017 (FAO, 2018) Max burden mg/kg DM
	mg/kg bw per day		mg/kg DM						
	Median	Maximum	Median	Maximum					
Cattle (all diets)	0.036	0.109	1.15	3.10	Dairy cattle	Barley	Straw	Y	18.42 (AUT dairy cattle)
Cattle (dairy only)	0.036	0.109	0.84	2.85	Dairy cattle	Barley	Straw	Y	21.60 (AUT beef cattle)
Sheep (all diets)	0.075	0.236	1.77	5.55	Lamb	Barley	Straw	Y	Not calculated
Sheep (ewe only)	0.059	0.185	1.77	5.55	Ram/ewe	Barley	Straw	Y	Not calculated
Swine (all diets)	0.015	0.018	0.49	0.64	Swine (finishing)	Swede	Roots	Y	Not calculated
Poultry (all diets)	0.035	0.059	0.52	0.86	Poultry layer	Wheat	Straw	Y	3.05 (EU poultry layer)
Poultry (layer only)	0.035	0.059	0.52	0.86	Poultry layer	Wheat	Straw	Y	Not calculated

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

The calculated dietary burdens for all groups of livestock exceeds the trigger value of 0.1 mg/kg DM.

7.2.4.2 Livestock feeding studies (KCP 6.4.1-6.4.3)

According DAR Prothioconazole - Volume 3, Annex B.7: Residues (2004):

In a 1998 livestock feeding study (EU and EPA guidelines), unlabelled JAU 6476-desthio (chemical purity 96.5%) was administered to lactating dairy cows (2.5-4 years old; 469-652 kg at administration). Nominal doses of 4, 25 and 100 mg/kg feed (approximately 1.3, 7 and 30N respectively, based on calculated animal intakes) were administered orally for 28 consecutive days to three replicate animals in each dose group. An additional control animal was not dosed.
During the dosing period, milk samples were collected twice daily for three days each week. Urine and faeces were not sampled and the health of animals during the study period was not reported. After sacrifice (within 24 hours of the final dose), liver, kidney, fat and muscle samples were taken for analysis. Samples were stored below -18°C until analysis. Tissue and milk samples were processed and analysed by HPLC/MS/MS for M14, M15 and JAU 6476-desthio, using the procedures described in residue analytical method and its modification for milk M001. Reported LOQs were 0.01 mg/kg for muscle, liver, kidney and fat, and 0.004 mg/kg for milk, as total residue. Total residues in milk at the 4 and 25 mg/kg dose levels were below the LOQ. At the 100 mg/kg dose level, total residues increased from <0.004 mg/kg (day 1) to a plateau level of 0.008 to 0.012 mg/kg

(day 4 to day 29). Residues in tissues after sacrifice are given in table below and residues in all control samples were below the LOQ.

Dose group	Liver				Kidney			
	M14	M15	M04	Total	M14	M15	M04	Total
4 mg/kg	0.01	0.01	0.02	0.04	0.01	0.01	<0.01	0.02
25 mg/kg	0.05	0.03	0.15	0.22	0.06	0.06	0.03	0.14
100 mg/kg	0.18	0.11	0.93	0.95	0.28	0.25	0.13	0.65
	Muscle				Fat			
4 mg/kg	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
25 mg/kg	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01
100 mg/kg	<0.01	<0.01	<0.01	0.02	0.01	0.01	0.05	0.07

zRMS comments:
The Applicant did not submit any new livestock feeding studies. The studies that have been assessed at Community level at the inclusion of prothioconazole are sufficient.

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

No significant residues, i.e. >0.1 mg/kg, were found in grain (both notifiers) and therefore pro-cessing studies are not required. No further studies have been performed

zRMS comments:
Not required.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

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

zRMS comments:
According to the 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*
Considering that the proposed uses are not more critical than those assessed at Community level, no risk mitigation measures need to be proposed.

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

New studies residue in honey matrix have been submitted by the applicant in the framework of this application, which covers cGAP for CHR/F/PROTAZO 375 SC

Table 7.2-10: Summary of EU reported and new data supporting the intended uses of CHR/F/PROTAZO and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Honey	A.Perny, Study code: C0278 C0239 C0278 C0279	EU	Prothioconazole: 4 x<0.003 Prothioconazole-desthio: 3x <0.003, 1x <0.01	N/A				
	Overall	EU	Prothioconazole: 4	<0.003	<0.01		0.05	Yes

	supporting data for cGAP		x<0.003 Prothioconazole-desthio: 3x <0.003, 1x <0.01					

zRMS comments:
According to the SANTE/11956/2016 rev.9 rape seed, soya, sunflower seed, mustard seed have melliferous capacity. In addition proposed use in rape seed is during flowering and prothioconazole is systemic substance. Taking into account the above, a residue trials in honey are required. The studies provided by the Applicant are relevant and sufficient. Additional studies are not required.

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

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

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-11: 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 Prothioconazole-desthio~~				
~~Wheat~~	~~0.01~~	~~Reg. (EU) 2019/552~~	~~0.01~~	~~Reg. (EU) 2019/552~~
~~Barley~~	~~0.01~~	~~Reg. (EU) 2019/552~~	~~0.01~~	~~Reg. (EU) 2019/552~~
~~Oilseed rape~~	~~0.15~~	~~Reg. (EU) 2019/552~~	~~0.15~~	~~Reg. (EU) 2019/552~~
~~Rye~~	~~0.05~~	~~Reg. (EU) 2019/552~~	~~0.05~~	~~Reg. (EU) 2019/552~~
~~Poppy seed~~	~~0.09~~	~~Reg. (EU) 2019/552~~	~~0.09~~	~~Reg. (EU) 2019/552~~
~~Sunflower seed~~	~~0.200~~	~~Reg. (EU) 2019/552~~	~~0.200~~	~~Reg. (EU) 2019/552~~
~~Soyabeams~~	~~0.200~~	~~Reg. (EU) 2019/552~~	~~0.200~~	~~Reg. (EU) 2019/552~~
~~Mustard seed~~	~~0.090~~	~~Reg. (EU) 2019/552~~	~~0.090~~	~~Reg. (EU) 2019/552~~

zRMS comments:
The Applicant did not submit any new residue studies for TDMs. The assessment performed by EFSA (EFSA Journal 2018;16(7):5376) appears to be appropriate*: The 'worst-case' consumer dietary intake assessment with regard to the TDMs for the complete group of triazole active substances that were*

assessed in the framework of these confirmatory data has been conducted by the RMS using the EFSA PRIMo rev.3 and by EFSA using the EFSA PRIMo rev.2A since PRIMo rev.3 is not applicable in the framework of confirmatory data assessed here.
The chronic and acute dietary intakes have been carried out using the highest input residue values for risk assessment (STMR values and the HR values), derived for each TDM for each crop groups and each product of animal origin. Since in most of the residue trials in primary and rotational crops, higher residue levels of the TDMs in the control samples were observed, these levels were also considered in the dietary intake calculation. Using the EFSA PRIMo rev.3, the IEDI accounted for 93% of the ADI (NL toddler) for 1,2,4-T, 6% of the ADI (NL toddler) for TA, 1% of the ADI (NL toddler) for TAA and 1% of the ADI (NL toddler) for TLA. No acute intake concern was identified as the calculated international estimated short-term intake (IESTI) accounted for up to 40% of the ARfD (cattle milk) for 1,2,4-T, 28% of the ARfD (oranges) for TA, 1% of the ARfD (oranges) for TAA and 7% of the ARfD (potatoes) for TLA.
No chronic or acute intake concerns were identified.
zRMS does not agree with the Applicant's risk assessment. The input values in Table 7.2-10 are not MRL values according to the Reg. (EU) 2019/552 as suggested in the Table. In addition, the Applicant did not include the conversion factors (CF) between the residue definition for enforcement and risk assessment in the calculations.
The calculations for chronic risk assessment were performed using MRLs in force and adequate CF (EFSA Journal 2014;12(5):3689):
2 for cereal grain, pulses and oilseeds, leafy vegetables, root and tuber vegetables and pig and ruminant liver
9 for pig and ruminant kidney. PRIMo rev. 3.1 was used for the calculations.
For acute risk assessment only HR values (input values form EFSA Journal 2020;18(2):5999) for intended crops (wheat, barley, oilseed rape, soya, rye, sunflower, poppy seeds and mustard seeds) and all animal products were used for calculations.

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-12: Consumer risk assessment

~~TMDI (% ADI) according to EFSA PRIMo~~	~~8 % (based on GEMS/Food G11)~~
~~IEDI (% ADI) according to EFSA PRIMo~~	~~8 % (based on GEMS/Food G11)~~
~~IESTI (% ARfD) according to EFSA PRIMo*~~	~~Sunflower: 6 % (based on children) (unprocessed)~~ ~~Soyabeans: 11% (based on adult)(unprocessed)~~ ~~Soyabeans: 8 % (based on based on children)(processed)~~ ~~Barley: 0.7% (based on adult)(processed)~~

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

TMDI (% ADI) according to EFSA PRIMo	48 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% ARfD) according to EFSA PRIMo	Bovine kidney: 51% (based on children) Wheat: 29% (based on children) Barley: 22% (based on children) Sunflower seeds: 13 % (based on children) Soybeans: 9% (based on adult) Rapeseeds: 4% (based on based on children) Mustard seeds: 2% (based on based on children) Wheat (flour): 24% (based on based on children) Soya drink: 17 % (based on based on children) Barley (beer): 29% (based on adult)

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Prothioconazole

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,01	ARfD (mg/kg bw):	0,01
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2005	Year of evaluation:	2005

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
48%	NL toddler	4,76	14%	Maize/corn	8%	Wheat	6%	Milk: Cattle		
36%	GEMS/Food G10	3,55	13%	Soyabeans	8%	Wheat	2%	Barley		
35%	GEMS/Food G11	3,54	15%	Soyabeans	7%	Wheat	3%	Barley		
35%	GEMS/Food G06	3,46	14%	Wheat	5%	Soyabeans	3%	Maize/corn		
34%	GEMS/Food G15	3,43	9%	Wheat	7%	Soyabeans	3%	Barley		
34%	GEMS/Food G07	3,36	8%	Wheat	7%	Soyabeans	2%	Barley		
34%	GEMS/Food G08	3,35	8%	Wheat	8%	Soyabeans	4%	Barley		
24%	IE adult	2,43	6%	Peas	5%	Wheat	3%	Lentils		
24%	FR child 3 15 yr	2,37	9%	Wheat	4%	Lentils	2%	Milk: Cattle		
23%	NL child	2,31	8%	Wheat	2%	Milk: Cattle	1%	Sunflower seeds		
22%	ES child	2,25	9%	Wheat	5%	Lentils	2%	Peas		
22%	DK child	2,24	9%	Wheat	6%	Rye	3%	Carrots		
22%	RO general	2,24	10%	Wheat	3%	Sunflower seeds	3%	Head cabbages		
21%	UK infant	2,06	5%	Wheat	4%	Milk: Cattle	3%	Carrots		
20%	DE child	1,97	8%	Wheat	2%	Carrots	2%	Milk: Cattle		
18%	FR toddler 2 3 yr	1,85	6%	Wheat	3%	Milk: Cattle	2%	Lentils		
17%	UK toddler	1,65	8%	Wheat	2%	Milk: Cattle	1%	Carrots		
16%	IT toddler	1,63	13%	Wheat	0,7%	Lentils	0,4%	Carrots		
16%	PT general	1,57	8%	Wheat	1%	Carrots	1%	Soyabeans		
15%	SE general	1,47	6%	Wheat	2%	Carrots	1%	Milk: Cattle		
14%	ES adult	1,37	5%	Wheat	2%	Lentils	2%	Barley		
13%	NL general	1,31	4%	Wheat	1%	Barley	0,8%	Milk: Cattle		
12%	DE general	1,24	4%	Wheat	2%	Barley	1%	Milk: Cattle		
11%	DE women 14-50 yr	1,15	4%	Wheat	1%	Milk: Cattle	0,8%	Barley		
11%	FR adult	1,09	4%	Wheat	1%	Lentils	0,4%	Milk: Cattle		
11%	IT adult	1,06	8%	Wheat	0,4%	Lentils	0,3%	Carrots		
10%	FI 3 yr	0,98	2%	Wheat	2%	Carrots	0,9%	Potatoes		
9%	FR infant	0,90	2%	Carrots	2%	Milk: Cattle	2%	Wheat		
9%	UK vegetarian	0,86	4%	Wheat	0,8%	Lentils	0,6%	Peas		
8%	FI 6 yr	0,85	2%	Wheat	1%	Peas	1%	Carrots		
7%	FI adult	0,72	3%	Coffee beans	0,7%	Peas	0,7%	Rye		
7%	LT adult	0,71	2%	Wheat	1%	Rye	0,7%	Head cabbages		
7%	UK adult	0,68	3%	Wheat	0,4%	Carrots	0,3%	Milk: Cattle		
6%	DK adult	0,63	2%	Wheat	1,0%	Carrots	0,5%	Milk: Cattle		
4%	PL general	0,40	0,7%	Potatoes	0,7%	Head cabbages	0,6%	Carrots		
4%	IE child	0,38	2%	Wheat	0,4%	Milk: Cattle	0,3%	Carrots		

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

Acute risk assessment / adults / general population

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

Acute risk assessment /children

Hide IESTI new calculations

Acute risk assessment / adults / general population

Show IESTI new calculations

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

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

Show results for all crops

Unprocessed commodities

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

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

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
51%	Bovine: Kidney	0,15 / 1,35	5,1
37%	Bovine: Liver	0,23 / 0,46	3,7
29%	Wheat	0,1 / 0,2	2,9
22%	Barley	0,2 / 0,4	2,2
17%	Swine: Kidney	0,15 / 1,35	1,7
13%	Sunflower seeds	0,2 / 0,4	1,3
11%	Bovine: Edible offals (other	0,15 / 0,15	1,1
9%	Soyabeans	0,2 / 0,4	0,92
6%	Rye	0,05 / 0,1	0,63
6%	Milk: Cattle	0,01 / 0,01	0,62
6%	Swine: Liver	0,23 / 0,46	0,56
5%	Swine: Edible offals (other	0,15 / 0,15	0,45
4%	Rapeseeds/canola seeds	0,15 / 0,3	0,41
2%	Mustard seeds	0,09 / 0,18	0,18
2%	Honey and other apiculture	0,05 / 0,05	0,18

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
30%	Swine: Kidney	0,15 / 1,35	3,0
28%	Bovine: Kidney	0,15 / 1,35	2,8
22%	Soyabeans	0,2 / 0,4	2,2
19%	Barley	0,2 / 0,4	1,9
18%	Bovine: Liver	0,23 / 0,46	1,8
17%	Wheat	0,1 / 0,2	1,7
16%	Swine: Other products	0,5 / 0,5	1,6
13%	Sheep: Liver	0,23 / 0,46	1,3
10%	Bovine: Other products	0,5 / 0,5	1,00
6%	Swine: Liver	0,23 / 0,46	0,65
5%	Bovine: Edible offals (other	0,15 / 0,15	0,50
5%	Rye	0,05 / 0,1	0,49
4%	Sunflower seeds	0,2 / 0,4	0,40
4%	Swine: Edible offals (other	0,15 / 0,15	0,39
3%	Poultry: Liver	0,07 / 0,07	0,33

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
51%	Bovine: Kidney	0,15 / 1,35	5,1
37%	Bovine: Liver	0,23 / 0,46	3,7
29%	Wheat	0,1 / 0,2	2,9
22%	Barley	0,2 / 0,4	2,2
17%	Swine: Kidney	0,15 / 1,35	1,7
13%	Sunflower seeds	0,2 / 0,4	1,3
11%	Bovine: Edible offals (other	0,15 / 0,15	1,1
9%	Soyabeans	0,2 / 0,4	0,92
6%	Rye	0,05 / 0,1	0,63
6%	Milk: Cattle	0,01 / 0,01	0,62
6%	Swine: Liver	0,23 / 0,46	0,56
5%	Swine: Edible offals (other	0,15 / 0,15	0,45
4%	Rapeseeds/canola seeds	0,15 / 0,3	0,41
2%	Mustard seeds	0,09 / 0,18	0,18
2%	Honey and other apiculture	0,05 / 0,05	0,18

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
30%	Swine: Kidney	0,15 / 1,35	3,0
28%	Bovine: Kidney	0,15 / 1,35	2,8
22%	Soyabeans	0,2 / 0,4	2,2
19%	Barley	0,2 / 0,4	1,9
18%	Bovine: Liver	0,23 / 0,46	1,8
17%	Wheat	0,1 / 0,2	1,7
16%	Swine: Other products	0,5 / 0,5	1,6
13%	Sheep: Liver	0,23 / 0,46	1,3
10%	Bovine: Other products	0,5 / 0,5	1,00
6%	Swine: Liver	0,23 / 0,46	0,65
5%	Bovine: Edible offals (other than	0,15 / 0,15	0,50
5%	Rye	0,05 / 0,1	0,49
4%	Sunflower seeds	0,2 / 0,4	0,40
4%	Swine: Edible offals (other than liver	0,15 / 0,15	0,39
3%	Poultry: Liver	0,07 / 0,07	0,33

Processed commodities

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

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

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

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
24%	Wheat / milling (flour)	0,1 / 0,2	2,4
17%	Soyabeans / soya drink	0,2 / 0,4	1,7
15%	Barley / cooked	0,2 / 0,4	1,5
11%	Wheat / milling (wholemeal)-I	0,1 / 0,2	1,1
9%	Sunflower seeds / oils	0,2 / 0,8	0,94
7%	Barley / milling (flour)	0,2 / 0,4	0,72
6%	Soyabeans / boiled	0,2 / 0,16	0,58
4%	Rye / boiled	0,05 / 0,1	0,36
4%	Rye / milling (wholemeal)-bal	0,05 / 0,1	0,35
2%	Rapeseeds / oils	0,15 / 0,6	0,18
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

Expand/collapse list

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
29%	Barley / beer	0,2 / 0,08	2,9
9%	Wheat / bread/pizza	0,1 / 0,2	0,88
8%	Wheat / pasta	0,1 / 0,2	0,76
7%	Wheat / bread (wholemeal)	0,1 / 0,2	0,70
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
24%	Wheat / milling (flour)	0,1 / 0,2	2,4
17%	Soyabeans / soya drink	0,2 / 0,4	1,7
15%	Barley / cooked	0,2 / 0,4	1,5
11%	Wheat / milling (wholemeal)-	0,1 / 0,2	1,1
9%	Sunflower seeds / oils	0,2 / 0,8	0,94
7%	Barley / milling (flour)	0,2 / 0,4	0,72
6%	Soyabeans / boiled	0,2 / 0,16	0,58
4%	Rye / boiled	0,05 / 0,1	0,36
4%	Rye / milling (wholemeal)-	0,05 / 0,1	0,35
2%	Rapeseeds / oils	0,15 / 0,6	0,18
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
29%	Barley / beer	0,2 / 0,08	2,9
9%	Wheat / bread/pizza	0,1 / 0,2	0,88
8%	Wheat / pasta	0,1 / 0,2	0,76
7%	Wheat / bread (wholemeal)	0,1 / 0,2	0,70
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

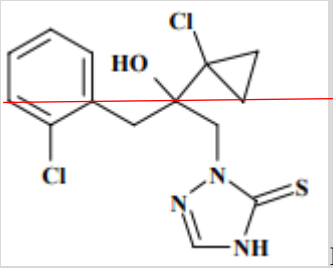
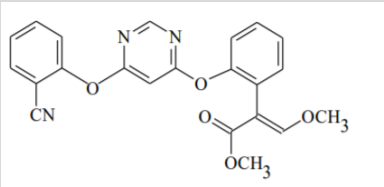
Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Prothioconazole is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

The proposed uses of prothioconazole in the formulation CHR/F/PROTAZO do not represent unacceptable acute and chronic risks for the consumer.

7.3 Azoxystrobin

General data on Azoxystrobin are summarized in the table below (last updated 2007/12/10)

Table 7.3-1: General information on Azoxystrobin

Active substance (ISO Common Name)	Azoxystrobin
IUPAC	methyl (E)-2-{2[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate
Chemical structure	 Not correct  Correct
Molecular formula	C22H17N3O5
Molar mass	403.4
Chemical group	aryloxypyrimidine
Mode of action (if available)	inhibit mitochondrial respiration by blocking electron transpor
Systemic	Yes
Company (ies)	Syngenta
Rapporteur Member State (RMS)	~~AT~~ UK
Approval status	Approve Date of approval 01.01.2012, Reg. (EU) 703/2011
Restriction	SANCO/11027/2011 Rev 3 20 March 20152 Only uses as fungicide may be authorised.
Review Report	SANCO/11027/2011 Rev 3 20 March 2015~~2~~
Current MRL regulation	~~Reg. (EU) 2019/552~~ Reg. (EU) 2021/1807
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	EFSA Journal 2010; 8(4):1542
EFSA Journal : Conclusion on the peer review	EFSA Journal 2010; 8(4):1542
EFSA Journal: conclusion on article 12	EFSA Journal 2010; 8(4):1542
Current MRL applications on intended uses	~~Reg. (EU) 2019/552~~ None

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

7.3.1 Stability of Residues (KCP 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat	High starch content	~~15 months~~ 24 month	Burke, S.R., 1995a EFSA 2013
Oilseed rape	High oil content	24 month	Burke, S.R., 1997

Conclusion on stability of residues during storage

The storage stability evaluated during Annex I inclusion covers plant matrices for use CHR/F/PROTAZO 375 SC according to the label.

7.3.1.2 Stability of residues in sample extracts (KCP 6.1)

From GLP study: J. Kicińska, Study code:
1) ZBBZ-2018/11/DPL/1CZ
2) 19/FSL/12/1PL
3) ZBBZ-2018/11/DPL/1DE
4) ZBBZ-2018/11/DPL/1PL
5) ZBBZ-2018/11/DPL/1FR2
6) ZBBZ-2018/11/DPL/1HU
7) 19/FSL/12/1CZ
Analysis time were less than 24 hours between extraction and analysis or it was shown that study extracts are stable.

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCP 6.2.1)

Available data

No new data submitted in the framework of this application.

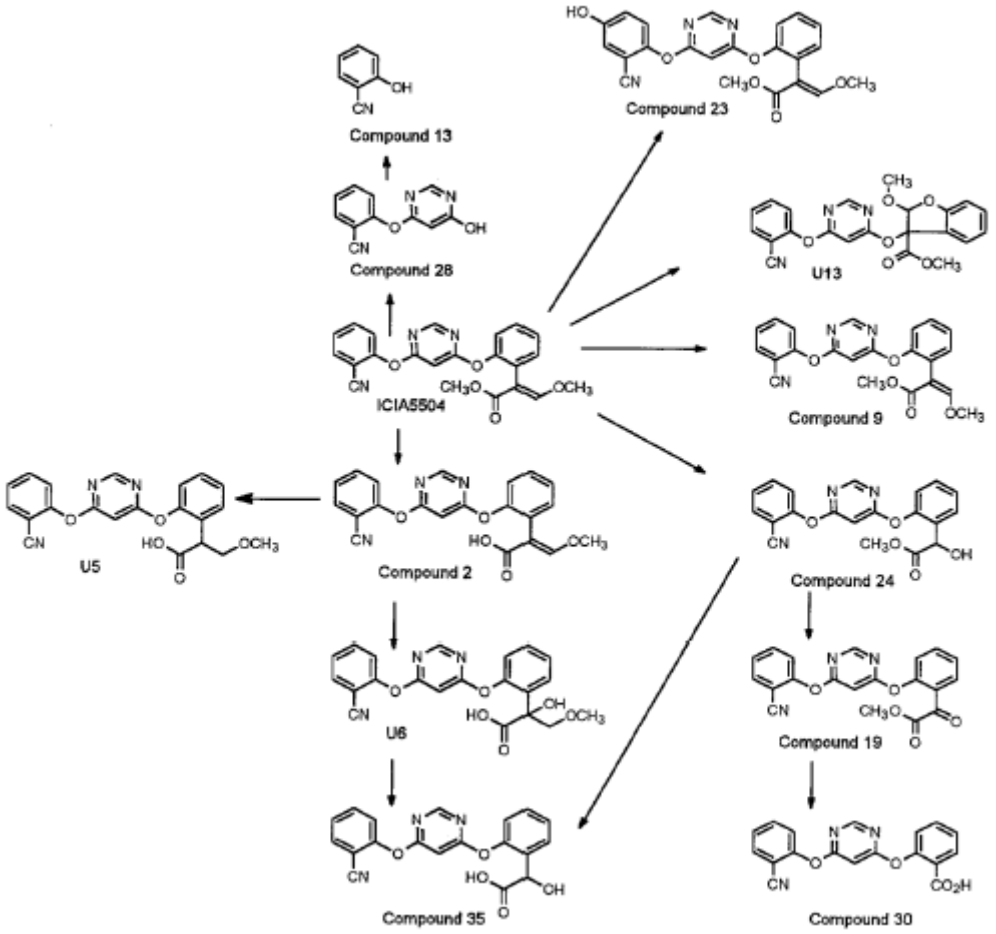
Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Pulses and oilseeds	Peanut	14C-pyrimidinyl	foliar treatment, F	850 g as/ha	2	10 days	-	Webb, J. et al, 1995
		14C-cyanophenyl						
		14C-phenylacrylate						
Cereals	Wheat	14C-pyrimidinyl	foliar treatment, F	500 g as/ha	2	13 and 62 days	-	Wilkinson, M. J. et al., 1994 Allin, R. et al., 1995
		14C-cyanophenyl						
		14C-phenylacrylate						

Summary of plant metabolism studies reported in the EU

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

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



Conclusion on metabolism in primary crops

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

zRMS comments:
Plant metabolism studies evaluated at Community level support the intended uses proposed in the GAP for CHR/F/PROTAZO 375 SC. The residue definition for enforcement and risk assessment in all plant commodities following foliar application is defined as azoxystrobin.

7.3.2.2 Nature of residue in rotational crops (KCP 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetable	lettuce	14C-pyrimidinyl	F	2.21 kg as/ha	30, 200 and 365 days	30, 200 and 365 days	-	Goldsby, G., et al., 1995
		14C-cyanophenyl		2.2 kg as/ha	30, 200 and 365 days	30, 200 and 365 days		Miller, M. M. and Wilson, W., 1995
		14C-phenylacrylate		2.2 kg as/ha	30, 200 and 365 days	30, 200 and 365 days		Tambling, D.R. et al., 1995
Root and tuber vegetables	Radish	14C-pyrimidinyl	F	2.21 kg as/ha	30, 200 and 365 days	30, 200 and 365 days	-	Goldsby, G., et al., 1995
		14C-cyanophenyl		2.2 kg as/ha	30, 200 and 365 days	30, 200 and 365 days		Miller, M. M. and Wilson, W., 1995
		14C-phenylacrylate		2.2 kg as/ha	30, 200 and 365 days	30, 200 and 365 days		Tambling, D.R. et al., 1995
Cereals	wheat	14C-pyrimidinyl	F	2.21 kg as/ha	30, 200 and 365 days	30, 200 and 365 days	-	Goldsby, G., et al., 1995
		14C-cyanophenyl		2.2 kg as/ha	30, 200 and 365 days	30, 200 and 365 days		Miller, M. M. and Wilson, W., 1995
		14C-phenylacrylate		2.2 kg as/ha	30, 200 and 365 days	30, 200 and 365 days		Tambling, D.R. et al., 1995

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

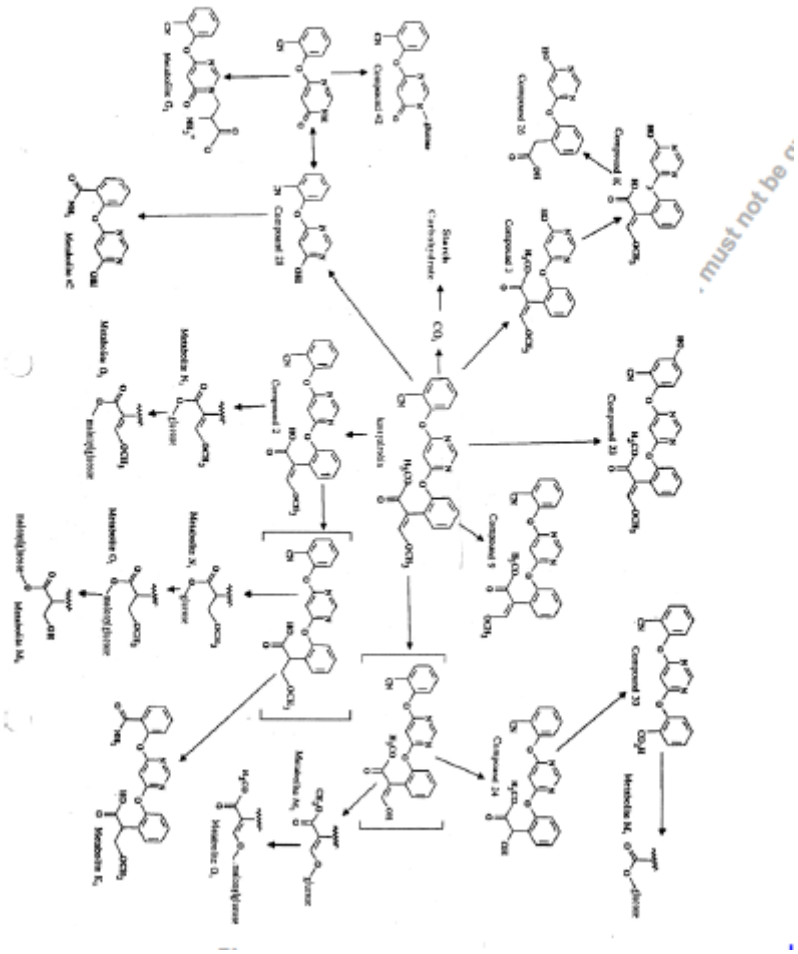
Summary of plant metabolism studies reported in the EU

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

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

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

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



Conclusion on metabolism in rotational crops

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

zRMS comments:
The nature of residues in rotational crops was evaluated at Community level. Additional studies are not required. It was concluded that metabolism of azoxystrobin in rotational crops is similar to the metabolism observed in primary crops. The relevant residue definition in rotational crops is parent azoxystrobin.

7.3.2.3 Nature of residues in processed commodities (KCP 6.5.1)

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

zRMS comments:
The nature of residues in processed commodities was evaluated at Community level. Addition studies are not required.

Conditions	Stable?	Reference
Pasteurisation (20 min, 90°C, pH 4)	Yes	EFSA 2010

Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	EFSA 2010
Sterilisation (20 min, 120°C, pH 6)	Yes	EFSA 2010

It was concluded that residue pattern in processed commodities is similar to residue pattern in raw commodities.

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

Table 7.3-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Pulses and oilseeds (Peanut) Cereals (Wheat) Fruit crops (grapes)
Rotational crops covered	Cereals (wheat) Leafy vegetables (lettuce) Root vegetables (radish)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Azoxystrobin (no significant degradation observed under standard hydrolysis conditions)
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Azoxystrobin
Plant residue definition for risk assessment	Azoxystrobin
Conversion factor from enforcement to RA	None

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

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

Available data

No new data submitted in the framework of this application.

Table 7.3-6: 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 samp-ling	
EU data								
Lactating ruminants	Goat	14C-pyrimidinyl	2	25	7	Milk	twice daily	xxxxxxx

		14C-cyanophenyl 14C-phenylacrylate				Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	14C-pyrimidinyl 14C-cyanophenyl 14C-phenylacrylate	6	15	10	Eggs	twice daily	xxxxxxx
						Excreta	regular intervals	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

Azoxystrobin is rapidly excreted and extensively metabolised by hens, with 92 to 98% of the total radioactivity excreted within 23 hours after the final dose. The highest TRRs were in the egg yolk (0.144 mg/kg, [14C-pyrimidinyl]-azoxystrobin) and liver (up to 0.11 mg/kg, [14C-phenylacrylate]-azoxystrobin). The recovery data indicate transfer of azoxystrobin and its metabolites into tissues and eggs is low. Azoxystrobin and R401553 were identified in egg yolk at levels of <0.001-0.006 mg/kg azoxystrobin (parent) equivalents. In all tissues (for all labels):

* all components present at levels between 0.01 and 0.05 mg/kg were characterised
* no components were present at levels >0.05 mg/kg and no further work was therefore required to identify them.

Even at the exaggerated dose rate used (8N), the transfer of residue into tissues and egg was very small. Expected transfer of the residue into tissues under normal use patterns will be significantly lower than 0.01 mg/kg.

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

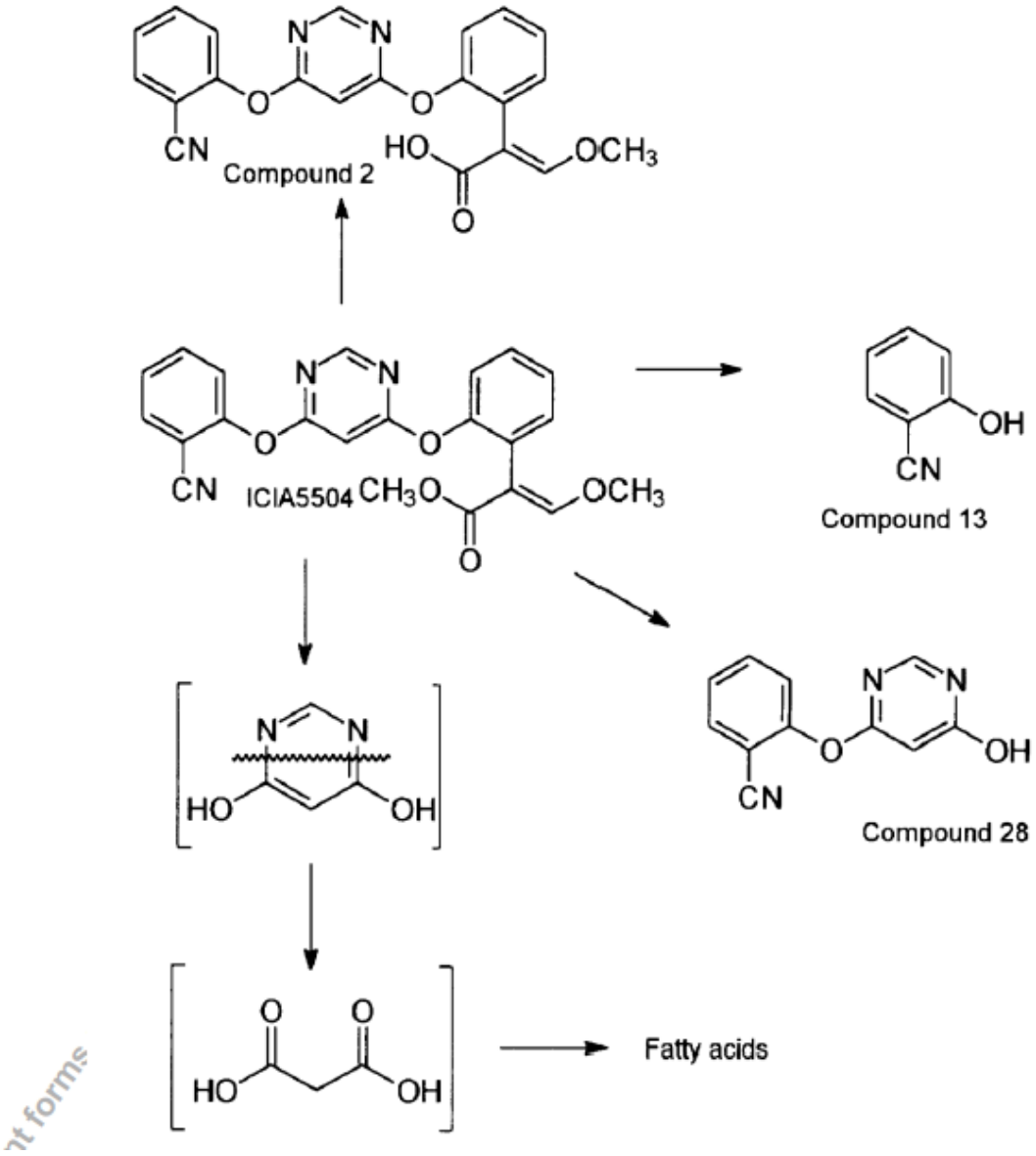
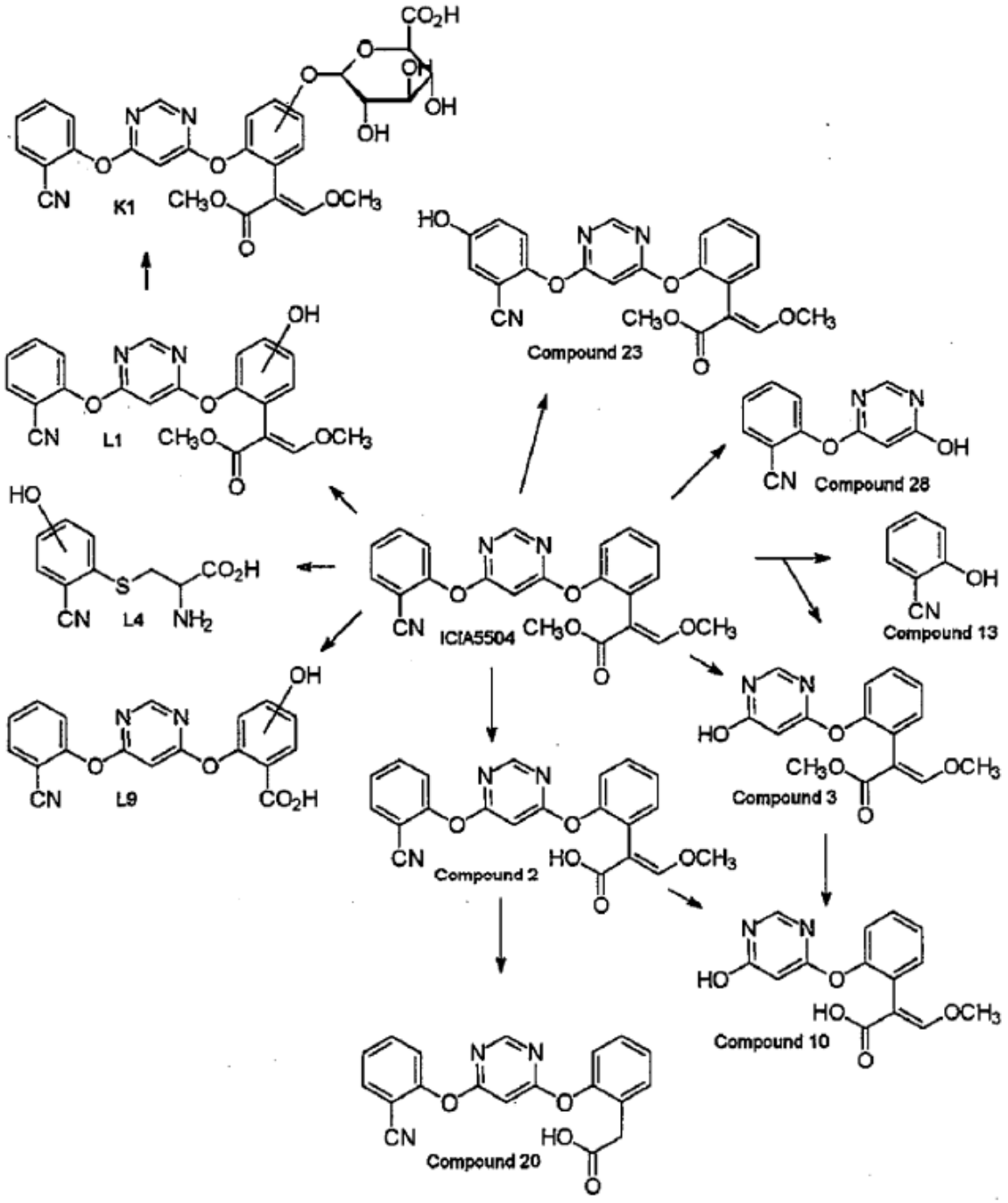


Figure B.7.2.1-2 Proposed Biotransformation Pathway of Azoxystrobin in the Goat



Conclusion on metabolism in livestock

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

zRMS comments:
The livestock metabolism studies were evaluated at Community level. The general metabolic pathways in rodents and ruminants were found to be comparable therefore extrapolation from ruminants to pig is possible. The residue definition for enforcement is defined as azoxystrobin. No conclusion could be

drown on the toxicological profile of metabolites L1, L4 and L9 (genotoxicity of these metabolites can be ruled out), additional data at EU level are required. It is proposed on tentative basis, to define the residue definition for risk assessment as azoxystrobin. Additional studies are not required for this dossier.

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

Table 7.3-7: Summary on the nature of residues in commodities of animal origin

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

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

7.3.3 Magnitude of residues in plants (KCP 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, ~~which covers cGAP for CHR/F/PROTAZO 250 EC~~. Please refer to the J. Kicińska, Study code:
1) ZBBZ-2018/11/DPL/1CZ
2) 19/FSL/12/1PL
3) ZBBZ-2018/11/DPL/1DE
4) ZBBZ-2018/11/DPL/1PL
5) ZBBZ-2018/11/DPL/1FR2
6) ZBBZ-2018/11/DPL/1HU
7) 19/FSL/12/1CZ.
These studies are summarized in the Table below.

Table 7.3-8: Summary of EU reported and new data supporting the intended uses of CHR/F/PROTAZO and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Wheat (Grain) extrapolation on rye	EFSA Journal 2010; 8(4):1542 31	N-EU	GAP on which MRL/EU a.s. assessment is based: 3 x 0.2 kg as/ha, BBCH 69, PHI 35d, outdoor E: 3 x <0.01, 0.01, 2 x 0.04, 0.07, 0.09, 0.23 RA: 3 x <0.01, 0.01, 2 x 0.04, 0.07, 0.09, 0.23	N/A				
	Overall supporting data for cGAP	N-EU	E : 3 x <0.01, 0.01, 2 x 0.04, 0.07, 0.09, 0.23 RA: 3 x <0.01, 0.01, 2 x 0.04, 0.07, 0.09, 0.23	0.04	0.23	0.342	0.5 for wheat and rye	Yes
Wheat (straw)	EFSA Scientific Report (2007) 106,	EU	GAP on which MRL/EU a.s. assessment is based: 3 x 0.2 kg as/ha, BBCH 69, PHI 35d, outdoor	N/A				

	1-98		E: 0.34, 0.58, 0.65, 0.75, 0.82, 1.5, 2x 1.6, 2.0 RA: 0.34, 0.58, 0.65, 0.75, 0.82, 1.5, 2x 1.6, 2.0					
	Overall supporting data for cGAP	EU	E: 0.34, 0.58, 0.65, 0.75, 0.82, 1.5, 2x 1.6, 2.0 RA: 0.34, 0.58, 0.65, 0.75, 0.82, 1.5, 2x 1.6, 2.0	0.82	2.0		~~0.5~~	~~Yes/~~
Barley (grain)	EFSA Journal 2010; 8(4):1542 31	EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.2 kg as/ha, BBCH 61, PHI 35d, outdoor E: <0.01, 0.01, 0.02, 2x 0.04, 0.08, 0.20, 0.43 RA: <0.01, 0.01, 0.02, 2x 0.04, 0.08, 0.20, 0.43	N/A				
	Overall supporting data for cGAP	EU	E: <0.01, 0.01, 0.02, 2x 0.04, 0.08, 0.20, 0.43 RA: <0.01, 0.01, 0.02, 2x 0.04, 0.08, 0.20, 0.43	0.04	0.43	0.687	1.5	Yes
Barley (straw)	EFSA Journal 2010; 8(4):1542 31	EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.2 kg as/ha, BBCH 61, PHI 35d, outdoor E: 0.11, 0.39, 0.48, 0.91, 1.3, 1.5, 2.7, 5.1 RA: 0.11, 0.39, 0.48, 0.91, 1.3, 1.5, 2.7, 5.1	N/A				
	Overall supporting data for cGAP	EU	E: 0.11, 0.39, 0.48, 0.91, 1.3, 1.5, 2.7, 5.1 RA: 0.11, 0.39, 0.48, 0.91, 1.3, 1.5, 2.7, 5.1	0.91	5.1		~~1.5~~	~~Yes~~
Oilseed rape (Seeds) extrapolation on soybeans, mustard seeds, sunflower seeds, poppy seeds	New trials J. Kicińska, Study code: 1) ZBBZ-2018/11/DPL/1CZ 2) 19/FSL/12/1PL 3) ZBBZ-2018/11/DPL/1DE 4) ZBBZ-2018/11/DPL/1PL 5) ZBBZ-2018/11/DPL/1FR2 6) ZBBZ-2018/11/DPL/1HU 7) 19/FSL/12/1CZ T. Peda, Study code: 20SGS10	EU	Trials GAP: 1 x 0.25 kg as/ha, PHI ~~60~~35d, E: <0.01, 0.026, 0.032, 0.035, 0.036, 0.042, 0.046, 0.069, 0.098 RA: <0.01 0.026, 0.032, 0.035, 0.036, 0.042, 0.046, 0.098 Residue trials performed with SE formulation.	N/A				

	Overall supporting data for cGAP	EU	E : <0.01, 0.026, 0.032, 0.035, 0.036, 0.042, 0.046, 0.069, 0.098 RA: <0.01, 0.026, 0.035, 0.036, 0.042, 0.046, 0.069, 0.098	0.036	0.098	0.147	0.5 for rapeseed, mustard seeds, soybeans, poppy seads, sunflower seeds	Yes
Oilseed rape (Seeds) extrapolation on soybeans, mustard seeds, sunflower seeds, poppy seeds	Unproteced studies from Amistar 250 SC – Bridging studies: Report No RJ2366B Report No RJ2419B Report No RJ2524B Report No RJ2591B	EU	Trials GAP: 1 x 0.25 kg as/ha, PHI 35d, E: 4x <0.01 RA: 4x <0.01	<0.01	<0.01		0.5 for rapeseed, mustard seeds, soybeans, poppy seads, sunflower seeds	Yes
	Overall supporting data for cGAP	EU	E : 4x <0.01 RA: 4x <0.01	NA				

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

According to COMMISSION REGULATION (EU) No 283/2013 point “Magnitude of residue trials in plants” studies shall always be performed where the plant protection product is to be applied to plants or plant products that are used as food or feed. Tobacco is a crop designed for smoking, not for eating. Tobacco have no edible part therefore residues evaluation isn’t necessary according to EU 283/2013.

According to COMMISSION REGULATION (EU) No 283/2013 point “Magnitude of residue trials in plants” studies shall always be performed where the plant protection product is to be applied to plants or plant products that are used as food or feed. Coniferous / deciduous forest nurseries and Ornamental shrubs have no edible part therefore residues evaluation isn’t necessary according to EU 283/2013.

According to COMMISSION REGULATION (EU) No 283/2013 point “Magnitude of residue trials in plants” studies shall always be performed where the plant protection product is to be applied to plants or plant products that are used as food or feed. *Salix viminalis and* Wicker are used for crafting and green energy purposes and have no edible part so residues evaluation isn’t necessary according to EU 283/2013.

According to COMMISSION REGULATION (EU) No 283/2013 point “Magnitude of residue trials in plants” studies shall always be performed where the plant protection product is to be applied to plants or plant products that are used as food or feed. Ornamentals are used for crafting and green energy purposes and have no edible part so residues evaluation isn’t necessary according to EU 283/2013

According to SANCO 7525/VI/95 Rev. 10.2, 23 September 2016 guidance document, residue data set for sunflower, soya, mustard, breadseed poppy, spring oil seed rape can be obtained winter oilseed rape. According to GAP both all crop covered by winter oil seed rape is designed in end phases BBCH 66 which is “before forming the edible part” situation. The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assessment. Data/information which are source of extrapolation to sunflower, soya, mustard, breadseed poppy, spring oil seed rape on residues in winter oil seed rape were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated according to Guidance Document SANCO 7525/VI/95 Rev. 10.2.23 September 2016.

According to SANCO 7525/VI/95 Rev. 10.2, 23 September 2016 guidance document, residue data set for spring rye can be obtained wheat. According to GAP spring rye is designed in the same phases BBCH is “before forming the edible part” situation. The applied for GAP is considered to be covered by the critical EU GAP that was used for the MRL setting assessment. Data/information which are source of extrapolation to spring rye on residues in wheat were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated according to Guidance Document SANCO 7525/VI/95 Rev. 10.2.23 September 2016

7.3.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on cereals and oilseed rape are was considered acceptable, for ~~both indoor and~~ outdoor uses.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

zRMS comments:
GAP proposed for CHR/F/PROTAZO 375 SC is covered by GAP evaluated at EU level. For the proposed use in oilseed rape, the Applicant has provided 8 trials. According to the SANCO 7525/VI/95 Rev. 10.3 oilseed rape is regarded as a major crop therefore 8 trials are required.
According to the SANTE/2019/12752, it is possible to extrapolate from any representatives of the oilseeds group (except peenuts) to the whole group in the case the use takes place before forming of the edible part. The proposed use in max BBCH(69) for sunflower, soya, poppy seeds and mustard seeds concerns the flowering phase, ie before the development of the edible parts of the plant. Therefore, the proposed extrapolation of residue results from rapeseed to sunflower, soya, poppy seeds and mustard seeds is accepted. In all cases, the results show no residues above the applicable MRLs.
However, the studies submitted by the Applicant were performed for formulation SE, while the proposed formulation is SC. For this reason the Applicant has provided bridging studies showing that the residue levels will not be higher when used in the formulation proposed in the GAP for CHR/F/PROTAZO 375 SC. These studies have been approved. No additional studies are required.

7.3.4 Magnitude of residues in livestock

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

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

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

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

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

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

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

- Malting and brewing; one balance and three follow-up studies
- Production of pot barley; two balance and two follow-up studies

For wheat two sequentional processes were investigated:

- Milling: one balance and three follow-up, followed by
- Baking: one balance and three follow-up

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

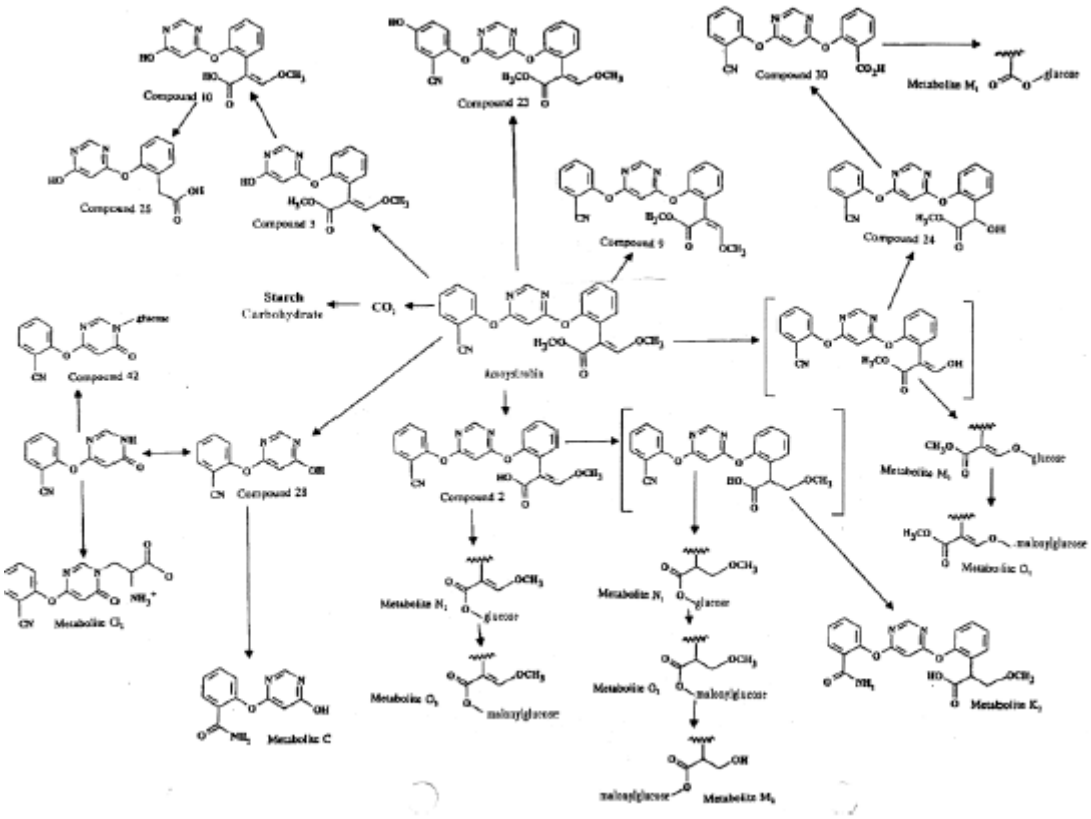
Bean processing studies were evaluated to support uses on cauliflower, broccoli, kale (leafy brassicas) and Brussels sprouts.

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

7.3.6 Magnitude of residues in representative succeeding crops

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

<u>Proposed metabolism of azoxystrobin in rotational crops:</u>



The three field rotational crop studies conducted in the USA and summarised in Evans , P 2009 were all conducted at exaggerated rates (compared with the proposed use pattern of azoxystrobin in cereals and brassicae in the EU).

The RMS concludes that the field rotational crop studies provide sufficient evidence to demonstrate that relevant residues (with reference to SANCO 7254) are not present and none of the already established MRLs will be exceed as a result of the cultivation of rotational crops.

Residues of azoxystrobin from field rotational crops

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

Registration must not be granted on the basis of this summary alone and should not be read in isolation.

Residues of azoxystrobin from field rotational crops

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

of an EC evaluation of a dossier and should not be read in isolation. Registration must not be granted on the bas,

zRMS comments:
According to the EFSA Journal 2020;18(8):6231: *Several rotational crop field trials were evaluated in the framework of the peer review (United Kingdom, 2009). 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 where the highest residues were expected to be 0.05 mg/kg and 0.04 mg/kg, respectively. However, no impact on the residue level in products of animal origin is expected (EFSA, 2013).*
Based on field rotational crop studies evaluated at Community level residues in rotational and succeeding crops have no impact on the MRLs in plants and livestock commodities.
Considering that the proposed uses are not more critical than those assessed at Community level, no risk mitigation measures need to be proposed.

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

New studies residue in honey matrix have been submitted by the applicant in the framework of this application, which covers cGAP for CHR/F/PROTAZO 375 SC

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of CHR/F/PROTAZO and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Honey	A.Perny, Study code: C0278 C0239	EU	Azoxystrobin: 3x <0.003, 1x <0.01	N/A				

	C0278 C0279							
	Overall supporting data for cGAP	EU	Azoxystrobin: 3x <0.003, 1x <0.01	<0.003	<0.01		0.05	Yes

zRMS comments:
According to the SANTE/11956/2016 rev.9 rape seed, soya bean, sunflower seed, mustard seed have melliferous capacity. In addition proposed use in rape seed is during flowering and azoxystrobin is systemic substance. Taking into account the above, a residue trials in honey for these crops, are required and were provided by the Applicant. The provided studies were accepted and show no prothioconazole and azoxystrobin residues in the honey after CHR/F/PROTAZO 375 SC application according to the proposed GAP.

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

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

7.3.8.1 Input values for the consumer risk assessment

Table 7.3-10: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue Azoxystrobin				
Wheat	0.5	Reg. (EU) 2019/552	~~0.5~~	~~Reg. (EU) 2019/552~~
Barley	1.5	Reg. (EU) 2019/552	~~1.5~~	~~Reg. (EU) 2019/552~~
Oilseed rape	0.5	Reg. (EU) 2019/552	~~0.5~~	~~Reg. (EU) 2019/552~~
Rye	0.5	Reg. (EU) 2019/552	~~0.5~~	~~Reg. (EU) 2019/552~~
Poppy seed	0.5	Reg. (EU) 2019/552	~~0.5~~	~~Reg. (EU) 2019/552~~
Sunflower seed	0.5	Reg. (EU) 2019/552	~~0.5~~	~~Reg. (EU) 2019/552~~
Soyabeams	0.5	Reg. (EU) 2019/552	~~0.5~~	~~Reg. (EU) 2019/552~~
Mustard seed	0.5	Reg. (EU) 2019/552	~~0.5~~	~~Reg. (EU) 2019/552~~

zRMS comments:
Acute risk assessment is not relevant since no ARfD was deemed necessary. Additionally, a chronic risk assessment was performed using PRIMo rev. 3.1 and taking into account all applicable MRL values (overestimation). Results are presented below.

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Azoxystrobin

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,2	ARfD (mg/kg bw):	insert valid entry
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
82%	NL toddler	164,94	17%	Oranges	15%	Potatoes	13%	Sugar beet roots		
69%	DE child	138,19	30%	Oranges	9%	Potatoes	3%	Mandarins		
68%	NL child	135,62	21%	Sugar beet roots	12%	Potatoes	11%	Oranges		
57%	FR child 3 15 yr	113,13	26%	Oranges	9%	Sugar beet roots	5%	Potatoes		
50%	GEMS/Food G06	99,35	7%	Oranges	7%	Potatoes	5%	Tomatoes		
48%	UK toddler	95,95	15%	Oranges	12%	Potatoes	8%	Sugar beet roots		
47%	IE adult	93,17	8%	Potatoes	8%	Oranges	5%	Grapefruits		
46%	GEMS/Food G07	92,29	13%	Potatoes	10%	Oranges	2%	Wine grapes		
45%	GEMS/Food G10	90,54	10%	Potatoes	8%	Oranges	3%	Rice		
44%	FR toddler 2 3 yr	88,06	11%	Oranges	7%	Sugar beet roots	7%	Potatoes		
44%	GEMS/Food G11	87,59	14%	Potatoes	5%	Oranges	3%	Lemons		
44%	DE women 14-50 yr	87,35	14%	Oranges	11%	Sugar beet roots	4%	Potatoes		
43%	SE general	86,86	15%	Potatoes	6%	Oranges	3%	Mandarins		
41%	GEMS/Food G08	82,93	14%	Potatoes	3%	Oranges	3%	Onions		
40%	DE general	79,64	12%	Oranges	11%	Sugar beet roots	4%	Potatoes		
39%	GEMS/Food G15	78,47	12%	Potatoes	5%	Oranges	3%	Onions		
39%	PT general	77,61	19%	Potatoes	5%	Oranges	4%	Wine grapes		
38%	RO general	76,13	13%	Potatoes	4%	Onions	4%	Head cabbages		
37%	ES child	74,30	16%	Oranges	6%	Potatoes	3%	Lettuces		
37%	NL general	73,09	9%	Potatoes	8%	Oranges	7%	Sugar beet roots		
36%	UK infant	71,27	11%	Potatoes	10%	Oranges	4%	Sugar beet roots		
34%	FI 3 yr	67,05	17%	Potatoes	3%	Mandarins	2%	Onions		
27%	FI 6 yr	54,14	14%	Potatoes	2%	Mandarins	1%	Onions		
27%	ES adult	53,86	10%	Oranges	4%	Lettuces	3%	Potatoes		
23%	UK vegetarian	46,85	6%	Oranges	5%	Potatoes	1%	Sugar beet roots		
23%	FR infant	46,40	7%	Potatoes	3%	Sugar beet roots	2%	Spinaches		
23%	DK child	45,69	9%	Potatoes	1%	Rye	1%	Oranges		
22%	IT toddler	44,98	4%	Oranges	3%	Potatoes	2%	Lettuces		
22%	FR adult	43,28	4%	Oranges	3%	Wine grapes	3%	Potatoes		
20%	IT adult	40,81	3%	Lettuces	3%	Oranges	2%	Potatoes		
20%	PL general	39,56	12%	Potatoes	2%	Onions	1%	Tomatoes		
19%	UK adult	38,49	5%	Potatoes	4%	Oranges	2%	Wine grapes		
16%	LT adult	32,82	11%	Potatoes	1,0%	Head cabbages	0,9%	Tomatoes		
15%	FI adult	29,68	4%	Potatoes	3%	Oranges	1%	Lettuces		
14%	DK adult	27,38	4%	Potatoes	1%	Wine grapes	1%	Oranges		
6%	IE child	11,34	2%	Potatoes	0,7%	Rice	0,6%	Oranges		

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

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-11: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	2 % (based on GEMS/Food G11)
IEDI (% ADI) according to EFSA PRIMo	2 % (based on GEMS/Food G11)

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

The proposed uses of azoxystrobin in the formulation CHR/F/PROTAZO do not represent unacceptable acute and chronic risks for the consumer.

zRMS comments:

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

7.4 Combined exposure and risk assessment

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

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

The following paragraphs are to be considered as proposals, based on "standard" criteria.

The product is a mixture of three active substances, but for only one of them has an acute reference dose been allocated

zRMS comments:
The zRMS does not agree with the calculations provided below by the Applicant. No EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances.

7.4.1 Acute consumer risk assessment from combined exposure

In a first step, 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 active substances in the PPP that are acutely toxic by performing deterministic IESTI/NESTI calculations with the calculation models EFSA PRIMO (rev.2) and appropriate national models, if required, and dividing the individual exposure levels by the respective ARfD. Addition of the individual HQs irrespective of any considerations on phenomenological effects or mode(s)/mechanisms of action results in the HI. The results of the HQ/HI calculations are summarized in the following table.

Table 7.4-1: Acute consumer risk assessment from combined exposure

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo)
All crope	Prothioconazole-desthio	0.08
	Azoxystrobin	0.02
	Cumulative risk Maize (HI)	**0.1**

* if national model wanted, otherwise to be deleted

The Hazard Index is <1. Thus combined exposure to all active substances in CHR/F/PROTAZO is not expected to present a consumer risk. No further refinement of the assessment is required.

7.4.2 Chronic consumer risk assessment from combined exposure

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

References

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
KCP 6.3/01	J. Dievold	2020	Determination of Prothioconazole-desthio (sum of isomers) Residues in Oilseed rape Following One Foliar application with CHR/F/PROTIO 250 EC under Field Conditions in Northern Europe in 2019 Study No.: B9146 Anadiag, 16 rue Ampere, 67500 Haguenau, France GLP Unpublished		
KCP 6.3/02	J. Dievold	2020	Determination of Prothioconazole-desthio (sum of isomers) Residues in Oilseed rape Following One Foliar application with CHR/F/PROTIO 250 EC under Field Conditions in Northern Europe in 2019 Study No.: B9147 Anadiag, 16 rue Ampere, 67500 Haguenau, France GLP Unpublished	N	Chemirol
KCP 6.3/03	J. Dievold	2020	Determination of Prothioconazole-desthio (sum of isomers) Residues in Oilseed rape Following One Foliar application with CHR/F/PROTIO 250 EC under Field Conditions in Northern Europe in 2019 Study No.: B9148 Anadiag, 16 rue Ampere, 67500 Haguenau, France GLP Unpublished	N	Chemirol
KCP 6.3/04	J. Dievold	2020	Determination of Prothioconazole-desthio (sum of isomers) Residues in Oilseed rape Following One Foliar application with CHR/F/PROTIO 250 EC under Field Conditions in Northern Europe in 2019 Study No.: B9149 Anadiag, 16 rue Ampere, 67500 Haguenau, France GLP Unpublished	N	Chemirol
KCP 6.3/05	J. Dievold	2020	Determination of Prothioconazole-desthio (sum of isomers) Residues in Oilseed rape Following One Foliar application with CHR/F/PROTIO 250 EC under Field Conditions in Northern Europe in 2019	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Study No.: B9150 Anadiag, 16 rue Ampere, 67500 Haguenau, France GLP Unpublished		
KCP 6.3/06	J. Dievold	2020	Determination of Prothioconazole-desthio (sum of isomers) Residues in Oilseed rape Following One Foliar application with CHR/F/PROTIO 250 EC under Field Conditions in Northern Europe in 2019 Study No.: B9151 Anadiag, 16 rue Ampere, 67500 Haguenau, France GLP Unpublished	N	Chemirol
KCP 6.3/07	J. Kicińska	2019	DETERMINATION OF AZOXYSTROBIN IN OILSEED RAPE AFTER APPLICATION OF AZOXYSTROBIN 250 SE IN CZECH REPUBLIC – 2018 Study code: ZBBZ-2018/11/DPL/1CZ FOOD Safety Laboratory Research Intitute of Horticulture, Skierniecwice, Poland GLP Unpublished	N	Chemirol
KCP 6.3/08	J. Kicińska	2019	DETERMINATION OF AZOXYSTROBIN IN OILSEED RAPE AFTER APPLICATION OF AZOXYSTROBIN 250 SE IN POLAND – 2019 Study code: 19/FSL/12/1PL FOOD Safety Laboratory Research Intitute of Horticulture, Skierniecwice, Poland GLP Unpublished	N	Chemirol
KCP 6.3/09	J. Kicińska	2019	DETERMINATION OF AZOXYSTROBIN IN OILSEED RAPE AFTER APPLICATION OF AZOXYSTROBIN 250 SE IN GERMANY – 2018 Study code: ZBBZ-2018/11/DPL/1DE FOOD Safety Laboratory Research Intitute of Horticulture, Skierniecwice, Poland GLP Unpublished	N	Chemirol
KCP 6.3/010	J. Kicińska	2019	DETERMINATION OF AZOXYSTROBIN IN OILSEED RAPE AFTER APPLICATION OF AZOXYSTROBIN 250 SE IN POLAND – 2018	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Study code: ZBBZ-2018/11/DPL/1PL FOOD Safety Laboratory Research Intitute of Horticulture, Skierniecwice, Poland GLP Unpublished		
KCP 6.3/11	J. Kicińska	2019	DETERMINATION OF AZOXYSTROBIN IN OILSEED RAPE AFTER APPLICATION OF AZOXYSTROBIN 250 SE IN NORTHERN FRANCE – 2018 Study code: ZBBZ-2018/11/DPL/1FR2 FOOD Safety Laboratory Research Intitute of Horticulture, Skierniecwice, Poland GLP Unpublished	N	Chemirol
KCP 6.3/12	J. Kicińska	2019	DETERMINATION OF AZOXYSTROBIN IN OILSEED RAPE AFTER APPLICATION OF AZOXYSTROBIN 250 SE IN HUNGARY – 2018 Study code: ZBBZ-2018/11/DPL/1HU FOOD Safety Laboratory Research Intitute of Horticulture, Skierniecwice, Poland GLP Unpublished	N	Chemirol
KCP 6.3/13	J. Kicińska	2019	DETERMINATION OF AZOXYSTROBIN IN OILSEED RAPE AFTER APPLICATION OF AZOXYSTROBIN 250 SE IN CZECH REPUBLIC – 2019 Study code: 19/FSL/12/1CZ FOOD Safety Laboratory Research Intitute of Horticulture, Skierniecwice, Poland GLP Unpublished	N	Chemirol
KCP 6.3/14	C. Ertus	2018	Determination of Prothioconazole-desthio (sum of isomers) Residues in Oilseed rape Following One Generation of Field Specimens for the determination of Azoxystrobin Residues in Oilseed Rape Following Foliar application with Azoxystrobin 250 SE under Field Conditions in Hungary in 2018 Study No.: B8178 Anadiag, 16 rue Ampere, 67500 Haguenau, France GLP Unpublished	N	Chemirol
KCP	C. Ertus	2018	Generation of Field Specimens for the determination of Azoxystrobin Residues in Oilseed Rape	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
6.3/15			Following Foliar application with AZOXYSTROBIN 250 SE under Field Conditions in Czech Republic in 2018 Study No.: B8186 Anadiag, 16 rue Ampere, 67500 Haguenau, France GLP Unpublished		
KCP 6.3/16	C. Ertus	2018	Generation of Field Specimens for the determination of Azoxystrobin Residues in Oilseed Rape Following Foliar application with AZOXYSTROBIN 250 SE under Field Conditions in Poland in 2018 Study No.: B8187 Anadiag, 16 rue Ampere, 67500 Haguenau, France GLP Unpublished	N	Chemirol
KCP 6.3/17	C. Ertus	2018	Generation of Field Specimens for the determination of Azoxystrobin Residues in Oilseed Rape Following Foliar application with AZOXYSTROBIN 250 SE under Field Conditions in Germany in 2018 Study No.: B8188 Anadiag, 16 rue Ampere, 67500 Haguenau, France GLP Unpublished	N	Chemirol
KCP 6.3/18	C. Ertus	2018	Generation of Field Specimens for the determination of Azoxystrobin Residues in Oilseed Rape Following Foliar application with AZOXYSTROBIN 250 SE under Field Conditions in Northern France in 2018 Study No.: B8190 Anadiag, 16 rue Ampere, 67500 Haguenau, France GLP Unpublished	N	Chemirol
KCP 6.3/19	C. Ertus	2019	Generation of field specimens for the determination of Azoxystrobin residues in Oilseed rape following foliar application with AZOXYSTROBIN 250 SE under field Conditions in Czech Republic in 2019 Study No.: B9215 Anadiag, 16 rue Ampere, 67500 Haguenau, France GLP	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 6.3/20	C. Ertus	2019	Generation of field specimens for the determination of Azoxystrobin residues in Oilseed rape following foliar application with AZOXYSTROBIN 250 SE under field Conditions in Poland in 2019 Study No.: B9216 Anadiag, 16 rue Ampere, 67500 Haguenau, France GLP Unpublished	N	Chemirol
KCP 6.3/21	T. Peda	2021	Magnitude of the residue of azoxystrobin in Oil Seed Rape (Raw Agricultural Commodity) after one application of CHR/F/AZX – one harvest trial in Poland - 2020 Study No.: 20SGS10 SGS Poland Sp. z o.o., ul. Jana Kazimierza 3, 01-248 Warszawa, Polska GLP Unpublished	N	Chemirol
KCP 6.3/22	A. Perny	2021	Determination of Prothioconazole and Azoxystrobin Residues in Honey and Pollen Following Foliar application on Phacelia with CHR/F/PROTAZO 375 SC under semi field Conditions in Northern Europe in 2020 Study No.: C0277 Anadiag, 16 rue Ampere, 67500 Haguenau, France GLP Unpublished	N	Chemirol
KCP 6.3/23	A. Perny	2021	Determination of Prothioconazole, Prothioconazole-desthio and Azoxystrobin Residues in Honey and Pollen Following Foliar application on Phacelia with CHR/F/PROTAZO 375 SC under semi field Conditions in Southern Europe in 2020 Study No.: C0278 Anadiag, 16 rue Ampere, 67500 Haguenau, France GLP Unpublished	N	Chemirol
KCP 6.3/24	A. Perny	2021	Determination of Prothioconazole and Azoxystrobin Residues in Honey and Pollen Following Foliar application on Phacelia with CHR/F/PROTAZO 375 SC under semi field Conditions in Southern Europe in 2020	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Study No.: C0279 Anadiag, 16 rue Ampere, 67500 Haguenau, France GLP Unpublished		
KCP 6.3/25	A. Perny	2021	Determination of Prothioconazole and Azoxystrobin Residues in Honey and Pollen Following Foliar application on Phacelia with CHR/F/PROTAZO 375 SC under semi field Conditions in Northern Europe in 2020 Study No.: C0239 Anadiag, 16 rue Ampere, 67500 Haguenau, France GLP Unpublished	N	Chemirol

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1/01	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, Report No.: MR-282/00, GLP Unpublish	N	BAY
KCP 6.1/02	Freitag, T.	2005	Storage stability of prothioconazole-desthio in/on canola, spinach, sugar beet, tomato and pea during freezer strorage for 24 months. Bayer CropScience AG Report No.: MR-07/282, Edition number: M-258955-02-1 GLP Unpublished	N	BAY

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2.1/01	Haas, M. Bornatsch, W.	2000	Metabolism of JAU6476 in spring wheat (after foliar application) Bayer AG, Report No.: MR-198/99 GLP Unpublished	N	BAY
KCP 6.2.1/02	Vogeler, K. Sakamoto, H. Brauner, A.	1993	Metabolism of SXX 0665 in summer wheat Bayer AG, Report No.: PF3906, GLP Unpublished	N	BAY
KCP 6.2.1/03	Haas, M.	2001	Extraction efficiency testing of the residue method (00647) for the determination of JAU 6476 residues in spring wheat using aged radioactive residues Bayer AG, Report No.: MR-084/01, GLP Unpublished	N	BAY
KCP 6.2.1/04	Haas, M.	2001	Metabolism of [phenyl-UL-14C]JAU6476 in peanuts Bayer AG, Report No.: MR-193/01, GLP Unpublished	N	BAY
KCP 6.2.2/01	xxxxxxxxxxx	2001	[Phenyl-UL-14C]JAU6476 Absorption, distribution, excretion and metabolism in the lactating goat xxxxxxxxxxx, Report No.: MR-092/01 GLP Unpublished	Y	BAY
KCP 6.2.2/02	xxxxxxxxxxx	2002	[Phenyl-UL-14C]JAU6476-desthio Absorption, distribution, excretion, and metabolism in the lactating goat xxxxxxxxxxxxx, Report No.: MR-091/01 GLP Unpublished	Y	BAY
KCP	xxxxxxxxxxx	2001	[Phenyl-UL-14C]JAU6476 Absorption, distribution, excretion and metabolism in laying hens	Y	BAY

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
6.2.2/03			xxxxxxxxx, Report No.: MR-309/01 GLP Unpublished		
KCP 6.3/01	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, Report No.: RA-2003/99, Report includes Trial Nos.: R 1999 0023/6 R 1999 0025/2 R 1999 0026/0 R 1999 0027/9 R 1999 0266/2 GLP Unpublished	N	BAY
KCP 6.3/02	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, Report No.: RA-2104/00, Report includes Trial Nos.: R 2000 0454/0 R 2000 0457/5 R 2000 0474/5 R 2000 0475/3 R 2000 0476/1 GLP Unpublished	N	BAY
KCP 6.3/03	Heinemann, O.	2001	Determination of residues of JAU6476-Desthio on winter wheat following seed treatmen of JAU6476 200 FS and spray application of JAU6476 250 EC in France, Spain and Italy Bayer AG, Report No.: RA-2149/98, Report includes Trial Nos.: R 1998 1314/1	N	BAY

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			R 1998 1586/1 R 1998 1588/8 R 1998 1589/6 GLP Unpublished		
KCP 6.3/04	Heinemann, O.	2001	Determination of residues of JAU 6476-desthio in/on wheat and triticale after spray application of JAU 6476 250 EC in Spain and France Bayer AG, Report No.: RA-2105/00, Report includes Trial Nos.: R 2000 0482/6 R 2000 0479/6 R 2000 0478/8 R 2000 0455/9 GLP Unpublished	N	BAY
KCP 6.3/05	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, Report No.: RA-2150/98, GLP Unpublished	N	BAY
KCP 6.3/06	Heinemann, O. Elke, K.	2001	Determintion 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, Report No.: RA-2140/98, Report includes Trial Nos.: R 1998 1582/9 R 1998 1581/0 R 1998 1580/2 R 1998 1247/1 GLP	N	BAY

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
			Unpublished		
KCP 6.3/07	Heinemann, O.	2001	Determination of residues of JAU 6476-desthio on spring barley after spray application of JAU 6476 250 EC in Sweden, Germany, Nothern France and Great Britain Bayer AG, Report No.: RA-2101/00, Report includes Trial Nos.: R 2000 0452/4 R 2000 0456/7 R 2000 0462/1 R 2000 0464/8 R 2000 0465/6 GLP Unpublished	N	BAY
KCP 6.4.1/01	xxxxxxxxxxxxx	2001	JAU 6476-desthio - Dairy cattle feeding study xxxxxxxxxxxxxxx, Report No.: MR-535/00, Report includes Trial Nos.: P 673003007 GLP Unpublished	Y	BAY
KCP 6.6.1/01	Haas, M.	2001	Confined rotational crop study with JAU6476 Bayer AG, Report No.: MR-159/00 GLP Unpublished	N	BAY
Azoxystrobin					
KCP 6.1/03	Burke, S.R.	1997	Azoxystrobin and R230310: storage stability in various crops stored deep frozen for up to two years. Final report Report RJ2404B ZENECA agrochemicals	N	Syngenta
KCP	Burke, S.R.	1995a	ICIA5504 and R230310: Storage stability in Various Crops Stored Deep Frozen for up to two	N	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
6.1/04			years. Interim Report 1 (Cereals, Grapes and Wine) RJ1858B, RIP96-00140		
KCP 6.2.1/05	Weeb, J. et al.	1995	ICIA5504: Metabolism in Peanuts RJ1807B RIP96-001006	N	Syngenta
KCP 6.2.1/06	Wilkinson, M.J.et al.	1994	ICIA5504: Metabolism in Winter Wheat RJ1682B RIP96-00103	N	Syngenta
KCP 6.2.1/07	Allin, R. et al.	1995	ICIA5504: Metabolism in Winter Wheat RJ1888B RIP96-00104	N	Syngenta
KCP 6.6.1/02	Goldsby, G. et al.	1995	ICIA5504 (14C-pyrimidinyl): Confined Rotatioanl Crop study RR 95-034B RIP96-00143	N	Syngenta
KCP 6.6.1/03	Miller, M.M and Wilson, W.	1995	ICIA5504-Cyanophenyl: Confined Rotational Crop Study RR 95-017B RIP96-00144	N	Syngenta
KCP 6.6.1/04	Rambling, D. D..R., Labatore, D.N. and Walker, F.H.	1995	ICIA5504 (14-phenylacrylate): Confined Rotational Crop Study RR 95-011B RIP96-00142	N	Syngenta
KCP 6.2.2/04	xxxxxxxxxxxx	1995	ICIA5504: Metablism of Orally Administered Multiple Doses in the Lactating Goat RJ1805B RIP96-00107	Y	Syngenta
KCP 6.2.2/05	xxxxxxxxxxxx	1996	ICIA5504: Metabolism of orally Administered Multiple Doses in Lactating Goat RJ2083B	Y	Syngenta

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.5.2/02	Clarke, D.M. and Chamier, O.D.	1997	Processing study: milling/baking of wheat RJ2297B	N	Syngenta
KCP 6.3/26	Sapiets, A. Bailey, A.	1997	Azoxystrobin and Flutriafol – Residua Levels in Oil Seed Rape from Trials conducted in the United Kingdom during 1996 Report No RJ2366B Zeneca Agrochemicals, Jealott's Hill, UK GLP Unpublished	N	Syngenta
KCP 6.3/27	Sapiets, A. Bailey, A.	1998	Azoxystrobin and Flutriafol – Residua Levels in Oil Seed Rape from Trials conducted in the France during 1996 Report No RJ2419B Zeneca Agrochemicals, Jealott's Hill, UK GLP Unpublished	N	Syngenta
KCP 6.3/28	Sapiets, A. Bailey, A.	1998	Azoxystrobin and Flutriafol – Residuea Levels in Oil Seed Rape from Trials conducted in the France during 1997 Report No RJ2524B Zeneca Agrochemicals, Jealott's Hill, UK GLP Unpublished	N	Syngenta
KCP 6.3/29	Sapiets, A. Bailey, A.	1998	Azoxystrobin and Flutriafol – Residuea Levels in Oil Seed Rape from Trials conducted in the United Kingdom during 1997 Report No RJ2591B Zeneca Agrochemicals, Jealott's Hill, UK GLP Unpublished	N	Syngenta

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Prothioconazole

A 2.1.1 Stability of residues

No new studies was performed.

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

No new studies was performed.

A 2.1.3 Magnitude of residues in plants

Type of GAP	Number of applications	Application rate per treatment	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, 2004)	Max. 2	175 g/ha	14-28 days	Application from BBCH 53	56
cGAP EU (Art. 12, 2014)	Max. 2	120 g a.i./ha	14 days	-	28
Intended cGAP	Max. 1	175 g a.s./ha	-	BBCH 69	56

A 2.1.3.1 Study 1

Comments of zRMS:	Not accepted. The study does not support the proposed use. The proposed PHI (56) is shorter than DALA in the study (64). No residue results for seeds for PHI56.

Reference:	KCP 6.3/01
Report	Determination of Prothioconazole-desthio (sum of isomers) Residues in Oilseed rape Following One Foliar application with CHR/F/PROTIO 250 EC under Field Conditions in Northern Europe in 2019, J. Diebold, Study code: B9146
Guideline(s):	Regulation (EC) No. 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue levels of prothioconazole-desthio (sum of isomers) in oilseed rape raw agricultural commodity after one foliar application of the formulated product CHR/F/PROTIO 250 EC (250 g prothioconazole/L), at the rate of 0.8 L/ha. The study consisted of two phases: the field phase and the analytical phase. The study was conducted under field conditions at 1 site in Czech Republic. The trial was sampled frequently to monitor the decline of residues shortly after the treatment and at harvest. One plot was treated once with CHR/F/PROTIO 250 EC at the application rate of 0.8 L/ha (200 g prothioconazole/ha). The application was made at BBCH 65-67 and 64 days before harvest. One plot remained untreated. Sampling was performed just before application in the untreated plot, just after application in the treated plot, then 14, 32, 46 and 64 days after the application (at maturity of the crop) in both plots. Prothioconazole-desthio (sum of isomers) residues were analysed in samples harvested during the field phase.

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address): ANADIAG - 16 rue Ampère, 67500 Haguenau, France
Producer of commercial product: PUH Chemirol sp. Z.o.o. Page: 1/1
Pesticide (s) (common name (s)): Prothioconazole-desthio Country: Northern Europe
CCPR No (s). -
Trade name(s): **CHR/F/PROTIO 250 EC**
Main uses e.g. insecticide, fungicide: Fungicide

Use Pattern

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Crop and/or situation	F, G or I	Pest or group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
			Type	Conc. of a.s.	Method kind	growth stage & season	number min-max	interval between applications (days)	g a.s./ha (max)	water L/ha	g a.s./hL (max)		
(a)	(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)	(min)				(l)	(m)
Oilseed rape	F	Fungi	EC Emulsifiable concentrate	247 g/L	Medium volume spraying Overall spraying	67-69	1	60	200	200-400	100.0	60	-

Remarks:
(a) For crops, the EU and Codex Classification (both) should be used; where relevant, the use situation should be described (e.g. fumigation of the structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soilborn insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, etc.
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/L
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI = Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

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

Active ingredient:	**Prothioconazole-desthio**	Producer of commercial product:	PUH Chemirol sp. Z.o.o.
Crop/crop group:	Rape/Oilseed		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France		
Country:	Czech Republic	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	247 g/L	Other a.s. in formulation:	-
Formulation (e.g. WP):	EC	(common name and content):	
Commercial product (name):	**Commercial product**	Residues calculated as:	mg/kg prothioconazole-desthio

1	2	3	4	5			6	7	8	9	10	11
Report-No ; Location including Postal Code	Commodity /Variety	Date of 1) Planting 2) Flowering 3) Harvest	Method of treatment	Application rate per treatment (actual)			Dates of treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	DALA (days)	Remarks
				g a.s./ha	Water (L/ha)	g a.s./hL						
	(a)	(b)	(c)				(d)	(e)	(a)		(f)	(g)
B9146 CZ1 Rudoltice 56125 Czech Republic	Oilseed Rape / PIONEER PT271	1) 29/08/2018 2) 22/04/2019 to 25/05/2019 3) 22/07/2019 to 25/07/2019	Medium volume spraying Overall spraying	213.3	320	66.7	17/05/2019	67	Whole plant Whole plant Whole plant Whole plant Seeds	0.49 0.15 < LOQ 0.01 NDR	0 14 32 46 64	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

Remarks:
(a) According to EEC and Codex Classification (both) should be used
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) DALA: Days after last Application
(g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included
< LOQ: residues below the LOQ
NDR: no detectable residues (below the LOD)

Field specimens were collected, frozen and dispatched to ANADIAG laboratory for residue analysis by the persons in charge of the field trials.

The specimens were treated according to ANADIAG SOPs for receipt, identification and storage.

Analytical references and storage time are summarized in the following table:

TRIAL No. B9147 PL1

Analytical Sample No.	Field Sample No.	Harvest / Sampling Date	Extraction Date	Storage time of samples*	Analysis date	Storage time of extracts**
B9146 01 01	B9146 CZ1 / U0 / A	17/05/2019	19/08/2019	94	22/08/2019	3
B9146 01 02	B9146 CZ1 / T0 / A	17/05/2019	19/08/2019	94	22/08/2019	3
B9146 01 03	B9146 CZ1 / U1 / A	31/05/2019	19/08/2019	80	22/08/2019	3
B9146 01 04	B9146 CZ1 / T1 / A	31/05/2019	19/08/2019	80	22/08/2019	3
B9146 01 05	B9146 CZ1 / U2 / A	18/06/2019	19/08/2019	62	22/08/2019	3
B9146 01 06	B9146 CZ1 / T2 / A	18/06/2019	19/08/2019	62	22/08/2019	3
B9146 01 07	B9146 CZ1 / U3 / A	02/07/2019	19/08/2019	48	22/08/2019	3
B9146 01 08	B9146 CZ1 / T3 / A	02/07/2019	19/08/2019	48	22/08/2019	3
B9146 01 09	B9146 CZ1 / UH / A	20/07/2019	09/08/2019	20	09/08/2019	0
B9146 01 10	B9146 CZ1 / TH / A	20/07/2019	09/08/2019	20	09/08/2019	0

*Storage time of samples at ≤ -18°C from sampling to extraction (days)

**Storage time of final extracts at ≤ -18°C, from extraction to analysis (days)

Storage stability of extracts

After extraction, oilseed rape seeds samples were analyzed within 24 hours. Oilseed rape whole plant samples were stored below -18°C and analyzed after 3 days. Results of storage stability of extracts in ANADIAG validation study No. B9154 entitled “Validation of the Analytical Method for the Analysis of Prothioconazole-desthio (sum of isomers) in Oilseed rape (Whole Plant and Seeds)” showed good stability of prothioconazole-desthio residues in oilseed rape whole plant and seeds for at least 14 days of frozen storage.

Specimen preparation

The specimens were prepared according to ANADIAG SOPs. The specimen was blended with dry ice and placed for at least 12 hours at T ≤ -18°C for sublimation of dry ice. The amount required by the analytical method (5 g) was weighed from this homogeneous matrix.

Specimen analysis

Samples were extracted and analysed using an in-house method validated under ANADIAG study No B9154 entitled “Validation of the Analytical Method for the Analysis of Prothioconazole-desthio (sum of isomers) in Oilseed rape (Whole Plant and Seeds)”.

Outline of ANADIAG method:

Residues are extracted with acetonitrile in the presence of water, magnesium sulfate and sodium chloride. The extract obtained after centrifugation is purified, filtered and analyzed by liquid chromatography with MS/MS detection. ANADIAG References (French version) of the method are

for the preparation and extraction of the samples: **SOP MP 630**
for the analysis of extracts and for the calibration: **SOP MA 1490**

Details of the analytical conditions are described in Appendix III.

Limits of detection and quantification

LOD

The limit of detection is the lowest measurable standard concentration estimated at 3 times the background noise under the analytical conditions used.

LOQ

The limit of quantification has been validated by fortifications at this level.

Analyte	Method	Matrix	LOD (mg/kg)	LOQ (mg/kg)
Prothioconazole-desthio	MA1490-01	Oilseed rape (seeds and whole plant)	0.003	0.01

Preparation of standard solutions

Calibration and spiking solutions were prepared by dilution of a stock solution resulting from a commercial reference item.

	Solvent	Concentration	Storage conditions	Expiry date (Preparation + …)
Stock solutions	Acetonitrile	1 mg/mL	≤ -18°C	6 months
Spiking solutions	Acetonitrile	500 and 5000 ng/mL	≤ -18°C	1 month
Intermediate calibration solutions	Acetonitrile	15 to 600 ng/mL	≤ -18°C	1 month
Matrix-matched calibration solutions	Control extract	1.5 to 60 ng/mL	≤ -18°C	2 weeks

Calibration curves

Aliquots of the calibration solutions were injected into the analytical system using the same conditions as the specimens. Peak areas obtained from chromatograms were plotted versus concentrations and the calibration functions were determined by least square fit. Number and concentrations of standards used, as well as acceptability criteria (correlation coefficient for a curve (r)≥ 0.990) are described in ANADIAG SOPs.

Fortification **procedure**

Fortifications were performed by adding known amounts of the spiking solutions to control specimens just prior to the extraction step (spiking solutions were added to the control specimens, before mixing with the extraction solvent). During the residue analysis, control samples were fortified, extracted and stored together with field samples until analysis. These fortified extracts were run during the analysis of the other extracts.

Analytical Sample No.	Matrix	Fortification level (mg/kg)	% Recovery	Extraction date
B9146 01 01 AA	Whole plant	0.01	**86.6%**	19/08/2019
B9146 01 01 BA	Whole plant	0.10	**93.8%**	19/08/2019
B9146 01 01 CA d10	Whole plant	0.60	**91.9%**	09/09/2019
B9146 01 09 AA	Seeds	0.01	**70.3%**	09/08/2019
B9146 01 09 BA	Seeds	0.10	**70.0%**	09/08/2019

Summary of fortifications

Matrix	Mean % recovery	Standard deviation %	Relative standard deviation %	Number of spiked samples
Whole plant	90.8%	3.7%	4.1%	3
Seeds	70.2%	-	-	2
All matrices	82.5%	11.6%	14.1%	5

Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. B9147 PL1

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Prothioconazole-desthio residues found (mg/kg)
B9146 01 01	B9146 CZ1 / U0 / A	-	Whole plant	0 **DBA**	**NDR**
B9146 01 02	B9146 CZ1 / T0 / A	CHR/F/PROTIO 250 EC	Whole plant	0 DAA	**0.49**
B9146 01 03	B9146 CZ1 / U1 / A	-	Whole plant	14 DAA	**NDR**
B9146 01 04	B9146 CZ1 / T1 / A	CHR/F/PROTIO 250 EC	Whole plant	14 DAA	**0.15**
B9146 01 05	B9146 CZ1 / U2 / A	-	Whole plant	32 DAA	**NDR**
B9146 01 06	B9146 CZ1 / T2 / A	CHR/F/PROTIO 250 EC	Whole plant	32 DAA	**< LOQ**
B9146 01 07	B9146 CZ1 / U3 / A	-	Whole plant	46 DAA	**NDR**
B9146 01 08	B9146 CZ1 / T3 / A	CHR/F/PROTIO 250 EC	Whole plant	46 DAA	**0.01**
B9146 01 09	B9146 CZ1 / UH / A	-	Seeds	64 DAA	**NDR**
B9146 01 10	B9146 CZ1 / TH / A	CHR/F/PROTIO 250 EC	Seeds	64 DAA	**NDR**

DBA: Days before application
DAA: Days after application
NCH: Normal Commercial Harvest
<LOQ: Residues between LOQ and LOD
NDR: No detectable residues (residues below the limit of detection)
LOD = 0.003 mg/kg
LOQ = 0.01 mg/kg

A 2.1.3.2 Study 2

Comments of zRMS:	The study is accepted, however is should be noted that formulation in the study is EC while in the proposed GAP SC.

Reference: KCP 6.3/02

Report: Determination of Prothioconazole-desthio (sum of isomers) Residues in Oilseed rape Following One Foliar application with CHR/F/PROTIO 250 EC under Field Conditions in Northern Europe in 2019, J. Diebold, Study code: B9147

Guideline(s): Regulation (EC) No. 1107/2009

Deviations: No

GLP: Yes

Acceptability: Yes

The objective of the study was to determine the residue levels of prothioconazole-desthio (sum of isomers) in oilseed rape raw agricultural commodity after one foliar application of the formulated product CHR/F/PROTIO 250 EC (250 g prothioconazole/L), at the rate of 0.8 L/ha. The study consisted of two phases: the field phase and the analytical phase. The study was conducted under field conditions at 1 site in Poland. The trial was sampled frequently to monitor the decline of residues shortly after the treatment and at harvest. One plot was treated once with CHR/F/PROTIO 250 EC at the application rate of 0.8 L/ha (200 g prothioconazole/ha). The application was made at BBCH 67 and 56 days before harvest. One plot remained untreated. Sampling was performed just before application in the untreated plot, just after application in the treated plot, then 14, 31, 45 and 56 days after the application (at maturity of the crop) in both plots. Prothioconazole-desthio (sum of isomers) residues were analysed in samples harvested during the field phase

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address):	ANADIAG - 16 rue Ampère, 67500 Haguenau, France		
Producer of commercial product:	PUH Chemirol sp. Z.o.o.	Page:	1/1
Pesticide (s) (common name (s)):	Prothioconazole	Country:	Northern Europe
CCPR No (s).	-		
Trade name(s):	**CHR/F/PROTIO 250 EC**		
Main uses e.g. insecticide, fungicide:	Fungicide		

Use Pattern

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Crop and/or situation	**F, G or I**	**Pest or group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Remarks**
			Type	**Conc. of a.s.**	**Method kind**	**growth stage & season**	**number min-max**	**interval between applications (days)**	**g a.s./ha (max)**	**water L/ha**	**g a.s./hL (max)**		
(a)	**(b)**	**(c)**	**(d-f)**	**(i)**	**(f-h)**	**(j)**	**(k)**	**(min)**				**(l)**	**(m)**
Oilseed rape	F	Fungi	EC Emulsifiable concentrate	250 g/L	Medium volume spraying Overall spraying	65-67	1	-	200.0	200-400	100.0	60	-

Remarks:
(a) For crops, the EU and Codex Classification (both) should be used; where relevant, the use situation should be described (e.g. fumigation of the structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soilborn insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, etc.
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/L
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI = Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

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

Active ingredient:	**Prothioconazole**	Producer of commercial product:	PUH Chemirol sp. Z.o.o.
Crop/crop group:	Rape/Oilseed		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France		
Country:	Poland	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	250 g/L	Other a.s. in formulation:	-
Formulation (e.g. WP):	EC	(common name and content):	
Commercial product (name):	**CHR/F/PROTIO 250 EC**	Residues calculated as:	mg/kg prothioconazole-desthio

1	2	3	4	5			6	7	8	9	10	11
Report-No ; Location including Postal Code	**Commodity /Variety**	**Date of 1) Planting 2) Flowering 3) Harvest**	**Method of treatment**	**Application rate per treatment (actual)**			**Dates of treatment(s) or No. of treatment(s) and last date**	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**	**DAA (days)**	**Remarks**
				g a.s./ha	**Water (L/ha)**	**g a.s./hL**						
	(a)	**(b)**	**(c)**				**(d)**	**(e)**	**(a)**		**(f)**	**(g)**
B9147 PL1 Dmosin 95-061 Poland	Oilseed Rape / SHERPA	1) 21/08/2018 2) 20/04/2019 to 22/05/2019 3) 12/07/2019	Medium volume spraying Overall spraying	197.3	296	66.7	17/05/2019	67	Whole plant Whole plant Whole plant Whole plant Seeds	0.74 0.19 0.02 < LOQ NDR	0 14 31 45 56	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

Remarks:
(a) According to EEC and Codex Classification (both) should be used
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) DAA: Days after last Application
(g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included
< LOQ: residues below the LOQ
NDR: no detectable residues (below the LOD)

Storage and identification of specimens

Field specimens were collected, frozen and dispatched to ANADIAG laboratory for residue analysis by the persons in charge of the field trials.

The specimens were treated according to ANADIAG SOPs for receipt, identification and storage.

Analytical references and storage time are summarized in the following table:

TRIAL No. B9147 PL1

Analytical Sample No.	Field Sample No.	Harvest / Sampling Date	Extraction Date	Storage time of samples*	Analysis date	Storage time of extracts**
B9147 01 01	B9147 PL1 / U0 / A	17/05/2019	09/09/2019	115	10/09/2019	1
B9147 01 02	B9147 PL1 / T0 / A	17/05/2019	09/09/2019	115	10/09/2019	1
B9147 01 03	B9147 PL1 / U1 / A	31/05/2019	09/09/2019	101	10/09/2019	1
B9147 01 04	B9147 PL1 / T1 / A	31/05/2019	09/09/2019	101	10/09/2019	1
B9147 01 05	B9147 PL1 / U2 / A	17/06/2019	09/09/2019	84	10/09/2019	1
B9147 01 06	B9147 PL1 / T2 / A	17/06/2019	09/09/2019	84	10/09/2019	1
B9147 01 07	B9147 PL1 / U3 / A	01/07/2019	09/09/2019	70	10/09/2019	1
B9147 01 08	B9147 PL1 / T3 / A	01/07/2019	09/09/2019	70	10/09/2019	1
B9147 01 09	B9147 PL1 / UH / A	12/07/2019	09/08/2019	28	20/08/2019	11
B9147 01 10	B9147 PL1 / TH / A	12/07/2019	09/08/2019	28	20/08/2019	11

*Storage time of samples at ≤ -18°C from sampling to extraction (days)

**Storage time of final extracts at ≤ -18°C, from extraction to analysis (days)

Storage stability of extracts

After extraction, samples were stored below -18°C and analyzed after maximum 11 days for oilseed rape seeds and 1 day for oilseed rape whole plant. Results of storage stability of extracts in ANADIAG validation study No. B9154 entitled "Validation of the Analytical Method for the Analysis of Prothioconazole-desthio (sum of isomers) in Oilseed rape (Whole Plant and Seeds)" showed good stability of prothioconazole-desthio residues in oilseed rape whole plant and seeds for at least 14 days of frozen storage.

Specimen preparation

The specimens were prepared according to ANADIAG SOPs. The specimen was blended with dry ice and placed for at least 12 hours at T ≤ -18°C for sublimation of dry ice. The amount required by the analytical method (5 g) was weighed from this homogeneous matrix.

Specimen analysis

Samples were extracted and analysed using an in-house method validated under ANADIAG study No B9154 entitled "Validation of the Analytical Method for the Analysis of Prothioconazole-desthio (sum of isomers) in Oilseed rape (Whole Plant and Seeds)".

Outline of ANADIAG method:

Residues are extracted with acetonitrile in the presence of water, magnesium sulfate and sodium chloride. The extract obtained after centrifugation is purified, filtered and analyzed by liquid chromatography with MS/MS detection. ANADIAG References (French version) of the method are

for the preparation and extraction of the samples: **SOP MP 630**
for the analysis of extracts and for the calibration: **SOP MA 1490**

Details of the analytical conditions are described in Appendix III.

Limits of detection and quantification

LOD

The limit of detection is the lowest measurable standard concentration estimated at 3 times the background noise under the analytical conditions used.

LOQ

The limit of quantification has been validated by fortifications at this level.

Analyte	Method	Matrix	LOD (mg/kg)	LOQ (mg/kg)
Prothioconazole-desthio	MA1490-01	Oilseed rape whole plant	0.003	0.01
Prothioconazole-desthio	MA1490-02	Oilseed rape seeds	0.003	0.01

Preparation of standard solutions

Calibration and spiking solutions were prepared by dilution of a stock solution resulting from a commercial reference item.

	Solvent	Concentration	Storage conditions	Expiry date (Preparation + …)
Stock solutions	Acetonitrile	1 mg/mL	≤ -18°C	6 months
Spiking solutions	Acetonitrile	500 and 5000 ng/mL	≤ -18°C	1 month
Intermediate calibration solutions	Acetonitrile	15 to 600 ng/mL	≤ -18°C	1 month
Matrix-matched calibration solutions	Control extract	1.5 to 60 ng/mL	≤ -18°C	2 weeks

Calibration curves

Aliquots of the calibration solutions were injected into the analytical system using the same conditions as the specimens. Peak areas obtained from chromatograms were plotted versus concentrations and the calibration functions were determined by least square fit. Number and concentrations of standards used, as well as acceptability criteria (correlation coefficient for a curve (r)≥ 0.990) are described in ANADIAG SOPs.

Fortification **procedure**

Fortifications were performed by adding known amounts of the spiking solutions to control specimens just prior to the extraction step (spiking solutions were added to the control specimens, before mixing with the extraction solvent). During the residue analysis, control samples were fortified, extracted and stored together with field samples until analysis. These fortified extracts were run during the analysis of the other extracts.

Analytical Sample No.	Matrix	Fortification level (mg/kg)	% Recovery	Extraction date
B9147 01 01 AA	Whole plant	0.01	**90.5%**	09/09/2019
B9147 01 01 BA d10	Whole plant	0.60	**91.7%**	09/09/2019
B9147 01 01 CA d10	Whole plant	1.01	**93.0%**	12/09/2019
B9147 01 09 AB	Seeds	0.01	**80.4%**	09/08/2019
B9147 01 09 BB	Seeds	0.10	**76.0%**	09/08/2019

Summary of fortifications

Matrix	Mean % recovery	Standard deviation %	Relative standard deviation %	Number of spiked samples

Whole plant	91.7%	1.3%	1.4%	3
Seeds	78.2%	-	-	2
All matrices	86.3%	7.6%	8.8%	5

Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. B9147 PL1

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Prothioconazole-desthio residues found (mg/kg)
B9147 01 01	B9147 PL1 / U0 / A	-	Whole plant	0 **DBA**	**NDR**
B9147 01 02	B9147 PL1 / T0 / A	CHR/F/PROTIO 250 EC	Whole plant	0 DAA	**0.74**
B9147 01 03	B9147 PL1 / U1 / A	-	Whole plant	14 DAA	**NDR**
B9147 01 04	B9147 PL1 / T1 / A	CHR/F/PROTIO 250 EC	Whole plant	14 DAA	**0.19**
B9147 01 05	B9147 PL1 / U2 / A	-	Whole plant	31 DAA	**NDR**
B9147 01 06	B9147 PL1 / T2 / A	CHR/F/PROTIO 250 EC	Whole plant	31 DAA	**0.02**
B9147 01 07	B9147 PL1 / U3 / A	-	Whole plant	45 DAA	**NDR**
B9147 01 08	B9147 PL1 / T3 / A	CHR/F/PROTIO 250 EC	Whole plant	45 DAA	**< LOQ**
B9147 01 09	B9147 PL1 / UH / A	-	Seeds	56 DAA (NCH)	**NDR**
B9147 01 10	B9147 PL1 / TH / A	CHR/F/PROTIO 250 EC	Seeds	56 DAA (NCH)	**NDR**

DBA: Days before application
DAA: Days after application
NCH: Normal Commercial Harvest
<LOQ: Residues between LOQ and LOD
NDR: No detectable residues (residues below the limit of detection)
LOD = 0.003 mg/kg
LOQ = 0.01 mg/kg

A 2.1.3.3 Study 3

Comments of zRMS:	Not accepted. The study does not support the proposed use. The proposed PHI (56) is shorter than DALA in the study (59). No residue results for seeds for PHI 56.

Reference:	KCP 6.3/03
Report	Determination of Prothioconazole-desthio (sum of isomers) Residues in Oilseed rape Following One Foliar application with CHR/F/PROTIO 250 EC under Field Conditions in Northern Europe in 2019, J. Diebold, Study code: B9148
Guideline(s):	Regulation (EC) No. 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue levels of prothioconazole-desthio (sum of isomers) in oilseed rape raw agricultural commodity after one foliar application of the formulated product CHR/F/PROTIO 250 EC (250 g prothioconazole/L), at the rate of 0.8 L/ha. The study consisted of two phases: the field phase and the analytical phase. The study was conducted under field conditions at 1 site in Northern France. The trial was sampled frequently to monitor the decline of residues shortly after the treatment and at harvest. One plot was treated once with CHR/F/PROTIO 250 EC at the application rate of 0.8 L/ha (200 g prothioconazole/ha). The application was made at BBCH 65-67 and 59 days before harvest. One plot remained untreated.

Sampling was performed just before application in the untreated plot, just after application in the treated plot, then 15, 29, 43 and 59 days after the application (at maturity of the crop) in both plots. Prothioconazole-desthio (sum of isomers) residues were analysed in samples harvested during the field phase.

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address):	ANADIAG - 16 rue Ampère, 67500 Haguenau, France		
Producer of commercial product:	PUH Chemirol sp. Z.o.o.	Page:	1/1
Pesticide (s) (common name (s)):	Prothioconazole	Country:	Northern Europe
CCPR No (s).	-		
Trade name(s):	**CHR/F/PROTIO 250 EC**		
Main uses e.g. insecticide, fungicide:	Fungicide		

Use Pattern

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Crop and/or situation	**F, G or I**	**Pest or group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Remarks**
			Type	**Conc. of a.s.**	**Method kind**	**growth stage & season**	**number min-max**	**interval between applications (days)**	**g a.s./ha (max)**	**water L/ha**	**g a.s./hL (max)**		
(a)	**(b)**	**(c)**	**(d-f)**	**(i)**	**(f-h)**	**(j)**	**(k)**	**(min)**				**(l)**	**(m)**
Oilseed rape	F	Fungi	EC Emulsifiable concentrate	250 g/L	Medium volume spraying Overall spraying	65-67	1	-	200.0	200-400	100.0	60	-

Remarks:
(a) For crops, the EU and Codex Classification (both) should be used; where relevant, the use situation should be described (e.g. fumigation of the structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soilborn insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, etc.
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/L
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI = Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

PUH Chemirol sp. Z.o.o. Residues 2019

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

Active ingredient:	**Prothioconazole**	Producer of commercial product:	PUH Chemirol sp. Z.o.o.
Crop/crop group:	Rape/Oilseed		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France		
Country:	France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	250 g/L	Other a.s. in formulation:	-
Formulation (e.g. WP):	EC	(common name and content):	
Commercial product (name):	**CHR/F/PROTIO 250 EC**	Residues calculated as:	mg/kg prothioconazole-desthio

1	2	3	4	5			6	7	8	9	10	11
Report-No ; Location including Postal Code	**Commodity /Variety**	**Date of 1) Planting 2) Flowering 3) Harvest**	**Method of treatment**	**Application rate per treatment (actual)**			**Dates of treatment(s) or No. of treatment(s) and last date**	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**	**DAA (days)**	**Remarks**
				g a.s./ha	**Water (L/ha)**	**g a.s./hL**						
	(a)	**(b)**	**(c)**				**(d)**	**(e)**	**(a)**		**(f)**	**(g)**
B9148 AN1 Ingolsheim 67250 France	Oilseed Rape / ATTLETIC	1) 22/08/2018 2) 05/04/2019 to 17/05/2019 3) 08/07/2019	Medium volume spraying Overall spraying	193.3	290	66.7	07/05/2019	65-67	Whole plant Whole plant Whole plant Whole plant Seeds	0.34 0.05 0.01 < LOQ NDR	0 15 29 43 59	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

Remarks:
(a) According to EEC and Codex Classification (both) should be used
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) DAA: Days after Application
(g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included
< LOQ: residues below the LOQ
NDR: no detectable residues (below the LOD)

Storage and identification of specimens

Field specimens were collected, frozen and dispatched to ANADIAG laboratory for residue analysis by the persons in charge of the field trials.

The specimens were treated according to ANADIAG SOPs for receipt, identification and storage.

Analytical references and storage time are summarized in the following table:

TRIAL No. B9148 AN1

Analytical Sample No.	Field Sample No.	Harvest / Sampling Date	Extraction Date	Storage time of samples*	Analysis date	Storage time of extracts**
B9148 01 01	B9148 AN1 / U0 / A	07/05/2019	11/07/2019	65	12/07/2019	1
B9148 01 02	B9148 AN1 / T0 / A	07/05/2019	11/07/2019	65	16/07/2019	5
B9148 01 03	B9148 AN1 / U1 / A	22/05/2019	11/07/2019	50	12/07/2019	1
B9148 01 04	B9148 AN1 / T1 / A	22/05/2019	11/07/2019	50	12/07/2019	1
B9148 01 05	B9148 AN1 / U2 / A	05/06/2019	11/07/2019	36	12/07/2019	1
B9148 01 06	B9148 AN1 / T2 / A	05/06/2019	11/07/2019	36	12/07/2019	1
B9148 01 07	B9148 AN1 / U3 / A	19/06/2019	11/07/2019	22	12/07/2019	1
B9148 01 08	B9148 AN1 / T3 / A	19/06/2019	11/07/2019	22	12/07/2019	1
B9148 01 09	B9148 AN1 / UH / A	05/07/2019	11/07/2019	6	12/07/2019	1
B9148 01 10	B9148 AN1 / TH / A	05/07/2019	11/07/2019	6	12/07/2019	1

*Storage time of samples at ≤ -18°C from sampling to extraction (days)

**Storage time of final extracts at ≤ -18°C, from extraction to analysis (days)

Storage stability of extracts

After extraction, samples were stored below -18°C and analyzed after maximum 1 day for oilseed rape seeds and 5 days for oilseed rape whole plant. Results of storage stability of extracts in ANADIAG validation study No. B9154 entitled "Validation of the Analytical Method for the Analysis of Prothioconazole-desthio (sum of isomers) in Oilseed rape (Whole Plant and Seeds)" showed good stability of prothioconazole-desthio residues in oilseed rape whole plant and seeds for at least 14 days of frozen storage.

Specimen preparation

The specimens were prepared according to ANADIAG SOPs. The specimen was blended with dry ice and placed for at least 12 hours at T ≤ -18°C for sublimation of dry ice. The amount required by the analytical method (5 g) was weighed from this homogeneous matrix.

Specimen analysis

Samples were extracted and analysed using an in-house method validated under ANADIAG study No B9154 entitled "Validation of the Analytical Method for the Analysis of Prothioconazole-desthio (sum of isomers) in Oilseed rape (Whole Plant and Seeds)".

Outline of ANADIAG method:

Residues are extracted with acetonitrile in the presence of water, magnesium sulfate and sodium chloride. The extract obtained after centrifugation is purified, filtered and analyzed by liquid chromatography with MS/MS detection. ANADIAG References (French version) of the method are

for the preparation and extraction of the samples: **SOP MP 630**
for the analysis of extracts and for the calibration: **SOP MA 1490**

Details of the analytical conditions are described in Appendix III.

Limits of detection and quantification

LOD

The limit of detection is the lowest measurable standard concentration estimated at 3 times the background noise under the analytical conditions used.

LOQ

The limit of quantification has been validated by fortifications at this level.

Analyte	Method	Matrix	LOD (mg/kg)	LOQ (mg/kg)
Prothioconazole-desthio	MA1490-01	Oilseed rape (seeds and whole plant)	0.003	0.01

Preparation of standard solutions

Calibration and spiking solutions were prepared by dilution of a stock solution resulting from a commercial reference item.

	Solvent	Concentration	Storage conditions	Expiry date (Preparation + …)
Stock solutions	Acetonitrile	1 mg/mL	≤ -18°C	6 months
Spiking solutions	Acetonitrile	500 and 5000 ng/mL	≤ -18°C	1 month
Intermediate calibration solutions	Acetonitrile	15 to 600 ng/mL	≤ -18°C	1 month
Matrix-matched calibration solutions	Control extract	1.5 to 60 ng/mL	≤ -18°C	2 weeks

Calibration curves

Aliquots of the calibration solutions were injected into the analytical system using the same conditions as the specimens. Peak areas obtained from chromatograms were plotted versus concentrations and the calibration functions were determined by least square fit. Number and concentrations of standards used, as well as acceptability criteria (correlation coefficient for a curve (r)≥ 0.990) are described in ANADIAG SOPs.

Fortification procedure

Fortifications were performed by adding known amounts of the spiking solutions to control specimens just prior to the extraction step (spiking solutions were added to the control specimens, before mixing with the extraction solvent). During the residue analysis, control samples were fortified, extracted and stored together with field samples until analysis. These fortified extracts were run during the analysis of the other extracts.

Analytical Sample No.	Matrix	Fortification level (mg/kg)	% Recovery	Extraction date
B9148 01 07 AA	Whole plant	0.01	**88.4%**	11/07/2019
B9148 01 07 BA	Whole plant	0.10	**107.7%**	11/07/2019
B9148 01 05 AA D5	Whole plant	0.50	**88.4%**	16/07/2019
B9148 01 09 AA	Seeds	0.01	**72.8%**	11/07/2019
B9148 01 09 BA	Seeds	0.10	**77.1%**	11/07/2019

Summary of fortifications

Matrix	Mean % recovery	Standard deviation %	Relative standard deviation %	Number of spiked samples
Whole plant	94.8%	11.1%	11.7%	3
Seeds	75.0%	-	-	2
All matrices	86.9%	13.5%	15.6%	5

Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. B9148 AN1

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Prothioconazole-desthio residues found (mg/kg)
B9148 01 01	B9148 AN1 / U0 / A	-	Whole plant	0 **DBA**	**NDR**
B9148 01 02	B9148 AN1 / T0 / A	CHR/F/PROTIO 250 EC	Whole plant	0 DAA	**0.34**
B9148 01 03	B9148 AN1 / U1 / A	-	Whole plant	15 DAA	**NDR**
B9148 01 04	B9148 AN1 / T1 / A	CHR/F/PROTIO 250 EC	Whole plant	15 DAA	**0.05**
B9148 01 05	B9148 AN1 / U2 / A	-	Whole plant	29 DAA	**NDR**
B9148 01 06	B9148 AN1 / T2 / A	CHR/F/PROTIO 250 EC	Whole plant	29 DAA	**0.01**
B9148 01 07	B9148 AN1 / U3 / A	-	Whole plant	43 DAA	**NDR**
B9148 01 08	B9148 AN1 / T3 / A	CHR/F/PROTIO 250 EC	Whole plant	43 DAA	**< LOQ**
B9148 01 09	B9148 AN1 / UH / A	-	Seeds	59 DAA	**NDR**
B9148 01 10	B9148 AN1 / TH / A	CHR/F/PROTIO 250 EC	Seeds	59 DAA (NCH)	**NDR**

DBA: Days before application
DAA: Days after application
NCH: Normal Commercial Harvest
< LOQ: Residues between LOQ and LOD
NDR: No detectable residues (residues below the limit of detection)
LOD = 0.003 mg/kg
LOQ = 0.01 mg/kg

A 2.1.3.4 Study 4

Comments of zRMS:	The study is accepted, however is should be noted that formulation in the study is EC while in the proposed GAP SC.

Reference:	KCP 6.3/04
Report	Determination of Prothioconazole-desthio (sum of isomers) Residues in Oilseed rape Following One Foliar application with CHR/F/PROTIO 250 EC under Field Conditions in Northern Europe in 2019, J. Diebold, Study code: B9149
Guideline(s):	Regulation (EC) No. 1107/2009
Deviations:	No
GLP:	Yes

Acceptability: Yes

The objective of the study was to determine the residue levels of prothioconazole-desthio (sum of isomers) in oilseed rape raw agricultural commodity after one foliar application of the formulated product CHR/F/PROTIO 250 EC (250 g prothioconazole/L), at the rate of 0.8 L/ha. The study consisted of two phases: the field phase and the analytical phase. The study was conducted under field conditions at 1 site in Northern France. The trial was sampled frequently to monitor the decline of residues shortly after the treatment and at harvest. One plot was treated once with CHR/F/PROTIO 250 EC at the application rate of 0.8 L/ha (200 g prothioconazole/ha). The application was made at BBCH 67 and 60 57 days before harvest. One plot remained untreated. Sampling was performed just before application in the untreated plot, just after application in the treated plot, then 14, 29, 44 and 57 days after the application (at maturity of the crop) in both plots. Prothioconazole-desthio (sum of isomers) residues were analysed in samples harvested during the field phase..

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address):	ANADIAG - 16 rue Ampère, 67500 Haguenau, France		
Producer of commercial product:	PUH Chemirol sp. Z.o.o.	Page:	1/1
Pesticide (s) (common name (s)):	Prothioconazole	Country:	Northern Europe
CCPR No (s).	-		
Trade name(s):	**CHR/F/PROTIO 250 EC**		
Main uses e.g. insecticide, fungicide:	Fungicide		

Use Pattern

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Crop and/or situation	**F, G or I**	**Pest or group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Remarks**
			Type	**Conc. of a.s.**	**Method kind**	**growth stage & season**	**number min-max**	**interval between applications (days)**	**g a.s./ha (max)**	**water L/ha**	**g a.s./hL (max)**		
(a)	**(b)**	**(c)**	**(d-f)**	**(i)**	**(f-h)**	**(j)**	**(k)**	**(min)**				**(l)**	**(m)**
Oilseed rape	F	Fungi	EC Emulsifiable concentrate	250 g/L	Medium volume spraying Overall spraying	65-67	1	-	200.0	200-400	100.0	60	-

Remarks:
(a) For crops, the EU and Codex Classification (both) should be used; where relevant, the use situation should be described (e.g. fumigation of the structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soilborn insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, etc.
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/L
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI = Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

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

Active ingredient:	**Prothioconazole**	Producer of commercial product:	PUH Chemirol sp. Z.o.o.
Crop/crop group:	Rape/Oilseed		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France		
Country:	France	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	250 g/L	Other a.s. in formulation:	-
Formulation (e.g. WP):	EC	(common name and content):	
Commercial product (name):	**CHR/F/PROTIO 250 EC**	Residues calculated as:	mg/kg prothioconazole-desthio

1	2	3	4	5			6	7	8	9	10	11
Report-No ; Location including Postal Code	**Commodity /Variety**	**Date of 1) Planting 2) Flowering 3) Harvest**	**Method of treatment**	**Application rate per treatment (actual)**			**Dates of treatment(s) or No. of treatment(s) and last date**	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**	**DAA (days)**	**Remarks**
				g a.s./ha	**Water (L/ha)**	**g a.s./hL**						
	(a)	**(b)**	**(c)**				**(d)**	**(e)**	**(a)**		**(f)**	**(g)**
B9149 MA1 Donnelay 57810 France	Oilseed Rape / MAMBO	1) 08/08/2018 2) 02/05/2019 to 29/05/2019 3) 16/07/2019	Medium volume spraying Overall spraying	206.7	310	66.7	15/05/2019	67	Whole plant Whole plant Whole plant Whole plant Seeds	0.89 0.38 0.05 0.02 0.01	0 14 29 44 57	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

Remarks:
(a) According to EEC and Codex Classification (both) should be used
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) DAA: Days after Application
(g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included

Storage and identification of specimens

Field specimens were collected, frozen and dispatched to ANADIAG laboratory for residue analysis by the persons in charge of the field trials.

The specimens were treated according to ANADIAG SOPs for receipt, identification and storage.

Analytical references and storage time are summarized in the following table:

TRIAL No. B9149 MA1

Analytical Sample No.	Field Sample No.	Harvest / Sampling Date	Extraction Date	Storage time of samples*	Analysis date	Storage time of extracts**
B9149 01 01	B9149 MA1 / U0 / A	15/05/2019	12/09/2019	120	12/09/2019	0
B9149 01 02	B9149 MA1 / T0 / A	15/05/2019	12/09/2019	120	12/09/2019	0
B9149 01 03	B9149 MA1 / U1 / A	29/05/2019	12/09/2019	106	12/09/2019	0
B9149 01 04	B9149 MA1 / T1 / A	29/05/2019	12/09/2019	106	16/09/2019	4***
B9149 01 05	B9149 MA1 / U2 / A	13/06/2019	12/09/2019	91	12/09/2019	0
B9149 01 06	B9149 MA1 / T2 / A	13/06/2019	12/09/2019	91	12/09/2019	0
B9149 01 07	B9149 MA1 / U3 / A	28/06/2019	12/09/2019	76	12/09/2019	0
B9149 01 08	B9149 MA1 / T3 / A	28/06/2019	12/09/2019	76	12/09/2019	0
B9149 01 09	B9149 MA1 / UH / A	11/07/2019	08/08/2019	28	08/08/2019	0
B9149 01 10	B9149 MA1 / TH / A	11/07/2019	08/08/2019	28	08/08/2019	0

*Storage time of samples at ≤ -18°C from sampling to extraction (days)

**Storage time of final extracts at +4°C, from extraction to analysis (days)

***Storage time of final extracts at ≤ -18°C, from extraction to analysis (days)

Storage stability of extracts

After extraction, oilseed rape seeds samples were analyzed within 24 hours. Oilseed rape whole plant samples were stored below -18°C and analyzed after maximum 4 days. Results of storage stability of extracts in ANADIAG validation study No. B9154 entitled “Validation of the Analytical Method for the Analysis of Prothioconazole-desthio (sum of isomers) in Oilseed rape (Whole Plant and Seeds)” showed good stability of prothioconazole-desthio residues in oilseed rape whole plant and seeds for at least 14 days of frozen storage.

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Specimen preparation

The specimens were prepared according to ANADIAG SOPs. The specimen was blended with dry ice and placed for at least 12 hours at T ≤ -18°C for sublimation of dry ice. The amount required by the analytical method (5 g) was weighed from this homogeneous matrix.

Specimen analysis

Samples were extracted and analysed using an in-house method validated under ANADIAG study No B9154 entitled “Validation of the Analytical Method for the Analysis of Prothioconazole-desthio (sum of isomers) in Oilseed rape (Whole Plant and Seeds)”.

Outline of ANADIAG method:

Residues are extracted with acetonitrile in the presence of water, magnesium sulfate and sodium chloride. The extract obtained after centrifugation is purified, filtered and analyzed by liquid chromatography with MS/MS detection. ANADIAG References (French version) of the method are

for the preparation and extraction of the samples: **SOP MP 630**
for the analysis of extracts and for the calibration: **SOP MA 1490**

Details of the analytical conditions are described in Appendix III.

Limits of detection and quantification

LOD

The limit of detection is the lowest measurable standard concentration estimated at 3 times the background noise under the analytical conditions used.

LOQ

The limit of quantification has been validated by fortifications at this level.

Analyte	Method	Matrix	LOD (mg/kg)	LOQ (mg/kg)
Prothioconazole-desthio	MA1490-01	Oilseed rape (seeds and whole plant)	0.003	0.01

Preparation of standard solutions

Calibration and spiking solutions were prepared by dilution of a stock solution resulting from a commercial reference item.

	Solvent	Concentration	Storage conditions	Expiry date (Preparation + …)
Stock solutions	Acetonitrile	1 mg/mL	≤ -18°C	6 months
Spiking solutions	Acetonitrile	500 and 5000 ng/mL	≤ -18°C	1 month
Intermediate calibration solutions	Acetonitrile	15 to 600 ng/mL	≤ -18°C	1 month
Matrix-matched calibration solutions	Control extract	1.5 to 60 ng/mL	≤ -18°C	2 weeks

Calibration curves

Aliquots of the calibration solutions were injected into the analytical system using the same conditions as the specimens. Peak areas obtained from chromatograms were plotted versus concentrations and the calibration functions were determined by least square fit. Number and concentrations of standards used, as well as acceptability criteria (correlation coefficient for a curve (r)≥ 0.990) are described in ANADIAG SOPs.

Fortification procedure

Fortifications were performed by adding known amounts of the spiking solutions to control specimens just prior to the extraction step (spiking solutions were added to the control specimens, before mixing with the extraction solvent). During the residue analysis, control samples were fortified, extracted and stored together with field samples until analysis. These fortified extracts were run during the analysis of the other extracts.

Analytical Sample No.	Matrix	Fortification level (mg/kg)	% Recovery	Extraction date
B9149 01 01 AA	Whole plant	0.01	**84.9%**	12/09/2019
B9149 01 01 BA d10	Whole plant	1.0	**91.3%**	12/09/2019
B9149 01 09 AA	Seeds	0.01	**91.9%**	08/08/2019
B9149 01 09 BA	Seeds	0.10	**74.2%**	08/08/2019

Summary of fortifications

Matrix	Mean % recovery	Standard deviation %	Relative standard deviation %	Number of spiked samples
Whole plant	88.1%	-	-	2
Seeds	83.1%	-	-	2
All matrices	85.6%	8.2%	9.6%	4

Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. B9149 MA1

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Prothioconazole-desthio residues found (mg/kg)
B9149 01 01	B9149 MA1 / U0 / A	-	Whole plant	0 **DBA**	**NDR**
B9149 01 02	B9149 MA1 / T0 / A	CHR/F/PROTIO 250 EC	Whole plant	0 DAA	**0.89**
B9149 01 03	B9149 MA1 / U1 / A	-	Whole plant	14 DAA	**NDR**
B9149 01 04	B9149 MA1 / T1 / A	CHR/F/PROTIO 250 EC	Whole plant	14 DAA	**0.38**
B9149 01 05	B9149 MA1 / U2 / A	-	Whole plant	29 DAA	**NDR**
B9149 01 06	B9149 MA1 / T2 / A	CHR/F/PROTIO 250 EC	Whole plant	29 DAA	**0.05**
B9149 01 07	B9149 MA1 / U3 / A	-	Whole plant	44 DAA	**NDR**
B9149 01 08	B9149 MA1 / T3 / A	CHR/F/PROTIO 250 EC	Whole plant	44 DAA	**0.02**
B9149 01 09	B9149 MA1 / UH / A	-	Seeds	57 DAA	**NDR**
B9149 01 10	B9149 MA1 / TH / A	CHR/F/PROTIO 250 EC	Seeds	57 DAA (NCH)	**0.01**

DBA: Days before application
DAA: Days after application
NCH: Normal Commercial Harvest
NDR: No detectable residues (residues below the limit of detection)
LOD = 0.003 mg/kg
LOQ = 0.01 mg/kg

A 2.1.3.5 Study 5

Comments of zRMS:	The study is accepted, however is should be noted that formulation in the study is EC while in the proposed GAP SC.

Reference:	KCP 6.3/05
Report	Determination of Prothioconazole-desthio (sum of isomers) Residues in Oilseed rape Following One Foliar application with CHR/F/PROTIO 250 EC under Field Conditions in Northern Europe in 2019, J. Diebold, Study code: B9150
Guideline(s):	Regulation (EC) No. 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue levels of prothioconazole-desthio (sum of isomers) in oilseed rape raw agricultural commodity after one foliar application of the formulated product CHR/F/PROTIO 250 EC (250 g prothioconazole/L), at the rate of 0.8 L/ha. The study consisted of two phases: the field phase and the analytical phase. The study was conducted under field conditions at 1 site in Germany. The trial was sampled frequently to monitor the decline of residues shortly after the treatment and at harvest. One plot was treated once with CHR/F/PROTIO 250 EC at the application rate of 0.8 L/ha (200 g prothioconazole/ha). The application was made at BBCH 67 and 55 days before harvest. One plot remained untreated. Sampling was performed just before application in the untreated plot, just after application in the treated plot, then 14, 32, 42 and 55 days after the application (at maturity of the crop) in both plots. Prothioconazole-desthio (sum of isomers) residues were analysed in samples harvested during the field phase.

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address):	ANADIAG - 16 rue Ampère, 67500 Haguenau, France		
Producer of commercial product:	PUH Chemirol sp. Z.o.o.	Page:	1/1
Pesticide (s) (common name (s)):	Prothioconazole	Country:	Northern Europe
CCPR No (s).	-		
Trade name(s):	**CHR/F/PROTIO 250 EC**		
Main uses e.g. insecticide, fungicide:	Fungicide		

Use Pattern

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Crop and/or situation	**F, G or I**	**Pest or group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Remarks**
			Type	**Conc. of a.s.**	**Method kind**	**growth stage & season**	**number min-max**	**interval between applications (days)**	**g a.s./ha (max)**	**water L/ha**	**g a.s./hL (max)**		
(a)	**(b)**	**(c)**	**(d-f)**	**(i)**	**(f-h)**	**(j)**	**(k)**	**(min)**				**(l)**	**(m)**
Oilseed rape	F	Fungi	EC Emulsifiable concentrate	250 g/L	Medium volume spraying Overall spraying	65-67	1	-	200.0	200-400	100.0	60	-

Remarks:
(a) For crops, the EU and Codex Classification (both) should be used; where relevant, the use situation should be described (e.g. fumigation of the structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soilborn insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, etc.
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/L
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI = Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

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

Active ingredient:	**Prothioconazole**	Producer of commercial product:	PUH Chemirol sp. Z.o.o.
Crop/crop group:	Rape/Oilseed		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France		
Country:	Germany	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	250 g/L	Other a.s. in formulation:	-
Formulation (e.g. WP):	EC	(common name and content):	
Commercial product (name):	**CHR/F/PROTIO 250 EC**	Residues calculated as:	mg/kg prothioconazole-desthio

1	2	3	4	5			6	7	8	9	10	11
Report-No ; Location including Postal Code	**Commodity /Variety**	**Date of 1) Planting 2) Flowering 3) Harvest**	**Method of treatment**	**Application rate per treatment (actual)**			**Dates of treatment(s) or No. of treatment(s) and last date**	**Growth stage at last treatment or date**	**Portion analysed**	**Residues (mg/kg)**	**DAA (days)**	**Remarks**
				g a.s./ha	**Water (L/ha)**	**g a.s./hL**						
	(a)	**(b)**	**(c)**				**(d)**	**(e)**	**(a)**		**(f)**	**(g)**
B9150 BW1 Breisach-am-Rhein 79206 Germany	Oilseed Rape / ARISTOTELES	1) 03/09/2018 2) 22/04/2019 to 05/06/2019 3) 23/06/2019 to 24/06/2019	Medium volume spraying Overall spraying	200.0	300	66.7	24/05/2019	67	Whole plant Whole plant Whole plant Whole plant Seeds	0.46 0.10 < LOQ < LOQ < LOQ	0 14 32 42 55	LOQ = 0.01 mg/kg LOD = 0.003 mg/kg

Remarks:
(a) According to EEC and Codex Classification (both) should be used
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) DAA: Days after last Application
(g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included
< LOQ: residues below the LOQ

Storage and identification of specimens

Field specimens were collected, frozen and dispatched to ANADIAG laboratory for residue analysis by the persons in charge of the field trials.

The specimens were treated according to ANADIAG SOPs for receipt, identification and storage.

Analytical references and storage time are summarized in the following table:

TRIAL No. B9150 BW1

Analytical Sample No.	Field Sample No.	Harvest / Sampling Date	Extraction Date	Storage time of samples*	Analysis date	Storage time of extracts**
B9150 01 01	B9150 BW1 / U0 / A	24/05/2019	16/07/2019	53	16/07/2019	0
B9150 01 02	B9150 BW1 / T0 / A	24/05/2019	16/07/2019	53	16/07/2019	0
B9150 01 03	B9150 BW1 / U1 / A	07/06/2019	16/07/2019	39	16/07/2019	0
B9150 01 04	B9150 BW1 / T1 / A	07/06/2019	16/07/2019	39	16/07/2019	0
B9150 01 05	B9150 BW1 / U2 / A	25/06/2019	16/07/2019	21	16/07/2019	0
B9150 01 06	B9150 BW1 / T2 / A	25/06/2019	16/07/2019	21	16/07/2019	0
B9150 01 07	B9150 BW1 / U3 / A	05/07/2019	16/07/2019	11	16/07/2019	0
B9150 01 08	B9150 BW1 / T3 / A	05/07/2019	16/07/2019	11	16/07/2019	0
B9150 01 09	B9150 BW1 / UH / A	18/07/2019	08/08/2019	21	08/08/2019	0
B9150 01 10	B9150 BW1 / TH / A	18/07/2019	08/08/2019	21	08/08/2019	0

*Storage time of samples at ≤ -18°C from sampling to extraction (days)

**Storage time of final extracts at ≤ -18°C, from extraction to analysis (days)

Storage stability of extracts

After extraction, samples were analyzed within 24 hours. Results of storage stability of extracts in ANADIAG validation study No. B9154 entitled “Validation of the Analytical Method for the Analysis of Prothioconazole-desthio (sum of isomers) in Oilseed rape (Whole Plant and Seeds)” showed good stability of prothioconazole-desthio residues in oilseed rape whole plant and seeds for at least 14 days of frozen storage.

Specimen preparation

The specimens were prepared according to ANADIAG SOPs. The specimen was blended with dry ice and placed for at least 12 hours at T ≤ -18°C for sublimation of dry ice. The amount required by the analytical method (5 g) was weighed from this homogeneous matrix.

Specimen analysis

Samples were extracted and analysed using an in-house method validated under ANADIAG study No B9154 entitled “Validation of the Analytical Method for the Analysis of Prothioconazole-desthio (sum of isomers) in Oilseed rape (Whole Plant and Seeds)”.

Outline of ANADIAG method:

Residues are extracted with acetonitrile in the presence of water, magnesium sulfate and sodium chloride. The extract obtained after centrifugation is purified, filtered and analyzed by liquid chromatography with MS/MS detection. ANADIAG References (French version) of the method are

for the preparation and extraction of the samples: **SOP MP 630**
for the analysis of extracts and for the calibration: **SOP MA 1490**

Details of the analytical conditions are described in Appendix III.

Limits of detection and quantification

LOD

The limit of detection is the lowest measurable standard concentration estimated at 3 times the background noise under the analytical conditions used.

LOQ

The limit of quantification has been validated by fortifications at this level.

Analyte	Method	Matrix	LOD (mg/kg)	LOQ (mg/kg)
Prothioconazole-desthio	MA1490-01	Oilseed rape (seeds and whole plant)	0.003	0.01

Preparation of standard solutions

Calibration and spiking solutions were prepared by dilution of a stock solution resulting from a commercial reference item.

	Solvent	Concentration	Storage conditions	Expiry date (Preparation + …)
Stock solutions	Acetonitrile	1 mg/mL	≤ -18°C	6 months
Spiking solutions	Acetonitrile	500 and 5000 ng/mL	≤ -18°C	1 month
Intermediate calibration solutions	Acetonitrile	15 to 600 ng/mL	≤ -18°C	1 month
Matrix-matched calibration solutions	Control extract	1.5 to 60 ng/mL	≤ -18°C	2 weeks

Calibration curves

Aliquots of the calibration solutions were injected into the analytical system using the same conditions as the specimens. Peak areas obtained from chromatograms were plotted versus concentrations and the calibration functions were determined by least square fit. Number and concentrations of standards used, as well as acceptability criteria (correlation coefficient for a curve (r)≥ 0.990) are described in ANADIAG SOPs.

Fortification procedure

Fortifications were performed by adding known amounts of the spiking solutions to control specimens just prior to the extraction step (spiking solutions were added to the control specimens, before mixing with the extraction solvent). During the residue analysis, control samples were fortified, extracted and stored together with field samples until analysis. These fortified extracts were run during the analysis of the other extracts.

Analytical Sample No.	Matrix	Fortification level (mg/kg)	% Recovery	Extraction date
B9150 01 07 AA	Whole plant	0.01	**77.8%**	16/07/2019
B9150 01 07 BA D5	Whole plant	0.50	**92.7%**	16/07/2019
B9150 01 09 AA	Seeds	0.01	**89.6%**	08/08/2019
B9150 01 09 BA	Seeds	0.10	**75.0%**	08/08/2019

Summary of fortifications

Matrix	Mean % recovery	Standard deviation %	Relative standard deviation %	Number of spiked samples

Whole plant	85.3%	-	-	2
Seeds	82.3%	-	-	2
All matrices	83.8%	8.7%	10.4%	4

Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. B9150 BW1

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Prothioconazole-desthio residues found (mg/kg)
B9150 01 01	B9150 BW1 / U0 / A	-	Whole plant	0 **DBA**	**NDR**
B9150 01 02	B9150 BW1 / T0 / A	CHR/F/PROTIO 250 EC	Whole plant	0 DAA	**0.46**
B9150 01 03	B9150 BW1 / U1 / A	-	Whole plant	14 DAA	**NDR**
B9150 01 04	B9150 BW1 / T1 / A	CHR/F/PROTIO 250 EC	Whole plant	14 DAA	**0.10**
B9150 01 05	B9150 BW1 / U2 / A	-	Whole plant	32 DAA	**NDR**
B9150 01 06	B9150 BW1 / T2 / A	CHR/F/PROTIO 250 EC	Whole plant	32 DAA	**< LOQ**
B9150 01 07	B9150 BW1 / U3 / A	-	Whole plant	42 DAA	**NDR**
B9150 01 08	B9150 BW1 / T3 / A	CHR/F/PROTIO 250 EC	Whole plant	42 DAA	**< LOQ**
B9150 01 09	B9150 BW1 / UH / A	-	Seeds	55 DAA	**NDR**
B9150 01 10	B9150 BW1 / TH / A	CHR/F/PROTIO 250 EC	Seeds	55 DAA (NCH)	**< LOQ**

DBA: Days before application
DAA: Days after application
NCH: Normal Commercial Harvest
< LOQ: residues between LOQ and LOD
NDR: No detectable residues (residues below the limit of detection)
LOD = 0.003 mg/kg
LOQ = 0.01 mg/kg

A 2.1.3.6 Study 6

Comments of zRMS:	Not accepted. The study does not support the proposed use. The proposed PHI (56) is shorter than DALA in the study (64). No residue results for seeds for PHI56.

Reference:	KCP 6.3/06
Report	Determination of Prothioconazole-desthio (sum of isomers) Residues in Oilseed rape Following One Foliar application with CHR/F/PROTIO 250 EC under Field Conditions in Northern Europe in 2019, J. Diebold, Study code: B9151
Guideline(s):	Regulation (EC) No. 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue levels of prothioconazole-desthio (sum of isomers) in oilseed rape raw agricultural commodity after one foliar application of the formulated product CHR/F/PROTIO 250 EC (250 g prothioconazole/L), at the rate of 0.8 L/ha. The study consisted of two phases: the field phase and the analytical phase. The study was conducted under field conditions at 1 site in Czech Republic. The trial was sampled frequently to monitor the decline of residues shortly after the treatment and at harvest. One plot was treated once with CHR/F/PROTIO 250 EC at the application rate of 0.8 L/ha (200 g prothioconazole/ha). The application was made at BBCH 65-67 and 63 days before harvest. One plot remained untreated. Sampling was performed just before application in the untreated plot, just after application in the treated plot, then 14, 30, 46 and 63 days after the application (at maturity of the crop) in both plots. Prothioconazole-desthio (sum of isomers) residues were analysed in samples harvested during the field phase.

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address):	ANADIAG - 16 rue Ampère, 67500 Haguenau, France		
Producer of commercial product:	PUH Chemirol sp. Z.o.o.	Page:	1/1
Pesticide (s) (common name (s)):	Prothioconazole-desthio	Country:	Northern Europe
CCPR No (s).	-		
Trade name(s):	**CHR/F/PROTIO 250 EC**		
Main uses e.g. insecticide, fungicide:	Fungicide		

Use Pattern

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Crop and/or situation	**F, G or I**	**Pest or group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Remarks**
			Type	**Conc. of a.s.**	**Method kind**	**growth stage & season**	**number min-max**	**Interval between applications (days)**	**g a.s/ha (max)**	**water L/ha**	**g a.s/hL (max)**		
(a)	**(b)**	**(c)**	**(d-f)**	**(i)**	**(f-h)**	**(j)**	**(k)**	**(min)**				**(l)**	**(m)**
Oilseed rape	F	Fungi	EC Emulsifiable concentrate	247 g/L	Medium volume spraying Overall spraying	67-69	1	60	200	200-400	100.0	60	-

Remarks:
(a) For crops, the EU and Codex Classification (both) should be used; where relevant, the use situation should be described (e.g. fumigation of the structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soilborn insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, etc.
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/L
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI = Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

PUH Chemirol sp. Z.o.o. Residues 2019

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

Active ingredient:	**Prothioconazole-desthio**	Producer of commercial product:	PUH Chemirol sp. Z.o.o.
Crop/crop group:	Rape/Oilseed		
Responsible body for reporting:	ANADIAG, 16 rue Ampère		
(name, address):	67500 HAGUENAU, France		
Country:	Czech Republic	Indoor/Glasshouse/Outdoor:	Outdoor
Content of active substance (g/kg or g/L):	247 g/L	Other a.s. in formulation:	-
Formulation (e.g. WP):	EC	(common name and content):	
Commercial product (name):	**Commercial product**	Residues calculated as:	mg/kg prothioconazole-desthio

1	2	3	4	5			6	7	8	9	10	11
Report-No ; Location including Postal Code	Commodity /Variety	Date of 1) Planting 2) Flowering 3) Harvest	Method of treatment	Application rate per treatment (actual)			Dates of treatment(s) or No. of treatment(s) and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	DALA (days)	Remarks
				g a.s./ha	Water (L/ha)	g a.s./hL						
	(a)	(b)	(c)				(d)	(e)	(a)		(f)	(g)
B9151 CZE Slatina nad Zdobnici 51756 Czech Republic	Oilseed Rape / ARCHITEKT	1) 28/08/2018 2) 08/05/2019 to 20/05/2019 3) 20/07/2019 to 27/07/2019	Medium volume spraying Overall spraying	204.7	307	66.7	16/05/2019	67-69	Whole plant Whole plant Whole plant Whole plant Seeds	0.71 0.62 0.03 0.02 NDR	0 14 30 46 63	LOQ = 0.01 mg/kg LOD= 0.003 mg/kg

Remarks:
(a) According to EEC and Codex Classification (both) should be used
(b) Only if relevant
(c) High or low volume spraying, spreading, dusting etc
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4
(f) DALA: Days after last Application
(g) Remarks may include: Climatic conditions; Reference to analytical method and information on which metabolites are included
NDR: no detectable residues (below the LOD)

Storage and identification of specimens

Field specimens were collected, frozen and dispatched to ANADIAG laboratory for residue analysis by the persons in charge of the field trials.

The specimens were treated according to ANADIAG SOPs for receipt, identification and storage.
Analytical references and storage time are summarized in the following table:

TRIAL No. B9150 BW1

Analytical Sample No.	Field Sample No.	Harvest / Sampling Date	Extraction Date	Storage time of samples*	Analysis date	Storage time of extracts**
B9151 01 01	B9151 CZ1 / U0 / A	16/05/2019	16/09/2019	123	16/09/2019	0
B9151 01 02	B9151 CZ1 / T0 / A	16/05/2019	16/09/2019	123	16/09/2019	0
B9151 01 03	B9151 CZ1 / U1 / A	30/05/2019	16/09/2019	109	16/09/2019	0
B9151 01 04	B9151 CZ1 / T1 / A	30/05/2019	16/09/2019	109	16/09/2019	0
B9151 01 05	B9151 CZ1 / U2 / A	15/06/2019	16/09/2019	93	16/09/2019	0
B9151 01 06	B9151 CZ1 / T2 / A	15/06/2019	16/09/2019	93	16/09/2019	0
B9151 01 07	B9151 CZ1 / U3 / A	01/07/2019	16/09/2019	77	16/09/2019	0
B9151 01 08	B9151 CZ1 / T3 / A	01/07/2019	16/09/2019	77	16/09/2019	0
B9151 01 09	B9151 CZ1 / UH / A	18/07/2019	09/08/2019	22	09/08/2019	0
B9151 01 10	B9151 CZ1 / TH / A	18/07/2019	09/08/2019	22	09/08/2019	0

*Storage time of samples at ≤ -18°C from sampling to extraction (days)

Storage stability of extracts

After extraction, samples were analyzed within 24 hours. Results of storage stability of extracts in ANADIAG validation study No. B9154 entitled “Validation of the Analytical Method for the Analysis of Prothioconazole-desthio (sum of isomers) in Oilseed rape (Whole Plant and Seeds)” showed good stability of prothioconazole-desthio residues in oilseed rape whole plant and seeds for at least 14 days of frozen storage.

Specimen preparation

The specimens were prepared according to ANADIAG SOPs. The specimen was blended with dry ice and placed for at least 12 hours at T ≤ -18°C for sublimation of dry ice. The amount required by the analytical method (5 g) was weighed from this homogeneous matrix.

Specimen analysis

Samples were extracted and analysed using an in-house method validated under ANADIAG study No B9154 entitled “Validation of the Analytical Method for the Analysis of Prothioconazole-desthio (sum of isomers) in Oilseed rape (Whole Plant and Seeds)”.

Outline of ANADIAG method:

Residues are extracted with acetonitrile in the presence of water, magnesium sulfate and sodium chloride. The extract obtained after centrifugation is purified, filtered and analyzed by liquid chromatography with MS/MS detection. ANADIAG References (French version) of the method are

for the preparation and extraction of the samples: **SOP MP 630**
for the analysis of extracts and for the calibration: **SOP MA 1490**

Details of the analytical conditions are described in Appendix III.

Limits of detection and quantification

LOD

The limit of detection is the lowest measurable standard concentration estimated at 3 times the background noise under the analytical conditions used.

LOQ

The limit of quantification has been validated by fortifications at this level.

Analyte	Method	Matrix	LOD (mg/kg)	LOQ (mg/kg)
Prothioconazole-desthio	MA1490-01	Oilseed rape (seeds and whole plant)	0.003	0.01

Preparation of standard solutions

Calibration and spiking solutions were prepared by dilution of a stock solution resulting from a commercial reference item.

	Solvent	Concentration	Storage conditions	Expiry date (Preparation + …)
Stock solutions	Acetonitrile	1 mg/mL	≤ -18°C	6 months
Spiking solutions	Acetonitrile	500 and 5000 ng/mL	≤ -18°C	1 month
Intermediate calibration solutions	Acetonitrile	15 to 600 ng/mL	≤ -18°C	1 month
Matrix-matched calibration solutions	Control extract	1.5 to 60 ng/mL	≤ -18°C	2 weeks

Calibration curves

Aliquots of the calibration solutions were injected into the analytical system using the same conditions as the specimens. Peak areas obtained from chromatograms were plotted versus concentrations and the calibration functions were determined by least square fit. Number and concentrations of standards used, as well as acceptability criteria (correlation coefficient for a curve (r)≥ 0.990) are described in ANADIAG SOPs.

Fortification procedure

Fortifications were performed by adding known amounts of the spiking solutions to control specimens just prior to the extraction step (spiking solutions were added to the control specimens, before mixing with the extraction solvent). During the residue analysis, control samples were fortified, extracted and stored together with field samples until analysis. These fortified extracts were run during the analysis of the other extracts.

Analytical Sample No.	Matrix	Fortification level (mg/kg)	% Recovery	Extraction date
B9151 01 07 AA	Whole plant	0.01	**88.1%**	16/09/2019
B9151 01 07 BA d10	Whole plant	1.0	**89.5%**	16/09/2019
B9151 01 09 AA	Seeds	0.01	**70.4%**	09/08/2019
B9151 01 09 BA	Seeds	0.10	**71.0%**	09/08/2019

Summary of fortifications

Matrix	Mean % recovery	Standard deviation %	Relative standard deviation %	Number of spiked samples
Whole plant	88.8%	-	-	2
Seeds	70.7%	-	-	2

All matrices	79.8%	10.5%	13.1%	4

Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. B9150 BW1

Analytical sample No.	Field sample No.	Treatment	Matrix	Timing	Prothioconazole-desthio residues found (mg/kg)
B9151 01 01	B9151 CZ1 / U0 / A	-	Whole plant	0 **DBA**	**< LOQ**
B9151 01 02	B9151 CZ1 / T0 / A	CHR/F/PROTIO 250 EC	Whole plant	0 DAA	**0.71**
B9151 01 03	B9151 CZ1 / U1 / A	-	Whole plant	14 DAA	**NDR**
B9151 01 04	B9151 CZ1 / T1 / A	CHR/F/PROTIO 250 EC	Whole plant	14 DAA	**0.62**
B9151 01 05	B9151 CZ1 / U2 / A	-	Whole plant	30 DAA	**NDR**
B9151 01 06	B9151 CZ1 / T2 / A	CHR/F/PROTIO 250 EC	Whole plant	30 DAA	**0.03**
B9151 01 07	B9151 CZ1 / U3 / A	-	Whole plant	46 DAA	**NDR**
B9151 01 08	B9151 CZ1 / T3 / A	CHR/F/PROTIO 250 EC	Whole plant	46 DAA	**0.02**
B9151 01 09	B9151 CZ1 / UH / A	-	Seeds	63 DAA	**NDR**
B9151 01 10	B9151 CZ1 / TH / A	CHR/F/PROTIO 250 EC	Seeds	63 DAA	**NDR**

DBA: Days before application
DAA: Days after application
NCH: Normal Commercial Harvest
< LOQ: residues between LOQ and LOD
NDR: No detectable residues (residues below the limit of detection)
LOD = 0.003 mg/kg
LOQ = 0.01 mg/kg

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new studies was performed.

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

No new studies was performed.

A 2.1.6 Magnitude of residues in representative succeeding crops

No new studies was performed.

A 2.1.7 Other/Special Studies

No new studies was performed.

A 2.2 Azoxystrobin

A 2.2.1 Stability of residues

No new studies was performed.

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

No new studies was performed.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Study 1

Comments of zRMS:	The study is accepted, however is should be noted that formulation in the study is SE while in the proposed GAP SC. The Applicant has provided bridging studies showing that the residue levels will not be higher when used in the formulation proposed in the GAP for CHR/F/PROTAZO 375 SC.

Reference:	KCP 6.3/15
Report	Generation of Field Specimens for the determination of Azoxystrobin Residues in Oilseed Rape Following Foliar application with AZOXYSTROBIN 250 SE under Field Conditions in Czech Republic in 2018, C. Ertus, Study Code: B8186
Guideline(s):	Regulation (EC) No 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address): ANADIAC - 16 rue Ampère, 67500 Haguenau, France
Producer of commercial product: PUH Chemirol sp. z.o.o.
Pesticide (s) (common name (s)): azoxystrobin
CCPR No (s).
Trade name(s): **AZOXYSTROBIN 250 SE**
Main uses e.g. insecticide, fungicide: Insecticide

Page: 1/1
Country: Northern Europe

Use Pattern

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Crop and/or situation	F, G or I	Pest or group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
			Type	Conc. of a.s.	Method kind	growth stage & season	number min-max	interval between applications (days)	g a.s./ha (max)	water L/ha	g a.s./hL (max)		
(a)	(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)	(min)				(l)	(m)
Oilseed rape	F	Biting and sucking insects	SE Suspo-emulsion	250 g/L	Medium volume spraying Overall spraying	-	1	-	250	300	83.3	35	-

Remarks:
(a) For crops, the EU and Codex Classification (both) should be used; where relevant, the use situation should be described (e.g. fumigation of the structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soilborn insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, etc.
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI = Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

The objective of the study was to generate specimens of oilseed rape raw agricultural commodity after one foliar application of the formulated product AZOXYSTROBIN 250 SE (250 g azoxystrobin /L) at the rate of 1 L/ha.
The following pattern was designed for the treatments and the samplings:

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	**AZOXYSTROBIN 250 SE**	T1	35 (±3) DBH	1 L/ha	250 g/ha	300 L/ha (±10%)

DBH: Days before harvest

1.1.2 Location of the trial

The trial was performed on soil type and under cultural practices typical for oilseed rape production and on typical cultivar of the regional commercial production.

Trial No.	Principal Investigator	Crop	Type of trial	European area	Region, country
B8186 CZ1	Iva SIMEK	Oilseed rape	DC	North	Hradec Kralove, Czech Republic

DC: Decline curve

Location

1 Trial B8186 CZ1

1.2.2 Crop and soil Information

Trial No.	Crop	Variety	Sowing density	Sowing date	Soil type	pH	Organic matter (%)
B8186 CZ1	Oilseed rape	Rescator	4 kg/ha	28/08/2017	Clay loam	5.9	1.6

1.2.4 Sampling of specimens

The samplings were carried out according to ANADIAG SOPs and to the specifications of the study plan).

Sampling summary

Trial No	Sampling	Actual Date	Actual DAA	Actual Growth Stage (BBCH)
B8186 CZ1	1	14/06/2018	0	77-79
	2	28/06/2018	14	85
	3	03/07/2018	19	87
	4	13/07/2018	29	87-89
	5	20/07/2018	36	89

DAA: Days after application

Reference: KCP 6.3/07

Report DETERMINATION OF AZOXYSTROBIN IN OILSEED RAPE AFTER APPLICATION OF AZOXYSTROBIN 250 SE IN CZECH REPUBLIC –

	2018, J. Kicińska, Study Code: ZBBZ-2018/11/DPL/1CZ
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of this study was to determine the decline and the magnitude of residues Azoxystrobin in Oilseed rape (pods and seeds) samples taken from the field trial, after applications of AZOXYSTROBIN 250 SE, under open field conditions. To achieve the objective, appropriate analytical method for determination of Azoxystrobin was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2018/11/DPL/1. The validated limit of quantification is 0.01 mg/kg.

EXPERIMENTAL SECTION

Test system, Specimen Origin, Preparation and Storage

The samples were delivered from field study conducted by ANADIAG France 16 rue Ampère, 67500 HAGUENAU – France

Field study title: Generation of field specimens for the determination of Azoxystrobin Residues in Oilseed Rape Following Foliar application with AZOXYSTROBIN 250 SE under Field Condition in Czech Republic – 2018.

Field study number for Oilseed rape: B8186

Untreated and treated specimens from field trial were supplied by and under Sponsor responsibility. Provided samples were thoroughly homogenized in a knife mill with dry ice. Each of the processed sample was divided into four subsamples (three analytical and one archival) and was transferred to polyethylene bags. Sub-samples were stored at the temperature ≤ -18 °C in the dark (allowing the dry ice to sublime) until extraction. Final specimen extracts were stored at 5 ± 4 °C in the dark until analysis. The extracts were analyzed within 24 hours and were not frozen.

Table 3: Detailed list of samples

Crop (matrix)	GLP sample code	Sample description	Sampling date	Lab. Sample ID
Oilseed rape (pods)	B8186 CZ1/U0/A	Untreated	0 DAA* / U	18/11/DPL/1CZ/1
	B8186 CZ1/T0/A	Treated (AZOXYSTROBIN 250 SE)	0 DAA / T	18/11/DPL/1CZ/2
	B8186 CZ1/U14/A	Untreated	14 (±1) DAA / U	18/11/DPL/1CZ/3
	B8186 CZ1/T14/A	Treated (AZOXYSTROBIN 250 SE)	14 (±1) DAA / T	18/11/DPL/1CZ/4
	B8186 CZ1/U21/A	Untreated	21 (±2) DAA / U	18/11/DPL/1CZ/5
	B8186 CZ1/T21/A	Treated (AZOXYSTROBIN 250 SE)	21 (±2) DAA / T	18/11/DPL/1CZ/6
Oilseed rape (seeds)	B8186 CZ1/U28/A	Untreated	28 (±2) DAA / U	18/11/DPL/1CZ/7
	B8186 CZ1/T28/A	Treated (AZOXYSTROBIN 250 SE)	28 (±2) DAA / T	18/11/DPL/1CZ/8
Oilseed rape (seeds)	B8186 CZ1/U35/A	Untreated	35 (±3) DAA, NCH** / U	18/11/DPL/1CZ/9
	B8186 CZ1/T35/A	Treated (AZOXYSTROBIN 250 SE)	35 (±3) DAA, NCH / T	18/11/DPL/1CZ/10

Additional sample information

Lab. Sample ID	Date of reception	Date of extraction	Date of GC-MS/MS analyses
18/11/DPL/1CZ/1	24.07.2018	09.11.2018	10.11.2018
18/11/DPL/1CZ/2	24.07.2018	08.11.2018	09.11.2018
18/11/DPL/1CZ/3	24.07.2018	09.11.2018	10.11.2018
18/11/DPL/1CZ/4	24.07.2018	08.11.2018	09.11.2018
18/11/DPL/1CZ/5	24.07.2018	09.11.2018	10.11.2018
18/11/DPL/1CZ/6	24.07.2018	08.11.2018	09.11.2018
18/11/DPL/1CZ/7	24.07.2018	13.11.2018	13.11.2018
18/11/DPL/1CZ/8	24.07.2018	08.11.2018	08.11.2018
18/11/DPL/1CZ/9	24.07.2018	13.11.2018	14.11.2018
18/11/DPL/1CZ/10	24.07.2018	13.11.2018	14.11.2018

Stability of Analytes in Standard Solutions

Working solutions used for preparation calibration samples were stored in refrigerator at 5 ± 4°C during study. At the end of experimental phase, the solution used for preparation calibration level at LOQ was reanalysed by thrice injection and compared to freshly prepared. One (1) ion mass transition was used for evaluation and the other ion mass transition was monitored for confirmation purpose only.

Difference between stored and newly prepared solution is < 10%. The results indicated that Azoxystrobin working solutions prepared in acetonitrile were stable during study under refrigerated conditions.

Calibration Level (µg/mL)	Date of preparation (dd.mm.yy)	Working solution ID	Relative peak area	RSD (%)	Difference (%)
Azoxystrobin Ion Mass Transition 344.0→172.0 (Quantification)					
0.005 (LOQ)	06.11.2018	1S1W7	18168/19095/17888/18439/17243	3.8	3.0
	13.11.2018	1S1W12	19014/17532/17635/17006/16999	4.7	

DETAILED RESULTS FROM FIELD TRIALS

Following table presents detailed results of Azoxystrobin residues analyses in Oilseed rape (pods and seeds).

Variant	GLP Sample code	Sampling data	Lab. Sample ID	Azoxystrobin	
				Residues [mg/kg]	Mean Residues [mg/kg]
Oilseed rape (pods)	B8186 CZ1/U0/A	0 DAA* / U	18/11/DPL/1CZ/1A	< LOD	< LOD
			18/11/DPL/1CZ/1B	< LOD	
			18/11/DPL/1CZ/1C	< LOD	
	B8186 CZ1/T0/A	0 DAA / T	18/11/DPL/1CZ/2A	5.3	5.4
			18/11/DPL/1CZ/2B	5.7	
			18/11/DPL/1CZ/2C	5.2	
	B8186 CZ1/U14/A	14 (±1) DAA / U	18/11/DPL/1CZ/3A	< LOD	< LOD
			18/11/DPL/1CZ/3B	< LOD	
			18/11/DPL/1CZ/3C	< LOD	
	B8186 CZ1/T14/A	14 (±1) DAA / T	18/11/DPL/1CZ/4A	3.6	3.8
			18/11/DPL/1CZ/4B	3.9	
			18/11/DPL/1CZ/4C	3.9	
	B8186 CZ1/U21/A	21 (±2) DAA / U	18/11/DPL/1CZ/5A	< LOD	< LOD
			18/11/DPL/1CZ/5B	< LOD	
			18/11/DPL/1CZ/5C	< LOD	
	B8186 CZ1/T21/A	21 (±2) DAA / T	18/11/DPL/1CZ/6A	4.5	4.7
			18/11/DPL/1CZ/6B	4.8	
			18/11/DPL/1CZ/6C	4.7	
Oilseed rape (seeds)	B8186 CZ1/U28/A	28 (±2) DAA / U	18/11/DPL/1CZ/7A	< LOD	< LOD
			18/11/DPL/1CZ/7B	< LOD	
			18/11/DPL/1CZ /7C	< LOD	
	B8186 CZ1/T28/A	28 (±2) DAA / T	18/11/DPL/1CZ/8A	0.029	0.026
			18/11/DPL/1CZ/8B	0.025	
			18/11/DPL/1CZ/8C	0.023	

LOD (limit of detection) – 0.002 mg/kg for Oilseed rape (pods and seeds)
LOQ (limit of quantification) – 0.01 mg/kg

Variant	GLP Sample code	Sampling data	Lab. Sample ID	Azoxystrobin	
				Residues [mg/kg]	Mean Residues [mg/kg]
Oilseed rape (seeds)	B8186 CZ1/U35/A	35 (±3) DAA, NCH** / U	18/11/DPL/1CZ/9A	< LOD	< LOD
			18/11/DPL/1CZ/9B	< LOD	
			18/11/DPL/1CZ/9C	< LOD	
	B8186 CZ1/T35/A	35 (±3) DAA, NCH / T	18/11/DPL/1CZ/10A	0.032	0.032
			18/11/DPL/1CZ/10B	0.034	
			18/11/DPL/1CZ/10C	0.030	

LOD (limit of detection) – 0.002 mg/kg for Oilseed rape (pods and seeds)
LOQ (limit of quantification) – 0.01 mg/kg

CONCLUSIONS

The method was shown to be highly selective, as it includes two parent-daughter ion transitions for Azoxystrobin and it yields accurate and repeatable results. The limit of quantification (LOQ) was established at 0.01 mg/kg for all analytes, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for Oilseed rape (pods and seeds).

It is concluded that method fulfils the requirements as defined in EC Guidance document on residue analytical methods (SANCO/3029/99, rev. 4 and SANCO/825/00, rev. 8.1.) and is, applicable as enforcement and data generation method for determination of Azoxystrobin in Oilseed rape after application of AZOXYSTROBIN 250 SE.

A 2.2.3.2 Study 2

Comments of zRMS:	The study is accepted, however is should be noted that formulation in the study is SE while in the proposed GAP SC. The Applicant has provided bridging studies showing that the residue levels will not be higher when used in the formulation proposed in the GAP for CHR/F/PROTAZO 375 SC.

Reference:	KCP 6.3/20
Report	Generation of field specimens for the determination of Azoxystrobin residues in Oilseed rape following foliar application with AZOXYSTROBIN 250 SE under field Conditions in Poland in 2019, C. Ertus, Study Code: B9216
Guideline(s):	Regulation (EC) No 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address): ANADIAG - 16 rue Ampère, 67500 Haguenau, France
Producer of commercial product: PUH Chemirol sp. z.o.o.
Pesticide (s) (common name (s)): azoxystrobin
CCPR No (s).
Trade name(s): **AZOXYSTROBIN 250 SE**
Main uses e.g. insecticide, fungicide: Fungicide

Page: 1/1
Country: Northern Europe

Use Pattern

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Crop and/or situation	F, G or I	Pest or group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
			Type	Conc. of a.s.	Method kind	growth stage & season	number min-max	interval between applications (days)	g a.s./ha (max)	water L/ha	g a.s./hL (max)		
(a)	(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)	(min)				(l)	(m)
Oilseed rape	F	Foliar fungi	SE Suspo-emulsion	250 g/L	Medium volume spraying Overall spraying	≈ BBCH 79-81	1	-	250	300	83.3	35	-

Remarks:
(a) For crops, the EU and Codex Classification (both) should be used; where relevant, the use situation should be described (e.g. fumigation of the structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soilborn insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, etc.
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI = Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

The objective of the study was to generate specimens of oilseed rape raw agricultural commodity after one foliar application of the formulated product AZOXYSTROBIN 250 SE (250 g azoxystrobin /L) at the rate of 1 L/ha.
The following pattern was designed for the treatments and the samplings:

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	**AZOXYSTROBIN 250 SE**	T1	35 (±3) DBH	1 L/ha	250 g/ha	300 L/ha (±10%)

DBH: Days before harvest

1.1.2 Location of the trial

The trial was performed on soil type and under cultural practices typical for oilseed rape production and on typical cultivar of the regional commercial production.

Trial No.	Principal Investigator	Type of trial	Crop	European area	Region, Country
B9216 PL1	Krzysztof NOWAK	RH	Oilseed rape	North	Lodzkie, Poland

RH: Residue at harvest

Location

1 Trial B9216 PL1

1.2.2 Crop and soil Information

Trial No.	Crop	Variety	Sowing density	Sowing date	Soil type	pH	Organic matter (%)
B9216 PL1	Oilseed rape	Tajfun	2.5 kg/ha	20/08/2018	Sandy loam	6.5	1.0

1.2.4 Sampling of specimens

The samplings were carried out according to ANADIAG SOPs and to the specifications of the study plan).

Trial No	Sampling	Actual Date	Actual DAA	Actual Growth Stage (BBCH)
B9216 PL1	1	08/07/2019	27*	89

DAA: Days after application
*See Deviation No.190715

Reference:	KCP 6.3/08
Report	DETERMINATION OF AZOXYSTROBIN IN OILSEED RAPE AFTER APPLICATION OF AZOXYSTROBIN 250 SE IN POLAND - 2019, J. Kicińska, Study Code: 19/FSL/12/1PL
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of this study was to determine the decline and the magnitude of residues Azoxystrobin in Oilseed rape (seeds) samples taken from the field trial, after applications of AZOXYSTROBIN 250 SE, under open field conditions. To achieve the objective, appropriate analytical method for determination of Azoxystrobin was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2018/11/DPL/1. The validated limit of quantification is 0.01 mg/kg.

EXPERIMENTAL SECTION

Test system, Specimen Origin, Preparation and Storage

The samples were delivered from field study conducted by ANADIAG SAS, Sadowa 16/22 Str., 95-100 Zgierz (ANADIAG France 16 rue Ampère, F-67500 HAGUENAU – France)
Field study title: Generation of field specimens for the determination of Azoxystrobin residues in Oilseed rape following foliar application with AZOXYSTROBIN 250 SE under Field Condition in Poland in 2019Field study number for Oilseed rape: B9216
Untreated and treated specimens from field trial were supplied by and under Sponsor responsibility. Provided samples were thoroughly homogenized in a knife mill with dry ice. Each of the processed sample was divided into four subsamples (three analytical and one archival) and was transferred to polyethylene bags. Sub-samples were stored at the temperature ≤ -18 °C in the dark (allowing the dry ice to sublime) until extraction. Final specimen extracts were stored at 5 ± 4 °C in the dark until analysis. The extracts were analyzed within 24 hours and were not frozen.

Crop (matrix)	GLP sample code	Sample description	Sampling date	Lab. Sample ID
Oilseed rape (seeds)	B9216 PL1/UH/A	Untreated	35 (±3) DAA, NCH / U	19/FSL/12/1PL/1
	B9216 PL1/TH/A	Treated (AZOXYSTROBIN 250 SE)	35 (±3) DAA, NCH / T	19/FSL/12/1PL /2

Additional sample information

Lab. Sample ID	Date of reception	Date of extraction	Date of GC-MS/MS analyses
19/FSL/12/1PL/1	01.08.2019	16.09.2019	16.09.2019
19/FSL/12/1PL /2	01.08.2019	16.09.2019	17.09.2019

Stability of Analytes in Standard Solutions

Working solutions used for preparation calibration samples were stored in refrigerator at 5 ± 4°C during study. At the end of experimental phase, the solution used for preparation calibration level at LOQ was reanalysed by thrice injection and compared to freshly prepared. One (1) ion mass transition was used for evaluation and the other ion mass transition was monitored for confirmation purpose only.

Difference between stored and newly prepared solution is < 10%. The results indicated that Azoxystrobin working solutions prepared in acetonitrile were stable during study under refrigerated conditions.

Calibration Level (µg/mL)	Date of preparation (dd.mm.yy)	Working solution ID	Relative peak area	RSD (%)	Difference (%)
Azoxystrobin Ion Mass Transition 344.0→172.0 (Quantification)					
0.005 (LOQ)	11.09.2019	1S1W7	16529 / 15764 / 14889	5.2	-7.8
	16.09.2019	1S1W12	17622 / 18168 / 15393	8.6	

DETAILED RESULTS FROM FIELD TRIALS

Following table presents detailed results of Azoxystrobin residues analyses in Oilseed rape (seeds).

Table 10: Detailed results of Azoxystrobin residue analyses in Oilseed rape

Variant	GLP Sample code	Sampling data	Lab. Sample ID	Azoxystrobin	
				Residues [mg/kg]	Mean Residues [mg/kg]
Oilseed rape (seeds)	B9216 PL1/UH/A	35 (±3) DAA, NCH / U	19/FSL/12/1PL/1A	< LOD	< LOD
			19/FSL/12/1PL/1B	< LOD	
			19/FSL/12/1PL/1C	< LOD	
	B9216 PL1/TH/A	35 (±3) DAA, NCH / T	19/FSL/12/1PL/2A	0.033	0.035
			19/FSL/12/1PL/2B	0.039	
			19/FSL/12/1PL/2C	0.033	

LOD (limit of detection) – 0.002 mg/kg for Oilseed rape (seeds)
LOQ (limit of quantification) – 0.01 mg/kg

CONCLUSIONS

The method was shown to be highly selective, as it includes two parent-daughter ion transitions for Azoxystrobin and it yields accurate and repeatable results. The limit of quantification (LOQ) was established at 0.01 mg/kg for all analytes, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for Oilseed rape (seeds).

It is concluded that method fulfils the requirements as defined in EC Guidance document on residue analytical methods (SANCO/3029/99, rev. 4 and SANCO/825/00, rev. 8.1.) and is, applicable as enforcement and data generation method for determination of Azoxystrobin in Oilseed rape after application of AZOXYSTROBIN 250 SE.

A 2.2.3.3 Study 3

Comments of zRMS:	The study is accepted, however is should be noted that formulation in the study is SE while in the proposed GAP SC. The Applicant has provided bridging studies showing that the residue levels will not be higher when used in the formulation proposed in the GAP for CHR/F/PROTAZO 375 SC

Reference:	KCP 6.3/17
Report	Generation of Field Specimens for the determination of Azoxystrobin Residues in Oilseed Rape Following Foliar application with AZOXYSTROBIN 250 SE under Field Conditions in Germany in 2018, C.

	Ertus, Study Code: B8188
Guideline(s):	Regulation (EC) No 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address): ANADIAG - 16 rue Ampère, 67500 Haguenau, France
Producer of commercial product: PUH Chemirol sp. z.o.o.
Pesticide (s) (common name (s)): azoxystrobin
CCPR No (s).
Trade name(s): **AZOXYSTROBIN 250 SE**
Main uses e.g. insecticide, fungicide: Fungicide

Page: 1/1
Country: Northern Europe

Use Pattern

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Crop and/or situation	F, G or I	Pest or group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
			Type	Conc. of a.s.	Method kind	growth stage & season	number min-max	interval between applications (days)	g a.s./ha (max)	water L/ha	g a.s./hL (max)		
(a)	(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)	(min)				(l)	(m)
Oilseed rape	F	Foliar fungi	SE Suspo-emulsion	250 g/L	Medium volume spraying Overall spraying	-	1	-	250	300	83.3	35	-

Remarks:
(a) For crops, the EU and Codex Classification (both) should be used; where relevant, the use situation should be described (e.g. fumigation of the structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soilborn insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, etc.
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI = Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

The objective of the study was to generate specimens of oilseed rape raw agricultural commodity after one foliar application of the formulated product AZOXYSTROBIN 250 SE (250 g azoxystrobin /L) at the rate of 1 L/ha.
The following pattern was designed for the treatments and the samplings:

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	**AZOXYSTROBIN 250 SE**	T1	35 (±3) DBH	1 L/ha	250 g/ha	300 L/ha (±10%)

DBH: Days before harvest

1.1.2 Location of the trial

The trial was performed on soil type and under cultural practices typical for oilseed rape production and on typical cultivar of the regional commercial production.

Trial No.	Principal Investigator	Crop	Type of trial	European area	Region, country
B8188 BW1	Audrey MEYER	Oilseed rape	DC	North	Baden-Württemberg, Germany

DC: Decline curve

Location

1 Trial B8188 BW1

1.2.2 Crop and soil Information

Trial No.	Crop	Variety	Sowing density	Sowing date	Soil type	pH	Organic matter (%)
B8188 BW1	Oilseed rape	Aristoteles	3.0 kg/ha	18/09/2017	Sandy loam	≈7.0	2.0-2.3

1.2.4 Sampling of specimens

The samplings were carried out according to ANADIAG SOPs and to the specifications of the study plan).

Trial No	Sampling	Actual Date	Actual DAA	Actual Growth Stage (BBCH)
B8188 BW1	1	05/06/2018	0	80-82
	2	19/06/2018	14	83-85
	3	26/06/2018	21	89
	4	Not taken*	*	*
	5	Not taken*	*	*

DAA: Days after application

*See deviation No.180626

Reference:	KCP 6.3/09
Report	DETERMINATION OF AZOXYSTROBIN IN OILSEED RAPE AFTER APPLICATION OF AZOXYSTROBIN 250 SE IN GERMANY - 2018, J. Kicińska, Study Code: ZBBZ-2018/11/DPL/1DE
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of this study was to determine the decline and the magnitude of residues Azoxystrobin in Oilseed rape (pods and seeds) samples taken from the field trial, after applications of AZOXYSTROBIN 250 SE, under open field conditions. To achieve the objective, appropriate analytical method for determination of Azoxystrobin was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2018/11/DPL/1. The validated limit of quantification is 0.01 mg/kg.

EXPERIMENTAL SECTION

Test system, Specimen Origin, Preparation and Storage

The samples were delivered from field study conducted by ANADIAG France 16 rue Ampère, 67500 HAGUENAU – France

Field study title: Generation of field specimens for the determination of Azoxystrobin Residues in Oilseed Rape Following Foliar application with AZOXYSTROBIN 250 SE under Field Condition in Germany - 2018

Field study number for Oilseed rape: B8188

Untreated and treated specimens from field trial were supplied by and under Sponsor responsibility. Provided samples were thoroughly homogenized in a knife mill with dry ice. Each of the processed sample was divided into four subsamples (three analytical and one archival) and was transferred to polyethylene bags. Sub-samples were stored at the temperature ≤ -18 °C in the dark (allowing the dry ice to sublime) until extraction. Final specimen extracts were stored at 5 ± 4 °C in the dark until analysis. The extracts were analyzed within 24 hours and were not frozen.

Crop (matrix)	GLP sample code	Sample description	Sampling date	Lab. Sample ID
Oilseed rape (pods)	B8188 BW1/U0/A	Untreated	0 DAA* / U	18/11/DPL/1DE/1
	B8188 BW1/T0/A	Treated (AZOXYSTROBIN 250 SE)	0 DAA / T	18/11/DPL/1DE/2
	B8188 BW1/U14/A	Untreated	14 (±1) DAA / U	18/11/DPL/1DE/3
	B8188 BW1/T14/A	Treated (AZOXYSTROBIN 250 SE)	14 (±1) DAA / T	18/11/DPL/1DE/4
Oilseed rape (seeds)	B8188 BW1/U21/A	Untreated	21 (±2) DAA / U	18/11/DPL/1DE/5
	B8188 BW1/T21/A	Treated (AZOXYSTROBIN 250 SE)	21 (±2) DAA / T	18/11/DPL/1DE/6

Additional sample information

Lab. Sample ID	Date of reception	Date of extraction	Date of GC-MS/MS analyses
18/11/DPL/1DE/1	24.07.2018	09.11.2018	10.11.2018
18/11/DPL/1DE/2	24.07.2018	08.11.2018	09.11.2018
18/11/DPL/1DE/3	24.07.2018	09.11.2018	10.11.2018
18/11/DPL/1DE/4	24.07.2018	08.11.2018	09.11.2018
18/11/DPL/1DE/5	24.07.2018	13.11.2018	13.11.2018
18/11/DPL/1DE/6	24.07.2018	13.11.2018	14.11.2018

Stability of Analytes in Standard Solutions

Working solutions used for preparation calibration samples were stored in refrigerator at 5 ± 4°C during study. At the end of experimental phase, the solution used for preparation calibration level at LOQ was reanalysed by thrice injection and compared to freshly prepared. One (1) ion mass transition was used for evaluation and the other ion mass transition was monitored for confirmation purpose only. Difference between stored and newly prepared solution is < 10%. The results indicated that Azoxystrobin working solutions prepared in acetonitrile were stable during study under refrigerated conditions.

Calibration Level (µg/mL)	Date of preparation (dd.mm.yy)	Working solution ID	Relative peak area	RSD (%)	Difference (%)
Azoxystrobin Ion Mass Transition 344.0→172.0 (Quantification)					
0.005 (LOQ)	06.11.2018	1S1W7	18168/19095/17888/18439/17243	3.8	3.0
	13.11.2018	1S1W12	19014/17532/17635/17006/16999	4.7	

DETAILED RESULTS FROM FIELD TRIALS

Following table presents detailed results of Azoxystrobin residues analyses in Oilseed rape (pods and seeds).

Variant	GLP Sample code	Sampling data	Lab. Sample ID	Azoxystrobin	
				Residues [mg/kg]	Mean Residues [mg/kg]
Oilseed rape (pods)	B8188 BW1/U0/A	0 DAA* / U	18/11/DPL/1DE/1A	0.012	0.012
			18/11/DPL/1DE/1B	0.013	
			18/11/DPL/1DE/1C	0.012	
	B8188 BW1/T0/A	0 DAA / T	18/11/DPL/1DE/2A	5.9	6.1
			18/11/DPL/1DE/2B	6.1	
			18/11/DPL/1DE/2C	6.3	
	B8188 BW1/U14/A	14 (±1) DAA / U	18/11/DPL/1DE/3A	< LOD	< LOD
			18/11/DPL/1DE/3B	< LOD	
			18/11/DPL/1DE/3C	< LOD	
	B8188 BW1/T14/A	14 (±1) DAA / T	18/11/DPL/1DE/4A	0.74	0.75
			18/11/DPL/1DE/4B	0.74	
			18/11/DPL/1DE/4C	0.75	
Oilseed rape (seeds)	B8188 BW1/U21/A	21 (±2) DAA / U	18/11/DPL/1DE/5A	< LOD	< LOD
			18/11/DPL/1DE/5B	< LOD	
			18/11/DPL/1DE/5C	< LOD	
	B8188 BW1/T21/A	21 (±2) DAA / T	18/11/DPL/1DE/6A	0.039	0.036
			18/11/DPL/1DE/6B	0.036	
			18/11/DPL/1DE/6C	0.033	

LOD (limit of detection) – 0.002 mg/kg for Oilseed rape (pods and seeds)
LOQ (limit of quantification) – 0.01 mg/kg

CONCLUSIONS

The method was shown to be highly selective, as it includes two parent-daughter ion transitions for Azoxystrobin and it yields accurate and repeatable results. The limit of quantification (LOQ) was established at 0.01 mg/kg for all analytes, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for Oilseed rape (pods and seeds).

It is concluded that method fulfils the requirements as defined in EC Guidance document on residue analytical methods (SANCO/3029/99, rev. 4 and SANCO/825/00, rev. 8.1.) and is, applicable as enforcement and data generation method for determination of Azoxystrobin in Oilseed rape after application of AZOXYSTROBIN 250 SE.

A 2.2.3.4 Study 4

Comments of zRMS:	The study is accepted, however is should be noted that formulation in the study is SE while in the proposed GAP SC. The Applicant has provided bridging studies showing that the residue levels will not be higher when used in the formulation proposed in the GAP for CHR/F/PROTAZO 375 SC.

Reference:	KCP 6.3/16
Report	Generation of Field Specimens for the determination of Azoxystrobin Residues in Oilseed Rape Following Foliar application with AZOXYSTROBIN 250 SE under Field Conditions in Poland in 2018, C. Ertus, Study Code: B9187

Guideline(s): Regulation (EC) No 1107/2009

Deviations: No

GLP: Yes

Acceptability: Yes

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address): ANADIAG - 16 rue Ampère, 67500 Haguenau, France
Producer of commercial product: PUH Chemirol sp. z.o.o.
Pesticide (s) (common name (s)): azoxystrobin
CCPR No (s).
Trade name(s): **AZOXYSTROBIN 250 SE**
Main uses e.g. insecticide, fungicide: Insecticide

Page: 1/1
Country: Northern Europe

Use Pattern

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Crop and/or situation	F, G or I	Pest or group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
			Type	Conc. of a.s.	Method kind	growth stage & season	number min-max	interval between applications (days)	g a.s./ha (max)	water L/ha	g a.s./hL (max)		
(a)	(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)	(min)				(l)	(m)
Oilseed rape	F	Biting and sucking insects	SE Suspo-emulsion	250 g/L	Medium volume spraying Overall spraying	-	1	-	250	300	83.3	35	-

Remarks:
(a) For crops, the EU and Codex Classification (both) should be used; where relevant, the use situation should be described (e.g. fumigation of the structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soilborn insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, etc.
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI = Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

The objective of the study was to generate specimens of oilseed rape raw agricultural commodity after one foliar application of the formulated product AZOXYSTROBIN 250 SE (250 g azoxystrobin /L) at the rate of 1 L/ha.
The following pattern was designed for the treatments and the samplings:

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	**AZOXYSTROBIN 250 SE**	T1	35 (±3) DBH	1 L/ha	250 g/ha	300 L/ha (±10%)

DBH: Days before harvest

1.1.2 Location of the trial

The trial was performed on soil type and under cultural practices typical for oilseed rape production and on typical cultivar of the regional commercial production.

Trial No.	Principal Investigator	Crop	Type of trial	European area	Region, country
B8187 PL1	Krzysztof NOWAK	Oilseed rape	DC	North	Lodzkie, Poland

DC: Decline curve

Location

1 Trial B8187 PL1

1.2.2 Crop and soil Information

Trial No.	Crop	Variety	Sowing density	Sowing date	Soil type	pH	Organic matter (%)
B8187 PL1	Oilseed rape	Visby	3.2 kg/ha	28/08/2017	Sandy clay	6.5	1.5

1.2.4 Sampling of specimens

The samplings were carried out according to ANADIAG SOPs and to the specifications of the study plan).

Trial No	Sampling	Actual Date	Actual DAA	Actual Growth Stage (BBCH)
B8187 PL1	1	08/06/2018	0	75-76
	2	21/06/2018	13	81-82
	3	28/06/2018	20	82-83
	4	04/07/2018	26	85-86
	5	09/07/2018	31*	89

DAA: Days after application

*See deviation No.180709

Reference:	KCP 6.3/10
Report	DETERMINATION OF AZOXYSTROBIN IN OILSEED RAPE AFTER APPLICATION OF AZOXYSTROBIN 250 SE IN POLAND - 2018, J. Kicińska, Study Code: ZBBZ-2018/11/DPL/1PL
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of this study was to determine the decline and the magnitude of residues Azoxystrobin in Oilseed rape (pods and seeds) samples taken from the field trial, after applications of AZOXYSTROBIN 250 SE, under open field conditions. To achieve the objective, appropriate analytical method for determination of Azoxystrobin was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2018/11/DPL/1. The validated limit of quantification is 0.01 mg/kg.

EXPERIMENTAL SECTION

Test system, Specimen Origin, Preparation and Storage

The samples were delivered from field study conducted by ANADIAG France 16 rue Ampère, 67500 HAGUENAU – France

Field study title: Generation of field specimens for the determination of Azoxystrobin Residues in Oilseed Rape Following Foliar application with AZOXYSTROBIN 250 SE under Field Condition in Poland - 2018

Field study number for Oilseed rape: B8187

Untreated and treated specimens from field trial were supplied by and under Sponsor responsibility. Provided samples were thoroughly homogenized in a knife mill with dry ice. Each of the processed sample was divided into four subsamples (three analytical and one archival) and was transferred to polyethylene bags. Sub-samples were stored at the temperature ≤ -18 °C in the dark (allowing the dry ice to sublime) until extraction. Final specimen extracts were stored at 5 ± 4 °C in the dark until analysis. The extracts were analyzed within 24 hours and were not frozen.

Crop (matrix)	GLP sample code	Sample description	Sampling date	Lab. Sample ID
Oilseed rape (pods)	B8187 PL1/U0/A	Untreated	0 DAA* / U	18/11/DPL/1PL/1
	B8187 PL1/T0/A	Treated (AZOXYSTROBIN 250 SE)	0 DAA / T	18/11/DPL/1PL/2
	B8187 PL1/U14/A	Untreated	14 (±1) DAA / U	18/11/DPL/1PL/3
	B8187 PL1/T14/A	Treated (AZOXYSTROBIN 250 SE)	14 (±1) DAA / T	18/11/DPL/1PL/4
	B8187 PL1/U21/A	Untreated	21 (±2) DAA / U	18/11/DPL/1PL/5
	B8187 PL1/T21/A	Treated (AZOXYSTROBIN 250 SE)	21 (±2) DAA / T	18/11/DPL/1PL/6
Oilseed rape (seeds)	B8187 PL1/U28/A	Untreated	28 (±2) DAA / U	18/11/DPL/1PL/7
	B8187 PL1/T28/A	Treated (AZOXYSTROBIN 250 SE)	28 (±2) DAA / T	18/11/DPL/1PL/8
Oilseed rape (seeds)	B8187 PL1/U35/A	Untreated	35 (±3) DAA, NCH** / U	18/11/DPL/1PL/9
	B8187 PL1/T35/A	Treated (AZOXYSTROBIN 250 SE)	35 (±3) DAA, NCH / T	18/11/DPL/1PL/10

Additional sample information

Lab. Sample ID	Date of reception	Date of extraction	Date of GC-MS/MS analyses
18/11/DPL/1PL/1	24.07.2018	09.11.2018	10.11.2018
18/11/DPL/1PL/2	24.07.2018	08.11.2018	08.11.2018
18/11/DPL/1PL/3	24.07.2018	09.11.2018	10.11.2018
18/11/DPL/1PL/4	24.07.2018	08.11.2018	08.11.2018
18/11/DPL/1PL/5	24.07.2018	09.11.2018	10.11.2018
18/11/DPL/1PL/6	24.07.2018	08.11.2018	08.11.2018
18/11/DPL/1PL/7	24.07.2018	09.11.2018	10.11.2018
18/11/DPL/1PL/8	24.07.2018	08.11.2018	08.11.2018
18/11/DPL/1PL/9	24.07.2018	13.11.2018	13.11.2018
18/11/DPL/1PL/10	24.07.2018	13.11.2018	14.11.2018

Stability of Analytes in Standard Solutions

Working solutions used for preparation calibration samples were stored in refrigerator at 5 ± 4°C during study. At the end of experimental phase, the solution used for preparation calibration level at LOQ was reanalysed by thrice injection and compared to freshly prepared. One (1) ion mass transition was used for evaluation and the other ion mass transition was monitored for confirmation purpose only.

Difference between stored and newly prepared solution is < 10%. The results indicated that Azoxystrobin working solutions prepared in acetonitrile were stable during study under refrigerated conditions.

Calibration Level (µg/mL)	Date of preparation (dd.mm.yy)	Working solution ID	Relative peak area	RSD (%)	Difference (%)
Azoxystrobin Ion Mass Transition 344.0→172.0 (Quantification)					
0.005 (LOQ)	06.11.2018	1S1W7	18168/19095/17888/18439/17243	3.8	3.0
	13.11.2018	1S1W12	19014/17532/17635/17006/16999	4.7	

DETAILED RESULTS FROM FIELD TRIALS

Following table presents detailed results of Azoxystrobin residues analyses in Oilseed rape (pods and seeds).

Variant	GLP Sample code	Sampling data	Lab. Sample ID	Azoxystrobin	
				Residues [mg/kg]	Mean Residues [mg/kg]
Oilseed rape (pods)	B8187 PL1/U0/A	0 DAA* / U	18/11/DPL/1PL/1A	< LOD	< LOD
			18/11/DPL/1PL/1B	< LOD	
			18/11/DPL/1PL/1C	< LOD	
	B8187 PL1/T0/A	0 DAA / T	18/11/DPL/1PL/2A	9.9	9.3
			18/11/DPL/1PL/2B	9.9	
			18/11/DPL/1PL/2C	8.1	
	B8187 PL1/U14/A	14 (±1) DAA / U	18/11/DPL/1PL/3A	< LOD	< LOD
			18/11/DPL/1PL/3B	< LOD	
			18/11/DPL/1PL/3C	< LOD	
	B8187 PL1/T14/A	14 (±1) DAA / T	18/11/DPL/1PL/4A	4.7	4.7
			18/11/DPL/1PL/4B	5.0	
			18/11/DPL/1PL/4C	4.6	
	B8187 PL1/U21/A	21 (±2) DAA / U	18/11/DPL/1PL/5A	< LOD	< LOD
			18/11/DPL/1PL/5B	< LOD	
			18/11/DPL/1PL/5C	< LOD	
	B8187 PL1/T21/A	21 (±2) DAA / T	18/11/DPL/1PL/6A	1.5	1.4
			18/11/DPL/1PL/6B	1.4	
			18/11/DPL/1PL/6C	1.4	
	B8187 PL1/U28/A	28 (±2) DAA / U	18/11/DPL/1PL/7A	< LOD	< LOD
			18/11/DPL/1PL/7B	< LOD	
			18/11/DPL/1PL/7C	< LOD	
	B8187 PL1/T28/A	28 (±2) DAA / T	18/11/DPL/1PL/8A	1.7	1.7
			18/11/DPL/1PL/8B	1.6	
			18/11/DPL/1PL/8C	1.7	

LOD (limit of detection) – 0.002 mg/kg for Oilseed rape (pods and seeds)
LOQ (limit of quantification) – 0.01 mg/kg

Variant	GLP Sample code	Sampling data	Lab. Sample ID	Azoxystrobin	
				Residues [mg/kg]	Mean Residues [mg/kg]
Oilseed rape (seeds)	B8187 PL1/U35/A	35 (±3) DAA, NCH** / U	18/11/DPL/1PL/9A	< LOD	< LOD
			18/11/DPL/1PL/9B	< LOD	
			18/11/DPL/1PL/9C	< LOD	
	B8187 PL1/T35/A	35 (±3) DAA, NCH / T	18/11/DPL/1PL/10A	0.044	0.042
			18/11/DPL/1PL/10B	0.039	
			18/11/DPL/1PL/10C	0.042	

LOD (limit of detection) – 0.002 mg/kg for Oilseed rape (pods and seeds)
LOQ (limit of quantification) – 0.01 mg/kg

CONCLUSIONS

The method was shown to be highly selective, as it includes two parent-daughter ion transitions for Azoxystrobin and it yields accurate and repeatable results. The limit of quantification (LOQ) was

established at 0.01 mg/kg for all analytes, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for Oilseed rape (pods and seeds).

It is concluded that method fulfils the requirements as defined in EC Guidance document on residue analytical methods (SANCO/3029/99, rev. 4 and SANCO/825/00, rev. 8.1.) and is, applicable as enforcement and data generation method for determination of Azoxystrobin in Oilseed rape after application of AZOXYSTROBIN 250 SE.

A 2.2.3.5 Study 5

Comments of zRMS:	The study is accepted, however is should be noted that formulation in the study is SE while in the proposed GAP SC. The Applicant has provided bridging studies showing that the residue levels will not be higher when used in the formulation proposed in the GAP for CHR/F/PROTAZO 375 SC.

Reference:	KCP 6.3/18
Report	Generation of Field Specimens for the determination of Azoxystrobin Residues in Oilseed Rape Following Foliar application with AZOXYSTROBIN 250 SE under Field Conditions in Northern France in 2018, C. Ertus, Study Code: B8190
Guideline(s):	Regulation (EC) No 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address): ANADIAG - 16 rue Ampère, 67500 Haguenau, France
Producer of commercial product: PUH Chemirol sp. z.o.o.
Pesticide (s) (common name (s)): azoxystrobin
CCPR No (s).
Trade name(s): **AZOXYSTROBIN 250 SE**
Main uses e.g. insecticide, fungicide: Fungicide

Page: 1/1
Country: Northern Europe

Use Pattern

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Crop and/or situation	F, G or I	Pest or group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
			Type	Conc. of a.s.	Method kind	growth stage & season	number min-max	interval between applications (days)	g a.s./ha (max)	water L/ha	g a.s./hL (max)		
(a)	(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)	(min)				(l)	(m)
Oilseed rape	F	Foliar fungi	SE Suspo-emulsion	250 g/L	Medium volume spraying Overall spraying	-	1	-	250	300	83.3	35	-

Remarks:
(a) For crops, the EU and Codex Classification (both) should be used; where relevant, the use situation should be described (e.g. fumigation of the structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soilborn insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, etc.
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI = Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

The objective of the study was to generate specimens of oilseed rape raw agricultural commodity after one foliar application of the formulated product AZOXYSTROBIN 250 SE (250 g azoxystrobin /L) at the rate of 1 L/ha.
The following pattern was designed for the treatments and the samplings:

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	**AZOXYSTROBIN 250 SE**	T1	35 (±3) DBH	1 L/ha	250 g/ha	300 L/ha (±10%)

DBH: Days before harvest

1.1.2 Location of the trial

The trial was performed on soil type and under cultural practices typical for oilseed rape production and on typical cultivar of the regional commercial production.

Trial No.	Principal Investigator	Crop	Type of trial	European area	Region, country
B8190 MA1	Benoît BOYETTE	Oilseed rape	DC	North	Grand-Est, France

DC: Decline curve

Location

1 Trial B8190 MA1

1.2.2 Crop and soil Information

Trial No.	Crop	Variety	Sowing density	Sowing date	Soil type	pH	Organic matter (%)
B8190 MA1	Oilseed rape	Dariot	1.5 – 2.0 kg/ha	20/08/2017	Clay	8	3

1.2.4 Sampling of specimens

The samplings were carried out according to ANADIAG SOPs and to the specifications of the study plan).

Trial No	Sampling	Actual Date	Actual DAA	Actual Growth Stage (BBCH)
B8190 MA1	1	31/05/2018	0	69-71
	2	14/06/2018	14	75
	3	22/06/2018	22	75-85
	4	26/06/2018	26	81-87
	5	02/07/2018	32	89

DAA: Days after application

Reference:	KCP 6.3/11
Report	DETERMINATION OF AZOXYSTROBIN IN OILSEED RAPE AFTER APPLICATION OF AZOXYSTROBIN 250 SE IN NORTHERN FRANCE - 2018, J. Kicińska, Study Code: ZBBZ-2018/11/DPL/1FR2
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of this study was to determine the decline and the magnitude of residues Azoxystrobin in Oilseed rape (pods and seeds) samples taken from the field trial, after applications of AZOXYSTROBIN 250 SE, under open field conditions. To achieve the objective, appropriate analytical method for determination of Azoxystrobin was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2018/11/DPL/1. The validated limit of quantification is 0.01 mg/kg.

EXPERIMENTAL SECTION

Test system, Specimen Origin, Preparation and Storage

The samples were delivered from field study conducted by ANADIAG France 16 rue Ampère, 67500 HAGUENAU – France

Field study title: Generation of field specimens for the determination of Azoxystrobin Residues in Oilseed Rape Following Foliar application with AZOXYSTROBIN 250 SE under Field Condition in Northern France - 2018

Field study number for Oilseed rape: B8190

Untreated and treated specimens from field trial were supplied by and under Sponsor responsibility. Provided samples were thoroughly homogenized in a knife mill with dry ice. Each of the processed sample was divided into four subsamples (three analytical and one archival) and was transferred to polyethylene bags. Sub-samples were stored at the temperature ≤ -18 °C in the dark (allowing the dry ice to sublime) until extraction. Final specimen extracts were stored at 5 ± 4 °C in the dark until analysis. The extracts were analysed within 24 hours and were not frozen. If the sequence is longer than 24 hours, the confirmation of stability of analyte in samples is to use SST (suitability system test). The use of injections of standards at LOQ level in triplicate at the beginning and at the end of the sequence to insure integrity of the analytical sequence sufficiently demonstrate the stability of analyte in the final dilution.

Crop (matrix)	GLP sample code	Sample description	Sampling date	Lab. Sample ID
Oilseed rape (pods)	B8190 MA1/U0/A	Untreated	0 DAA* / U	18/11/DPL/1FR2/1
	B8190 MA1/T0/A	Treated (AZOXYSTROBIN 250 SE)	0 DAA / T	18/11/DPL/1FR2/2
	B8190 MA1/U14/A	Untreated	14 (±1) DAA / U	18/11/DPL/1FR2/3
	B8190 MA1/T14/A	Treated (AZOXYSTROBIN 250 SE)	14 (±1) DAA / T	18/11/DPL/1FR2/4
	B8190 MA1/U21/A	Untreated	21 (±2) DAA / U	18/11/DPL/1FR2/5
	B8190 MA1/T21/A	Treated (AZOXYSTROBIN 250 SE)	21 (±2) DAA / T	18/11/DPL/1FR2/6
Oilseed rape (seeds)	B8190 MA1/U28/A	Untreated	28 (±2) DAA / U	18/11/DPL/1FR2/7
	B8190 MA1/T28/A	Treated (AZOXYSTROBIN 250 SE)	28 (±2) DAA / T	18/11/DPL/1FR2/8
Oilseed rape (seeds)	B8190 MA1/U35/A	Untreated	35 (±3) DAA, NCH / U	18/11/DPL/1FR2/9
	B8190 MA1/T35/A	Treated (AZOXYSTROBIN 250 SE)	35 (±3) DAA, NCH / T	18/11/DPL/1FR2/10

Additional sample information

Lab. Sample ID	Date of reception	Date of extraction	Date of GC-MS/MS analyses
18/11/DPL/1FR2/1	24.07.2018	09.11.2018	11.11.2018
18/11/DPL/1FR2/2	24.07.2018	08.11.2018	09.11.2018
18/11/DPL/1FR2/3	24.07.2018	09.11.2018	11.11.2018
18/11/DPL/1FR2/4	24.07.2018	08.11.2018	09.11.2018
18/11/DPL/1FR2/5	24.07.2018	09.11.2018	11.11.2018
18/11/DPL/1FR2/6	24.07.2018	08.11.2018	09.11.2018
18/11/DPL/1FR2/7	24.07.2018	09.11.2018	11.11.2018
18/11/DPL/1FR2/8	24.07.2018	08.11.2018	09.11.2018
18/11/DPL/1FR2/9	24.07.2018	13.11.2018	14.11.2018
18/11/DPL/1FR2/10	24.07.2018	13.11.2018	14.11.2018

Stability of Analytes in Standard Solutions

Working solutions used for preparation calibration samples were stored in refrigerator at 5 ± 4°C during study. At the end of experimental phase, the solution used for preparation calibration level at LOQ was reanalysed by thrice injection and compared to freshly prepared. One (1) ion mass transition was used for evaluation and the other ion mass transition was monitored for confirmation purpose only. Difference between stored and newly prepared solution is < 10%. The results indicated that Azoxystrobin working solutions prepared in acetonitrile were stable during study under refrigerated conditions.

Calibration Level (µg/mL)	Date of preparation (dd.mm.yy)	Working solution ID	Relative peak area	RSD (%)	Difference (%)
Azoxystrobin Ion Mass Transition 344.0→172.0 (Quantification)					
0.005 (LOQ)	06.11.2018	1S1W7	18168/19095/17888/18439/17243	3.8	3.0
	13.11.2018	1S1W12	19014/17532/17635/17006/16999	4.7	

DETAILED RESULTS FROM FIELD TRIALS

Following table presents detailed results of Azoxystrobin residues analyses in Oilseed rape (pods and seeds).

Variant	GLP Sample code	Sampling data	Lab. Sample ID	Azoxystrobin	
				Residues [mg/kg]	Mean Residues [mg/kg]
Oilseed rape (pods)	B8190 MA1/U0/A	0 DAA* / U	18/11/DPL/1FR2/1A	< LOD	< LOD
			18/11/DPL/1FR2/1B	< LOD	
			18/11/DPL/1FR2/1C	< LOD	
	B8190 MA1/T0/A	0 DAA / T	18/11/DPL/1FR2/2A	6.9	7.0
			18/11/DPL/1FR2/2B	7.4	
			18/11/DPL/1FR2/2C	6.8	
	B8190 MA1/U14/A	14 (±1) DAA / U	18/11/DPL/1FR2/3A	< LOD	< LOD
			18/11/DPL/1FR2/3B	< LOD	
			18/11/DPL/1FR2/3C	< LOD	
	B8190 MA1/T14/A	14 (±1) DAA / T	18/11/DPL/1FR2/4A	0.50	0.50
			18/11/DPL/1FR2/4B	0.50	
			18/11/DPL/1FR2/4C	0.51	
	B8190 MA1/U21/A	21 (±2) DAA / U	18/11/DPL/1FR2/5A	< LOD	< LOD
			18/11/DPL/1FR2/5B	< LOD	
			18/11/DPL/1FR2/5C	< LOD	
	B8190 MA1/T21/A	21 (±2) DAA / T	18/11/DPL/1FR2/6A	0.32	0.34
			18/11/DPL/1FR2/6B	0.34	
			18/11/DPL/1FR2/6C	0.34	
	B8190 MA1/U28/A	28 (±2) DAA / U	18/11/DPL/1FR2/7A	< LOD	< LOD
			18/11/DPL/1FR2/7B	< LOD	
			18/11/DPL/1FR2/7C	< LOD	
	B8190 MA1/T28/A	28 (±2) DAA / T	18/11/DPL/1FR2/8A	0.29	0.29
			18/11/DPL/1FR2/8B	0.30	
			18/11/DPL/1FR2/8C	0.29	

LOD (limit of detection) – 0.002 mg/kg for Oilseed rape (pods and seeds)
LOQ (limit of quantification) – 0.01 mg/kg

Variant	GLP Sample code	Sampling data	Lab. Sample ID	Azoxystrobin	
				Residues [mg/kg]	Mean Residues [mg/kg]
Oilseed rape (seeds)	B8190 MA1/U35/A	35 (±3) DAA, NCH** / U	18/11/DPL/1FR2/9A	< LOD	< LOD
			18/11/DPL/1FR2/9B	< LOD	
			18/11/DPL/1FR2/9C	< LOD	
	B8190 MA1/T35/A	35 (±3) DAA, NCH / T	18/11/DPL/1FR2/10A	0.051	0.046
			18/11/DPL/1FR2/10B	0.045	
			18/11/DPL/1FR2/10C	0.043	

LOD (limit of detection) – 0.002 mg/kg for Oilseed rape (pods and seeds)
LOQ (limit of quantification) – 0.01 mg/kg

CONCLUSIONS

The method was shown to be highly selective, as it includes two parent-daughter ion transitions for Azoxystrobin and it yields accurate and repeatable results. The limit of quantification (LOQ) was established at 0.01 mg/kg for all analytes, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for Oilseed rape (pods and seeds).

It is concluded that method fulfils the requirements as defined in EC Guidance document on residue analytical methods (SANCO/3029/99, rev. 4 and SANCO/825/00, rev. 8.1.) and is, applicable as enforcement and data generation method for determination of Azoxystrobin in Oilseed rape after application of AZOXYSTROBIN 250 SE.

A 2.2.3.6 Study 6

Comments of zRMS:	The study is accepted, however is should be noted that formulation in the study is SE while in the proposed GAP SC. The Applicant has provided bridging studies showing that the residue levels will not be higher when used in the formulation proposed in the GAP for CHR/F/PROTAZO 375 SC.

Reference:	KCP 6.3/14
Report	Generation of field specimens for the determination of Azoxystrobin residues in Oilseed rape following foliar application with AZOXYSTROBIN 250 SE under field Conditions in Hungary in 2018, C. Ertus, Study Code: B8178
Guideline(s):	Regulation (EC) No 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address): ANADIAG - 16 rue Ampère, 67500 Haguenau, France
Producer of commercial product: PUH Chemirol sp. z.o.o.
Pesticide (s) (common name (s)): azoxystrobin
CCPR No (s).
Trade name(s): **AZOXYSTROBIN 250 SE**
Main uses e.g. insecticide, fungicide: Fungicide

Page: 1/1
Country: Northern Europe

Use Pattern

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Crop and/or situation	F, G or I	Pest or group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
			Type	Conc. of a.s.	Method kind	growth stage & season	number min-max	Interval between applications (days)	g a.s./ha (max)	water L/ha	g a.s./hL (max)		
(a)	(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)	(min)				(l)	(m)
Oilseed rape	F	Foliar fungi	SE Suspo-emulsion	250 g/L	Medium volume spraying Overall spraying	-	1	-	250	300	83.3	35	-

Remarks:
(a) For crops, the EU and Codex Classification (both) should be used; where relevant, the use situation should be described (e.g. fumigation of the structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soilborn insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, etc.
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI = Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

The objective of the study was to generate specimens of oilseed rape raw agricultural commodity after one foliar application of the formulated product AZOXYSTROBIN 250 SE (250 g azoxystrobin /L) at the rate of 1 L/ha.
The following pattern was designed for the treatments and the samplings:

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	**AZOXYSTROBIN 250 SE**	T1	35 (±3) DBH	1 L/ha	250 g/ha	300 L/ha (±10%)

DBH: Days before harvest

1.1.2 Location of the trial

The trial was performed on soil type and under cultural practices typical for oilseed rape production and

on typical cultivar of the regional commercial production.

Trial No.	Principal Investigator	Crop	Type of trial	European area	Region, country
B8178 HU1	Mónika PETUS	Oilseed rape	DC	North	Central Transdanubia, Hungary

DC: Decline curve

Location

1 Trial B8178 HU1

1.2.2 Crop and soil Information

Trial No.	Crop	Variety	Sowing density	Sowing date	Soil type	pH	Organic matter (%)
B8178 HU1	Oilseed rape	GK Reka	5.0 kg/ha	18/08/2017	Clay loam	8.2	2.7

1.2.4 Sampling of specimens

The samplings were carried out according to ANADIAG SOPs and to the specifications of the study plan).

Trial No	Sampling	Actual Date	Actual DAA	Actual Growth Stage (BBCH)
B8178 HU1	1	22/05/2018	0	75
	2	04/06/2018	13	77
	3	12/06/2018	21	80-81
	4	19/06/2018	28	87
	5	26/06/2018	35	89

DAA: Days after application

Reference:	KCP 6.3/12
Report	DETERMINATION OF AZOXYSTROBIN IN OILSEED RAPE AFTER APPLICATION OF AZOXYSTROBIN 250 SE IN HUNGARY - 2018, J. Kicińska, Study Code: ZBBZ-2018/11/DPL/1HU
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of this study was to determine the decline and the magnitude of residues Azoxystrobin in Oilseed rape (pods and seeds) samples taken from the field trial, after applications of AZOXYSTROBIN 250 SE, under open field conditions. To achieve the objective, appropriate analytical method for determination of Azoxystrobin was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2018/11/DPL/1. The validated limit of quantification is 0.01 mg/kg.

EXPERIMENTAL SECTION

Test system, Specimen Origin, Preparation and Storage

The samples were delivered from field study conducted by ANADIAG France 16 rue Ampère, 67500 HAGUENAU – France

Field study title: Generation of field specimens for the determination of Azoxystrobin Residues in Oilseed Rape Following Foliar application with AZOXYSTROBIN 250 SE under Field Condition in Hungary - 2018Field study number for Oilseed rape: B8178

Untreated and treated specimens from field trial were supplied by and under Sponsor responsibility. Provided samples were thoroughly homogenized in a knife mill with dry ice. Each of the processed sample was divided into four subsamples (three analytical and one archival) and was transferred to polyethylene bags. Sub-samples were stored at the temperature ≤ -18 °C in the dark (allowing the dry ice to sublime) until extraction. Final specimen extracts were stored at 5 ± 4 °C in the dark until analysis. The extracts were analyzed within 24 hours and were not frozen.

Crop (matrix)	GLP sample code	Sample description	Sampling date	Lab. Sample ID
Oilseed rape (pods)	B8178 HU1/U0/A	Untreated	0 DAA* / U	18/11/DPL/1HU/1
	B8178 HU1/T0/A	Treated (AZOXYSTROBIN 250 SE)	0 DAA / T	18/11/DPL/1HU/2
	B8178 HU1/U14/A	Untreated	14 (±1) DAA / U	18/11/DPL/1HU/3
	B8178 HU1/T14/A	Treated (AZOXYSTROBIN 250 SE)	14 (±1) DAA / T	18/11/DPL/1HU/4
	B8178 HU1/U21/A	Untreated	21 (±2) DAA / U	18/11/DPL/1HU/5
	B8178 HU1/T21/A	Treated (AZOXYSTROBIN 250 SE)	21 (±2) DAA / T	18/11/DPL/1HU/6
Oilseed rape (seeds)	B8178 HU1/U28/A	Untreated	28 (±2) DAA / U	18/11/DPL/1HU/7
	B8178 HU1/T28/A	Treated (AZOXYSTROBIN 250 SE)	28 (±2) DAA / T	18/11/DPL/1HU/8
Oilseed rape (seeds)	B8178 HU1/U35/A	Untreated	35 (±3) DAA, NCH** / U	18/11/DPL/1HU/9
	B8178 HU1/T35/A	Treated (AZOXYSTROBIN 250 SE)	35 (±3) DAA, NCH / T	18/11/DPL/1HU/10

Additional sample information

Lab. Sample ID	Date of reception	Date of extraction	Date of GC-MS/MS analyses
18/11/DPL/1HU/1	24.07.2018	09.11.2018	10.11.2018
18/11/DPL/1HU/2	24.07.2018	08.11.2018	09.11.2018
18/11/DPL/1HU/3	24.07.2018	09.11.2018	10.11.2018
18/11/DPL/1HU/4	24.07.2018	08.11.2018	09.11.2018
18/11/DPL/1HU/5	24.07.2018	09.11.2018	10.11.2018
18/11/DPL/1HU/6	24.07.2018	08.11.2018	09.11.2018
18/11/DPL/1HU/7	24.07.2018	13.11.2018	13.11.2018
18/11/DPL/1HU/8	24.07.2018	13.11.2018	14.11.2018
18/11/DPL/1HU/9	24.07.2018	13.11.2018	14.11.2018
18/11/DPL/1HU/10	24.07.2018	13.11.2018	14.11.2018

Stability of Analytes in Standard Solutions

Working solutions used for preparation calibration samples were stored in refrigerator at 5 ± 4°C during study. At the end of experimental phase, the solution used for preparation calibration level at LOQ was reanalysed by thrice injection and compared to freshly prepared. One (1) ion mass transition was used for evaluation and the other ion mass transition was monitored for confirmation purpose only. Difference between stored and newly prepared solution is < 10%. The results indicated that Azoxystrobin working solutions prepared in acetonitrile were stable during study under refrigerated conditions..

Calibration Level (µg/mL)	Date of preparation (dd.mm.yy)	Working solution ID	Relative peak area	RSD (%)	Difference (%)
Azoxystrobin Ion Mass Transition 344.0→172.0 (Quantification)					
0.005 (LOQ)	06.11.2018	1S1W7	18168/19095/17888/18439/17243	3.8	3.0
	13.11.2018	1S1W12	19014/17532/17635/17006/16999	4.7	

DETAILED RESULTS FROM FIELD TRIALS

Following table presents detailed results of Azoxystrobin residues analyses in Oilseed rape (pods and seeds).

Variant	GLP Sample code	Sampling data	Lab. Sample ID	Azoxystrobin	
				Residues [mg/kg]	Mean Residues [mg/kg]
Oilseed rape (pods)	B8178 HU1/U0/A	0 DAA* / U	18/11/DPL/1HU/1A	< LOD	< LOD
			18/11/DPL/1HU/1B	< LOD	
			18/11/DPL/1HU/1C	< LOD	
	B8178 HU1/T0/A	0 DAA / T	18/11/DPL/1HU/2A	8.0	8.2
			18/11/DPL/1HU/2B	8.6	
			18/11/DPL/1HU/2C	8.1	
	B8178 HU1/U14/A	14 (±1) DAA / U	18/11/DPL/1HU/3A	< LOD	< LOD
			18/11/DPL/1HU/3B	< LOD	
			18/11/DPL/1HU/3C	< LOD	
	B8178 HU1/T14/A	14 (±1) DAA / T	18/11/DPL/1HU/4A	1.1	1.1
			18/11/DPL/1HU/4B	1.1	
			18/11/DPL/1HU/4C	0.99	
	B8178 HU1/U21/A	21 (±2) DAA / U	18/11/DPL/1HU/5A	< LOD	< LOD
			18/11/DPL/1HU/5B	< LOD	
			18/11/DPL/1HU/5C	< LOD	
	B8178 HU1/T21/A	21 (±2) DAA / T	18/11/DPL/1HU/6A	0.39	0.38
			18/11/DPL/1HU/6B	0.35	
			18/11/DPL/1HU/6C	0.40	
Oilseed rape (seeds)	B8178 HU1/U28/A	28 (±2) DAA / U	18/11/DPL/1HU/7A	< LOD	< LOD
			18/11/DPL/1HU/7B	< LOD	
			18/11/DPL/1HU/7C	< LOD	
	B8178 HU1/T28/A	28 (±2) DAA / T	18/11/DPL/1HU/8A	0.071	0.069
			18/11/DPL/1HU/8B	0.067	
			18/11/DPL/1HU/8C	0.069	

LOD (limit of detection) – 0.002 mg/kg for Oilseed rape (pods and seeds)
LOQ (limit of quantification) – 0.01 mg/kg

Variant	GLP Sample code	Sampling data	Lab. Sample ID	Azoxystrobin	
				Residues [mg/kg]	Mean Residues [mg/kg]
Oilseed rape (seeds)	B8178 HU1/U35/A	35 (±3) DAA, NCH** / U	18/11/DPL/1HU/9A	< LOD	< LOD
			18/11/DPL/1HU/9B	< LOD	
			18/11/DPL/1HU/9C	< LOD	
	B8178 HU1/T35/A	35 (±3) DAA, NCH / T	18/11/DPL/1HU/10A	0.028	0.026
			18/11/DPL/1HU/10B	0.026	
			18/11/DPL/1HU/10C	0.024	

LOD (limit of detection) – 0.002 mg/kg for Oilseed rape (pods and seeds)
LOQ (limit of quantification) – 0.01 mg/kg

CONCLUSIONS

The method was shown to be highly selective, as it includes two parent-daughter ion transitions for Azoxystrobin and it yields accurate and repeatable results. The limit of quantification (LOQ) was established at 0.01 mg/kg for all analytes, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for Oilseed rape (pods and seeds).

It is concluded that method fulfils the requirements as defined in EC Guidance document on residue analytical methods (SANCO/3029/99, rev. 4 and SANCO/825/00, rev. 8.1.) and is, applicable as enforcement and data generation method for determination of Azoxystrobin in Oilseed rape after application of AZOXYSTROBIN 250 SE.

A 2.2.3.7 Study 7

Comments of zRMS:	The study is accepted, however is should be noted that formulation in the study is SE while in the proposed GAP SC. The Applicant has provided bridging studies showing that the residue levels will not be higher when used in the formulation proposed in the GAP for CHR/F/PROTAZO 375 SC.

Reference:	KCP 6.3/15
Report	Generation of field specimens for the determination of Azoxystrobin residues in Oilseed rape following foliar application with AZOXYSTROBIN 250 SE under field Conditions in Czech Republic in 2019, C. Ertus, Study Code: B9215
Guideline(s):	Regulation (EC) No 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Responsible body for reporting (name, address): ANADIAG - 16 rue Ampère, 67500 Haguenau, France
Producer of commercial product: PUH Chemirol sp. z.o.o.
Pesticide (s) (common name (s)): azoxystrobin
CCPR No (s).
Trade name(s): **AZOXYSTROBIN 250 SE**
Main uses e.g. insecticide, fungicide: Fungicide

Page: 1/1
Country: Northern Europe

Use Pattern

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Crop and/or situation	F, G or I	Pest or group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
			Type	Conc. of a.s.	Method kind	growth stage & season	number min-max	interval between applications (days)	g a.s./ha (max)	water L/ha	g a.s./hL (max)		
(a)	(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)	(min)				(l)	(m)
Oilseed rape	F	Foliar fungi	SE Suspo-emulsion	250 g/L	Medium volume spraying Overall spraying	= BBCH 79-81	1	-	250	300	83.3	35	-

Remarks:
(a) For crops, the EU and Codex Classification (both) should be used; where relevant, the use situation should be described (e.g. fumigation of the structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soilborn insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench, etc.
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI = Pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

The objective of the study was to generate specimens of oilseed rape raw agricultural commodity after one foliar application of the formulated product AZOXYSTROBIN 250 SE (250 g azoxystrobin /L) at the rate of 1 L/ha.
The following pattern was designed for the treatments and the samplings:

Plot	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	**AZOXYSTROBIN 250 SE**	T1	35 (±3) DBH	1 L/ha	250 g/ha	300 L/ha (±10%)

DBH: Days before harvest

1.1.2 Location of the trial

The trial was performed on soil type and under cultural practices typical for oilseed rape production and on typical cultivar of the regional commercial production.

Trial No.	Principal Investigator	Type of trial	Crop	European area	Region, Country
B9215 CZ1	Iva SIMEK	RH	Oilseed rape	North	Hradec Kralové, Czech Republic

RH: Residue at harvest

Location

1 Trial B9215 CZ1

1.2.2 Crop and soil Information

Trial No.	Crop	Variety	Sowing density	Sowing date	Soil type	pH	Organic matter (%)
B9215 CZ1	Oilseed rape	Architect	3.3 kg/ha	28/08/2018	Loam	5.3	3.1

1.2.4 Sampling of specimens

The samplings were carried out according to ANADIAG SOPs and to the specifications of the study plan).

Trial No	Sampling	Actual Date	Actual DAA	Actual Growth Stage (BBCH)
B9215 CZ1	1	30/07/2019	35	89

DAA: Days after application

Reference:	KCP 6.3/13
Report	DETERMINATION OF AZOXYSTROBIN IN OILSEED RAPE AFTER APPLICATION OF AZOXYSTROBIN 250 SE IN CZECH REPUBLIC - 2019, J. Kicińska, Study Code: 19/FSL/12/1CZ
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21-Oct-2009 concerning the placing of plant protection products on the market and repealing council Directives 79/117/EEC and 91/414/EC EU Guidance Document SANCO/3029/99 rev. 4 EU Guidance Document SANCO/825/00 rev. 8.1
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of this study was to determine the decline and the magnitude of residues Azoxystrobin in Oilseed rape (seeds) samples taken from the field trial, after applications of AZOXYSTROBIN 250 SE, under open field conditions. To achieve the objective, appropriate analytical method for determination of Azoxystrobin was validated in accordance to the guidance documents SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4 of the European Commission and to meet residue regulatory requirements. The validation data were presented in the Final Report No. ZBBZ-2018/11/DPL/1. The validated limit of quantification is 0.01 mg/kg.

EXPERIMENTAL SECTION

Test system, Specimen Origin, Preparation and Storage

The samples were delivered from field study conducted by ANADIAG SA, CZ osp, Chleny 46, 517 45 CHLENY CZECH REPUBLIC (ANADIAG France 16 rue Ampère, F-67500 HAGUENAU – France)
Field study title: Generation of field specimens for the determination of Azoxystrobin Residues in Oilseed Rape Following Foliar application with AZOXYSTROBIN 250 SE under Field Condition in Czech Republic - 2019
Field study number for Oilseed rape: B9215
Untreated and treated specimens from field trial were supplied by and under Sponsor responsibility. Provided samples were thoroughly homogenized in a knife mill with dry ice. Each of the processed sample was divided into four subsamples (three analytical and one archival) and was transferred to polyethylene bags. Sub-samples were stored at the temperature ≤ -18 °C in the dark (allowing the dry ice to sublime) until extraction. Final specimen extracts were stored at 5 ± 4 °C in the dark until analysis. The extracts were analyzed within 24 hours and were not frozen.

Crop (matrix)	GLP sample code	Sample description	Sampling date	Lab. Sample ID
Oilseed rape (seeds)	B9215 CZ1/UH/A	Untreated	35 (±3) DAA, NCH / U	19/FSL/12/1CZ/1
	B9215 CZ1/TH/A	Treated (AZOXYSTROBIN 250 SE)	35 (±3) DAA, NCH / T	19/FSL/12/1CZ/2

Additional sample information			
Lab. Sample ID	Date of reception	Date of extraction	Date of GC-MS/MS analyses
19/FSL/12/1CZ/1	01.08.2019	16.09.2019	17.09.2019
19/FSL/12/1CZ/2	01.08.2019	16.09.2019	17.09.2019

Stability of Analytes in Standard Solutions

Working solutions used for preparation calibration samples were stored in refrigerator at 5 ± 4°C during study. At the end of experimental phase, the solution used for preparation calibration level at LOQ was

reanalysed by thrice injection and compared to freshly prepared. One (1) ion mass transition was used for evaluation and the other ion mass transition was monitored for confirmation purpose only. Difference between stored and newly prepared solution is < 10%. The results indicated that Azoxystrobin working solutions prepared in acetonitrile were stable during study under refrigerated conditions.

Calibration Level (µg/mL)	Date of preparation (dd.mm.yy)	Working solution ID	Relative peak area	RSD (%)	Difference (%)
Azoxystrobin Ion Mass Transition 344.0→172.0 (Quantification)					
0.005 (LOQ)	11.09.2019	1S1W7	16529 / 15764 / 14889	5.2	-7.8
	16.09.2019	1S1W12	17622 / 18168 / 15393	8.6	

DETAILED RESULTS FROM FIELD TRIALS

Following table presents detailed results of Azoxystrobin residues analyses in Oilseed rape (seeds).

Variant	GLP Sample code	Sampling data	Lab. Sample ID	Azoxystrobin	
				Residues [mg/kg]	Mean Residues [mg/kg]
Oilseed rape (seeds)	B9215 CZ1/UH/A	35 (±3) DAA, NCH / U	19/FSL/12/1CZ/1A	< LOD	< LOD
			19/FSL/12/1CZ/1B	< LOD	
			19/FSL/12/1CZ /1C	< LOD	
	B9215 CZ1/TH/A	35 (±3) DAA, NCH / T	19/FSL/12/1CZ/2A	0.094	0.098
			19/FSL/12/1CZ/2B	0.090	
			19/FSL/12/1CZ/2C	0.11	

LOD (limit of detection) – 0.002 mg/kg for Oilseed rape (seeds)
LOQ (limit of quantification) – 0.01 mg/kg

CONCLUSIONS

The method was shown to be highly selective, as it includes two parent-daughter ion transitions for Azoxystrobin and it yields accurate and repeatable results. The limit of quantification (LOQ) was established at 0.01 mg/kg for all analytes, interfering signals in control specimen were negligible, and thus the limit of detection (LOD) is 0.002 mg/kg for Oilseed rape (seeds).
It is concluded that method fulfils the requirements as defined in EC Guidance document on residue analytical methods (SANCO/3029/99, rev. 4 and SANCO/825/00, rev. 8.1.) and is, applicable as enforcement and data generation method for determination of Azoxystrobin in Oilseed rape after application of AZOXYSTROBIN 250 SE

Comments of zRMS:	The study is accepted.

A 2.2.3.8 Study 8

Reference: KCP 6.3/21

Report: Magnitude of the residue of azoxystrobin in Oil Seed Rape (Raw Agriculture Commodity) after one application of CHR/F/AZX – one harvest trial in Poland - 2020, T. Peda, Study Code: 20SGS10

Guideline(s): Regulations (EU) 283/2013 and 284/2013 implementing Regulation (EC) 1107/2009 of the European Parliament and of the Council of 21 October

2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
Commission Working Document 7029/VI/95 Rev. 5, General Recommendations for the Design, Preparation and Realization of Residue Trials, July 22, 1997
OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009)
SANCO/825/00, rev. 8.1; 16/11/2010
SANCO/3029/99, rev. 4; 11/07/2000

Deviations:	No
GLP:	Yes
Acceptability:	Yes

One harvest study trial (HS) was established in Poland. Trial consisted of one untreated plot U and one treated plot T.
Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.
One typical for fungicide application was performed in trial with boom sprayer on the treated plots at the target dose rate of 1,0 l/ha. The reported dose rate actually ranged 0,953 l/ha.
The target spray volume was 300 litres per hectare according to Good Agricultural Practices. The reported spray volume was actually 286,0 l/ha.
Application was performed in BBCH 69 (foliar).
The spray mixture volume remaining after application was measured and the volume applied to the treated plot was calculated to verify delivery rates. The calculations and the delivery rates were verified by the Study Director.
Deviations to the target rates were all between ± 5% as requested in the study plan.
In harvest trial (HS), RAC specimens for analyses (whole plants, seeds) were collected at:
S1 - 35(±1) DALA (whole plants)
S2 – CH – Commercial harvest (seeds)
Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial sites.
Sampling dates and weights of collected specimens are presented in Table 15 – Sampling procedures and shipment of RAC specimens.
RAC specimens were put in deep freezing conditions at a target temperature of ≤ -18° C on the day of sampling, within 12 hours after sampling.
All specimens remained deep frozen during storage at the test site, during shipment to The SGS Polska Sp. z o. o. Environmental Laboratory

The following residues concentration was determined in the field samples analyzed on 16.12.2020:

Table 12 Residue concentrations of acetamiprid detected in analyzed field samples (Study No.: 20SGS10, Trial No.: 20SGS10-01 Harvest Study)

No	Timing	Study sample code	Type of commodity	Sample number given by the laboratory	Result [mg/kg]
1	S1 = 35(±1) DALA*	20SGS10-01-1	OSR (whole plant without root)	DPL/193/2020/01U	<LOD
2		20SGS10-01-2	OSR (whole plant without root)	DPL/193/2020/02T	<LOQ
3	S2 =CH*	20SGS10-01-3	OSR (seeds)	DPL/193/2020/03U	<LOD
4		20SGS10-01-4	OSR (seeds)	DPL/193/2020/04T	<LOD

*DALA – Days After Last Application. CH – Commercial Harvest

Residues are not corrected for procedural recoveries;
Calculation based on unrounded values, LOD = 0.003 mg/kg, LOQ = 0.01 mg/kg

CONCLUSION

This study was fully performed as anticipated, in accordance with the study plan and the amendments issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s). Method of determination by LC-MS fulfils the requirements as defined in EC Guidance document on residue analytical methods (SANCO/825/00, rev. 8.1. and SANCO/3029/99, rev. 4) and is applicable as enforcement and data generation method for determination of azoxystrobin in oil seed rape after one application of CHR/F/AZX. Residues of azoxystrobin were not detected (<LOD) in any of the untreated samples.

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

No new studies was performed.

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

No new studies was performed.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new studies was performed.

A 2.2.7 Other/Special Studies

No new studies was performed.

A 2.3 Both active substance – Prothioconazole and Azoxystrobin

A 2.3.1 Stability of residues

No new studies was performed.

A 2.3.2 Nature of residues in plants, livestock and processed commodities

No new studies was performed.

A 2.3.3 Magnitude of residues in plants

A 2.3.3.1 Study 1

A 2.3.4 Magnitude of residues in livestock

A 2.3.4.1 Livestock feeding studies

No new studies was performed.

A 2.3.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new studies was performed.

A 2.3.6 Magnitude of residues in representative succeeding crops

No new studies was performed.

A 2.3.7 Other/Special Studies

A 2.3.7.1 Study 1

Comments of zRMS:	The study is accepted.

Reference:	KCP 6.3/22
Report	Determination of Prothioconazole and Azoxystrobin Residues in Honey and Pollen Following Foliar application on Phacelia with CHR/F/PROTAZO 375 SC under semi field Conditions in Northern Europe in 2020, A. PERNY, Study Code: C0277
Guideline(s):	Regulation (EC) No 1107/2009

Deviations: No

GLP: Yes

Acceptability: Yes

The objective of the study was to determine the residue levels of prothioconazole , prothioconazole-desthio and azoxystrobin in honey and pollen from bees foraging on Phacelia following one foliar application at flowering stage of the formulated product CHR/F/PROTAZO 375 SC (175 g prothioconazole/L + 200 g azoxystrobin /L), under semi-field conditions.
The study consisted of 2 phases: the field phase, and the analytical phase.
The study was conducted under semi-field conditions at one site in Northern Europe

On the site, 2 tunnels covered with anti-insect nets were used: Phacelia was grown under both tunnels. At flowering of the crop one tunnel was treated once with CHR/F/PROTAZO 375 SC at the rate of 1.25 L product/ha (219 g prothioconazole/ha + 250 g azoxystrobin /ha) The second tunnel was kept untreated. One honeybee colony was installed under each tunnel and bees foraging was restricted to the tunnels. Honey and pollen were sampled (at commercial maturity), and the residue level of prothioconazole , prothioconazole-desthio and azoxystrobin analysed in the samples.

SUMMARIZED RESULTS

Residues in honey control samples were non-detectable or below the limit of quantification, except for azoxystobin residues in control honey that were above the limit of quantification. The residue results for azoxystrobin, prothioconazole and prothioconazole-desthio in the treated specimens are summarized below:

Trial No.	Matrix	Azoxystrobin residues (mg/kg) at maturity	Prothioconazole residues (mg/kg) at maturity	Prothioconazole-desthio residues (mg/kg) at maturity
C0277 PL1	Honey	< LOQ	NDR	NDR
	Pollen	12.91	6.86	1.54

DALA: Days after last application
< LOQ: Residues between LOD and LOQ
NDR: No detectable residues (residues below the limit of detection)
LOD = 0.003 mg/kg
LOQ = 0.01 mg/kg

The following pattern was designed for the treatments and the samplings:

Application details

Tunnel	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	CHR/F/PROTAZO 375 SC	T1	Full flowering	1.25 L/ha	Prothioconazole: 219 g/ha Azoxystrobin: 250 g/ha	200-400 L/ha (±10%)

Location of the trial

Trial No.	Principal Investigator	Type of trial	Crop	European area	Country, Region
C0277 PL1	Krzysztof NOWAK	Semi-field	Phacelia	North	Poland, Łodzkie

Location

1 Trial C0277 PL1

Crop and soil Information

Trial No.	Crop	Variety	Crop density (kg/ha)	Sowing / Planting date	Soil type	pH	Organic matter (%)
C0277 PL1	Phacelia	Stala	10	21/04/2020	Loamy sand	7.4	1.36

Sampling of specimens

The samplings were carried out according to ANADIAG SOPs and to the specifications of the study plan (see details for min. weight in section 1.1.1 Objective).

Sampling summary

Trial No	Sampling	Actual Date	Actual DALA	Actual Growth Stage (BBCH)

C0277 PL1	1	14/07/2020 17/07/2020 (U)	14	Commercial maturity

Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. C0277 PL1

Analytical sample No.	Field sample No.	Treatment	Matrix	DAA	Azoxystrobin residues found (mg/kg)	
C0277 01 01	C0277 PL1 / UH / A	-	Honey	-	**0.02** **0.01**	**Mean** **0.02**
C0277 01 03	C0277 PL1 / UP / A	-	Pollen	-	**NDR**	
C0277 01 02	C0277 PL1 / TH / A	CHR/F/PROTAZO 375 SC	Honey	14	**< LOQ**	
C0277 01 04	C0277 PL1 / TP / A	CHR/F/PROTAZO 375 SC	Pollen	14	**12.91**	

Analytical sample No.	Field sample No.	Treatment	Matrix	DAA	Prothioconazole residues found (mg/kg)	Prothioconazole-desthio residues found (mg/kg)
C0277 01 01	C0277 PL1 / UH / A	-	Honey	-	**NDR**	**NDR**
C0277 01 03	C0277 PL1 / UP / A	-	Pollen	-	**NDR**	**NDR**
C0277 01 02	C0277 PL1 / TH / A	CHR/F/PROTAZO 375 SC	Honey	14	**NDR**	**NDR**
C0277 01 04	C0277 PL1 / TP / A	CHR/F/PROTAZO 375 SC	Pollen	14	**6.86**	**1.54**

DAA: Days after application
< LOQ: Residues between LOD and LOQ NDR: No detectable residues (residues below the limit of detection)
LOD = 0.003 mg/kg LOQ = 0.01 mg/kg

Comments of zRMS:	The study is accepted.

A 2.3.7.2 Study 2

Reference:	KCP 6.3/25
Report	Determination of Prothioconazole and Azoxystrobin Residues in Honey and Pollen Following Foliar application on Phacelia with CHR/F/PROTAZO 375 SC under semi field Conditions in Northern Europe in 2020, A. Perny, Study Code: C0239
Guideline(s):	Regulation (EC) No. 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue levels of prothioconazole, prothioconazole-desthio and azoxystrobin in honey and pollen from bees foraging on Phacelia following one foliar application at flowering stage of the formulated product CHR/F/PROTAZO 375 SC (175 g prothioconazole/L + 200 g azoxystrobin /L), under semi-field conditions.
The study consisted of 2 phases: the field phase, and the analytical phase.
The study was conducted under semi-field conditions at one site in Northern Europe

On the site, 2 tunnels covered with anti-insect nets were used: Phacelia was grown under both tunnels. At flowering of the crop one tunnel was treated once with CHR/F/PROTAZO 375 SC at the rate of 1.25 L product/ha (219 g prothioconazole/ha + 250 g azoxystrobin /ha) The second tunnel was kept untreated. One honeybee colony was installed under each tunnel and bees foraging was restricted to the tunnels. Honey and pollen were sampled (at commercial maturity), and the residue level of prothioconazole, prothioconazole-desthio and azoxystrobin analysed in the samples.

SUMMARIZED RESULTS

Residues in honey control samples were non-detectable or below the limit of quantification, except for azoxystobin residues in control honey that were above the limit of quantification. The residue results for azoxystrobin, prothioconazole and prothioconazole-desthio in the treated specimens are summarized below:

Trial No.	Matrix	Azoxystrobin residues (mg/kg) at maturity	Prothioconazole residues (mg/kg) at maturity	Prothioconazole-desthio residues (mg/kg) at maturity
C0239 MA1	Honey	< LOQ	NDR	< LOQ
	Pollen	0.50	0.22	0.50

DALA: Days after last application
< LOQ: Residues between LOD and LOQ
NDR: No detectable residues (residues below the limit of detection)
LOD = 0.003 mg/kg
LOQ = 0.01 mg/kg

The following pattern was designed for the treatments and the samplings:

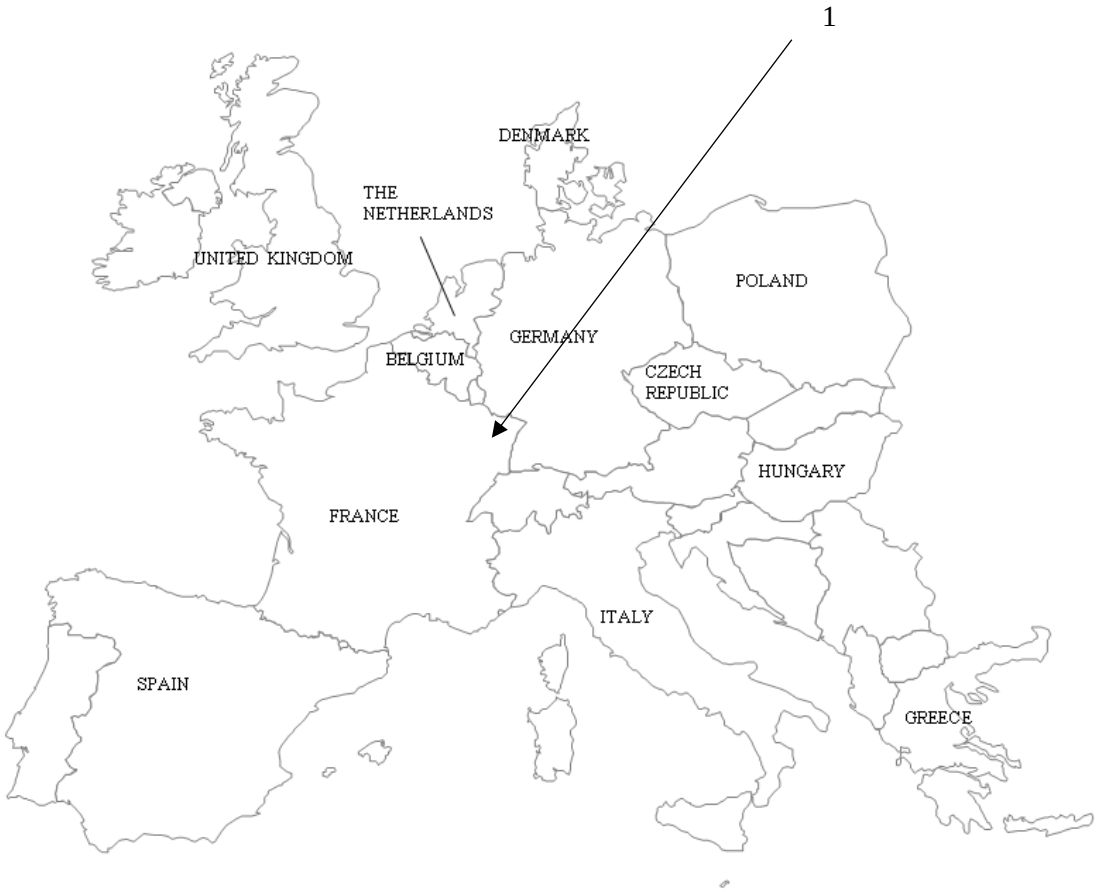
Application details

Tunnel	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	**CHR/F/PROTAZO 375 SC**	T1	Full flowering	1.25 L/ha	Prothioconazole: 219 g/ha Azoxystrobin: 250 g/ha	200-400 L/ha (±10%)

Location of the trial

Trial No.	Principal Investigator	Type of trial	Crop	European area	Country, Region
C0239 MA1	Benoît BOYETTE	Semi-field	Phacelia	North	France, Grand Est

Location



1 Trial C0239 MA1

Crop and soil Information

Trial No.	Crop	Variety	Crop density (kg/ha)	Sowing / Planting date	Soil type	pH	Organic matter (%)
C0239 MA1	Phacelia	Stala	10	21/04/2020	Loamy sand	7.4	1.36

Sampling of specimens

The samplings were carried out according to ANADIAG SOPs and to the specifications of the study plan (see details for min. weight in section 1.1.1 Objective).

Sampling summary

Trial No	Sampling	Actual Date	Actual DALA	Actual Growth Stage (BBCH)
C0239 MA1	1	16/07/2020	12 DALA	Commercial maturity

Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. C0239 MA1 – Azoxystrobin results

Analytical sample No.	Field sample No.	Treatment	Matrix	DAA	Azoxystrobin residues found (mg/kg)
C0239 01 01	C0239 MA1 / UH / A	-	Honey	-	**NDR**
C0239 01 03	C0239 MA1 / UP / A	-	Pollen	-	**NDR**
C0239 01 02	C0239 MA1 / TH / A	CHR/F/PROTAZO 375 SC	Honey	12	**< LOQ**
C0239 01 04	C0239 MA1 / TP / A	CHR/F/PROTAZO 375 SC	Pollen	12	**0.50**

DALA: Days after last application
< LOQ: Residues between LOD and LOQ
NDR: No detectable residues (residues below the limit of detection)
LOD = 0.003 mg/kg
LOQ = 0.01 mg/kg

Table 2 TRIAL No. C0239 MA1 – Prothioconazole and prothioconazole desthio results

Analytical sample No.	Field sample No.	Treatment	Matrix	DAA	Prothioconazole residues found (mg/kg)	Prothioconazole-desthio residues found (mg/kg)
C0239 01 01	C0239 MA1 / UH / A	-	Honey	-	**NDR**	**NDR**
C0239 01 03	C0239 MA1 / UP / A	-	Pollen	-	**NDR**	**NDR**
C0239 01 02	C0239 MA1 / TH / A	CHR/F/PROTAZO 375 SC	Honey	12	**NDR**	**< LOQ**
C0239 01 04	C0239 MA1 / TP / A	CHR/F/PROTAZO 375 SC	Pollen	12	**0.22**	**0.50**

DAA: Days after application
< LOQ: Residues between LOD and LOQ
NDR: No detectable residues (residues below the limit of detection)
LOD = 0.003 mg/kg
LOQ = 0.01 mg/kg

Comments of zRMS:	The study is accepted.

A 2.3.7.3 Study 3

Reference:	KCP 6.3/23
Report	Determination of Prothioconazole, Prothioconazole-desthio and Azoxystrobin Residues in Honey and Pollen Following Foliar application on Phacelia with CHR/F/PROTAZO 375 SC under semi field Conditions in Southern Europe in 2020, A. Perny, Study Code: C0278
Guideline(s):	Regulation (EC) No. 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue levels of prothioconazole , prothioconazole-desthio and azoxystrobin in honey and pollen from bees foraging on Phacelia following one foliar application at flowering stage of the formulated product CHR/F/PROTAZO 375 SC (175 g prothioconazole/L + 200 g azoxystrobin /L), under semi-field conditions.
The study consisted of 2 phases: the field phase, and the analytical phase.
The study was conducted under semi-field conditions at one site in Southern Europe

On the site, 2 tunnels covered with anti-insect nets were used: Phacelia was grown under both tunnels. At flowering of the crop one tunnel was treated once with CHR/F/PROTAZO 375 SC at the rate of 1.25 L product/ha (219 g prothioconazole/ha + 250 g azoxystrobin /ha) The second tunnel was kept untreated. One honeybee colony was installed under each tunnel and bees foraging was restricted to the tunnels. Honey and pollen were sampled (at commercial maturity), and the residue level of prothioconazole , prothioconazole-desthio and azoxystrobin analysed in the samples.

SUMMARIZED RESULTS

Residues in honey control samples were non-detectable or below the limit of quantification, except for azoxystobin residues in control honey that were above the limit of quantification. The residue results for azoxystrobin, prothioconazole and prothioconazole-desthio in the treated specimens are summarized below:

Trial No.	Matrix	Azoxystrobin residues (mg/kg) at maturity	Prothioconazole residues (mg/kg) at maturity	Prothioconazole-desthio residues (mg/kg) at maturity
C0278 EF1	Honey	< LOQ	NDR	NDR
	Pollen	11.64	7.52	0.92

DALA: Days after last application
< LOQ: Residues between LOD and LOQ
NDR: No detectable residues (residues below the limit of detection)
LOD = 0.003 mg/kg
LOQ = 0.01 mg/kg

The following pattern was designed for the treatments and the samplings:

Application details

Tunnel	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	**CHR/F/PROTAZO 375 SC**	T1	Full flowering	1.25 L/ha	Prothioconazole: 219 g/ha Azoxystrobin: 250 g/ha	200-400 L/ha (±10%)

Location of the trial

Trial No.	Principal Investigator	Type of trial	Crop	European area	Country, Region
C0278 EF1	Sandra LEGAL	Semi-field	Phacelia	South	France, Nouvelle-Aquitaine

Location

1 Trial C0278 EF1

Crop and soil Information

Trial No.	Crop	Variety	Crop density (kg/ha)	Sowing / Planting date	Soil type	pH	Organic matter (%)
C0278 EF1	Phacelia	Stala	10	17/04/2020	Silty loam	7.1	1.45

Sampling of specimens

The samplings were carried out according to ANADIAG SOPs and to the specifications of the study plan (see details for min. weight in section 1.1.1 Objective).

Sampling summary

Trial No	Sampling	Actual Date	Actual DALA	Actual Growth Stage (BBCH)
C0278 EF1	1	06/07/2020	17	Commercial maturity

Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. C0278 EF1

Analytical sample No.	Field sample No.	Treatment	Matrix	DAA	Azoxystrobin residues found (mg/kg)
C0278 01 01	C0278 EF1 / UH / A	-	Honey	-	**NDR**
C0278 01 03	C0278 EF1 / UP / A	-	Pollen	-	**NDR**
C0278 01 02	C0278 EF1 / TH / A	CHR/F/PROTAZO 375 SC	Honey	17	**< LOQ**
C0278 01 04	C0278 EF1 / TP / A	CHR/F/PROTAZO 375 SC	Pollen		**11.64**

Analytical sample No.	Field sample No.	Treatment	Matrix	DAA	Prothioconazole residues found (mg/kg)	Prothioconazole-desthio residues found (mg/kg)
C0278 01 01	C0278 EF1 / UH / A	-	Honey	-	**NDR**	**NDR**
C0278 01 03	C0278 EF1 / UP / A	-	Pollen	-	**NDR**	**NDR**
C0278 01 02	C0278 EF1 / TH / A	CHR/F/PROTAZO 375 SC	Honey	17	**NDR**	**NDR**
C0278 01 04	C0278 EF1 / TP / A	CHR/F/PROTAZO 375 SC	Pollen		**7.52**	**0.92**

DAA: Days after last application
< LOQ: Residues between LOD and LOQ
NDR: No detectable residues (residues below the limit of detection)
LOD = 0.003 mg/kg
LOQ = 0.01 mg/kg

Comments of zRMS:	The study is accepted.

A 2.3.7.4 Study 4

Reference:	KCP 6.3/24
Report	Determination of Prothioconazole and Azoxystrobin Residues in Honey and Pollen Following Foliar application on Phacelia with CHR/F/PROTAZO 375 SC under semi field Conditions in Southern Europe in 2020, A. Perny, Study Code: C0279
Guideline(s):	Regulation (EC) No. 1107/2009
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was to determine the residue levels of prothioconazole , prothioconazole-desthio and azoxystrobin in honey and pollen from bees foraging on Phacelia following one foliar application at flowering stage of the formulated product CHR/F/PROTAZO 375 SC (175 g prothioconazole/L + 200 g azoxystrobin /L), under semi-field conditions. The study consisted of 2 phases: the field phase, and the analytical phase. The study was conducted under semi-field conditions at one site in Southern Europe

On the site, 2 tunnels covered with anti-insect nets were used: Phacelia was grown under both tunnels. At flowering of the crop one tunnel was treated once with CHR/F/PROTAZO 375 SC at the rate of 1.25 L product/ha (219 g prothioconazole/ha + 250 g azoxystrobin /ha) The second tunnel was kept untreated.

One honeybee colony was installed under each tunnel and bees foraging was restricted to the tunnels. Honey and pollen were sampled (at commercial maturity), and the residue level of prothioconazole , prothioconazole-desthio and azoxystrobin analysed in the sample.

SUMMARIZED RESULTS

Residues in honey control samples were non-detectable or below the limit of quantification, except for azoxystobin residues in control honey that were above the limit of quantification. The residue results for azoxystrobin, prothioconazole and prothioconazole-desthio in the treated specimens are summarized below:

Trial No.	Matrix	Azoxystrobin residues (mg/kg) at maturity	Prothioconazole residues (mg/kg) at maturity	Prothioconazole-desthio residues (mg/kg) at maturity
C0279 PH1	Honey	Maturity	NDR	NDR
	Pollen	Maturity	3.28	1.89

DALA: Days after last application
< LOQ: Residues between LOD and LOQ
NDR: No detectable residues (residues below the limit of detection)
LOD = 0.003 mg/kg
LOQ = 0.01 mg/kg

The following pattern was designed for the treatments and the samplings:

Application details

Tunnel	Test Item	App. No.	Target Timing	Application Rate of the Formulated Product	Application Rate of the active substance	Spray volume
U	Untreated	--	--	--	--	--
T	**CHR/F/PROTAZO 375 SC**	T1	Full flowering	1.25 L/ha	Prothioconazole: 219 g/ha Azoxystrobin: 250 g/ha	200-400 L/ha (±10%)

Location of the trial

Trial No.	Principal Investigator	Type of trial	Crop	European area	Country, Region
C0279 PH1	Elisabeth SERVAJEAN	Semi-field	Phacelia	South	France, Nouvelle-Aquitaine

Location

1 Trial C0279 PH1

Crop and soil Information

Trial No.	Crop	Variety	Crop density (kg/ha)	Sowing / Planting date	Soil type	pH	Organic matter (%)
C0279 PH1	Phacelia	NATRA	10	11/04/2020	Loamy clay	6.1	2.78

Sampling of specimens

The samplings were carried out according to ANADIAG SOPs and to the specifications of the study plan (see details for min. weight in section 1.1.1 Objective).

Sampling summary

Trial No	Matrix	Actual Date	Timing
C0279 PH1	Honey	09/07/2020	Commercial maturity
	Pollen	From 23/06/2020 to 09/07/2020	Commercial maturity

Results

The analytical results obtained are summarized in the table(s) below.

Table 1 TRIAL No. C0279 PH1

Analytical sample No.	Field sample No.	Treatment	Matrix	DALA	Azoxystrobin residues found (mg/kg)	Prothioconazole residues found (mg/kg)	Prothioconazole-desthio residues found (mg/kg)
C0279 01 01	C0279 PH1 / UH / A	-	Honey	-	**NDR**	**NDR**	**NDR**
C0279 01 03	C0279 PH1 / UP / A	-	Pollen	-	**NDR**	**NDR**	**< LOQ**
C0279 01 02	C0279 PH1 / TH / A	CHR/F/PROTAZO 375 SC	Honey	Maturity	**NDR**	**NDR**	**NDR**
C0279 01 04	C0279 PH1 / TP / A	CHR/F/PROTAZO 375 SC	Pollen	Maturity	**3.28**	**1.89**	**0.73**

DALA: Days after last application
< LOQ: Residues between LOD and LOQ
NDR: No detectable residues (residues below the limit of detection)
LOD = 0.003 mg/kg
LOQ = 0.01 mg/kg

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Prothioconazole-desthio

LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.01**
Source of ADI:	**EFSA**	Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
8%	GEMS/Food G11	0.81	7%	Soyabeans	0.4%	Wheat	0.2%	Sunflower seeds		
8%	GEMS/Food G10	0.79	7%	Soyabeans	0.5%	Sunflower seeds	0.4%	Rapeseeds/canola seeds		
6%	GEMS/Food G08	0.62	4%	Soyabeans	1.0%	Sunflower seeds	0.5%	Rapeseeds/canola seeds		
6%	GEMS/Food G07	0.57	4%	Soyabeans	0.8%	Rapeseeds/canola seeds	0.8%	Sunflower seeds		
6%	GEMS/Food G15	0.55	3%	Soyabeans	1%	Sunflower seeds	0.5%	Wheat		
4%	GEMS/Food G06	0.37	2%	Soyabeans	0.7%	Wheat	0.5%	Sunflower seeds		
3%	DK child	0.32	3%	Rye	0.4%	Wheat	0.0%	Rapeseeds/canola seeds		
3%	NL toddler	0.30	1%	Rapeseeds/canola seeds	0.6%	Sunflower seeds	0.4%	Wheat		
2%	NL child	0.23	0.7%	Sunflower seeds	0.7%	Rapeseeds/canola seeds	0.4%	Soyabeans		
2%	RO general	0.18	1%	Sunflower seeds	0.5%	Wheat				
2%	PT general	0.16	0.6%	Soyabeans	0.6%	Sunflower seeds	0.4%	Wheat		
1%	NL general	0.13	0.4%	Sunflower seeds	0.4%	Rapeseeds/canola seeds	0.3%	Soyabeans		
1%	DE child	0.11	0.4%	Wheat	0.4%	Rye	0.2%	Sunflower seeds		
1%	FR child 3 15 yr	0.10	0.5%	Sunflower seeds	0.5%	Wheat	0.1%	Soyabeans		
0.9%	IT toddler	0.09	0.7%	Wheat	0.2%	Other cereals	0.0%	Sunflower seeds		
0.7%	DE general	0.07	0.3%	Rye	0.2%	Wheat	0.1%	Sunflower seeds		
0.7%	LT adult	0.07	0.5%	Rye	0.1%	Wheat	0.1%	Sunflower seeds		
0.7%	IE adult	0.07	0.4%	Sunflower seeds	0.2%	Wheat	0.1%	Rye		
0.7%	DE women 14-50 yr	0.07	0.2%	Rye	0.2%	Wheat	0.1%	Sunflower seeds		
0.7%	FR toddler 2 3 yr	0.07	0.3%	Wheat	0.3%	Sunflower seeds	0.1%	Soyabeans		
0.7%	ES child	0.07	0.4%	Wheat	0.2%	Sunflower seeds	0.0%	Soyabeans		
0.6%	FI 3 yr	0.06	0.3%	Rye	0.1%	Rapeseeds/canola seeds	0.1%	Wheat		
0.5%	IT adult	0.05	0.4%	Wheat	0.1%	Other cereals	0.0%	Sunflower seeds		
0.5%	FI 6 yr	0.05	0.3%	Rye	0.1%	Wheat	0.1%	Rapeseeds/canola seeds		
0.5%	ES adult	0.05	0.2%	Wheat	0.2%	Sunflower seeds	0.0%	Barley		
0.5%	FR adult	0.05	0.2%	Wheat	0.2%	Sunflower seeds	0.0%	Soyabeans		
0.5%	SE general	0.05	0.3%	Wheat	0.1%	Rye				
0.5%	FI adult	0.05	0.4%	Rye	0.0%	Soyabeans	0.0%	Wheat		
0.4%	UK toddler	0.04	0.4%	Wheat	0.0%	Rye	0.0%	Barley		
0.4%	DK adult	0.04	0.3%	Rye	0.1%	Wheat				
0.3%	UK infant	0.03	0.3%	Wheat		Grapefruits				
0.2%	UK vegetarian	0.02	0.2%	Wheat	0.0%	Rye	0.0%	Barley		
0.2%	UK adult	0.02	0.2%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	FR infant	0.01	0.1%	Wheat	0.0%	Sunflower seeds	0.0%	Soyabeans		
0.1%	IE child	0.01	0.1%	Wheat	0.0%	Barley				
0.0%	PL general	0.00	0.0%	Sunflower seeds	0.0%	Soyabeans	0.0%	Poppy seeds		

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Azoxystrobin

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0.2**	ARfD (mg/kg bw):	**not necessary**
Source of ADI:	**EFSA**	Source of ARfD:	
Year of evaluation:	**2010**	Year of evaluation:	

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
2%	GEMS/Food G11	4.89	0.9%	Soyabeans	0.9%	Wheat	0.6%	Barley		
2%	GEMS/Food G08	4.78	1%	Wheat	0.7%	Barley	0.5%	Soyabeans		
2%	GEMS/Food G10	4.72	1.0%	Wheat	0.8%	Soyabeans	0.4%	Barley		
2%	GEMS/Food G15	4.68	1%	Wheat	0.6%	Barley	0.4%	Soyabeans		
2%	GEMS/Food G06	4.47	2%	Wheat	0.3%	Soyabeans	0.1%	Sunflower seeds		
2%	GEMS/Food G07	4.37	1%	Wheat	0.5%	Barley	0.4%	Soyabeans		
2%	IT toddler	3.35	2%	Wheat	0.0%	Barley	0.0%	Sunflower seeds		
1%	NL toddler	2.93	1.0%	Wheat	0.2%	Rapeseeds/canola seeds	0.1%	Barley		
1%	RO general	2.87	1%	Wheat	0.2%	Sunflower seeds				
1%	NL child	2.59	1%	Wheat	0.1%	Rapeseeds/canola seeds	0.1%	Sunflower seeds		
1%	FR child 3 15 yr	2.46	1%	Wheat	0.1%	Sunflower seeds	0.0%	Soyabeans		
1%	PT general	2.30	1.0%	Wheat	0.1%	Soyabeans	0.1%	Sunflower seeds		
1%	ES child	2.28	1%	Wheat	0.0%	Sunflower seeds	0.0%	Barley		
1%	DK child	2.21	1%	Wheat	0.0%	Rapeseeds/canola seeds				
1%	DE child	2.20	1%	Wheat	0.0%	Sunflower seeds	0.0%	Soyabeans		
1%	IT adult	2.09	1%	Wheat	0.0%	Barley	0.0%	Sunflower seeds		
1.0%	UK toddler	1.98	1.0%	Wheat	0.0%	Barley				
1.0%	ES adult	1.96	0.6%	Wheat	0.4%	Barley	0.0%	Sunflower seeds		
0.9%	DE general	1.76	0.5%	Wheat	0.4%	Barley	0.0%	Sunflower seeds		
0.9%	NL general	1.71	0.5%	Wheat	0.2%	Barley	0.1%	Rapeseeds/canola seeds		
0.8%	FR toddler 2 3 yr	1.64	0.8%	Wheat	0.0%	Sunflower seeds	0.0%	Soyabeans		
0.8%	SE general	1.60	0.8%	Wheat		Grapefruits				
0.7%	DE women 14-50 yr	1.41	0.5%	Wheat	0.1%	Barley	0.0%	Sunflower seeds		
0.7%	UK infant	1.31	0.7%	Wheat		Grapefruits				
0.6%	IE adult	1.27	0.6%	Wheat	0.0%	Sunflower seeds	0.0%	Barley		
0.6%	FR adult	1.18	0.6%	Wheat	0.0%	Sunflower seeds	0.0%	Soyabeans		
0.5%	UK vegetarian	1.05	0.5%	Wheat	0.0%	Barley				
0.4%	UK adult	0.88	0.4%	Wheat	0.0%	Barley				
0.4%	FI 3 yr	0.74	0.3%	Wheat	0.0%	Barley	0.0%	Rapeseeds/canola seeds		
0.3%	LT adult	0.64	0.3%	Wheat	0.0%	Barley	0.0%	Sunflower seeds		
0.3%	FI 6 yr	0.61	0.2%	Wheat	0.0%	Barley	0.0%	Rapeseeds/canola seeds		
0.3%	IE child	0.59	0.3%	Wheat	0.0%	Barley				
0.3%	DK adult	0.56	0.3%	Wheat		Grapefruits				
0.2%	FR infant	0.41	0.2%	Wheat	0.0%	Sunflower seeds	0.0%	Soyabeans		
0.1%	FI adult	0.21	0.1%	Wheat	0.0%	Barley	0.0%	Soyabeans		
0.0%	PL general	0.00	0.0%	Sunflower seeds	0.0%	Soyabeans	0.0%	Poppy seeds		

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

A 3.2 IEDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Prothioconazole-desthio

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.01**
Source of ADI:	**EFSA**	Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
8%	GEMS/Food G11	0.81	7%	Soyabeans	0.4%	Wheat	0.2%	Sunflower seeds		
8%	GEMS/Food G10	0.79	7%	Soyabeans	0.5%	Sunflower seeds	0.4%	Rapeseeds/canola seeds		
6%	GEMS/Food G08	0.62	4%	Soyabeans	1.0%	Sunflower seeds	0.5%	Rapeseeds/canola seeds		
6%	GEMS/Food G07	0.57	4%	Soyabeans	0.8%	Rapeseeds/canola seeds	0.8%	Sunflower seeds		
6%	GEMS/Food G15	0.55	3%	Soyabeans	1%	Sunflower seeds	0.5%	Wheat		
4%	GEMS/Food G06	0.37	2%	Soyabeans	0.7%	Wheat	0.5%	Sunflower seeds		
3%	DK child	0.32	3%	Rye	0.4%	Wheat	0.0%	Rapeseeds/canola seeds		
3%	NL toddler	0.30	1%	Rapeseeds/canola seeds	0.6%	Sunflower seeds	0.4%	Wheat		
2%	NL child	0.23	0.7%	Sunflower seeds	0.7%	Rapeseeds/canola seeds	0.4%	Soyabeans		
2%	RO general	0.18	1%	Sunflower seeds	0.5%	Wheat				
2%	PT general	0.16	0.6%	Soyabeans	0.6%	Sunflower seeds	0.4%	Wheat		
1%	NL general	0.13	0.4%	Sunflower seeds	0.4%	Rapeseeds/canola seeds	0.3%	Soyabeans		
1%	DE child	0.11	0.4%	Wheat	0.4%	Rye	0.2%	Sunflower seeds		
1%	FR child 3 15 yr	0.10	0.5%	Sunflower seeds	0.5%	Wheat	0.1%	Soyabeans		
0.9%	IT toddler	0.09	0.7%	Wheat	0.2%	Other cereals	0.0%	Sunflower seeds		
0.7%	DE general	0.07	0.3%	Rye	0.2%	Wheat	0.1%	Sunflower seeds		
0.7%	LT adult	0.07	0.5%	Rye	0.1%	Wheat	0.1%	Sunflower seeds		
0.7%	IE adult	0.07	0.4%	Sunflower seeds	0.2%	Wheat	0.1%	Rye		
0.7%	DE women 14-50 yr	0.07	0.2%	Rye	0.2%	Wheat	0.1%	Sunflower seeds		
0.7%	FR toddler 2 3 yr	0.07	0.3%	Wheat	0.3%	Sunflower seeds	0.1%	Soyabeans		
0.7%	ES child	0.07	0.4%	Wheat	0.2%	Sunflower seeds	0.0%	Soyabeans		
0.6%	FI 3 yr	0.06	0.3%	Rye	0.1%	Rapeseeds/canola seeds	0.1%	Wheat		
0.5%	IT adult	0.05	0.4%	Wheat	0.1%	Other cereals	0.0%	Sunflower seeds		
0.5%	FI 6 yr	0.05	0.3%	Rye	0.1%	Wheat	0.1%	Rapeseeds/canola seeds		
0.5%	ES adult	0.05	0.2%	Wheat	0.2%	Sunflower seeds	0.0%	Barley		
0.5%	FR adult	0.05	0.2%	Wheat	0.2%	Sunflower seeds	0.0%	Soyabeans		
0.5%	SE general	0.05	0.3%	Wheat	0.1%	Rye				
0.5%	FI adult	0.05	0.4%	Rye	0.0%	Soyabeans	0.0%	Wheat		
0.4%	UK toddler	0.04	0.4%	Wheat	0.0%	Rye	0.0%	Barley		
0.4%	DK adult	0.04	0.3%	Rye	0.1%	Wheat				
0.3%	UK infant	0.03	0.3%	Wheat		Grapefruits				
0.2%	UK vegetarian	0.02	0.2%	Wheat	0.0%	Rye	0.0%	Barley		
0.2%	UK adult	0.02	0.2%	Wheat	0.0%	Rye	0.0%	Barley		
0.1%	FR infant	0.01	0.1%	Wheat	0.0%	Sunflower seeds	0.0%	Soyabeans		
0.1%	IE child	0.01	0.1%	Wheat	0.0%	Barley				
0.0%	PL general	0.00	0.0%	Sunflower seeds	0.0%	Soyabeans	0.0%	Poppy seeds		

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

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Azoxystrobin

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0.2**	ARfD (mg/kg bw):	**not necessary**
Source of ADI:	**EFSA**	Source of ARfD:	
Year of evaluation:	**2010**	Year of evaluation:	

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
2%	GEMS/Food G11	4.89	0.9%	Soyabeans	0.9%	Wheat	0.6%	Barley		
2%	GEMS/Food G08	4.78	1%	Wheat	0.7%	Barley	0.5%	Soyabeans		
2%	GEMS/Food G10	4.72	1.0%	Wheat	0.8%	Soyabeans	0.4%	Barley		
2%	GEMS/Food G15	4.68	1%	Wheat	0.6%	Barley	0.4%	Soyabeans		
2%	GEMS/Food G06	4.47	2%	Wheat	0.3%	Soyabeans	0.1%	Sunflower seeds		
2%	GEMS/Food G07	4.37	1%	Wheat	0.5%	Barley	0.4%	Soyabeans		
2%	IT toddler	3.35	2%	Wheat	0.0%	Barley	0.0%	Sunflower seeds		
1%	NL toddler	2.93	1.0%	Wheat	0.2%	Rapeseeds/canola seeds	0.1%	Barley		
1%	RO general	2.87	1%	Wheat	0.2%	Sunflower seeds				
1%	NL child	2.59	1%	Wheat	0.1%	Rapeseeds/canola seeds	0.1%	Sunflower seeds		
1%	FR child 3 15 yr	2.46	1%	Wheat	0.1%	Sunflower seeds	0.0%	Soyabeans		
1%	PT general	2.30	1.0%	Wheat	0.1%	Soyabeans	0.1%	Sunflower seeds		
1%	ES child	2.28	1%	Wheat	0.0%	Sunflower seeds	0.0%	Barley		
1%	DK child	2.21	1%	Wheat	0.0%	Rapeseeds/canola seeds				
1%	DE child	2.20	1%	Wheat	0.0%	Sunflower seeds	0.0%	Soyabeans		
1%	IT adult	2.09	1%	Wheat	0.0%	Barley	0.0%	Sunflower seeds		
1.0%	UK toddler	1.98	1.0%	Wheat	0.0%	Barley				
1.0%	ES adult	1.96	0.6%	Wheat	0.4%	Barley	0.0%	Sunflower seeds		
0.9%	DE general	1.76	0.5%	Wheat	0.4%	Barley	0.0%	Sunflower seeds		
0.9%	NL general	1.71	0.5%	Wheat	0.2%	Barley	0.1%	Rapeseeds/canola seeds		
0.8%	FR toddler 2 3 yr	1.64	0.8%	Wheat	0.0%	Sunflower seeds	0.0%	Soyabeans		
0.8%	SE general	1.60	0.8%	Wheat		Grapefruits				
0.7%	DE women 14-50 yr	1.41	0.5%	Wheat	0.1%	Barley	0.0%	Sunflower seeds		
0.7%	UK infant	1.31	0.7%	Wheat		Grapefruits				
0.6%	IE adult	1.27	0.6%	Wheat	0.0%	Sunflower seeds	0.0%	Barley		
0.6%	FR adult	1.18	0.6%	Wheat	0.0%	Sunflower seeds	0.0%	Soyabeans		
0.5%	UK vegetarian	1.05	0.5%	Wheat	0.0%	Barley				
0.4%	UK adult	0.88	0.4%	Wheat	0.0%	Barley				
0.4%	FI 3 yr	0.74	0.3%	Wheat	0.0%	Barley	0.0%	Rapeseeds/canola seeds		
0.3%	LT adult	0.64	0.3%	Wheat	0.0%	Barley	0.0%	Sunflower seeds		
0.3%	FI 6 yr	0.61	0.2%	Wheat	0.0%	Barley	0.0%	Rapeseeds/canola seeds		
0.3%	IE child	0.59	0.3%	Wheat	0.0%	Barley				
0.3%	DK adult	0.56	0.3%	Wheat		Grapefruits				
0.2%	FR infant	0.41	0.2%	Wheat	0.0%	Sunflower seeds	0.0%	Soyabeans		
0.1%	FI adult	0.21	0.1%	Wheat	0.0%	Barley	0.0%	Soyabeans		
0.0%	PL general	0.00	0.0%	Sunflower seeds	0.0%	Soyabeans	0.0%	Poppy seeds		

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

A 3.3 IESTI calculations - Raw commodities

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Sunflower seeds	0.2 / 0.2	0.64
5%	Soyabeans	0.2 / 0.2	0.46
3%	Rye	0.05 / 0.05	0.32
2%	Rapeseeds/canola	0.15 / 0.15	0.21
1%	Wheat	0.01 / 0.01	0.14
0.9%	Mustard seeds	0.09 / 0.09	0.09
0.6%	Barley	0.01 / 0.01	0.06

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
11%	Soyabeans	0.2 / 0.2	1.1
2%	Rye	0.05 / 0.05	0.24
2%	Sunflower seeds	0.2 / 0.2	0.20
0.8%	Wheat	0.01 / 0.01	0.08
0.8%	Rapeseeds/canola seeds	0.15 / 0.15	0.08
0.6%	Poppy seeds	0.09 / 0.09	0.06
0.6%	Poppy seeds	0.09 / 0.09	0.06
0.5%	Barley	0.01 / 0.01	0.05

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Soyabeans / soya drink	0.2 / 0.2	0.84
5%	Sunflower seeds / oils	0.2 / 0.4	0.47
3%	Soyabeans / boiled	0.2 / 0.08	0.29
2%	Rye / boiled	0.05 / 0.05	0.18
2%	Rye / milling (wholemeal)-l	0.05 / 0.05	0.18
1%	Wheat / milling (flour)	0.01 / 0.01	0.12
0.9%	Rapeseeds / oils	0.15 / 0.3	0.09
0.6%	Wheat / milling	0.01 / 0.01	0.06
0.4%	Barley / cooked	0.01 / 0.01	0.04
0.2%	Barley / milling (flour)	0.01 / 0.01	0.02
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Barley / beer	0.01 / 0	0.07
0.4%	Wheat / bread/pizza	0.01 / 0.01	0.04
0.4%	Wheat / pasta	0.01 / 0.01	0.04
0.3%	Wheat / bread	0.01 / 0.01	0.03
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A 3.4 IESTI calculations - Processed commodities

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Sunflower seeds	0.2 / 0.2	0.64
5%	Soyabeans	0.2 / 0.2	0.46
3%	Rye	0.05 / 0.05	0.32
2%	Rapeseeds/canola	0.15 / 0.15	0.21
1%	Wheat	0.01 / 0.01	0.14
0.9%	Mustard seeds	0.09 / 0.09	0.09
0.6%	Barley	0.01 / 0.01	0.06

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
11%	Soyabeans	0.2 / 0.2	1.1
2%	Rye	0.05 / 0.05	0.24
2%	Sunflower seeds	0.2 / 0.2	0.20
0.8%	Wheat	0.01 / 0.01	0.08
0.8%	Rapeseeds/canola seeds	0.15 / 0.15	0.08
0.6%	Poppy seeds	0.09 / 0.09	0.06
0.6%	Poppy seeds	0.09 / 0.09	0.06
0.5%	Barley	0.01 / 0.01	0.05

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
8%	Soyabeans / soya drink	0.2 / 0.2	0.84
5%	Sunflower seeds / oils	0.2 / 0.4	0.47
3%	Soyabeans / boiled	0.2 / 0.08	0.29
2%	Rye / boiled	0.05 / 0.05	0.18
2%	Rye / milling (wholemeal)-l	0.05 / 0.05	0.18
1%	Wheat / milling (flour)	0.01 / 0.01	0.12
0.9%	Rapeseeds / oils	0.15 / 0.3	0.09
0.6%	Wheat / milling	0.01 / 0.01	0.06
0.4%	Barley / cooked	0.01 / 0.01	0.04
0.2%	Barley / milling (flour)	0.01 / 0.01	0.02
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Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Barley / beer	0.01 / 0	0.07
0.4%	Wheat / bread/pizza	0.01 / 0.01	0.04
0.4%	Wheat / pasta	0.01 / 0.01	0.04
0.3%	Wheat / bread	0.01 / 0.01	0.03
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Appendix 4 Additional information provided by the applicant