FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: **CHR/F/PYRA 250 EC**

Product name(s): **Etiuda 250 EC, Fermata 250 EC**

Chemical active substance:

Pyraclostrobin, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Innvigo Sp. z o.o.

Submission date: October 2021

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Version history

When	What
December 2021	Dossier sent for evaluation
September 2022	zRMS evaluation of dRR
December 2022	Final version prepared by zRMS after Commenting period

Table of Contents

7 Metabolism and residue data (KCA section 6) 4

7.1 Summary and zRMS Conclusion 4
7.1.1 Critical GAP(s) and overall conclusion 7
7.1.2 Summary of the evaluation 11
7.1.2.1 Summary for Pyraclostrobin 11
7.1.2.2 Summary for CHR/F/PYRA 250 EC 12
7.2 Pyraclostrobin 12
7.2.1 Stability of Residues (KCA 6.1) 13
7.2.1.1 Stability of residues during storage of samples 13
7.2.1.2 Stability of residues in sample extracts (KCA 6.1) 14
7.2.2 Nature of residues in plants, livestock and processed commodities 14
7.2.2.1 Nature of residue in primary crops (KCA 6.2.1) 14
7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1) 18
7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1) 20
7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1) 20
7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5) 21
7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1) 22
7.2.3 Magnitude of residues in plants (KCA 6.3) 23
7.2.3.1 Summary of European data and new data supporting the intended uses 23
7.2.3.2 Conclusion on the magnitude of residues in plants 25
7.2.4 Magnitude of residues in livestock 25
7.2.4.1 Dietary burden calculation 25
7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3) 27
7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3) 30
7.2.5.1 Conclusion on processing studies 30
7.2.6 Magnitude of residues in representative succeeding crops 31
7.2.6.1 Field rotational crop studies (KCA 6.6.2) 31
7.2.7 Other / special studies (KCA6.10, 6.10.1) 31
7.2.8 Estimation of exposure through diet and other means (KCA 6.9) 32
7.2.8.1 Input values for the consumer risk assessment 32
7.2.8.2 Conclusion on consumer risk assessment 33
7.3 Combined exposure and risk assessment 36
7.4 References 36

Appendix 1 Lists of data considered in support of the evaluation 37

Appendix 2 Detailed evaluation of the additional studies relied upon 41

Appendix 3 Pesticide Residue Intake Model (PRIMo) 61

A 3.1 TMDI calculations 61
A 3.2 IEDI calculations 62
A 3.3 IESTI calculations - Raw commodities 63
A 3.4 IESTI calculations - Processed commodities 64

zRMS comments:
The text highlighted in grey was provided by the evaluator.

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

This application is in support of the use of CHR/F/PYRA 250 EC containing 250 g/L pyraclostrobin on wheat, triticale, barley and rye in Poland.

Critical GAP proposed for CHR/F/PYRA 250 EC on winter wheat, winter triticale and winter/spring rye: BBCH 25-69, max. 2 applications, min. interval between applications 21 days, max. application rate per application 0.25 kg a.s./ha, PHI-35 days.
Critical GAP proposed for CHR/F/PYRA 250 EC on spring barley: BBCH 25-59, max. 2 applications, min. interval between applications 21 days, max. application rate per application 0.25 kg a.s./ha, PHI-35 days.

Critical EU GAP on wheat and rye (art 12, EFSA Journal 2011;9(8):2344): formulation WG, max BBCH 69, max. 2 applications, max. application rate 0.25 kg a.s./ha, PHI-35 days.
Critical EU GAP on barley (art 12, EFSA Journal 2011;9(8):2344): formulation WG, max BBCH 61, max. 2 applications, max. application rate 0.25 kg a.s./ha, PHI-35 days.
The GAPs proposed for CHR/F/PYRA 250 EC are covered by GAPs evaluated at EU level.

Stability
The Applicant did not submit any new stability studies for pyraclostrobin residues.
According to the EFSA Journal 2011;9(8):2344: *The demonstrated storage stability of pyraclostrobin in treated crops was evaluated under the peer review of Directive 91/414/EEC (Germany, 2001). Studies demonstrated storage stability of pyraclostrobin in high oil content, high water content, acidic and dry commodities for up to 18 months when stored deep frozen.*
The storage stability of pyraclostrobin in animal products was evaluated under the peer review of Directive 91/414/EEC (Germany, 2001). Studies demonstrated storage stability of pyraclostrobin in milk and animal tissues for up to 8 months when stored deep frozen. No storage stability study was performed on poultry eggs.

Nature of residues in plants
The Applicant did not submit any new metabolism studies.
According to the EFSA Journal 2011;9(8):2344:
Metabolism of pyraclostrobin was investigated for foliar applications on cereals (wheat), on fruits and fruiting vegetables (grapes) and on root and tuber vegetables (potatoes) using [tolyl-U-14C]-pyraclostrobin and [chlorophenyl-U-14C]- pyraclostrobin (Germany, 2001). Generally it was concluded in the peer review (EC, 2002) that the metabolic pathway is similar in all crop groups investigated. Results from the supervised residue trials indicated that desmethoxy metabolite 500M07 occurs in crops in small amounts compared to parent pyraclostrobin; therefore in the peer review it was concluded that ***a general residue definition for risk assessment and enforcement should be set as parent pyraclostrobin only.***
In the peer review the metabolism of pyraclostrobin in rotational crops was studied in lettuce, radish and wheat with [tolyl-U-14C]-pyraclostrobin and [chlorophenyl-U-14C]-pyraclostrobin (Germany, 2001). The radiolabelled active substance was applied on a bare soil once at an application rate of 0.9 kg a.s./ha and respective crops were sown or planted at 30, 120 and 365 DAT. The peer review concluded that ***the metabolic pathway of pyraclostrobin in rotational crops is similar to that in primary crops and no formation of new metabolites was observed. There is no accumulation of pyraclostrobin or its degradation products (including 500M07) in the parts of plants used for human or animal consumption. The relevant residue in rotational crops therefore should be defined as parent pyraclostrobin.***
The total radioactive residues in the edible parts of succeeding crops were very low for all plant back intervals: radish roots, lettuce ≤ 0.04 mg/kg and wheat grain ≤0.089 mg/kg. No accumulation of

pyraclostrobin or its residues was observed in rotational crops. Application rates supported in the framework of this review range between 0.05 and 0.67 kg a.s./ha. Considering the overdosing factor of the above study and the fact that pyraclostrobin was applied to a bare soil (interception of pyraclostrobin by the plants is expected in practice), it is expected that residues of pyraclostrobin resulting from soil uptake will not exceed 0.01 mg/kg. ***Specific plant-back restrictions related to the use of pyraclostrobin are therefore not required, provided that pyraclostrobin is applied in compliance with the GAPs evaluated in the framework of this review.***

The effect of processing on the nature of pyraclostrobin residues was investigated in the framework of the peer review. A study was conducted simulating representative hydrolytic conditions forpasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C pH 5) and sterilisation (20 minutes at 120°C, pH 6). This study demonstrates that food processes such as brewing, cooking, sterilisation or pasteurisation, will not impact on the nature of pyraclostrobin residues. ***The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops****.*

Nature of residues in livestock

The Applicant did not submit any new metabolism studies.

According to the EFSA Journal 2011;9(8):2344:

The nature of pyraclostrobin residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (Germany, 2001). Reported metabolism studies include 4 studies, two in lactating goats and two in laying hens using 14C-chlorophenyl labeled pyraclostrobin and 14C-tolyl labeled pyraclostrobin. Studies of the metabolism of pyraclostrobin in goats showed that residues in products of animal origin derive from the parent compound as well as from its desmethoxy metabolite (500M07). After five consecutive daily oral administrations of 14C-pyraclostrobin at a nominal dosage of 12 or 50 mg/kg DM feed, there was rapid absorption from the gastrointestinal tract. Radioactivity was excreted mainly via the faeces. The radiolabel in milk accounted for only 0.1–0.5% of the total applied radioactivity. There was no indication of accumulation of 14C-pyraclostrobin in tissues. The parent compound was found in fat, muscle and, at lower amounts, in liver. Metabolites are formed in liver and kidney by hydroxylation of the chlorophenyl and tolyl rings and by cleavage of the molecule. Little extraction was seen in liver. ***Pyraclostrobin was present in all tissues and in milk and was the main residue component in muscle and in fat*** *(log Pow = 3.9) (FAO, 2004). Tissues and eggs from hens that received an exaggerated dose of 0.70 or 0.88 mg/kg bw/d on seven consecutive days contained low residue levels consisting of three main metabolites.* ***The parent compound was found in fat and eggs but not in liver. The main metabolite in liver was the glucuronic acid conjugate, which was bound to the tolyl ring of the demethoxylated parent structure. The desmethoxy metabolite (500M07) was also present in fat and eggs. The main metabolite in fat and eggs was 500M07, and that in liver was the glucuronic acid conjugate*** *(FAO, 2004).*

The ***relevant residue for risk assessment is defined as the sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety, expressed as pyraclostrobin****. EFSA proposes to set different levels of conversion factor from enforcement to risk assessment.* ***Conversion factors will be set at 4 for ruminant liver and at 1 for all other commodities.*** *In the framework of the peer review, the proposed residue definition was considered to be* ***fat soluble*** *based on the fact that the log Po/w of pyraclostrobin is higher than 3 (Germany, 2001).*

The magnitude of residues in plants

The Applicant did not submit any new studies. The available residue trials evaluated in the DAR, 2001 and in EFSA 2011 (art. 12) are considered adequate for the intended uses of CHR/F/PYRA 250 EC. The results of the available residue trials show no residues above the applicable MRLs (1 mg/kg for barley and 0.2 mg/kg for wheat and rye according to the Reg. (EU) 2020/1633).

According to the EFSA Journal 2011;9(8):2344: *Studies investigating the magnitude of residues in processed commodities of table and wine grapes, barley and wheat were also reported in the framework of the peer review (Germany, 2001).* ***Further processing studies are not required as they are not expected to affect the outcome of the risk assessment.*** *However, if there would be the intention to derive*

more robust processing factors, in particular for enforcement purposes, additional processing studies would be required.
The total radioactive residues in the edible parts of succeeding crops were very low for all plant back intervals: radish roots, lettuce ≤ 0.04 mg/kg and wheat grain ≤0.089 mg/kg. No accumulation of pyraclostrobin or its residues was observed in rotational crops. Application rates supported in the framework of this review range between 0.05 and 0.67 kg a.s./ha. Considering the overdosing factor of the above study and the fact that pyraclostrobin was applied to a bare soil (interception of pyraclostrobin by the plants is expected in practice), it is expected that residues of pyraclostrobin resulting from soil uptake will not exceed 0.01 mg/kg. Specific plant-back restrictions related to the use of pyraclostrobin are therefore not required, provided that pyraclostrobin is applied in compliance with the GAPs evaluated in the framework of this review.
The max. application rate proposed in the GAP for CHR/F/PYRA 250 EC is the same (0.25 kg a.s./ha), which has already been considered by EFSA. Specific plant-back restrictions related to the use of pyraclostrobin are therefore not required.

Livestock feeding studies
The Applicant did not submit any new studies. According to the EFSA Journal 2011;9(8):2344: *During the peer review of Directive 91/414/EEC the magnitude of pyraclostrobin residues in livestock was investigated in a feeding study with lactating cows (Germany, 2001). Three groups of lactating cows, each consisting of three animals, were dosed for 28 days with pyraclostrobin at levels of 0.22, 0.37 and 2.4 mg pyraclostrobin/kg bw/day. The samples were analyzed for parent pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety.*
No residues of pyraclostrobin and its metabolites could be detected in samples of milk from the 1x and 3x levels except for cream samples where residues in the range of 0.02 mg/kg to 0.04 mg/kg occurred. In the exaggerated 10 x dose group, residues up to 0.18 mg/kg were detected in milk, which mainly consisted of hydroxylated metabolites. As expected, the residue concentrations were higher in cream than in milk or skimmed milk, but the concentration was only moderate (Germany, 2001).
In fat and muscle, no residues have been detected at any dose level. In kidneys, residues were only found in the 10x group. In liver, the highest residues were found mainly consisting of hydroxylated metabolites. The withdrawal cows (daily dose of 1400 mg/day and animal) showed a rapid decline of residues. After seven days of withdrawal, residues could only be detected in liver (0.5 mg/kg). Therefore, it can be concluded that pyraclostrobin and its metabolites were eliminated rapidly from the animal (Germany, 2001). This livestock feeding study was rejected by JMPR because no residues were found in fat (FAO, 2004). However, under the peer-review, it was concluded that this livestock feeding study was acceptable (EC, 2002).
It is therefore concluded that significant residues in edible matrices of ruminants and pigs are not expected and that MRLs for these commodities can be established at the LOQ.
No livestock feeding study is available for poultry but the metabolism study in laying hens was performed at dose levels of approximately 0.7 and 0.88 mg/kg bw/d, which represents 100 times the calculated dietary intake. When extrapolating residue levels obtained in the metabolism study to the calculated intake, no residues above LOQ are expected in any poultry tissues or eggs.

Taking into account available feeding data, there is no risk for animal MRL to be exceeded.

Consumer risk assessment
The calculations on consumer risk assessment were performed using PRIMo rev. 3.1 for the crop under assessment and animal products, considering the MRLs in force (Reg. (EU) 2020/1633). The CF of 4 for ruminant liver and 6.8 for milk were also included (EFSA 2019:17(7)5797).
The proposed uses of pyraclostrobin in the formulation CHR/F/PYRA 250 EC do not represent unacceptable acute and chronic risks for the consumer.
There are sufficient studies to support the use of the CHR/F/PYRA 250 EC applied according to the proposed GAPs in Poland on wheat, barley, triticale and rye.

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/PYRA 250 EC are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central Zone for cereals. A list of all intended uses within the Central Zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment.
The assessment of this application is based on the toxicological reference values and endpoints determined in the framework of the inclusion of the active substance pyraclostrobin (SANCO/1420/2001-Final).
The review of all existing MRLs of Pyraclostrobin according to Article 12 is presented in EFSA Journal 2011;9(8):2344, the evaluation report (EMS= Italy) is available.
Sufficient residue trials on cereals are available to support the central zone assessment. The exceedance of the currently established MRLs of 1.0 mg/kg (barley) and 0.2 mg/kg (rye, wheat and triticale) for Pyraclostrobin as laid down in COMMISSION REGULATION (EU) ~~2020/856 is~~ 2020/1633 and SANTE/10016/2022 (new MRL values for pyraclostrobin will apply on a yet to be specified date) not expected.
The chronic and acute intakes of Pyraclostrobin residues are unlikely to present a public health concern.

Data gaps

Noticed data gaps are:
None

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

Table 8.1-2: Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn 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 [f]	ZRMs Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or 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 (TRZAW)	F	*Mycosphaerella graminicola, Fusarium avenaceum, Pyrenophora tritici, Puccinia striiformis, Blumeria graminis, Phaeosphaeria nodorum, Puccinia recondita*	Spray, medium sprayer	Spring BBCH 25-69	a) 2 b) 2	21	a) 1 l/ha b) 2 l/ha	a) 0,25 kg a.s./ha b) 0,5 kg a.s/ha	100-400	35		A
2	PL	Winter triticale (TTLWI)	F	*Rhynchosporium secalis, Blumeria graminis, Pyrenophora tritici-repentis , Mycosphaerella graminicola, Fusarium avenaceum*	Spray, medium sprayer	Spring BBCH 25-69	a) 2 b) 2	21	a) 1 l/ha b) 2 l/ha	a) 0,25 kg a.s./ha b) 0,5 kg a.s/ha	100-400	35		A
3	PL	Winter rye (SECCW)	F	*Rhynchosporium secalis, Puccinia recondita, Mycosphaerella graminicola, Blumeria graminis*	Spray, medium sprayer	Spring BBCH 25-69	a) 2 b) 2	21	a) 1 l/ha b) 2 l/ha	a) 0,25 kg a.s/ha b) 0,5 kg a.s/ha	100-400	35		A
4	PL	Spring barley (HORVS)	F	*Pyrenophora teres, Blumeria graminis, Rhynchosporium secalis, Cochliobolus sativus,*	Spray, medium sprayer	Spring BBCH 25-59	a) 2 b) 2	21	a) 1 l/ha b) 2 l/ha	a) 0,25 kg a.s/ha b) 0,5 kg a.s/ha	100-400	35		A

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn 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 [f]	ZRMs Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
				Puccinia hordei										
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)														
1														
2														
Minor uses according to Article 51 (zonal uses)														
1	PL	Spring Rye (SECCS)	F	*Rhynchosporium secalis, Puccinia recondita, Mycosphaerella graminicola , Blumeria graminis, Phaeosphaeria nodorum*	Spray, medium sprayer	Spring BBCH 25-69	a) 2 b) 2	21	a) 1 l/ha b) 2 l/ha	a) 0,25 kg a.s/ha b) 0,5 kg a.s/ha	100-400	35		A
2														
Minor uses according to Article 51 (interzonal uses)														
1														
2														

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/l

(d) Select relevant

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

(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 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
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and 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
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

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

** 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

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

7.1.2 Summary of the evaluation

The preparation CHR/F/PYRA 250 EC is composed of pyraclostrobin.

Table 7.1-3: Toxicological reference values for the dietary risk assessment of Pyraclostrobin

Reference value	Source	Year	Value	Study relied upon	Safety factor
Pyraclostrobin					
ADI	EFSA conclusion *EFSA Journal 2011;9(10):2417* SANCO/1420/2021-Final, 8 September 2004	2011 2004	**0.03 mg/kg bw/day**	Chronic rat study	100
ARfD	EFSA conclusion *EFSA Journal 2011;9(10):2417* SANCO/1420/2021-Final, 8 September 2004	2011 2004	**0.03 mg/kg bw**	Rabbit, developmental toxicity study	100

7.1.2.1 Summary for Pyraclostrobin

Table 7.1-4: Summary for Pyraclostrobin

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	No	No
2	Winter triticale	Yes	Yes	Yes	Yes	Yes	No	No
3	Winter rye	Yes	Yes	Yes	Yes	Yes	No	No
4	Spring barley	Yes	Yes	Yes	Yes	Yes	No	No
5	Spring rye	Yes	Yes	Yes	Yes	Yes	No	No

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

7.1.2.2 Summary for CHR/F/PYRA 250 EC

Table 7.1-5: Information on CHR/F/PYRA 250 EC (KCA 6.8)

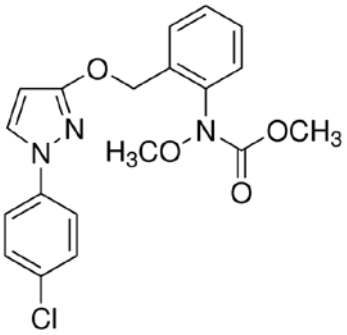
Crop	PHI for CHR/F/PYRA EC proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CHR/F/PYRA 250 EC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Pyraclostrobin		
Winter and spring cereals	35	35	35	-

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 Pyraclostrobin

General data on Pyraclostrobin are summarized in the table below (last updated August 2016)

Table 7.2-1: General information on Pyraclostrobin

Active substance (ISO Common Name)	Pyraclostrobin
IUPAC	(Methyl {2-[1-(4-chlorophenyl)-1H-pyrazol-3-yloxymethyl]phenyl}methoxycarbamate
Chemical structure	
Molecular formula	$C_{19}H_{18}ClN_3O_4$
Molar mass	387.82 g/mol
Chemical group	Strobilurines
Mode of action (if available)	Inhibition of mitochondrial respiration resulting from blockage of the mitochondrial electron transport chain, thus blocking phosphorylation further down in the respiratory chain. In consequence, this leads to a reduction of energy-rich ATP which is required to support a range of essential processes in the fungal cell. In the end, the various fungal development processes of spore germination, formation of infection structures, mycelium growth and sporulation are permanently disrupted.

Systemic	No (with local systemic activity)
Company (ies)	BASF
Rapporteur Member State (RMS)	Germany
Approval status	Approved 1/06/2004, refer to 2004/30/EC
Restriction	No
Review Report	SANCO/1420/2001-Final 08/09/2004
Current MRL regulation	COMMISSION REGULATION (EU) ~~2020/856~~ 2020/1633
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	EFSA Journal 2011;9(8):2344
EFSA Journal : Conclusion on the peer review	No**
EFSA Journal: conclusion on article 12	EFSA Journal 2017;15(1):4686 EFSA Journal 2011;9(8):2344
Current MRL applications on intended uses	No

* Notifier in the EU process to whom the a.s. belong(s)
** Not officially peer-reviewed by EFSA

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data have been submitted in the framework of this application.
The storage stability of Pyraclostrobin in plant and animal matrices was already evaluated and is summarized in the table below.

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 (Pyraclostrobin and metabolite 500M07)			
Wheat grain	High starch content	18 months	Abdel-Baky, S., 2001, 2000/5248
Wheat straw	Dry matrix	18 months	
Peanut nutmeat	High oil content	18 months	
Peanut oil	High oil content	18 months	
Sugar beet tops	High water content	18 months	
Sugar beet roots	High starch content	18 months	
Tomatoes	High water content	18 months	
Grape juice	High acid content	18 months	
Animal Products			

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Ruminant	Liver	8 months	Tilting, N., 2000, 2000/1017116 Tilting, N., Knoell, H.-E., 2000, 2000/1000002
Ruminant	Muscle	8 months	
Ruminant	Milk	8 months	

Conclusion on stability of residues during storage

The longest storage interval of cereal matrices to be covered in context of the residue studies was 10 months. This time period is well covered by the storage interval as evaluated in the DAR for cereals matrices (18 months).
The storage stability of Pyraclostrobin in samples of animal origin under deep freeze conditions is proved over a period of 8 months. Metabolite 500M35 (model compound) with slow degradation but stable enough to evaluate the submitted feeding study (analysed within 6 months.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

No new study on stability of residues in sample extracts was conducted.
~~For the active substance pyraclostrobin, investigations were performed using sample extracts out of ^{14}C-metabolism studies and fortified samples during validation of the residue analytical methods. In none of the extracts investigated any degradation as observed. Further details are provided in Part B5- Analytical methods. From the data available it can be concluded that pyraclostrobin is stable in sample extracts or solutions when stored during residue analysis.~~

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.
The table below contain summary of metabolism studies submitted in the framework of first inclusion of active substance. Please refer to the DAR of Pyraclostrobin.

Table 7.2-2: 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)	
Fruits and fruiting vegetables	Grapes	[totyl-U-^{14}C]-Pyraclostrobin and [chlorophenyl-U-^{14}C]-Pyraclostrobin	foliar treatment, F	0.48, 0.24, 0.18, 0.13, 0.24, 0.24	6	40	Hamm, R.T., 2000, 98/10988
Root and tuber vegetables	Potatoes	[totyl-U-^{14}C]-Pyraclostrobin	foliar treatment, F	0.30, 0.30, 0.30, 0.40,	7	7 days after 3rd	Bross, M., Mackenroth, C.,

		and [chlorophenyl-U-^{14}C]-Pyraclostrobin		0.30, 0.30		application 7 DALA	1999, 1999/11419
Cereals	Wheat	[totyl-U-^{14}C]-Pyraclostrobin and [chlorophenyl-U-^{14}C]-Pyraclostrobin	foliar treatment, F	0.30	2	0, 31, ~~0.~~41	Reinhard, K., 1999, 1999/11137

Summary of plant metabolism studies reported in the EU

Grapes
^{14}C-Pyraclostrobin was applied in the form of an EC-formulation to grapevines (variety: Mueller-Thurgau). In total, six applications were performed. The first application was performed at growing stage BBCH 53 – 55 (inflorescences visible to fully developed). The last application was done at growing stage 81 (beginning of ripening), 40 days before harvest. Samples were taken for analysis only at harvest, 40 days after the last application. The samples were separated into leaves and grapes. In grapes, ^{14}C-pyraclostrobin is metabolised by three key transformation steps: desmethoxlation at the oxime ether bond, hydroxylation of the tolyl and the chlorophenyl ring systems followed by glucosylation or methylation, and cleavage between both ring systems and subsequent transformation of the resulting intermediates by glucosylation.

Potatoes
^{14}C-Pyraclostrobin was applied in the form of an EC-formulation to potato plants. Six applications at an intended use rate of 300 g as/ha were performed. The first application was performed about 8 weeks after sowing at growth stage BBCH 31 (main stem elongation). The application was repeated 5 times approximately every 9 days thereafter. Samples were taken for analysis seven days after the third application and at full maturity (seven days after last application). The samples were separated into green matter, tubers and roots. In all green matter samples, the solvent extractability was high; it ranged from 91 to 95% of the TRR. In tubers, a slight difference between the extractabilities of the two labels could be observed. In the case of the tolyl label, 39% and 42% of the TRR could be extracted by methanol whereas the extractable portions from the tubers treated with the chlorophenyl label were higher ranging between 49% and 68% of the TRR. Due to this lower extractability, ammonia extraction was applied. After ammonia extraction, the non-extractable residue was significantly below 0.050 mg/kg.

Wheat
Summer wheat plants at growth stage BBCH 31 - 32 were dug up in an outdoor test site and planted in plastic pots which were kept under natural climatical conditions in a glass-roofed vegetation hall. Wheat samples were collected 0, 31 and 41 days after the last treatment. The harvest samples (41 DALT) were separated into straw, grain and chaff. Forage (31 DALT) as well as straw and grain represent the raw agricultural commodities and were therefore analysed in full detail. Except for grain, no significant differences in the TRR levels between the two labels occurred. By far the lowest TRR were found in grains varying between 0.098 mg/kg in the chlorophenyl labelled and 0.441 mg/kg in the tolyl labeled matrix. The difference by a factor of 4.5 in the TRR between chlorophenyl and tolyl labeled grain originates from the cleavage of the test substance and the subsequent translocation of one of the fragments (amino acid tryptophan). In forage and straw, the metabolite patterns looked almost identical with unchanged pyraclostrobin being the most prominent compound of the residue (53 – 58% TRR). In grain, smaller amounts of pyraclostrobin were found that differed between the tolyl and the chlorophenyl labeled matrix (8 and 36% TRR).

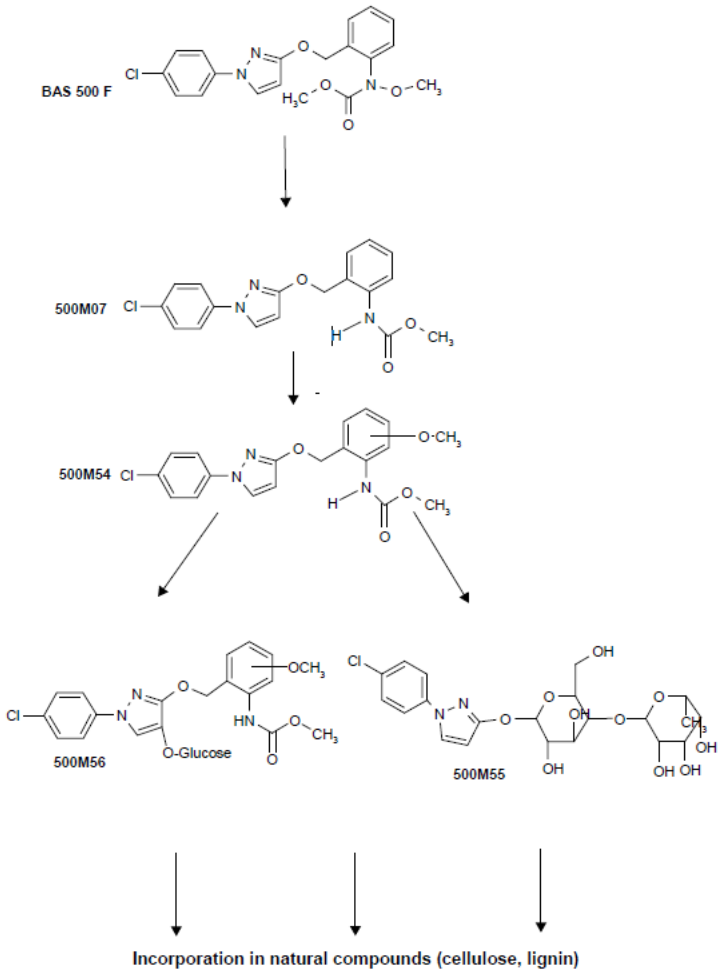
Summary of new plant metabolism studies

No new or additional studies have been submitted.

Conclusion on metabolism in primary crops

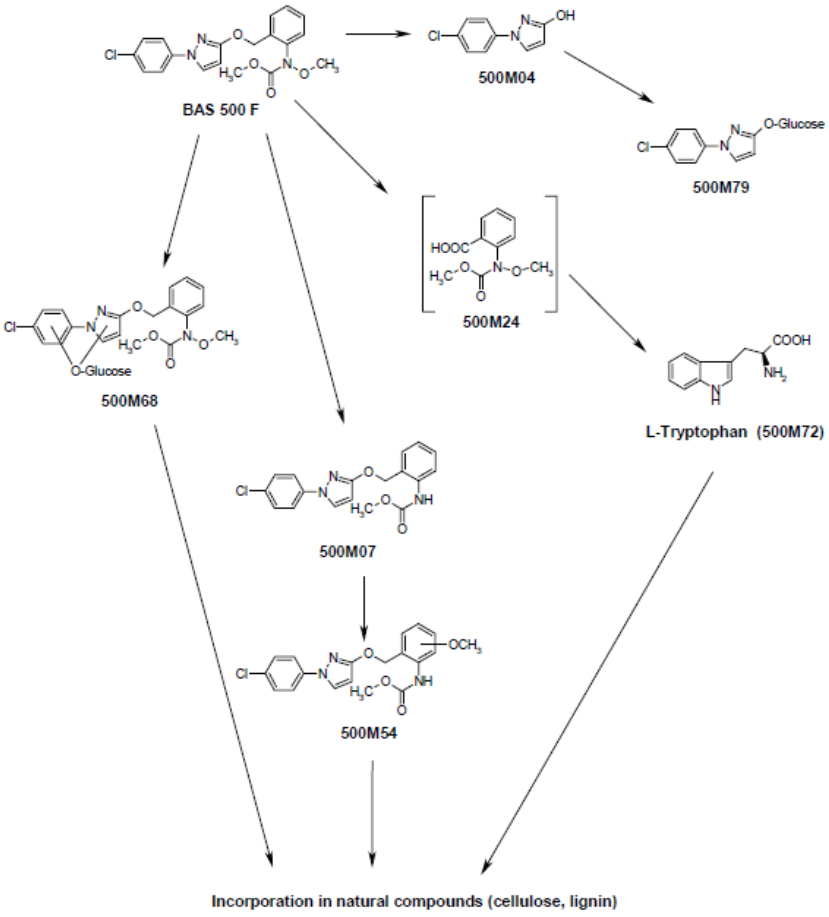
Grapes

The relevant residue in grapes consists of the parent compound pyraclostrobin (BAS 500 F) and its desmethoxy metabolite 500M07 (BF 500-3). Some other compounds identified as products formed by cleavage of the molecule, Oglucosylation or methoxylation turned out to be of minor importance because their respective amount is far below 10% of the TRR and the absolute amounts are low (< 0.05 mg/kg).



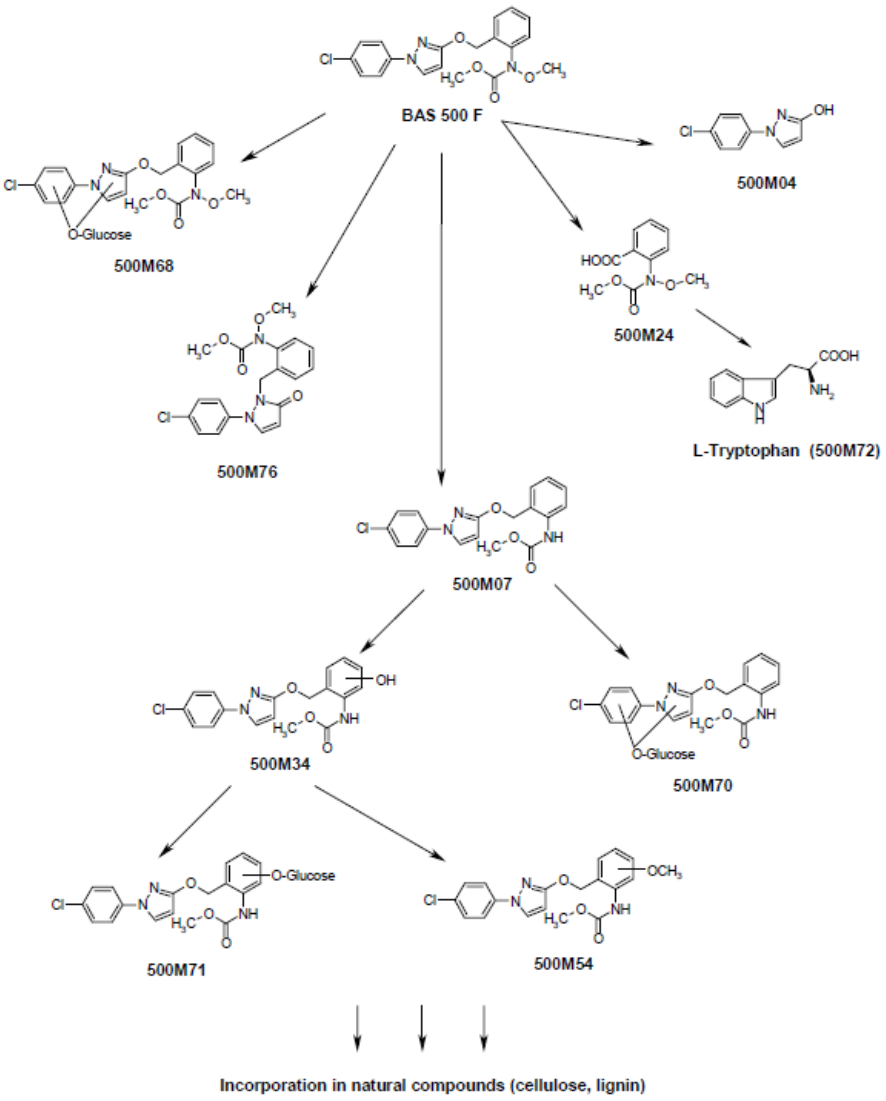
Potatoes

The residue situation after application of pyraclostrobin to potatoes is significant different in leaves and tubers. In leaves, which are in direct contact with the formulation applied, the metabolites are approximately the same as in grapes. The parent compound and its methoxy metabolite 500M07 (BF 500-3) are the main components of the residue. No other metabolite above 10 % TRR was found. The total residues in the edible portion (potato tubers) are very low. Only the parent compound and the naturally occurring amino acid L-tryptophan were determined in amounts above 0.01 mg/kg. Some other compounds which were identified as products formed by cleavage of the molecule, O-glucosylation or methoxylation turned out to be of minor importance.



Wheat

The relevant residue of 14C-pyraclostrobin in wheat consists of the unchanged parent compound and its desmethoxy metabolite 500M07 (BF 500-3). Tryptophan that is formed in considerable amounts from pyraclostrobin in grain is a natural ingredient and therefore of no toxicological concern. All other metabolites identified are clearly below 10% TRR and thus of minor importance. The low non-extractable residues in forage and straw demonstrate that pyraclostrobin and its metabolites do not tend to be firmly associated with cell wall polymers to a larger extent. Somewhat higher amounts of non-extractables were found in grain since portions of the radioactivity were incorporated into or associated with grain protein and starch.



7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.
The metabolism of pyraclostrobin in rotational crops (lettuce, radish and wheat) has been evaluated in the DAR (DE, 2001) during the EU review of the active substance. All data are out of data protection and can be used for the present central zone assessment. An overview on the metabolism studies is compiled in in table 7.2-4

Table 7.2-3: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details				Remarks	Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)		
EU data								
Leafy vegetables	Lettuce	[totyl-U-^{14}C]-Pyraclostrobin and [chlorophenyl-U-^{14}C]-Pyraclostrobin	foliar treatment, F	0.9	30, 120 365	60-61 75-76 61-62	One application to bare soil	Veit, P., 2000, 1999/11829
Root and tuber vegetables	Radish	[totyl-U-^{14}C]-Pyraclostrobin and [chlorophenyl-U-^{14}C]-Pyraclostrobin	foliar treatment, F	0.9	30, 120 365	47-48 64-65 47-48	One application to bare soil	
Cereals	Wheat	[totyl-U-^{14}C]-Pyraclostrobin and [chlorophenyl-U-^{14}C]-Pyraclostrobin	foliar treatment, F	0.9	30, 120 365	166-167 156-157 153-153	One application to bare soil	

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

Summary of plant metabolism studies reported in the EU

The residue levels and the nature of the residues in three different succeeding crops were investigated following application of 14C-pyraclostrobin (BAS 500 F) (tolyl and chlorophenyl label). The test compound was applied, as an acetonic solution, to the surface of a bare, loamy sand soil at an application rate equivalent to 900 g as/ha. After application, the soil was aged for 30 days (simulating an emergency plant back; 30 DAT), 120 days (simulating a fall plant back; 120 DAT) and 365 days (365 DAT) under natural climatic conditions. After those time intervals, ploughing was simulated by mixing the top layer of 20 cm soil. Afterwards radish, lettuce and wheat were sowed/planted.
After a plant back interval of 30 days, the highest total radioactive residues were found in wheat straw (0.114/ 0.112 mg/kg tolyl-/ chlorophenyl-label). In wheat grain, the residue levels were lower with a concentration of 0.082/ 0.078 mg/kg tolyl-/ chlorophenyl-label. The lowest residue levels were detected in lettuce head (0.013/ 0.011 mg/kg tolyl-/ chlorophenyl-label). The residue level in radish roots reached a concentration of 0.025/ 0.040 mg/kg tolyl-/chlorophenyl-label.

Summary of new plant metabolism studies

No new or additional studies have been submitted.

Conclusion on metabolism in rotational crops

The total radioactive residues in the edible parts of succeeding crops destined for human consumption are very low (radish roots, lettuce: < 0.040 mg/kg; wheat grain: < 0.089 mg/kg) after all 3 plant back intervals.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

No new data submitted in the framework of this application.
The metabolism of pyraclostrobin in processed commodities has been evaluated in the DAR (DE, 2001) during the EU review of the active substance. All data are out of data protection and can be used for the present central zone assessment. An overview on the metabolism studies is compiled in in table 7.2-5.

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

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	98.1% [Chlorophenyl label] 103.9% [Totyl label]	Scharf, J., 1998, 98/10840
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	110.9% [Chlorophenyl label] 98.1% [Totyl label]	
Sterilisation (20 minutes, 120°C, pH 6)	97.4% [Chlorophenyl label] 96.1% [Totyl label]	

Conclusion
Pyraclostrobin (BAS 500 F) was not degraded neither during the simulation of pasteurization (pH 4, 90°C) nor during the simulation of baking, boiling, brewing (pH 5, 100°C) or during sterilisation (pH 6, 120°C). Because no degradation occurred, no degradation products were observed.

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

Table 7.2-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Fruits and fruiting vegetables (Grapes) Root and tuber vegetables (Potatoes) Cereals (Wheat)
Rotational crops covered	Leafy vegetables (Lettuce) Root and tuber vegetables (Radish) Cereals (Wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Pyraclostrobin is stable under standard hydrolysis conditions.
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Pyraclostrobin
Plant residue definition for risk assessment	Pyraclostrobin
Conversion factor from enforcement to RA	Not applicable

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

Available data

No new data submitted in the framework of this application.
The metabolism of pyraclostrobin in livestock has been evaluated in the DAR (DE, 2001) during the EU review of the active substance, one on a lactating goat and one on laying hens. All data are out of data protection and can be used for the present central zone assessment. An overview on the metabolism studies is compiled in in table 7.2-7.

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	^{14}C-chlorophenyl	2 (low dose) *	0.9-1.0	5	Milk	Twice daily	xxxxxxxxxxx et al., 1998, 1998/10636
			1 (high dose) **	2.72		Urine and faeces	Daily	xxxxxxxxxx., 2000, 2000/1000004
		^{14}C-totyl	2 (low dose)*	0.65-0.75	5	Tissues	After sacrifice	
			1 (high dose) **	1.37				
Laying poultry	Hens	^{14}C-chlorophenyl	11*	0.70	7	Eggs	Twice daily	xxxxxxxxx et al., 1998, 98/10637
						Excreta	Daily	xxxxxxxxxx 1999, 1999/114xxxx80
		^{14}C-totyl	11*	0.88	7	Tissues	After sacrifice	

*dose corresponding to 12 mg/kg DM feed
**dose corresponding to 50 mg/kg DM feed

Summary of plant metabolism studies reported in the EU

The metabolic patterns identified for goats and hens were consistent with rat metabolism and a specific metabolism in pigs is not considered necessary. Pyraclostrobin was identified as the major indicator compound in commodities of animal origin except in ruminant liver and milk fat. Based on these finding the the JMPR defined the parent compound as the only relevant residues for enforcement and risk assessment but EFSA is of the opinion that consideration should be given to the presemce of the desmethyxo metabolite. An ideal residue definition would therefore include parent and at least metabolite 500M07, however the difficulty is that a method of analysis specific to individual metabolites is to available. Moreover, based on the available livestock feeding study in cows it is expected that relevant metabolites will only be present in liver and that residues will decline quickly after the end of dosing. EFSA proposes to set different levels of conversion factor from enforcement to risk assessment. Conversion factors will be set at 4 for ruminant liver and 1 for all other commodities.

Summary of new animal metabolism studies

No new or additional studies have been submitted.

Conclusion on metabolism in livestock

Tissues and eggs from hens that received an exaggerated dose of 0.70 or 0.88 mg/kg bw/d on seven consecutive days contained low residue levels consisting of three main metabolites. The parent compound was found in fat and eggs but not in liver. The main metabolite in liver was the glucuronic acid conjugate, which was bound to the tolyl ring of the demethoxylated parent structure. The desmethoxy metabolite (500M07) was also present in fat and eggs. The main metabolite in fat and eggs was 500M07, and that in liver was the glucuronic acid conjugate.

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

Table 7.2-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	3 days in milk
	No plateau reached within 7 days of dosing in eggs
Animal residue definition for monitoring	Pyraclostrobin
Animal residue definition for risk assessment	Pyraclostrobin except: Liver (except poultry liver) and milk fat only: Pyraclostrobin and its metabolites analysed as the hydroxypyrazoles BF 500-5 (500M04) and BF 500-8 (500M85), sum expressed as pyraclostrobin
Conversion factor	Liver (except poultry): 4 Milk: 6.8 (EFSA Journal 2019;17(7):5797) All other: 1
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.2-9: Summary of EU reported ~~and new~~ data supporting the intended uses of CHR/F/PYRA 250 EC 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								
Wheat (grain) Wheat and rye grain	DAR, 2001	NEU	DAR 2001 2 × 0.233 kg a.s./ha, BBCH 69, phi= 35d E/RA: 5 × < 0.02, 0.02, 0.05, 0.05 EFSA 2011, art.12 2× 0.25 kg a.s./ha, BBCH 69, PHI-35d E/RA: 12x<0.02; 0.02; 0.03; 2x0.04; 2x0.05	0.02 0.02	0.05 0.05	0.083 0.070	0.2	yes
Wheat (straw) Wheat and rye straw	DAR, 2001	NEU	DAR 2001 2 × 0.233 kg a.s./ha, BBCH 69, phi= 35d E/RA: 1.00, 1.22, 1.31, 1.40, 1.65, 1.90, 1.95, 2.13 EFSA 2011, art.12 2× 0.25 kg a.s./ha, BBCH 69, PHI-35d E/RA: 0.87; 1.0; 1.1; 1.19; 1.22; 2x1.31; 1.4; 1.65; 1.9; 1.95; 1.96; 2.13; 2.23; 2.34; 2.5; 3.14	1.525 1.65	2.13 3.14	-	-	-

Barley								
Barley (grain) Barley and oats grain	DAR, 2001	NEU	DAR 2001 2 × 0.233 kg a.s./ha, BBCH 69, phi= 35d E/RA: 4 × < 0.02, 3 × 0.03, 3 × 0.04, 2 × 0.05, 4 × 0.07, 0.09, 0.10, 0.12, 0.29 EFSA 2011, art.12 2× 0.25 kg a.s./ha, BBCH 61, PHI-35d E/RA: 4x<0.02; 4x0.03; 3x0.04; 2x0.05; 0.06; 4x0.07; 0.09; 2x0.1; 2x0.11; 2x0.12; 2x0.13; 0.14; 0.29	0.045 0.07	0.29 0.29	0.306 0.299	1.0	yes
Barley (straw) Barley and oats straw	DAR, 2001	NEU	DAR 2001 2 × 0.233 kg a.s./ha, BBCH 69, phi= 35d E/RA: 0.52, 0.78, 0.78, 0.82, 0.99, 1.48, 1.57, 1.72, 1.81, 2.0, 2.15, 2.23, 2.77, 2.94, 3.2, 3.26 3.83, 4.38, 4.56 5.68, 6.01 EFSA 2011, art.12 2× 0.25 kg a.s./ha, BBCH 61, PHI-35d E/RA: 0.52; 0.66; 2x0.78; 0.81; 0.84; 0.99; 1.1; 1.2; 1.5; 1.7; 1.9; 2x2.0; 2.2; 2.7; 2x2.8; 2.9; 3.0; 3.3; 2x3.6; 3.7; 2x4.4; 4.6; 5.7; 6.0	2.15 2.20	6.01 6.00	-	-	-
Winter triticale	Magnitude of residues studies performed on wheat and barley can be extrapolated on triticale according to SANTE/2019/12752.							
Winter and spring rye	Magnitude of residues studies performed on wheat can be extrapolated on triticale according to SANTE/2019/12752.							

7.2.3.2 Conclusion on the magnitude of residues in plants

The available residue trials were underdosed compared to the recommended GAP for the central zone (2× 250 g a.s./ha), but considered acceptable as application rate in studies can be 25% lower than nominal application rate. The currently established MRLs for wheat, barley, triticale and rye grains in the Reg. (EU) 2020/856 are not exceeded.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-10: Input values for the dietary burden calculation (considering the uses authorized within the zone and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Pyraclostrobin				
Barley, straw	2.15	STMR *DAR, 2001*	6.01	HR *DAR, 2001*
Rye, straw	1.53	STMR *DAR, 2001*	2.13	HR *DAR, 2001*
Triticale, straw	1.53	STMR *DAR, 2001*	2.13	HR *DAR, 2001*
Wheat, straw	1.53	STMR *DAR, 2001*	2.13	HR *DAR, 2001*
Barley, grain	0.05	STMR *DAR, 2001* STMR *DAR, 2001*	0.29	HR *DAR, 2001*
Rye, grain	0.02	STMR *DAR, 2001*	0.05	HR *DAR, 2001*
Triticale, grain	0.02	STMR *DAR, 2001*	0.05	HR *DAR, 2001*
Wheat, grain	0.02	STMR *DAR, 2001*	0.05	HR *DAR, 2001*
Brewer's grain, dried	0.15	STMR × default PF *DAR, 2001*	N/A	N/A
Distiller's grain, dried	0.07	STMR × default PF *DAR, 2001*	N/A	N/A
Wheat gluten, meal	0.04	STMR × default PF *DAR, 2001*	N/A	N/A
Wheat, milled by-products	0.14	STMR × default PF *DAR, 2001*	N/A	N/A

New Dietary Burden calculations were performed, taking into account STMR and HR values from residues trials presented in Table 7.2-9. New calculations were presented below with Animal model 2017.

Table 7.2-11: Results of the dietary burden calculation

Animal burden calculation												Pyraclostrobin		
According to:	"OECD Guidance Document, Series on testing and assessment No 64 and Series on pesticides No 32" and "OECD Guidance Document on Residues in livestock, Series on Pesticides No 73"													
Maximum Intake	Cattle						Sheep							
	Beef	500 kg 12 kg		Dairy	650 kg 25 kg		Ram/Ewe	75 kg 2.5 kg		Lamb	40 kg 1.7 kg			
(mg/kg bw/d)	0.0542	mg/kg bw/d	%	0.0848	mg/kg bw/d	%	0.1395	mg/kg bw/d	%	0.1778	mg/kg bw/d	%		
Contributor 1	Barley	straw	30	Barley	straw	30	Barley	straw	60	Barley	straw	60		
Contributor 2	Barley	grain	70	Barley	grain	40	Barley	grain	40	Barley	grain	40		
Contributor 3			0	Wheat	milled bypdt	30			0			0		
Contributor 4														
Median intake	0.0190	mg/kg bw/d		0.0305	mg/kg bw/d		0.0504	mg/kg bw/d		0.0643	mg/kg bw/d			

Maximum Intake	Swine						Intakes >0.004 mg/kg bw/d are highlighted
	Breeding	260 kg 6 kg		Finishing	100 kg 3 kg		
(mg/kg bw/d)	0.007	mg/kg bw/d	%	0.009	mg/kg bw/d	%	
Contributor 1	Barley	grain	80	Barley	grain	80	
Contributor 2	Wheat	milled bypdt	20	Wheat	milled bypdt	20	
Contributor 3							
Contributor 4							
Median intake	0.002	mg/kg bw/d		0.003	mg/kg bw/d		

Maximum Intake	Poultry								
	Broiler	1.7 kg 0.12 kg		Layer	1.9 kg 0.13 kg		Turkey	7 kg 0.5 kg	
(mg/kg bw/d)	0.019	mg/kg bw/d	%	0.045	mg/kg bw/d	%	0.014	mg/kg bw/d	%
Contributor 1	Barley	grain	70	Barley	straw	5	Barley	grain	50
Contributor 2	Wheat	milled bypdt	20	Barley	grain	95	Wheat	milled bypdt	20
Contributor 3						0			
Contributor 4									
Median intake	0.005	mg/kg bw		0.017	mg/kg bw		0.004	mg/kg bw	

Intakes expressed on the dry mater basis (mg/kg DM)						
mg/kg DM	Cattle		Sheep		Swine	
	Beef	Dairy	Ram/Ewe	Lamb	Breeding	Finishing
Maximum	2.2565	2.21	4.18	4.18	0.30	0.30
Median	0.7929	0.79	1.51	1.51	0.11	0.11

	Poultry			
	Broiler	Layer	Turkey	Intake >0.1 mg/kg DM in red characters
Maximum	0.26	0.65	0.20	
Median	0.07	0.24	0.06	

zRMS comments:

CHR/F/PYRA 250 EC is intended for use on crops that might be fed to livestock. In addition, the calculation of dietary burden were made using as input values data indicated in EFSA Journal 2011;9(8):2344 using the Animal Model 2017. Results of the livestock dietary burden calculation are presented in the Table below.

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,084	0,130	2,50	3,70	Dairy cattle	Barley	straw	Yes
Cattle (dairy only)	0,084	0,130	2,18	3,37	Dairy cattle	Barley	straw	Yes
Sheep (all diets)	0,126	0,227	3,61	6,00	Lamb	Barley	straw	Yes
Sheep (ewe only)	0,120	0,200	3,61	6,00	Ram/Ewe	Barley	straw	Yes
Swine (all diets)	0,018	0,019	0,76	0,81	Swine (breeding)	Potato	process waste	Yes
Poultry (all diets)	0,027	0,057	0,40	0,84	Poultry layer	Wheat	straw	Yes
Poultry (layer only)	0,027	0,057	0,40	0,84	Poultry layer	Wheat	straw	Yes

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

Data/information on poultry and lactating ruminant feeding studies for Pyraclostrobin were reviewed during the Annex I inclusion process and were considered to be acceptable. The following section was copied from the Draft Assessment Report, which was prepared by RMS Germany.

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: yes/~~no~~	Poultry: yes/~~no~~	Pig: yes/~~no~~
Muscle	< 0.05	< 0.05	< 0.05
Liver	< 0.05	< 0.05	< 0.05
Kidney	< 0.05	< 0.05	< 0.05
Fat	< 0.05	< 0.05	< 0.05
Milk	< 0.01	Not applicable	Not applicable
Eggs	Not applicable	< 0.05	Not applicable

Conclusion on feeding studies

Data/information on poultry and lactating ruminant feeding studies for Pyraclostrobin were reviewed during the Annex I inclusion process and were considered acceptable.

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

Commodity	Dietary burden			Results of the livestock feeding study						Median residue (mg/kg)[(b)]	Highest residue (mg/kg)[(c)]	Calculated MRL (mg/kg)	CF for RA[(d)]
	Med. (mg/kg bw/d)	Med. (mg/kg DM)	Diet contribution	Dose Level (mg/kg bw/d)[(a)]	No	Result for enforcement		Result for RA					
						Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (EFSA, 2011)													
Enforcement residue definition: *Pyracslotrobin (parent)* and risk assessment: *Pyracslotrobin (parent) except poultry liver and* milk fat only: *Pyraclostrobin and its metabolites analysed as the hydroxypyrazoles BF 500-5 (500M04) and BF 500-8 (500M85), sum expressed as pyraclostrobin.*													
Ruminant meat	0.0643	0.1778	20%	0.22	3	<0.05	n.r.	<0.05	n.r.	0.05	0.05	0.05* (tentative)	1
				0.67	3	<0.05	n.r.	<0.05	n.r.				
				2.40	3	<0.05	n.r.	<0.05	n.r.				
Ruminant fat	0.0643	0.1778	20%	0.22	3	<0.05	n.r.	<0.05	n.r.	0.05	0.05	0.05* (tentative)	1
				0.67	3	<0.05	n.r.	<0.05	n.r.				
				2.40	3	<0.05	n.r.	<0.05	n.r.				
Ruminant liver	0.0643	0.1778	20%	0.22	3	<0.05	n.r.	0.20	n.r.	0.05	0.05	0.05* (tentative)	4
				0.67	3	<0.05	n.r.	0.52	n.r.				
				2.40	3	<0.05	n.r.	2.48	n.r.				
Ruminant kidney	0.0643	0.1778	20%	0.22	3	<0.05	n.r.	<0.05	n.r.	0.05	0.05	0.05* (tentative)	1
				0.67	3	<0.05	n.r.	<0.05	n.r.				
				2.40	3	<0.05	n.r.	<0.05	n.r.				
Pig meat	0.03	0.009	0%	0.10	3	<0.05	n.r.	<0.05	n.r.	0.05	0.05	0.05* (tentative)	1
				0.30	3	<0.05	n.r.	<0.05	n.r.				
				1.50	3	<0.05	n.r.	<0.05	n.r.				
Pig fat	0.03	0.009	0%	0.10	3	<0.05	n.r.	<0.05	n.r.	0.05	0.05	0.05*	1

				0.30	3	<0.05	n.r.	<0.05	n.r.			(tentative)	
				1.50	4	<0.05	n.r.	<0.05	n.r.				
Pig liver	0.03	0.009	0%	0.10	3	<0.05	n.r.	0.20	n.r.	0.05	0.05	0.05* (tentative)	4
				0.30	3	<0.05	n.r.	0.52	n.r.				
				1.50	4	<0.05	n.r.	2.48	n.r.				
Pig kidney	0.03	0.009	0%	0.10	3	<0.05	n.r.	<0.05	n.r.	0.05	0.05	0.05* (tentative)	1
				0.30	3	<0.05	n.r.	<0.05	n.r.				
				1.50	4	<0.05	n.r.	<0.05	n.r.				
Milk	0.0504	0.1395	10%	0.22	12	<0.01	n.r.	<0.02	n.r.	0.01	0.01	0.01* (tentative)	1
				0.67	12	<0.01	n.r.	<0.02	n.r.				
				2.40	70	<0.01	n.r.	0.07	n.r.				

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.
n.r.: Not reported
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): MRL is expressed as mg/kg of fat contained in the whole product.
(a): Based on a xx kg animal consuming xx kg feed DM/day.
(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(d): The median conversion factor for enforcement to risk assessment.
(e): Mean residue level from day X until day XX (X cows, Y sampling days).

Conclusion

Regarding available feeding data, there is no unacceptable risk for animals.

zRMS comments:

Taking into account available feeding data, there is no risk for animal MRL to be exceeded.

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

No new data submitted in the framework of this application.
The processing study for pyraclostrobin has been evaluated in the DAR (DE, 2001) during the EU review of the active substance. All data are out of data protection and can be used for the present central zone assessment. An overview on the metabolism studies is compiled in in table 7.2-4

Table 7.2-13: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Processing factors recommended for enforcement and risk assessment (sufficiently supported by data)					
Barley, pot	3	0.7	1.00		Schulz, H., Scharm, M., 2000, 99/11826 Schulz, H., Scharm, M., 2000, 99/11827
Barley, pearling dust	3	11	1.00		
Barley, malt	3	1.3	1.00		
Barley, malt germs	3	2.3	1.00		
Barley, spent grain	3	10	1.00		
Barley, trub	3	0.7	1.00		
Barley, beer yeast	3	0.7	1.00		
Barley, beer	3	0.7	1.00		
Wheat, flour	3	0.06	1.00		Versoi, P. L., Abdel-Baky, S., Riley, M. E., 1999, 1999/5122
Wheat, bran	3	0.06	1.00		
Wheat, middlings	3	0.06	1.00		
Wheat, shorts	3	0.06	1.00		
Wheat, germs	3	0.8	1.00		

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

zRMS comments:

According to the EFSA Journal 2011;9(8):2344: *Studies investigating the magnitude of residues in processed commodities of table and wine grapes, barley and wheat were also reported in the framework of the peer review (Germany, 2001).* ***Further processing studies are not required as they are not expected to affect the outcome of the risk assessment.*** *However, if there would be the intention to derive more robust processing factors, in particular for enforcement purposes, additional processing studies would be required.*
Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Reference
Processing factors recommended for enforcement and risk assessment (sufficiently supported by data)				
Barley, brewing malt	4	1.20	1.00	Germany 2001, EFSA 2011
Barley, beer	4	0.70	1.00	
Indicative processing factors (limited data sets)				
Barley, pot/pearl	1	0.70	1.00	Germany 2001, EFSA 2011
Wheat and rye, white flour	1	0.06	1.00	

7.2.5.1 Conclusion on processing studies

In the process fractions obtained from pot barley and beer production such as pearling dust, malt, malt germs, spent grain, trub (flocs) and beer yeast which are all not meant for final consumption, the residues of pyraclostobin (BAS 500 F) show a certain concentration with factors ranging between 1.29 and 7.86. However, in the final products to be consumed such as pot barley and beer, no concentration of pyraclostobin (BAS 500 F) residues is observed expressed by concentration factors <1.
There are only very low residues of pyraclostrobin to be expected in wheat. In the trials conducted to get grain for processing only values near the limit of quantification were analysed in the RAC. In all commodities except germ no concentration of residues was observed.

7.2.6 Magnitude of residues in representative succeeding crops

Available data

The crops under consideration can be grown in rotation. No new data submitted in the framework of this application.
There is no accumulation of Pyraclostrobin or its degradation products in the parts of plants used for human or animal consumption. The relevant residue in rotational crops therefore should be defined as parent Pyraclostrobin.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

As concluded in chapter 7.2.2.2 the total radioactive residues in the edible parts of succeeding crops were very low for all plant back intevals: radish root, lettuce ≤0.04 mg/kg and wheat grain ≤0.089 mg/kg. No accumulation of Pyraclostrobin or its residues was observed in rotational crops.
No new data submitted in the framework of this application.

Conclusion on rotational crops studies

Considering the overdosing factor of the rotational crop metabolism study and the fact that Pyraclostrobin was applied to bare soil, it is expected that residues of Pyraclostrobin resulting from soil uptake will not exceed 0.01 mg/kg. Specific plant-back restrictions related to the use of Pyraclostrobin are therefore not required, provided that Pyraclostrobin is applied in compliance with the Gap table.

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

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of CHR/F/PYRA EC. Therefore, other special studies are not needed.

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

Table 7.2-14: Toxicological reference values for the dietary risk assessment of Pyraclostrobin

Reference value	Source	Year	Value	Study relied upon	Safety factor
ADI	EFSA conclusion *EFSA Journal 2011;9(10):2417*	2011	**0.03 mg/kg bw/day**	2 year rat study	100
ARfD	EFSA conclusion *EFSA Journal 2011;9(10):2417*	2011	**0.03 mg/kg bw/day**	90 day mouse	100

7.2.8.1 Input values for the consumer risk assessment

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Pyraclostrobin				
TMDI/IESTI				
Barley, grains	1.0	MRL Reg. (EU) 2020/856	1.0	MRL Reg. (EU) 2020/856
Rye, grains	0.2	MRL Reg. (EU) 2020/856	0.2	MRL Reg. (EU) 2020/856
Wheat, grains	0.2	MRL Reg. (EU) 2020/856	0.2	MRL Reg. (EU) 2020/856
Other cereals, grains	0.2	MRL Reg. (EU) 2020/856	0.2	MRL Reg. (EU) 2020/856
Barley, beer	-	-	0.07	MRL × PF Reg. (EU) 2020/856
Barley, milling (flour)	-	-	0.06	MRL × PF Reg. (EU) 2020/856
Barley, cooked	-	-	0.7	MRL × PF Reg. (EU) 2020/856
Rye, milling	-	-	0.2	MRL Reg. (EU) 2020/856
Rye, boiled	-	-	0.2	MRL Reg. (EU) 2020/856
Wheat, bread (wholemeal)	-	-	0.2	MRL Reg. (EU) 2020/856
Wheat, bread/pizza	-	-	0.2	MRL Reg. (EU) 2020/856

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat, pasta	-	-	0.2	MRL Reg. (EU) 2020/856
Wheat, milling-baking	-	-	0.2	MRL Reg. (EU) 2020/856
Wheat, milling (flour)	-	-	0.2	MRL Reg. (EU) 2020/856
IEDI/IESTI				
Barley, grains	0.045	STMR DAR, 2021	0.045	STMR DAR, 2021
Rye, grains	0.02	STMR DAR, 2021	0.02	STMR DAR, 2021
Wheat, grains	0.02	STMR DAR, 2021	0.02	STMR DAR, 2021
Other cereals, grains	0.02	STMR DAR, 2021	0.02	STMR DAR, 2021
Barley, beer	-	-	0.07	MRL × PF Reg. (EU) 2020/856
Barley, milling (flour)	-	-	0.06	MRL × PF Reg. (EU) 2020/856
Barley, cooked	-	-	0.7	MRL × PF Reg. (EU) 2020/856
Rye, milling	-	-	0.2	MRL Reg. (EU) 2020/856
Rye, boiled	-	-	0.2	MRL Reg. (EU) 2020/856
Wheat, bread (wholemeal)	-	-	0.2	MRL Reg. (EU) 2020/856
Wheat, bread/pizza	-	-	0.2	MRL Reg. (EU) 2020/856
Wheat, pasta	-	-	0.2	MRL Reg. (EU) 2020/856
Wheat, milling-baking	-	-	0.2	MRL Reg. (EU) 2020/856
Wheat, milling (flour)	-	-	0.2	MRL Reg. (EU) 2020/856

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-15: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev. 3.1	7 % (based on DK child)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	0.7 % (based on DK child)
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1 for unprocessed commodities	1.0% (Wheat)
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1 for processed commodities	0.8% (Wheat, milling (flour)

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

Conclusions

The estimated Theoretical Maximum Daily Intakes (TMDI) for pyraclostrobin is below the ADI for all consumer groups. The proposed uses of pyraclostrobin in the formulation CHR/F/PYRA 250 EC do not represent unacceptable acute and chronic risks for the consumer

zRMS comments:
In addition the calculations were performed for the crop under assessment and animal products, considering the MRLs in force (Reg. (EU) 2020/1633). The CF of 4 for ruminant liver and 6.8 for milk were also included.

efsa European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Pyraclostrobin

LOQs (mg/kg) range from: 0,01 to: 0,05

Toxicological reference values

ADI (mg/kg bw/day):	0,03	ARfD (mg/kg bw):	0,03
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
8%	DK child	2,37	4%	Rye	3%	Wheat	0,4%	Milk: Cattle	1%	
7%	GEMS/Food G08	2,07	3%	Barley	3%	Wheat	0,4%	Rye	0,8%	
7%	GEMS/Food G15	1,98	3%	Wheat	3%	Barley	0,2%	Swine: Muscle/meat	0,8%	
6%	NL toddler	1,80	3%	Wheat	2%	Milk: Cattle	0,6%	Barley	3%	
6%	GEMS/Food G11	1,75	3%	Barley	2%	Wheat	0,3%	Milk: Cattle	0,8%	
6%	GEMS/Food G07	1,72	3%	Wheat	2%	Barley	0,2%	Milk: Cattle	0,9%	
5%	GEMS/Food G10	1,63	3%	Wheat	2%	Barley	0,2%	Poultry: Muscle/meat	0,8%	
5%	GEMS/Food G06	1,62	5%	Wheat	0,2%	Barley	0,1%	Poultry: Muscle/meat	0,3%	
5%	FR child 3 15 yr	1,43	3%	Wheat	0,8%	Milk: Cattle	0,2%	Bovine: Muscle/meat	2%	
5%	DE child	1,35	3%	Wheat	0,7%	Milk: Cattle	0,5%	Rye	1%	
4%	IT toddler	1,34	4%	Wheat	0,0%	Barley				
4%	NL child	1,29	3%	Wheat	0,8%	Milk: Cattle	0,2%	Swine: Muscle/meat	1%	
4%	RO general	1,28	3%	Wheat	0,4%	Milk: Cattle	0,2%	Swine: Muscle/meat	0,9%	
4%	ES child	1,27	3%	Wheat	0,4%	Milk: Cattle	0,2%	Bovine: Muscle/meat	1%	
4%	DE general	1,24	2%	Barley	1%	Wheat	0,4%	Milk: Cattle	0,8%	
4%	ES adult	1,16	2%	Barley	2%	Wheat	0,2%	Milk: Cattle	0,7%	
4%	UK toddler	1,15	3%	Wheat	0,7%	Milk: Cattle	0,2%	Bovine: Muscle/meat	1%	
4%	FR toddler 2 3 yr	1,11	2%	Wheat	1,0%	Milk: Cattle	0,2%	Bovine: Muscle/meat	2%	
4%	SE general	1,09	2%	Wheat	0,7%	Bovine: Muscle/meat	0,4%	Milk: Cattle	1%	
4%	UK infant	1,08	2%	Wheat	1%	Milk: Cattle	0,2%	Eggs: Chicken	2%	
3%	DE women 14-50 yr	0,94	1%	Wheat	0,6%	Barley	0,4%	Milk: Cattle	0,7%	
3%	NL general	0,90	1%	Wheat	1,0%	Barley	0,3%	Milk: Cattle	0,7%	
3%	PT general	0,84	3%	Wheat	0,1%	Barley	0,1%	Rye		
3%	IT adult	0,84	3%	Wheat	0,0%	Barley				
2%	IE adult	0,66	2%	Wheat	0,1%	Milk: Cattle	0,1%	Rye	0,5%	
2%	LT adult	0,63	0,7%	Rye	0,7%	Wheat	0,2%	Barley	0,5%	
2%	FR adult	0,61	1%	Wheat	0,1%	Milk: Cattle	0,1%	Swine: Muscle/meat	0,5%	
2%	DK adult	0,50	0,7%	Wheat	0,4%	Rye	0,2%	Milk: Cattle	0,6%	
2%	UK vegetarian	0,49	1%	Wheat	0,1%	Milk: Cattle	0,1%	Barley	0,2%	
2%	UK adult	0,47	1%	Wheat	0,1%	Bovine: Muscle/meat	0,1%	Milk: Cattle	0,3%	
1%	FI 3 yr	0,43	0,8%	Wheat	0,4%	Rye	0,2%	Barley	0,0%	
1%	FR infant	0,38	0,6%	Milk: Cattle	0,5%	Wheat	0,1%	Swine: Muscle/meat	0,8%	
1%	FI 6 yr	0,38	0,6%	Wheat	0,4%	Rye	0,2%	Barley	0,0%	
1%	IE child	0,31	0,8%	Wheat	0,1%	Milk: Cattle	0,0%	Swine: Muscle/meat	0,2%	
0,7%	FI adult	0,22	0,5%	Rye	0,2%	Wheat	0,1%	Barley		
	Column7			FRUIT AND TREE NUTS		FRUIT AND TREE NUTS				

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

Acute risk assessment /children — Details - acute risk assessment /children

Acute risk assessment / adults / general population — 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. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Un

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
19%	Barley	1 / 1	5,6
10%	Wheat	0,2 / 0,2	2,9
4%	Rye	0,2 / 0,2	1,3
4%	Milk: Cattle	0,01 / 0,01	1,2
3%	Poultry: Muscle/meat	0,05 / 0,05	0,85
2%	Eggs: Chicken	0,05 / 0,05	0,62
2%	Swine: Muscle/meat	0,05 / 0,05	0,61
1%	Bovine: Liver	0,05 / 0,05	0,40
1%	Bovine: Edible offals (other	0,05 / 0,05	0,36
1%	Bovine: Muscle/meat	0,05 / 0,05	0,36
1%	Other farmed animals:	0,05 / 0,05	0,35
1%	Equine: Muscle/meat	0,05 / 0,05	0,30
0,9%	Sheep: Muscle/meat	0,05 / 0,05	0,27
0,8%	Milk: Goat	0,01 / 0,01	0,24
0,6%	Bovine: Kidney	0,05 / 0,05	0,19

Expand/collapse list

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

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
16%	Barley	1 / 1	4,8
6%	Wheat	0,2 / 0,2	1,7
3%	Rye	0,2 / 0,2	0,97
2%	Poultry: Muscle	0,05 / 0,05	0,59
1%	Milk: Cattle	0,01 / 0,01	0,39
0,9%	Bovine: Muscle	0,05 / 0,05	0,28
0,9%	Other farmed animals:	0,05 / 0,05	0,28
0,8%	Swine: Muscle/meat	0,05 / 0,05	0,24
0,8%	Equine: Muscle/meat	0,05 / 0,05	0,24
0,8%	Sheep: Muscle/meat	0,05 / 0,05	0,24
0,8%	Poultry: Liver	0,05 / 0,05	0,24
0,7%	Eggs: Chicken	0,05 / 0,05	0,21
0,7%	Bovine: Liver	0,05 / 0,05	0,20
0,6%	Milk: Goat	0,01 / 0,01	0,18
0,6%	Bovine: Edible offals (other	0,05 / 0,05	0,17

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
19%	Barley	1 / 1	5,6
10%	Wheat	0,2 / 0,2	2,9
4%	Rye	0,2 / 0,2	1,3
4%	Milk: Cattle	0,01 / 0,01	1,2
3%	Poultry: Muscle/meat	0,05 / 0,05	0,85
2%	Eggs: Chicken	0,05 / 0,05	0,62
2%	Swine: Muscle/meat	0,05 / 0,05	0,61
1%	Bovine: Liver	0,05 / 0,05	0,40
1%	Bovine: Edible offals (other	0,05 / 0,05	0,36
1%	Bovine: Muscle/meat	0,05 / 0,05	0,36
1%	Other farmed animals:	0,05 / 0,05	0,35
1%	Equine: Muscle/meat	0,05 / 0,05	0,30
0,9%	Sheep: Muscle/meat	0,05 / 0,05	0,27
0,8%	Milk: Goat	0,01 / 0,01	0,24
0,6%	Bovine: Kidney	0,05 / 0,05	0,19

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

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
16%	Barley	1 / 1	4,8
6%	Wheat	0,2 / 0,2	1,7
3%	Rye	0,2 / 0,2	0,97
2%	Poultry: Muscle	0,05 / 0,05	0,59
1%	Milk: Cattle	0,01 / 0,01	0,39
0,9%	Bovine: Muscle	0,05 / 0,05	0,28
0,9%	Other farmed animals: Muscle/meat	0,05 / 0,05	0,28
0,8%	Swine: Muscle/meat	0,05 / 0,05	0,24
0,8%	Equine: Muscle/meat	0,05 / 0,05	0,24
0,8%	Sheep: Muscle/meat	0,05 / 0,05	0,24
0,8%	Poultry: Liver	0,05 / 0,05	0,24
0,7%	Eggs: Chicken	0,05 / 0,05	0,21
0,7%	Bovine: Liver	0,05 / 0,05	0,20
0,6%	Milk: Goat	0,01 / 0,01	0,18
0,6%	Bovine: Edible offals (other than	0,05 / 0,05	0,17

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)
12%	Barley / cooked	1 / 1	3,6
8%	Wheat / milling (flour)	0,2 / 0,2	2,4
6%	Barley / milling (flour)	1 / 1	1,8
4%	Wheat / milling (wholemeal)-l	0,2 / 0,2	1,1
2%	Rye / boiled	0,2 / 0,2	0,73
2%	Rye / milling (wholemeal)-bal	0,2 / 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!

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)
24%	Barley / beer	1 / 0,2	7,2
3%	Wheat / bread/pizza	0,2 / 0,2	0,88
3%	Wheat / pasta	0,2 / 0,2	0,76
2%	Wheat / bread (wholemeal)	0,2 / 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!

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

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
12%	Barley / cooked	1 / 1	3,6
8%	Wheat / milling (flour)	0,2 / 0,2	2,4
6%	Barley / milling (flour)	1 / 1	1,8
4%	Wheat / milling (wholemeal)-	0,2 / 0,2	1,1
2%	Rye / boiled	0,2 / 0,2	0,73
2%	Rye / milling (wholemeal)-	0,2 / 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!

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

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
24%	Barley / beer	1 / 0,2	7,2
3%	Wheat / bread/pizza	0,2 / 0,2	0,88
3%	Wheat / pasta	0,2 / 0,2	0,76
2%	Wheat / bread (wholemeal)	0,2 / 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!

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

TMDI (% ADI), EFSA PRIMo rev. 3.1	8 % (based on DK child)
IESTI (% ARfD), EFSA PRIMo rev. 3.1 for unprocessed commodities	19% (barley)
IESTI (% ARfD), EFSA PRIMo rev. 3.1 for processed commodities	12% (barley/cooked)

The proposed uses of pyraclostrobin in the formulation CHR/F/PYRA 250 EC do not represent

unacceptable acute and chronic risks for the consumer.

7.3 Combined exposure and risk assessment

Not applicable.

7.4 References

Draft Assessment Report – Pyraclostrobin- 1 August 2001

EFSA Journal 2011;9(8):2344

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
KCA 6.3/01	Niewelt, S, Wańczyk, K.	2021	*Magnitude of residue and degradation time (DT50) of pyraclostrobin in winter wheat (Raw Agricultural Commodity) after one spray application of CHR/F/PYRA 250 EC in Northern France – 2021* DPL/37/2021, 21SGS39 SGS Poland GLP- Yes Unpublished	N	Chemirol
KCA 6.3/02	Niewelt, S, Wańczyk, K.	2021	*Magnitude of residue and degradation time (DT50) of pyraclostrobin in winter wheat (Raw Agricultural Commodity) after one spray application of CHR/F/PYRA 250 EC - in Hungary – 2021* DPL/38/2021, 21SGS40 SGS Poland GLP- Yes Unpublished	N	Chemirol
KCA 6.3/03	Paszek, G., Wańczyk, K.	2021	*Magnitude of residue and degradation time (DT50) of pyraclostrobin in winter wheat (Raw Agricultural Commodity) after one spray application of CHR/F/PYRA 250 EC - Germany – 2021* DPL/39/2021, 21SGS41 SGS Poland GLP- Yes Unpublished	N	Chemirol
KCA 6.3/04	Jędrusik, M. Wańczyk, K.	2021	*Magnitude of residue and degradation time (DT50) of pyraclostrobin in winter wheat (Raw Agricultural Commodity) after one spray application of CHR/F/PYRA 250 EC in Poland – 2021* DPL/40/2021, 21SGS42 SGS Poland GLP- Yes 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	Abdel-Baky, S.	2001	*Freezer storage stability of BAS 500 F and BF 500-3 in plant matrices including processed commodities.* 2001/5000232 BASF Agro Research RTP, Research Triangle Park NC, USA GLP Unpublished	N	BASF
KCP 6.1/02	Tilting, N.	2000	*Investigation of the Stability of Residues of BAS 500 F (Reg. No. 304428) in Sample Materials of Animal Origin Under usual Storage Conditions.* 2000/1017116 BASF Agro Research RTP, Research Triangle Park NC, USA GLP Unpublished	N	BASF
KCP 6.1/02	Tilting, N., Knoell, H.-E.	2000	*Investigation of the Stability of Residues of BAS 500 F (Reg. No. 304428) in Sample Materials of Animal Origin Under usual Storage Conditions.* 2000/1000002 BASF Agro Research RTP, Research Triangle Park NC, USA GLP Unpublished	N	BASF
KCA 6.2.1/01	Hamm, R. T.	1998	*Metabolism of BAS 500 F in Grapes* 98/10988 BASF Agro Research RTP, Research Triangle Park NC, USA GLP Unpublished	N	BASF
KCA 6.2.1/02	Bross, M., Mackenroth, C.	1999	*Metabolism of 14C-BAS 500 F (14C-Reg.No.304428) in Potato* 1999/11419 BASF Agro Research RTP, Research Triangle Park NC, USA GLP Unpublished	N	BASF
KCA 6.2.1/03	Reinhard, K.	1999	*Metabolism of 14C-BAS 500 F in Wheat.*	N	BASF

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**
			1999/11137 BASF Agro Research RTP, Research Triangle Park NC, USA GLP Unpublished		
KCA 6.6.1	Veit, P.	2000	*Confined rotational crop study with 12C-BAS 500 F.* 1999/11829 BASF Agro Research RTP, Research Triangle Park NC, USA GLP Unpublished	N	BASF
KCA 6.5.1	Scharf, J.	1998	*Hydrolysis of BAS 500 F at 90°C, 100°C, and 120°C.* 98/10840 BASF Agro Research RTP, Research Triangle Park NC, USA GLP Unpublished	N	BASF
KCA 6.2.2-6.2.5/01	xxxxxxxxxx	1998	*14C-BAS 500 F - Absorbtion, Distribution and Exkretion after Repeated Oral Adminstration in Lactating Goats.* 98/10636 xxxxxxxxxxxxxxxxxxxx GLP Unpublished	N	BASF
KCA 6.2.2-6.2.5/02	xxxxxxxxxx	2000	*Investigation of the Metabolism of 14C-BAS 500 F in the Goat.* 2000/1000004 xxxxxxxxxxxxxxxxxxx GLP Unpublished	N	BASF
KCA 6.2.2-6.2.5/03	xxxxxxxxxx	1998	*14C-BAS 500 F - Study of the Absorption, Distribution and Excretion after repeated Oral Administration to Layin Hens.* 98/10637 xxxxxxxxxxxxxxxxxxx GLP	N	BASF

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		
KCA 6.2.2-6.2.5/04	xxxxxxxxx	1999	*Metabolism of (14C) BAS 500 F in Laying Hens.* 99/11480 xxxxxxxxxxxxxxx GLP Unpublished	N	BASF
KCA 6.5.2-6.5.3/01	Schulz, H., Scharm, M.	2000	*Determination of the residues of BAS 500 F in Barley and processed products following treatment with BAS 500 01under field conditions in Germany.* 99/11826 BASF Agro Research RTP, Research Triangle Park NC, USA GLP Unpublished	N	BASF
KCA 6.5.2-6.5.3/02	Schulz, H., Scharm, M.	2000	*Determination of the residues of BAS 500 F in Barley and processed products following treatment with BAS 500 01 F under field conditions in Germany.* 99/11827 BASF Agro Research RTP, Research Triangle Park NC, USA GLP Unpublished	N	BASF
KCA 6.5.2-6.5.3/03	Versoi, P. L., Abdel-Baky, S., Riley, M. E.	1999	*Magnitude of BAS 500 F residues in wheat Processed fractions and aspirated grain fraction.* 1999/5122 BASF Agro Research RTP, Research Triangle Park NC, USA GLP Unpublished	N	BASF

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

No new studies submitted

A 2.1.1.1.1 Storage stability of residues in plant products

No new studies submitted

A 2.1.1.1.2 Storage stability of residues in animal products

No new studies submitted

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

A 2.1.2.1 Nature of residue in plants

No new studies submitted

A 2.1.2.1.1 Nature of residue in primary crops

zRMS comments	The study is not referenced in any point of the dRR for CHR/F/PYRA 250 EC. Not evaluated in the framework of this application and not considered for the assessment. EFSA Journal 2011;9(8):2344: According to the soil degradation studies performed in the framework of the peer review, the highest DT90 value of pyraclostrobin, based on the field and laboratory studies, is 230 and 163 days, respectively. The desmethoxy metabolite (500M07) shows higher persistency in the soil with a DT90 value amounting to 529 days (Germany, 2001).

Study 1

Reference:	KCA 6.3/01
Report	*Magnitude of residue and degradation time (DT50) of pyraclostrobin in winter wheat (Raw Agricultural Commodity) after one spray application of CHR/F/PYRA 250 EC in Northern France - 2021*, S. Niewelt, K. Wańczyk, DPL/37/2021, 21SGS39
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Regulation (EU) no 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) no 1107/2009 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, SANTE/2020/12830 Rev.1, 24 February 2021
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes

The objective of the study was the determination of degradation time (DT50) of pyraclostrobin in winter cereals (Raw Agricultural Commodity) after one application of CHR/F/PYRA 250 EC under field conditions under field conditions.

Materials and methods

8.1 TEST ITEM

Trade Name:	CHR/F/PYRA 250 EC
Name:	CHR/F/PYRA 250 EC (Pyraclostrobin 250 g/L)
Batch No.:	04/2020
Active substance (a. s.):	Pyraclostrobin
CAS Number:	175013-18-0
Formulation Name:	EC
Formulation Type:	Emulsion Concentrate
Main uses:	Fungicide
Actual density :	1,0637 g/cm^3 (from CoA)
Expiry date :	23/04/2022
Content of a. s.	nominal: 250,0 g/L
	analysed: 253,1 g/L
Certificate of Analysis dated:	04/08/2020

8.2 TEST SYSTEM

Crop	Winter wheat (*Triticum aestivum*)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex Alimentarius: GC 0654
RACs harvested	Whole plant without root

Field phase desription

One trial was established in Northern France. 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 applications of CHR/F/PYRA 250 EC were performed in trial with boom sprayer on the treated plot at the target dose rate of 1,0 l/ha. The reported dose rate actually was 0,991 l/ha.

The target spray volume was 100-400 litres per hectare according to Good Agricultural Practices. The reported spray volume was actually 247,6 l/ha.

Applications were performed at BBCH 29 (foliar).

The spray mixture volumes remaining after applications were measured and the volumes applied to the treated plot were 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 (actually it was -0,9 %.

To determinate degradation time 50, RAC specimens for analyses (whole plants without roots) were collected in intervals 0, 2,4,8,12,24,48,72,96,120,144 hours after application.

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial sites.

RAC specimens were put in deep freezing conditions at a target temperature
of ≤ -18° C on the day of sampling, within 15 minutes after sampling If period was longer sample was stored on dry ice.

All specimens remained deep frozen during storage at the test site.

Deviations

There were two deviations to the study plan. Application A1 was done at BBCH 29 instead BBCH 25. Second deviation concern increase temperature under -18oC in freezer with retain samples in period after shipment of specimens for analyses. In Both cases there were no impact to the study.

Conclusions- Field phase
This study was fully performed as anticipated, in accordance with the study plan and the amendment 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/MS fulfils the requirements as defined in EC Guidance document on residue analytical methods (SANTE/2020/12830 Rev.1) and is applicable as enforcement and data generation method for determination of pyraclostrobin in wheat after one application of CHR/F/PYRA 250 EC.

Specimen extraction and determination of residues of pyraclostrobin were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg.
Residues of pyraclostrobin were not detected (<LOD) in any of the untreated samples.

Residues concentration detected in analysed field samples:

Sample name	Timing	Matrix	Laboratory sample code	Residues Acetamiprid [mg/kg]
21SGS39-01 1	0 DBA*	Whole plant w/o roots	DPL/37/2021/01U	<LOD
21SGS39-01 2	0 DAA**	Whole plant w/o roots	DPL/37/2021/02T	16.10
21SGS39-01 3	2 HAA***	Whole plant w/o roots	DPL/37/2021/03T	15.53
21SGS39-01 4	4 HAA***	Whole plant w/o roots	DPL/37/2021/04T	14.62
21SGS39-01 5	8 HAA***	Whole plant w/o roots	DPL/37/2021/05T	11.95
21SGS39-01 6	12 HAA***	Whole plant w/o roots	DPL/37/2021/06T	10.89
21SGS39-01 7	24 HAA***	Whole plant w/o roots	DPL/37/2021/07T	10.75
21SGS39-01 8	48 HAA***	Whole plant w/o roots	DPL/37/2021/08T	10.64
21SGS39-01 9	72 HAA***	Whole plant w/o roots	DPL/37/2021/09T	8.33
21SGS39-01 10	96 HAA***	Whole plant w/o roots	DPL/37/2021/10T	5.59
21SGS39-01 11	120 HAA***	Whole plant w/o roots	DPL/37/2021/11T	5.68
21SGS39-01 12	144 HAA***	Whole plant w/o roots	DPL/37/2021/12U	<LOD
21SGS39-01 13	144 HAA***	Whole plant w/o roots	DPL/37/2021/13T	6.28

*DBA – Days Before Application; ** DAA- Days After Application ; ***HAA – Hours After Application

Study number	Trial number	DT_{50} [h]	DT_{50} [days]	Error[%]
21SGS39	21SGS39-01	89.1	3.71	9.91

Extraction
2 g of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of deionized water and 10 mL of acetonitrile was added. Next to the sample was added 20 µL of internal standard solution (1.3), and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogencitrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 10 min for phase separation. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

Fortification and control samples

For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples.

Table 2. Preparation of fortification and control samples

Fortification level	Amount of added standard solution [1.1] [µL]	Amount of added standard solution [1.2] [µL]	Amount of added internal standard solution [1.3] [µL]
Matrix blank	-	-	20.0
PK 0.010 mg/kg (LOQ)	-	20.0	20.0
PK 0.10 mg/kg (10 x LOQ)	20.0	-	20.0

Extraction of all field samples (treated and untreated), as well as control and fortified samples was performed on 21.04.2021 and after that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

Blank and fortification samples

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

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

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

The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 21.04.2021:

Table 10. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
DPL-37-2021, matrix blank.lcd	< LOD	-
DPL-37-2021, PK1 0,010 mg-kg.lcd	0.0090	89.5
DPL-37-2021, PK1 0,10 mg-kg.lcd	0.091	90.7
DPL-37-2021, PK2 0,010 mg-kg.lcd	0.0089	89.0
DPL-37-2021, PK2 0,10 mg-kg.lcd	0.083	82.8

LOD = 0.003 mg/kg, LOQ = 0.01 mg/kg

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

The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg (in the range of 70 – 120%) confirms the active substance stability during the analytical procedure. The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 560 min (9.3 h).

The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day (less than 13 h).

Conclusions- Analytical phase
The study was conducted using analytical method validated according to SANTE/2020/12830 Rev.1 guideline.
The limit of detection and quantification of the method was established at 0.003 and 0.010 mg/kg for wheat plant, respectively.
The performance of the method during the analytical study complies with SANTE/2020/12830 Rev.1 criteria (accuracy in the range 70 – 120%).
There were no interfering signals at retention time of analyzed compound in examined control matrix.

zRMS comments	The study is not referenced in any point of the dRR for CHR/F/PYRA 250 EC. Not evaluated in the framework of this application and not considered for the assessment. EFSA Journal 2011;9(8):2344: According to the soil degradation studies performed in the framework of the peer review, the highest DT90 value of pyraclostrobin, based on the field and laboratory studies, is 230 and 163 days, respectively. The desmethoxy metabolite (500M07) shows higher persistency in the soil with a DT90 value amounting to 529 days (Germany, 2001).

Study 2

Reference:	KCA 6.3/02
Report	*Magnitude of residue and degradation time (DT50) of pyraclostrobin in winter wheat (Raw Agricultural Commodity) after one spray application of CHR/F/PYRA 250 EC - in Hungary - 2021*, S. Niewelt, K. Wańczyk, DPL/38/2021, 21SGS40
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Regulation (EU) no 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) no 1107/2009 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, SANTE/2020/12830 Rev.1, 24 February 2021
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was the determination of degradation time (DT50) of pyraclostrobin in winter cereals (Raw Agricultural Commodity) after one application of CHR/F/PYRA 250 EC under field conditions under field conditions.

Materials and methods

8.1 TEST ITEM

Trade Name:	CHR/F/PYRA 250 EC
Name:	CHR/F/PYRA 250 EC (Pyraclostrobin 250 g/L)
Batch No.:	04/2020
Active substance (a. s.):	Pyraclostrobin
CAS Number:	175013-18-0
Formulation Name:	EC
Formulation Type:	Emulsion Concentrate
Main uses:	Fungicide
Actual density :	1,0637 g/cm^3 (from CoA)
Expiry date :	23/04/2022
Content of a. s.	nominal: 250,0 g/L
	analysed: 253,1 g/L
Certificate of Analysis dated:	04/08/2020

8.2 TEST SYSTEM

Crop	Winter wheat (*Triticum aestivum*)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex Alimentarius: GC 0654
RACs harvested	Whole plant without root

Field phase desription

One trial was established in Hungary. Trial consisted of one untreated plot U and one treated plot T divided in 2 subplots (subplot 1 and subplot 2). Sampling was done from both subplots randomly.

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 applications of CHR/F/PYRA 250 EC were performed in trial with boom sprayer on the treated plot at the target dose rate of 1,0 l/ha. The reported dose rate actually was 0,985 l/ha (subplot 1) and 0,982 l/ha (subplot 2).

The target spray volume was 100-400 litres per hectare according to Good Agricultural Practices. The reported spray volume was actually 216,7 l/ha and 216,0 l/ha.

Applications were performed at BBCH 25 (foliar).

The spray mixture volumes remaining after applications were measured and the volumes applied to the treated plot were 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 (actually it was -1,5% and -1,8 %).

To determinate degradation time 50, RAC specimens for analyses (whole plants without roots) were collected in intervals 0, 2,4,8,12,24,48,72,96,120,144 hours after application.

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial sites.

RAC specimens were put in deep freezing conditions at a target temperature
of ≤ -18° C on the day of sampling, within 15 minutes after sampling If period was longer sample was stored on dry ice.

All specimens remained deep frozen during storage at the test site.

Conclusions- Field phase
This study was fully performed as anticipated, in accordance with the study plan and the amendment 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/MS fulfils the requirements as defined in EC Guidance document on residue analytical methods (SANTE/2020/12830 Rev.1) and is applicable as enforcement and data generation method for determination of pyraclostrobin in Wheat after one application of CHR/F/PYRA 250 EC.

Specimen extraction and determination of residues of pyraclostrobin were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg.

Residues of pyraclostrobin were not detected (<LOD) in any of the untreated samples.

Residues concentration detected in analysed field samples:

Sample name	Timing	Matrix	Laboratory sample code	Residues Acetamiprid [mg/kg]
21SGS40-01 1	0 DBA*	Whole plant w/o roots	DPL/38/2021/01U	<LOD
21SGS40-01 2	0 DAA**	Whole plant w/o roots	DPL/38/2021/02T	16.45
21SGS40-01 3	2 HAA***	Whole plant w/o roots	DPL/38/2021/03T	16.25
21SGS40-01 4	4 HAA***	Whole plant w/o roots	DPL/38/2021/04T	16.02
21SGS40-01 5	8 HAA***	Whole plant w/o roots	DPL/38/2021/05T	15.93
21SGS40-01 6	12 HAA***	Whole plant w/o roots	DPL/38/2021/06T	15.71
21SGS40-01 7	24 HAA***	Whole plant w/o roots	DPL/38/2021/07T	14.76
21SGS40-01 8	48 HAA***	Whole plant w/o roots	DPL/38/2021/08T	11.68
21SGS40-01 9	72 HAA***	Whole plant w/o roots	DPL/38/2021/09T	7.08
21SGS40-01 10	96 HAA***	Whole plant w/o roots	DPL/38/2021/10T	3.97
21SGS40-01 11	120 HAA***	Whole plant w/o roots	DPL/38/2021/11T	3.67
21SGS40-01 12	144 HAA***	Whole plant w/o roots	DPL/38/2021/12U	<LOD
21SGS40-01 13	144 HAA***	Whole plant w/o roots	DPL/38/2021/13T	3.47

*DBA – Days Before Application; ** DAA- Days After Application ; ***HAA – Hours After Application

Study number	Trial number	DT_{50} [h]	DT_{50} [days]	Error[%]
21SGS40	21SGS40-01	59.8	2.49	7.19

Extraction
2 g of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of deionized water and 10 mL of acetonitrile was added. Next to the sample was added 20 µL of internal standard solution (1.3), and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogencitrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 10 min for phase separation. After that, the extract (organic phase) was filtered through a

membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

Fortification and control samples
For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples.

Table 2. Preparation of fortification and control samples

Fortification level	Amount of added standard solution [1.1] [µL]	Amount of added standard solution [1.2] [µL]	Amount of added internal standard solution [1.3] [µL]
Matrix blank	-	-	20.0
PK 0.010 mg/kg (LOQ)	-	20.0	20.0
PK 0.10 mg/kg (10 x LOQ)	20.0	-	20.0

Extraction of all field samples (treated and untreated), as well as control and fortified samples was performed on 22.04.2021 and after that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

Blank and fortification samples
For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.
Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.
Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level of 10 x LOQ per analytical set of respective matrix were analyzed during sequence.
The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 22.04.2021:

Table 10. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
DPL-38-2021, matrix blank.lcd	< LOD	-
DPL-38-2021, PK1 0,010 mg-kg.lcd	0.011	106.1
DPL-38-2021, PK1 0,10 mg-kg.lcd	0.098	98.2
DPL-38-2021, PK2 0,010 mg-kg.lcd	0.012	117.7
DPL-38-2021, PK2 0,10 mg-kg.lcd	0.10	103.1

LOD = 0.003 mg/kg, LOQ = 0.01 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance documents to SANTE/2020/12830 Rev.1.
The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for

residue analysis. The recovery values for PK2 0.010 mg/kg and PK2 0.10 mg/kg (in the range of 70 – 120%) confirms the active substance stability during the analytical procedure. The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 518 min (8.6 h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day (less than 12 h).
Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

Conclusions- Analytical phase
The study was conducted using analytical method validated according to SANTE/2020/12830 Rev.1 guideline.
The limit of detection and quantification of the method was established at 0.003 and 0.010 mg/kg for wheat plant, respectively.
The performance of the method during the analytical study complies with SANTE/2020/12830 Rev.1 criteria (accuracy in the range 70 – 120%).
There were no interfering signals at retention time of analyzed compound in examined control matrix.

zRMS comments	The study is not referenced in any point of the dRR for CHR/F/PYRA 250 EC. Not evaluated in the framework of this application and not considered for the assessment. EFSA Journal 2011;9(8):2344: According to the soil degradation studies performed in the framework of the peer review, the highest DT90 value of pyraclostrobin, based on the field and laboratory studies, is 230 and 163 days, respectively. The desmethoxy metabolite (500M07) shows higher persistency in the soil with a DT90 value amounting to 529 days (Germany, 2001).

Study 3

Reference:	KCA 6.3/03
Report	*Magnitude of residue and degradation time (DT50) of pyraclostrobin in winter wheat (Raw Agricultural Commodity) after one spray application of CHR/F/PYRA 250 EC - Germany – 2021,* G. Paszek, K. Wańczyk, DPL/39/2021, 21SGS41
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Regulation (EU) no 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) no 1107/2009 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, SANTE/2020/12830 Rev.1, 24 February 2021
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was the determination of degradation time (DT50) of pyraclostrobin in winter cereals (Raw Agricultural Commodity) after one application of CHR/F/PYRA 250 EC under field conditions under field conditions.

Materials and methods

8.1 TEST ITEM

Trade Name:	CHR/F/PYRA 250 EC
Name:	CHR/F/PYRA 250 EC (Pyraclostrobin 250 g/L)
Batch No.:	04/2020
Active substance (a. s.):	Pyraclostrobin
CAS Number:	175013-18-0
Formulation Name:	EC
Formulation Type:	Emulsion Concentrate
Main uses:	Fungicide
Actual density :	1,0637 g/cm^3 (from CoA)
Expiry date :	23/04/2022
Content of a. s.	nominal: 250,0 g/L
	analysed: 253,1 g/L
Certificate of Analysis dated:	04/08/2020

8.2 TEST SYSTEM

Crop	Winter wheat (*Triticum aestivum*)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex Alimentarius: GC 0654
RACs harvested	Whole plant without root

Field phase desription

One trial was established in Germany. 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 applications of CHR/F/PYRA 250 EC were performed in trial with boom sprayer on the treated plot at the target dose rate of 1,0 l/ha. The reported dose rate actually was 0,958 l/ha.
The target spray volume was 100-400 litres per hectare according to Good Agricultural Practices. The reported spray volume was actually 191,67 l/ha.
Applications were performed at BBCH 25 (foliar).
The spray mixture volumes remaining after applications were measured and the volumes applied to the treated plot were 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 (actually it was -4,2%).
To determinate degradation time 50, RAC specimens for analyses (whole plants without roots) were collected in intervals 0, 2,4,8,12,24,48,72,96,120,144 hours after application.
Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial sites.
RAC specimens were put in deep freezing conditions at a target temperature
of ≤ -18° C on the day of sampling, within 15 minutes after sampling If period was longer sample was stored on dry ice.
All specimens remained deep frozen during storage at the test site.

Conclusions- Field phase

This study was fully performed as anticipated, in accordance with the study plan and the amendment 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/MS fulfils the requirements as defined in EC Guidance document on residue analytical methods (SANTE/2020/12830 Rev.1) and is applicable as enforcement and data generation method for determination of pyraclostrobin in Wheat after one application of CHR/F/PYRA 250 EC.

Specimen extraction and determination of residues of pyraclostrobin were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg.

Residues of pyraclostrobin were not detected (<LOD) in any of the untreated samples.

Residues concentration detected in analysed field samples:

Sample name	Timing	Matrix	Laboratory sample code	Residues Acetamiprid [mg/kg]
21SGS41-01 1	0 DBA*	Whole plant w/o roots	DPL/39/2021/01U	<LOD
21SGS41-01 2	0 DAA**	Whole plant w/o roots	DPL/39/2021/02T	19.8
21SGS41-01 3	2 HAA***	Whole plant w/o roots	DPL/39/2021/03T	28.1
21SGS41-01 4	4 HAA***	Whole plant w/o roots	DPL/39/2021/04T	33.9
21SGS41-01 5	8 HAA***	Whole plant w/o roots	DPL/39/2021/05T	23.7
21SGS41-01 6	12 HAA***	Whole plant w/o roots	DPL/39/2021/06T	18.0
21SGS41-01 7	24 HAA***	Whole plant w/o roots	DPL/39/2021/07T	15.2
21SGS41-01 8	48 HAA***	Whole plant w/o roots	DPL/39/2021/08T	10.4
21SGS41-01 9	72 HAA***	Whole plant w/o roots	DPL/39/2021/09T	10.1
21SGS41-01 10	96 HAA***	Whole plant w/o roots	DPL/39/2021/10T	5.27
21SGS41-01 11	120 HAA***	Whole plant w/o roots	DPL/39/2021/11T	4.82
21SGS41-01 12	144 HAA***	Whole plant w/o roots	DPL/39/2021/12U	<LOD
21SGS41-01 13	144 HAA***	Whole plant w/o roots	DPL/39/2021/13T	2.41

Study number	Trial number	DT_{50} [h]	DT_{50} [days]	Error[%]
21SGS41	21SGS41-01	45.4	1.90	12.5

Extraction

2 g of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of deionized water and 10 mL of acetonitrile was added. Next to the sample was added 20 µL of internal standard solution (1.3), and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogencitrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 10 min for phase separation. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

Fortification and control samples
For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples.

Table 2. Preparation of fortification and control samples

Fortification level	Amount of added standard solution [1.1] [µL]	Amount of added standard solution [1.2] [µL]	Amount of added internal standard solution [1.3] [µL]
Matrix blank	-	-	20.0
PK 0.010 mg/kg (LOQ)	-	20.0	20.0
PK 0.10 mg/kg (10 x LOQ)	20.0	-	20.0

Extraction of all field samples (treated and untreated), as well as control and fortified samples was performed on 22.04.2021 and after that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

Blank and fortification samples
For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.
Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.
Sample blank matrix, two procedural recoveries at the level of LOQ and two at the level of 10 x LOQ per analytical set of respective matrix were analyzed during sequence.
The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 23.04.2021:

Table 10. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
p matrix blank.lcd	< LOD	-
p PK1 0,010 mg-kg.lcd	0,0079	79,1
p PK1 0,10 mg-kg.lcd	0,088	87,6
p' matrix blank.lcd	< LOD	-
p PK2 0,010 mg-kg.lcd	0,0086	86,2
p PK2 0,10 mg-kg.lcd	0,086	86,0

LOD = 0.003 mg/kg, LOQ = 0.01 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, Rev.1.
The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.01 mg/kg and PK2 0.10 mg/kg (in the range of 70 – 120%) confirms the active substance stability during the analytical procedure. The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 560 minutes (9.3

h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day (less than 13 h).
Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

Conclusions- Analytical phase
The study was conducted using analytical method validated according to SANTE/2020/12830 Rev.1 guideline.
The limit of detection and quantification of the method was established at 0.003 and 0.010 mg/kg for wheat plant, respectively.
The performance of the method during the analytical study complies with SANTE/2020/12830 Rev.1 criteria (accuracy in the range 70 – 120%).
There were no interfering signals at retention time of analyzed compound in examined control matrix.

zRMS comments	The study is not referenced in any point of the dRR for CHR/F/PYRA 250 EC. Not evaluated in the framework of this application and not considered for the assessment. EFSA Journal 2011;9(8):2344: According to the soil degradation studies performed in the framework of the peer review, the highest DT90 value of pyraclostrobin, based on the field and laboratory studies, is 230 and 163 days, respectively. The desmethoxy metabolite (500M07) shows higher persistency in the soil with a DT90 value amounting to 529 days (Germany, 2001).

Study 4

Reference:	KCA 6.3/04
Report	*Magnitude of residue and degradation time (DT50) of pyraclostrobin in winter wheat (Raw Agricultural Commodity) after one spray application of CHR/F/PYRA 250 EC in Poland - 2021*, M. Jędrusik, K. Wańczyk, DPL/40/2021, 21SGS42
Guideline(s):	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC Commission Regulation (EU) no 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) no 1107/2009 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes, SANTE/2020/12830 Rev.1, 24 February 2021
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The objective of the study was the determination of degradation time (DT50) of pyraclostrobin in winter cereals (Raw Agricultural Commodity) after one application of CHR/F/PYRA 250 EC under field conditions under field conditions.

Materials and methods

8.1 TEST ITEM

Trade Name:	CHR/F/PYRA 250 EC
Name:	CHR/F/PYRA 250 EC (Pyraclostrobin 250 g/L)
Batch No.:	04/2020
Active substance (a. s.):	Pyraclostrobin
CAS Number:	175013-18-0
Formulation Name:	EC
Formulation Type:	Emulsion Concentrate
Main uses:	Fungicide
Actual density :	1,0637 g/cm^3 (from CoA)
Expiry date :	23/04/2022
Content of a. s.	nominal: 250,0 g/L
	analysed: 253,1 g/L
Certificate of Analysis dated:	04/08/2020

8.2 TEST SYSTEM

Crop	Winter wheat (*Triticum aestivum*)
Variety, planting date	See Table 2 – Test system information
Crop Group classification	Codex Alimentarius: GC 0654
RACs harvested	Whole plant without root

Field phase desription

One trial was established in Poland. Trial consisted of one untreated plot U and one treated plot T divided in 2 subplots (subplot 1 and subplot 2). Sampling was done from both subplots randomly.
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 applications of CHR/F/PYRA 250 EC were performed in trial with boom sprayer on the treated plot at the target dose rate of 1,0 l/ha. The reported dose rate actually was 0,999 l/ha
The target spray volume was 100-400 litres per hectare according to Good Agricultural Practices. The reported spray volume was actually 299,7 l/ha.
Applications were performed at BBCH 25 (foliar).
The spray mixture volumes remaining after applications were measured and the volumes applied to the treated plot were 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 (actually it was -0,1 %
To determinate degration time 50, RAC specimens for analyses (whole plants without roots) were collected in intervals 0, 2,4,8,12,24,48,72,96,120,144 hours after application.
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 15 minutes after sampling If period was longer sample was stored on dry ice.
All specimens remained deep frozen during storage at the test site.

Conclusions- Field phase

This study was fully performed as anticipated, in accordance with the study plan and the amendment 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/MS fulfils the requirements as defined in EC Guidance document on

residue analytical methods (SANTE/2020/12830 Rev.1) and is applicable as enforcement and data generation method for determination of pyraclostrobin in Wheat after one application of CHR/F/PYRA 250 EC.

Specimen extraction and determination of residues of pyraclostrobin were performed according to the multi-residue QuEChERS method. Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg.

Residues of pyraclostrobin were not detected (<LOD) in any of the untreated samples.

Residues concentration detected in analysed field samples:

Sample name	Timing	Matrix	Laboratory sample code	Residues Acetamiprid [mg/kg]
21SGS42-01 1	0 DBA*	Whole plant w/o roots	DPL/40/2021/01U	<LOD
21SGS42-01 2	0 DAA**	Whole plant w/o roots	DPL/40/2021/02T	14.43
21SGS42-01 3	2 HAA***	Whole plant w/o roots	DPL/40/2021/03T	13.49
21SGS42-01 4	4 HAA***	Whole plant w/o roots	DPL/40/2021/04T	14.69
21SGS42-01 5	8 HAA***	Whole plant w/o roots	DPL/40/2021/05T	12.23
21SGS42-01 6	12 HAA***	Whole plant w/o roots	DPL/40/2021/06T	12.16
21SGS42-01 7	24 HAA***	Whole plant w/o roots	DPL/40/2021/07T	11.31
21SGS42-01 8	48 HAA***	Whole plant w/o roots	DPL/40/2021/08T	10.50
21SGS42-01 9	72 HAA***	Whole plant w/o roots	DPL/4/2021/09T	6.72
21SGS42-01 10	96 HAA***	Whole plant w/o roots	DPL/40/2021/10T	6.10
21SGS42-01 11	120 HAA***	Whole plant w/o roots	DPL/40/2021/11T	5.40
21SGS42-01 12	144 HAA***	Whole plant w/o roots	DPL/40/2021/12U	<LOD
21SGS42-01 13	144 HAA***	Whole plant w/o roots	DPL/40/2021/13T	3.46

*DBA – Days Before Application; ** DAA- Days After Application ; ***HAA – Hours After Application

Study number	Trial number	DT_{50} [h]	DT_{50} [days]	Error[%]
21SGS42	21SGS42-01	78.7	3.28	5.52

Extraction

2 g of the homogenized sample was weighed into a 50 mL centrifuge tube. 10 mL of deionized water and 10 mL of acetonitrile was added. Next to the sample was added 20 µL of internal standard solution (1.3), and the mixture was shaken vigorously by hand for one minute. After addition of buffering salts (4 g anhydrous magnesium sulfate, 1 g sodium chloride, 1 g trisodium citrate dehydrate, 0.5 g disodium hydrogencitrate sesquihydrate), the mixture was shaken again intensively for 1 min, then centrifuged at 4700 rpm for 10 min for phase separation. After that, the extract (organic phase) was filtered through a membrane filter and the final extract was directly employed for LC-MS/MS analysis. Quantification was performed using an internal standard, which was added to the extract after the initial addition of acetonitrile.

Fortification and control samples
For analytical sequence one sample blank matrix and two procedural recoveries at the level of LOQ and two at the level 10 x LOQ were prepared together with the study samples.

Table 2. Preparation of fortification and control samples

Fortification level	Amount of added standard solution [1.1] [µL]	Amount of added standard solution [1.2] [µL]	Amount of added internal standard solution [1.3] [µL]
Matrix blank	-	-	20.0
PK 0.010 mg/kg (LOQ)	-	20.0	20.0
PK 0.10 mg/kg (10 x LOQ)	20.0	-	20.0

Extraction of all field samples (treated and untreated), as well as control and fortified samples was performed on 26.04.2021 and after that the samples were directly employed for LC-MS/MS analysis, that was started on the same day.

Blank and fortification samples
For each analytical set the method's applicability in terms of accuracy was assessed by fortification of untreated test portions of the respective matrix and subsequent determination of the procedural recoveries upon applying the test method.
Procedural recoveries were handled and stored in the same way and for the same time period as the samples extracts that were generated within the same analytical set. Two of the fortification samples (LOQ and 10 x LOQ) were run at the very end of analytical sequence in order to ensure the active substance stability during the analytical method workflow.
Two sample blank matrix, two procedural recoveries at the level of LOQ and two at the level of 10 x LOQ per analytical set of respective matrix were analyzed during sequence.
The following results for matrix blank and fortified samples were obtained during analysis of untreated and treated samples 26.04.2021:

Table 10. Quality control samples

Sample Name	Result [mg/kg]	Recovery [%]
p matrix blank.lcd	< LOD	-
p PK1 0,010 mg-kg.lcd	0.011	109.3
p PK1 0,10 mg-kg.lcd	0.10	101.6
p' matrix blank.lcd	< LOD	-
p PK2 0,010 mg-kg.lcd	0.010	98.1
p PK2 0,10 mg-kg.lcd	0.091	90.7

LOD = 0.003 mg/kg, LOQ = 0.01 mg/kg

All recovery values at fortification levels of 0.010 mg/g and 0.10 mg/kg comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, Rev.1.
The stability of the analytes in the final extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the specimens for residue analysis. The recovery values for PK2 0.01 mg/kg and PK2 0.10 mg/kg (in the range of 70 – 120%) confirms the active substance stability during the analytical procedure. The duration of the extraction process was about 3 hours, the duration of the chromatographic analysis was 560 minutes (9.3

h). The total analytical procedure, from sample extraction till analysis, was performed and completed within 1 day (less than 13 h).
Extract stability is not considered to be an issue, since working standard that were used for quantification were always prepared on the same day as the work up of the specimen for residue analysis took place.

Conclusions- Analytical phase
The study was conducted using analytical method validated according to SANTE/2020/12830 Rev.1 guideline.
The limit of detection and quantification of the method was established at 0.003 and 0.010 mg/kg for wheat plant, respectively.
The performance of the method during the analytical study complies with SANTE/2020/12830 Rev.1 criteria (accuracy in the range 70 – 120%).
There were no interfering signals at retention time of analyzed compound in examined control matrix.

Summary of the field residue trials

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Spray volume applied (l/ha)	l prod./ha	Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Timing	Remarks
	(a)	(b)				(c)		(a)		(d)	(e)
21SGS39 – Northern France, Bourgogne	Winter wheat/Nemo	1) 06/11/2020 2) - 3) -	0.248	247.6	0.991	22/03/2021	BBCH 29	Whole plants	16.10 15.53 14.62 11.95 10.89 10.75 10.64 8.33 5.59 5.68 6.28	0 DAA 2 HAA 4 HAA 8 HAA 12 HAA 24 HAA 48 HAA 72 HAA 96 HAA 120 HAA 144 HAA	DT_{50}= 3.71 days
21SGS40 – Hungary, Monok	Winter wheat/ MU Ménròt	1) 22/09/2020 2) - 3) -	0.246	216	0.985	30/03/2021	BBCH 25	Whole plants	16.45 16.25 16.02 15.93 15.71 14.76 11.68 7.08 3.97 3.67 3.47	0 DAA 2 HAA 4 HAA 8 HAA 12 HAA 24 HAA 48 HAA 72 HAA 96 HAA 120 HAA 144 HAA	DT_{50}= 2.49 days

21SGS41 – Germany, Fahrdorf	Winter wheat/ RGT Reform	1) 15/09/2020 2) - 3) -	0.240	210	0.958	25/03/2021	BBCH 25	Whole plants	19.8 28.1 33.9 23.7 18.0 15.2 10.4 10.1 5.27 4.82 2.41	0 DAA 2 HAA 4 HAA 8 HAA 12 HAA 24 HAA 48 HAA 72 HAA 96 HAA 120 HAA 144 HAA	DT_{50}= 1.90 days
21SGS42– Poland, Cerekwica	Winter wheat/ Bataja	1) 23.09.2020 2) - 3) -	0.250	299.7	0.999	30/03/2021	BBCH 25	Whole plants	14.43 13.49 14.69 12.23 12.16 11.31 10.50 6.72 6.10 5.40 3.46	0 DAA 2 HAA 4 HAA 8 HAA 12 HAA 24 HAA 48 HAA 72 HAA 96 HAA 120 HAA 144 HAA	DT_{50}= 3.28 days

A 2.1.2.2 Nature of residues in livestock

No new studies submitted

A 2.1.3 Magnitude of residues in livestock

No new studies submitted

A 2.1.3.1 Livestock feeding studies

No new studies submitted

A 2.1.4 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.1.4.1 Processing studies on a core set of representative processes

No new studies submitted

A 2.1.5 Magnitude of residues in representative succeeding crops

No new studies submitted

A 2.1.6 Other/special studies

No new studies submitted

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
	3%	GEMS/Food G08	0.36	3%	Barley	0.3%	Wheat	0.0%	Rye		
	3%	GEMS/Food G15	0.87	3%	Barley	0.3%	Wheat	0.0%	Rye		
	3%	GEMS/Food G11	0.85	3%	Barley	0.2%	Wheat	0.0%	Rye		
	2%	GEMS/Food G07	0.63	2%	Barley	0.3%	Wheat	0.0%	Rye		
	2%	GEMS/Food G10	0.67	2%	Barley	0.3%	Wheat	0.0%	Rye		
	2%	DE general	0.56	2%	Barley	0.1%	Wheat	0.0%	Rye		
	2%	ES adult	0.54	2%	Barley	0.2%	Wheat				
	1%	NL general	0.33	1.0%	Barley	0.1%	Wheat	0.0%	Rye		
	0.9%	NL toddler	0.26	0.6%	Barley	0.3%	Wheat	0.0%	Rye		
	0.8%	DE women 14-50 yr	0.24	0.6%	Barley	0.1%	Wheat	0.0%	Rye		
	0.7%	GEMS/Food G06	0.22	0.5%	Wheat	0.2%	Barley	0.0%	Rye		
	0.7%	DK child	0.20	0.4%	Rye	0.3%	Wheat				
	0.6%	IT toddler	0.17	0.4%	Wheat	0.1%	Other cereals	0.0%	Barley		
	0.4%	PT general	0.11	0.3%	Wheat	0.1%	Barley	0.0%	Rye		
	0.4%	DE child	0.11	0.3%	Wheat	0.1%	Rye	0.0%	Barley		
	0.4%	IT adult	0.11	0.3%	Wheat	0.0%	Other cereals	0.0%	Barley		
	0.3%	LT adult	0.10	0.2%	Barley	0.1%	Rye	0.1%	Wheat		
	0.3%	FI 3 yr	0.10	0.2%	Barley	0.1%	Wheat	0.0%	Rye		
	0.3%	RO general	0.10	0.3%	Wheat		Grapefruits				
	0.3%	FR child 3 15 yr	0.10	0.3%	Wheat	0.0%	Barley	0.0%	Rye		
	0.3%	NL child	0.10	0.3%	Wheat	0.0%	Barley	0.0%	Rye		
	0.3%	UK toddler	0.09	0.3%	Wheat	0.0%	Barley	0.0%	Rye		
	0.3%	FI 6 yr	0.09	0.2%	Barley	0.1%	Wheat	0.0%	Rye		
	0.3%	ES child	0.09	0.3%	Wheat	0.0%	Barley				
	0.2%	SE general	0.07	0.2%	Wheat	0.0%	Rye				
	0.2%	FR toddler 2 3 yr	0.07	0.2%	Wheat	0.0%	Barley	0.0%	Rye		
	0.2%	UK vegetarian	0.06	0.1%	Wheat	0.1%	Barley	0.0%	Rye		
	0.2%	IE adult	0.06	0.2%	Wheat	0.0%	Barley	0.0%	Rye		
	0.2%	UK adult	0.06	0.1%	Wheat	0.1%	Barley	0.0%	Rye		
	0.2%	UK infant	0.05	0.2%	Wheat		Grapefruits				
	0.2%	FR adult	0.05	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
	0.1%	FI adult	0.04	0.1%	Barley	0.0%	Rye	0.0%	Wheat		
	0.1%	DK adult	0.03	0.1%	Wheat	0.0%	Rye				
	0.1%	IE child	0.03	0.1%	Wheat	0.0%	Barley				
	0.1%	FR infant	0.02	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
		Column7			Grapefruits		Grapefruits				

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

A 3.2 IEDI calculations

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.7%	DK child	0.20	0.4%	Rye	0.3%	Wheat				
	0.5%	IT toddler	0.16	0.4%	Wheat	0.1%	Other cereals	0.0%	Barley		
	0.5%	GEMS/Food G06	0.15	0.5%	Wheat	0.0%	Barley	0.0%	Rye		
	0.4%	GEMS/Food G08	0.13	0.3%	Wheat	0.1%	Barley	0.0%	Rye		
	0.4%	GEMS/Food G15	0.13	0.3%	Wheat	0.1%	Barley	0.0%	Rye		
	0.4%	GEMS/Food G07	0.11	0.3%	Wheat	0.1%	Barley	0.0%	Rye		
	0.4%	GEMS/Food G11	0.11	0.2%	Wheat	0.1%	Barley	0.0%	Rye		
	0.4%	GEMS/Food G10	0.11	0.3%	Wheat	0.1%	Barley	0.0%	Rye		
	0.3%	RO general	0.10	0.3%	Wheat		Grapefruits				
	0.3%	DE child	0.10	0.3%	Wheat	0.1%	Rye	0.0%	Barley		
	0.3%	IT adult	0.10	0.3%	Wheat	0.0%	Other cereals	0.0%	Barley		
	0.3%	NL toddler	0.09	0.3%	Wheat	0.0%	Rye	0.0%	Barley		
	0.3%	FR child 3 15 yr	0.09	0.3%	Wheat	0.0%	Barley	0.0%	Rye		
	0.3%	ES child	0.09	0.3%	Wheat	0.0%	Barley				
	0.3%	NL child	0.09	0.3%	Wheat	0.0%	Rye	0.0%	Barley		
	0.3%	PT general	0.08	0.3%	Wheat	0.0%	Rye	0.0%	Barley		
	0.3%	UK toddler	0.08	0.3%	Wheat	0.0%	Barley	0.0%	Rye		
	0.2%	DE general	0.07	0.1%	Wheat	0.1%	Barley	0.0%	Rye		
	0.2%	SE general	0.07	0.2%	Wheat	0.0%	Rye				
	0.2%	ES adult	0.07	0.2%	Wheat	0.1%	Barley				
	0.2%	FR toddler 2 3 yr	0.06	0.2%	Wheat	0.0%	Barley	0.0%	Rye		
	0.2%	DE women 14-50 yr	0.06	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
	0.2%	NL general	0.05	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
	0.2%	UK infant	0.05	0.2%	Wheat		Grapefruits				
	0.2%	IE adult	0.05	0.2%	Wheat	0.0%	Rye	0.0%	Barley		
	0.2%	LT adult	0.05	0.1%	Rye	0.1%	Wheat	0.0%	Barley		
	0.1%	FR adult	0.04	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
	0.1%	UK vegetarian	0.04	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
	0.1%	FI 3 yr	0.04	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
	0.1%	UK adult	0.03	0.1%	Wheat	0.0%	Barley	0.0%	Rye		
	0.1%	FI 6 yr	0.03	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
	0.1%	DK adult	0.03	0.1%	Wheat	0.0%	Rye				
	0.1%	IE child	0.02	0.1%	Wheat	0.0%	Barley				
	0.1%	FI adult	0.02	0.0%	Rye	0.0%	Wheat	0.0%	Barley		
	0.1%	FR infant	0.02	0.1%	Wheat	0.0%	Rye	0.0%	Barley		
		Column7			Grapefruits		Grapefruits				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Pyraclostrobin (F) 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 | Acute risk assessment /children | Acute risk assessment / adults / general population

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

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

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

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**IESTI new Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---				**IESTI new Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				IESTI new				IESTI new			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1.0%	Wheat	0.02 / 0.02	0.29	0.7%	Barley	1 / 0.05	0.22	19%	Barley	1 / 1	5.6	16%	Barley	1 / 1	4.8
0.8%	Barley	1 / 0.05	0.25	0.6%	Wheat	0.02 / 0.02	0.17	1.0%	Wheat	0.02 / 0.02	0.29	0.6%	Wheat	0.02 / 0.02	0.17
0.4%	Rye	0.02 / 0.02	0.13	0.3%	Rye	0.02 / 0.02	0.10	0.4%	Rye	0.02 / 0.02	0.13	0.3%	Rye	0.02 / 0.02	0.10
Expand/collapse list															
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)**							

A 3.4 IESTI calculations - Processed commodities

Processed commodities

Results for children				Results for adults				Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Rye / milling (wholemeal)-bal	0.02 / 0.22	0.77	0.4%	Barley / beer	1 / 0	0.11	8%	Barley / cooked	1 / 0.7	2.5	8%	Barley / beer	1 / 0.07	2.5
0.8%	Wheat / milling (flour)	0.02 / 0.02	0.24	0.3%	Wheat / bread/pizza	0.02 / 0.02	0.09	3%	Rye / milling (wholemeal)-	0.02 / 0.22	0.77	0.3%	Wheat / bread/pizza	0.02 / 0.02	0.09
0.4%	Barley / cooked	1 / 0.03	0.11	0.3%	Wheat / pasta	0.02 / 0.02	0.08	0.8%	Wheat / milling (flour)	0.02 / 0.02	0.24	0.3%	Wheat / pasta	0.02 / 0.02	0.08
0.4%	Wheat / milling (wholemeal)-l	0.02 / 0.02	0.11	0.2%	Wheat / bread (wholemeal)	0.02 / 0.02	0.07	0.4%	Wheat / milling (wholemeal)-	0.02 / 0.02	0.11	0.2%	Wheat / bread (wholemeal)	0.02 / 0.02	0.07
0.2%	Rye / boiled	0.02 / 0.01	0.05	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	0.4%	Barley / milling (flour)	1 / 0.06	0.11	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
0.0%	Barley / milling (flour)	1 / 0	0.00	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!	0.2%	Rye / boiled	0.02 / 0.01	0.05	#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Expand/collapse list															

Conclusion:

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