FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: CHR/H/FETEC – PART B 110 EC

Product name(s): Fenoxinn Max 110 EC, Herbos Max 110 EC

Chemical active substance:

Fenoxaprop-P-ethyl, 110 g/L

Cloquintocet-mexyl as a safener

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: February 2023

MS Finalisation date: 23/09/2024

Version history

When	What
05/2023	Dossier sent for evaluation
11/2023	zRMS evaluation of dRR
March 2024	Final version prepared by zRMS after Commenting period
September 2024	Evaluator's update in the context of the proposed TMs

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

The dRR was not rewritten. The zRMS text is on grey background.

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/H/FETEC – PART B 110 EC are presented in Table 7.1-1. They have been selected from the individual GAPs in the EU for cereals. A list of all intended uses within the EU is given in Part B, Section 0.

Overall conclusion

Solo use

The data available for the subject of the present authorisation request can be considered sufficient for risk assessment of the proposed solo uses of "CHR/H/ FETEC – PART B 110 EC" in cereals.
The applicant states that "no new data are submitted in the framework of this application. The studies were evaluated and accepted during registration of CHR/H/FETEC 110 EC (authorization number: R - 145/2016)". It is not clear whether this is exactly the same product or not because the code name is not the same. But this is the same formulation type, the same active, the same GAP and this is already approved PPP. Furthermore, there is also another product of the applicant with the same label, but the different code name again (CHR/H/FET 110 EC) also already approved (or renewed) in 2022 under authorization number R - 953/2022d of 30.11.2022.
The subject product, unlike the mentioned others, contains also Cloquintocet-mexyl – the safener, but Cloquintocet-mexyl has not been reviewed yet under Regulation (EC) No 1107/2009 and its data is not required according to the current legal framework. Thus, it can be concluded that no exceedance of the current MRL of 0.1 mg/kg for fenoxaprop-P-ethyl as laid down in Reg. (EU) 396/2005 is not expected. The chronic and the short-term intakes of fenoxaprop-P-ethyl residues are unlikely to present a public health concern.
Thus, as far as consumer health protection is concerned, zRMS agrees with the authorization of the intended solo uses in cereals for "CHR/H/ FETEC – PART B 110 EC". According to available data, no specific mitigation measures should apply.

TMs[1]

To expand the spectrum of weed control, the applicant in the GAP table (7.1.1) and the project of a label proposes to use "CHR/H/ FETEC – PART B 110 EC" in TMs with already registered PPPs containing Fluroxypyr and Tribenuron-methyl, as mixing partners.
~~However, zRMS points out that, the table 7.1.1 always must be treated as the subject of an assessment and of the formally submitted approval request. The present application does not include a formal approval request for the 2-actives mixes (solo PPP only), and also no such residue data were submitted.~~
~~The applicant within the justification of TMs proposal in the present dossier part A stated only that "The risk assessment for the combinations of CHR/H/FETEC-PART B 110 EC with Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC or with Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG is covered by~~

[1] Tank Mixes

~~the risk assessment of these plant protection products used separately (what is not necessarily true) and it is included in these products' registration dossiers".~~

Moreover, the applicant states (7.2.3.2.) that "studies (including uses with mention above tank mix) were evaluated and accepted during registration of CHR/H/FETEC 110 EC (Fenoxinn 110 EC – authorization number: R - 145/2016)". However, these studies were not submitted to support the intended TM GAP. Moreover, the RR of CHR/H/FET 110EC evaluated in March 2016 (different code name again - there was no CHR/H/FETEC 110 EC) was checked out on EU Circa and no such studies were evaluated and described there. The rest of the data in the yellowed text of 7.2.3.2 of the present B7 is the solo data originated from dossiers of mixing partners.

~~Thus, to make the approval of the intended TMs GAP formally possible and confirm the consumer safety after the intended treatments with TMs, the applicant should submit such application to the authority, and as usually submit the necessary data. If it cannot be excluded that the application as a TM presents a more critical case than the solo uses (this is the case), corresponding residue studies with the TM should be submitted. In zRMS opinion it should be at least 1 decline supervised residue field trial conducted consistently with the proposed each TM GAP. Moreover, the combined consumer exposure from the use of each proposed TM should be submitted by the applicant.~~

The legal basis for the above considerations is art. 29 of Regulation (EC) No 1107/2009 which states that the uniform principles of Regulation (EU) No 546/2011 are to be applied for the assessment during the authorization process of a plant protection products. Therefore, according to these principles and Article 29 (6), the interactions between active substances, safeners, synergists and co-formulants are taken into consideration when the plant protection products are evaluated. It is postulated that interactions with other plant protection products and their components must be considered in the context of the authorization procedure in the same way. To be able to judge such effects, additional data may have to be submitted with the application for authorization.

~~Finally concluding the applicant's case described above, the intended TMs must be removed from the GAP table (7.1.1) because for these uses there are no tool within the present dossier to evaluate them consistently with the regular authorization procedure.~~

However, the proposed TMs still can be within the label treated as untested TMs. The zRMS can differentiate here between untested and tested TMs[2]. The applicant's case are TMs without having been tested in the context of the authorisation procedure and for which no residue registration data were submitted. They are often used in common practice, for example due to advice which has been given or based on the operator's own experience. The instructions for use often state such mixes recommendations (in Poland also). Tested TMs on the other hand are evaluated by the authorities during the regular authorisation procedure and are declared as such. An application must be submitted by the applicant for this kind of TM. As far as tested TMs are concerned, according to Regulation (EC) No 546/2011 implementing Regulation (EC) No 1107/2009, a distinction is made between recommended tank mixes and required tank mixes.

In case of untested TMs however, Member States will need to consider if the submitted information is sufficient to support the claims made in their Member State, based on their knowledge of the active substances, the situations of use and national experience/conventions with labelling.

Data gaps

Noticed data gaps are: ~~for the case of so called "untested" TM~~, none

[2] Tank mixes in the authorization procedure for plant protection products, 2015 www.bvl.bund.de

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	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
					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), Winter triticale (TTLWI) Winter barley (HORVW)	F	monocotyledonous weeds	Spray, medium sprayer	spring BBCH 20-31	a)1 b)1	n/a	a) 0.7 l/ha b) 0.7 l/ha	a) 0.077 kg a.s./ha b) 0.077 kg a.s./ha	200-400	n/a	
2	PL	Spring wheat (TRZAS), Spring barley (HORVS)	F	monocotyledonous weeds	Spray, medium sprayer	spring BBCH 20-31	a)1 b)1	n/a	a) 0.7 l/ha b) 0.7 l/ha	a) 0.077 kg a.s./ha b) 0.077 kg a.s./ha	200-400	n/a	
3	PL	Winter wheat (TRZAW), Winter triticale (TTLWI) Winter barley (HORVW)	F	monocotyledonous and dicotyledonous weeds	Spray, medium sprayer	spring BBCH 20-31	a)1 b)1	n/a	a) 0.5 l/ha +25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG b) 0.5 l/ha +25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG	a) 0.055 kg a.s./ha + 0.0125 kg a.s/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG b) 0.055 kg a.s./ha + 0.0125 kg a.s/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG	200-400	n/a	**The products indicated as components of the proposed Tank Mix****, must be applied only according to their currently valid GAPs and consistently with the intended FENOXINN MAX 110 EC GAP.** Untested TM is acceptable in the label
4	PL	Spring wheat (TRZAS), Spring barley (HORVS)	F	monocotyledonous and dicotyledonous weeds	Spray, medium sprayer	spring BBCH 20-31	a)1 b)1	n/a	a) 0.5 l/ha +25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG b) 0.5 l/ha +25 g/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG	a) 0.055 kg a.s./ha + 0.0125 kg a.s/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG b) 0.055 kg a.s./ha + 0.0125 kg a.s/ha Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG	200-400	n/a	
5	PL	Winter wheat (TRZAW),	F	monocotyledonous and	Spray, medium	spring BBCH 20-31	a)1 b)1	n/a	a) 0.5 l/ha + 0.4 l/ha Galaper 200 EC/ Fluroherb 200	a) 0.055 kg a.s./ha + 0.08 kg a.s/ha Galaper 200 EC/	200-400	n/a	

		Winter triticale (TTLWI) Winter barley (HORVW)		dicotyledonous weeds	sprayer				EC/ Herbistar 200 EC b) 0.5 l/ha + 0.4 l/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC	Fluroherb 200 EC/ Herbistar 200 EC b) 0.055 kg a.s./ha + 0.08 kg a.s/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC			
6	PL	Spring wheat (TRZAS), Spring barley (HORVS)	F	monocotyledonous and dicotyledonous weeds	Spray, medium sprayer	spring BBCH 20-31	a)1 b)1	n/a	a) 0.5 l/ha + 0.4 l/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC b) 0.5 l/ha + 0.4 l/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC	a) 0.055 kg a.s./ha + 0.08 kg a.s/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC b) 0.055 kg a.s./ha + 0.08 kg a.s/ha Galaper 200 EC/ Fluroherb 200 EC/ Herbistar 200 EC	200-400	n/a	

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

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

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

**** The label indicates the following products for preparing tank mixtures: Tristar 50 SG/Toraya 50 SG/Triben Super 50 SG/Draco 50 SG and Galaper 200 EC/Fluroherb 200 EC/Herbistar 200 EC (applicant's notation). The composition of the tank mixture for the treatment is as follows: FENOXINN MAX 110 EC - 0.5 l/ha + Tristar 50 SG/Toraya 50 SG/Triben Super 50 SG/Draco 50 SG - 25 g/ha + Galaper 200 EC/Fluroherb 200 EC/Herbistar 200 EC - 0.40 l/ha. The evaluator does not have data that would allow a decision on which compositions/products are to be ultimately used. However, all products listed in the above GAP table and/or on the label must have current authorisations and as components of the proposed Tank Mix, can be applied only according to their currently valid GAPs and consistently with the intended FENOXINN MAX 110 EC GAP.

Explanation for Column 11 "Conclusion"

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

7.1.2 Summary of the evaluation

The preparation CHR/H/FETEC-PART B 110 EC is composed of fenoxaprop-P-ethyl.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of fenoxaprop-P-ethyl.

Reference value	Source	Year	Value	Study relied upon	Safety factor
fenoxaprop-P-ethyl - Parent compound (if applicable)					
ADI	EFSA Scientific Report (2007) 121, 1-76	2007	0.01	2-year dog study supported by the 2-year and multigeneration rat studies	100
ARfD	EFSA Scientific Report (2007) 121, 1-76	2007	0.1	based on the foetal NOAEL from the rat developmental study	100

7.1.2.1 Summary for fenoxaprop-P-ethyl

Table 7.1-3: Summary for fenoxaprop-P-ethyl

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
	Winter cereals	Yes	Yes	Yes	Yes	Yes	No	No
	Spring cereals	Yes	Yes	Yes	Yes	Yes		No

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

For cereals, no additional data are required in post-registration to confirm that a “no-residue” situation occurs in the worst case application: 1 application of 77 fenoxaprop-P-ethyl g/ha at growth stage BBCH 20-31.

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

The effects of processing on the nature of fenoxaprop-P-ethyl residues have been investigated. Data on effects of processing on the amount of residue have been submitted.

These data were considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.
MRLs in following crops/ following mitigation measures have been proposed: None

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

7.1.2.2 Summary for CHR/H/FETEC-PART B 110 EC

Table 7.1-4: Information on CHR/H/FETEC-PART B 110 EC (KCA 6.8)

Crop	PHI for CHR/H/FETEC-PART B 110 EC proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CHR/H/FETEC-PART B 110 EC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Fenoxaprop-P-ethyl		
Winter cereals	is covered by the normal vegetation period between last application and harvest	NR	n/a	
Spring cereals	is covered by the normal vegetation period between last application and harvest	NR		

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).

Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for CHR/H/FETEC-PART B 110 EC
Crop group	**Led by Fenoxaprop-P-ethyl**	
Leafy vegetables	NR	n/a
Root vegetables	NR	
Cereals	NR	

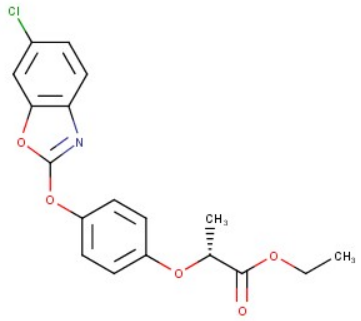
NR: not relevant

Assessment

7.2 Fenoxaprop-P-ethyl

General data on Fenoxaprop-P-ethyl are summarized in the table below.

Table 7.2-1: General information on Fenoxaprop-P-ethyl

Active substance (ISO Common Name)	Fenoxaprop-P-ethyl
IUPAC	ethyl (R)-2[4-[(6-chloro-2-benzoxazolyl)oxy]-phenoxy]-propanoate
Chemical structure	
Molecular formula	$C_{18}H_{16}ClNO_5$
Molar mass	361.8 g/mol
Chemical group	Group A
Mode of action (if available)	Inhibition of Acetyl CoA Carboxylase
Systemic	Yes
Company (ies)	Bayer CropScience AG
Rapporteur Member State (RMS)	Austria
Approval status	Approved COMMISSION IMPLEMENTING REGULATION (EU) 2022/1480 of 7 September 2022
Restriction (e.g. is restricted to use as "...")	SANCO/3777/08 – rev. 1 14 December 2007
Review Report	SANCO/3777/08 – rev. 1 14 December 2007
Current MRL regulation	Reg. (EC) No 149/2008
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	No
EFSA Journal : Conclusion on the peer review	EFSA Scientific Report (2007) 121, 1-76

EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	N/A – MRL already set

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

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

No new data submitted in the framework of this application. The studies were evaluated and accepted during registration of CHR/H/FETEC 110 EC (Fenoxinn 110 EC – authorization number: R - 145/2016).

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat grain	High starch content	24 months	Fuchsbichler, C. 1993, Document No: A51681, DAR, 2006, Fenoxaprop-P-ethyl - Volume 3, Annex B.7 Residue data
Barley straw and grain	High water and starch content	14 months	Fuchsbichler, C. 1993, Document No: A51681, DAR, 2006, Fenoxaprop-P-ethyl - Volume 3, Annex B.7 Residue data

Conclusion on stability of residues during storage

The storage stability evaluated during Annex I inclusion covers plant matrices for use CHR/H/FETEC-PART B 110 EC according to the label.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Stability of residues in sample extracts was evaluated at EU level. Additional studies are not required. The studies were evaluated and accepted during registration of CHR/H/FETEC 110 EC (Fenoxinn 110 EC – authorization number: R - 145/2016).

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 studies were evaluated and accepted during registration of CHR/H/FETEC 110 EC (Fenoxinn 110 EC – authorization number: R - 145/2016).

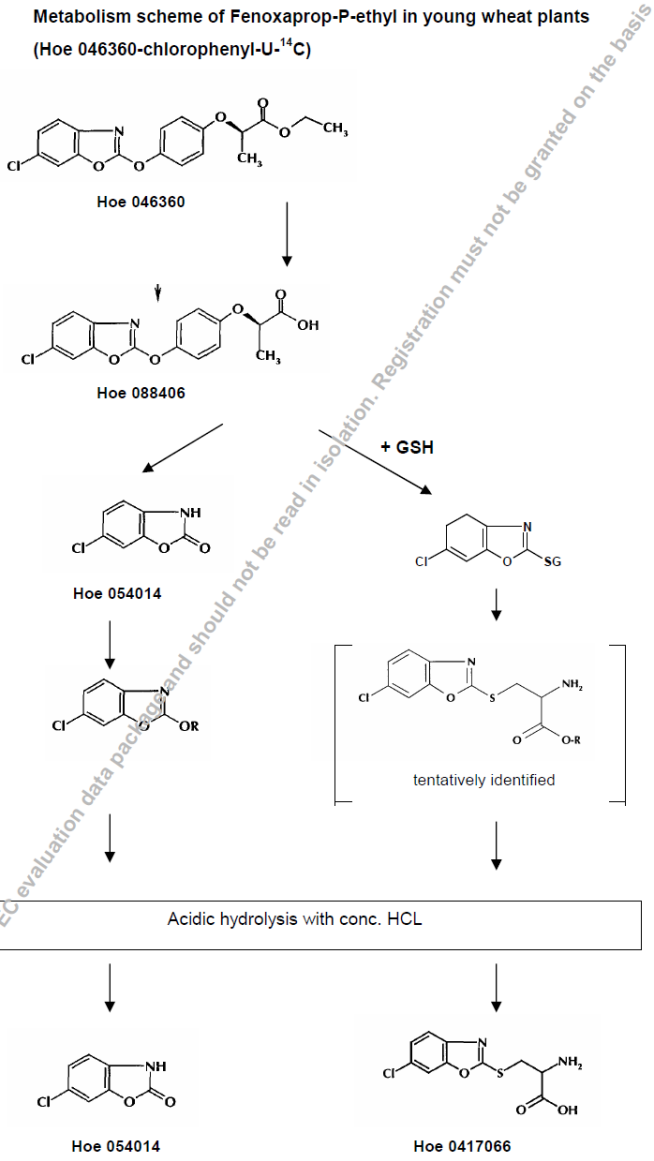
Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Cereals	wheat	chloro-phenyl-U-14C	Foliar, F	0.110	1	15, 30, 60, 109 days		A35778; Wink O., Kuenzler K., Lemke G.; 1987a
	wheat	chloro-phenyl-U-14C	Foliar, G	0.090	1	1, 7 days		C009798, Buerkle L.W.; 2000e
	wheat	chloro-phenyl-U-14C	Foliar, F	0.180	1	2, 4, 21, 27, 96 hours and 10 days		A36855; Schwalbe-Fehl M., Schmidt E., Koecher H.; 1987b
	wheat	chloro-phenyl-U-14C	Foliar, F	0.183	1	10, 37, 59, 83, 109 days		A34525; Schwalbe-Fehl M., Schmidt E., Koecher H.; 1986a
	barley	chloro-phenyl-U-14C	Foliar, G	0.090	1	3, 23, 47, 71 and 141 hours		A58851, Buerkle W.L., Becker A.; 1997a
	rice	chloro-phenyl-U-14C	Foliar, F	0.090	1	2, 6, 7, 9, 13, 17, 22, 36,		A38627, Wink O., Kuenzler

						63, 84 and 112 days		K., Lemke G., Haberkorn B., Mueller H.J.; 1988a
	rice	dioxyphenyl-1-14C	Foliar, F	0.090	1	0, 6, 112, 122 days		A40366, Buettner B., Kuenzler K., Lemke G., Mueller H.J.; 1988a
	soya beans and wheat	chloro-phenyl-U-14C	Foliar, G	0.110	1	5, 12 days		A35943, Wink O., Kuenzler K., Lemke G., Koecher H.; 1986a

Summary of plant metabolism studies reported in the EU

Metabolism studies were conducted on wheat, barley, rice and one study on wheat and soya beans with Fenoxaprop-P-ethyl (Hoe 046360) as well as with the racemic compound Fenoxaprop-ethyl (Hoe 033171). The results on the metabolism studies on wheat and rice are summarised in Table B.7.1.4 1. A no residue situation is given for wheat grain with values below 0.01 mg as-equ/kg. In wheat straw a residue level of 0.087 mg ai-equ/kg and in directly treated parts of rice straw a residue level of approx. mately 0.8 mg as-equ/kg was detected. The influence of the safener Hoe 107892 (Mefenpyr-diethyl) on the metabolism of the herbicide Fenoxaprop-P-ethyl was investigated on barley. The results showed that the metabolic profile in barley shoots was indepent from the presence or absence of the safener. No I formation was submitted about the stability and possible metabolic behaviour of the safener. There was no obvious difference in the metabolic behaviour of the racemic compound andnthe P-enantiomer observed. In both cases the parent compound is converted in the plant via ester hydrolysis to form Fenoxaprop-P (Hoe 088406 or the racemic form Hoe 053022, respectively), which showed still herbicidal activity. The cleavage of the ether-linkage between the benzoxazolone- and the phenoxy- part of the compound seemed to be the main step in the metabolism of this herbicide. Studies on rice with the dioxyphenyl-labeled Hoe 046360 showed that Hoe 096918 (hydroxyphenoxypropionic acid= HOPP acid) was also formed at cleavage of the ether bond. Under acidic conditions the compound chlorobenzoxazolone Hoe 054014 was formed by hydrolysis. A study on soya beans and wheat showed, that there was no racemization observed for the parent compound (Hoe 046360) or it´s rapidly formed main metabolite Fenoxaprop-P (Hoe 088406).



Conclusion on metabolism in primary crops

The metabolism in primary crops presented during Annex I inclusion, covers use of CHR/H/FETEC-PART B 110 EC on winter and spring cereals. No new studies were necessary.

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 studies were evaluated and accepted during registration of CHR/H/FETEC 110 EC (Fenoxinn 110 EC – authorization number: R - 145/2016).

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

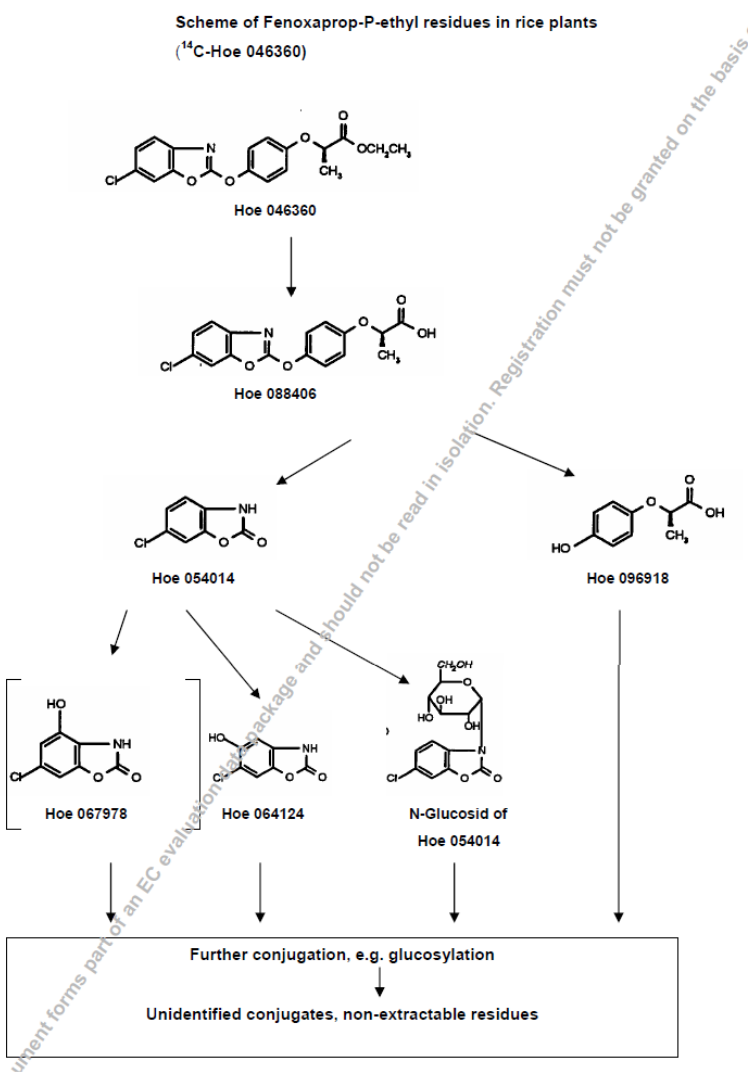
Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing inter-vals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Cereals	wheat and buckwheat	U-chlorophenyl-14C	Soil, F	0.113	30, 365	At maturnity		A37484: Buerkle L.; 1987a
	Wheat	A:chlorophenyl-U-14C and B:dioxyphenyl-1-14C	Foliar, G	A: 0.110 B: 0.070	111	268 (At maturnity)		A31992: Schwalbe-Fehl M.. Steinau M.. Mueller H.J.; 1985a
Leafy vegeta-bles	spinach and lettuce	U-chlorophenyl-14C	Soil, F	0.113	30, 365	At maturnity		A37484: Buerkle L.; 1987a
	spinach	A:chlorophenyl-U-14C and B:dioxyphenyl-1-14C	Foliar, G	A: 0.110 B: 0.070	111	250 (At maturnity)		A31992: Schwalbe-Fehl M.. Steinau M.. Mueller H.J.; 1985a
Root vegeta-bles	little radish and carrots	U-chlorophenyl-14C	Soil, F	0.113	30, 365	At maturnity		A37484: Buerkle L.; 1987a
	red beets	A:chlorophenyl-U-14C and B:dioxyphenyl-1-14C	Foliar, G	A: 0.110 B: 0.070	111	268 (At maturnity)		A31992: Schwalbe-Fehl M.. Steinau M.. Mueller H.J.; 1985a

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

Summary of plant metabolism studies reported in the EU

The possible intake of soil residues via succeeding crops was investigated by two studies using radiolabeled Fenoxaprop-P-ethyl (chlorophenyl-U-14C) and Fenoxaprop-ethyl (dioxyphenyl-1-14C and chl rophenyl-U-14C). Total radioactive residues in plants, sown 30 days, 120 days and one year after application were very low or even below the limits of quantification (LOQ) for all crops tested (leafy vegetables, root vegetables and cereals) at all time points investigated. Residues at low concentrations were found only in soil layers up to 5 cm. but there was no evidence either of residue uptake or accumulation by plants or soil

indicating a rapid metabolisation of Fenoxaprop-P-ethyl (Hoe 046360) and its racemic compound Fenoxaprop-ethyl (Hoe 033171), respectively. It can be concluded that the application of Fenoxaprop-P-ethyl according to the intended use will not lead to detectable residues in succeeding crops.



Conclusion on metabolism in rotational crops

The metabolism in rotational crops presented during Annex I inclusion, covers use of CHR/H/FETEC-PART B 110 EC on winter and spring cereals. No new studies were necessary.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

No significant residues, i.e. > 0.1 mg/kg, were found in winter and spring cereals and therefore processing studies are not required. No new studies are necessary for CHR/H/FETEC-PART B 110 EC, since all residues are expected to be below 0.1 mg/kg.

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

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

Endpoints	
Plant groups covered	Cereals (Wheat)
Rotational crops covered	Leafy vegetables (spinach, lettuce) Root vegetables (little radish, carrots, red beets), Cereals (wheat and buckwheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Expected to be similar considering the residue pattern in soil. Nevertheless residues in rotational crops were not identified due to their extremely low levels.
Processed commodities	Not required
Residue pattern in processed commodities similar to pattern in raw commodities?	Not required
Plant residue definition for monitoring	Sum of fenoxaprop-P-ethyl and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-P-ethyl. or alternatively: Sum of fenoxaprop-ethyl and all metabolites which may be converted to 6-chloro- 2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-ethyl.
Plant residue definition for risk assessment	Sum of fenoxaprop-P-ethyl and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-P-ethyl
Conversion factor from enforcement to RA	None

* If residue pattern in processed commodities is not similar to that in raw commodities

** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).

*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

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

Available data

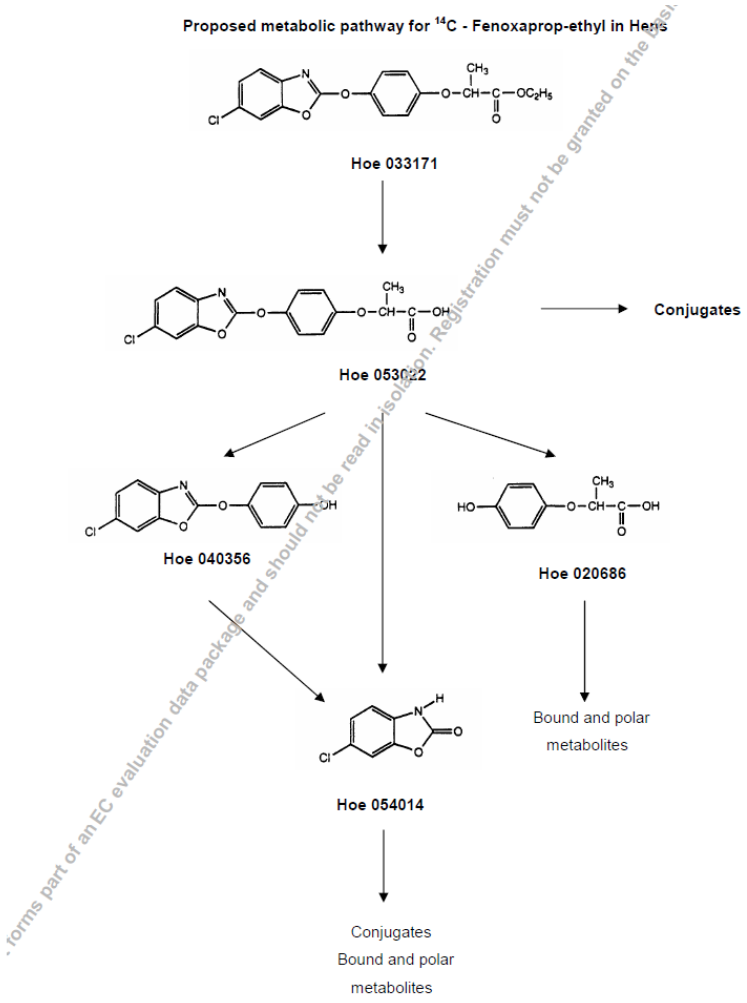
No new data submitted in the framework of this application. The studies were evaluated and accepted during registration of CHR/H/FETEC 110 EC (Fenoxinn 110 EC – authorization number: R - 145/2016).

Table 7.2-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	chlorophenyl-U-14C	1	5.5	3	Milk	twice daily	A41369; xxxxxxxx; 1989o Amendment A42690; xxxxxxxxx; 1990b
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	chlorophenyl-U-14C	12	0.41	5	Eggs	Twice daily	A40877;xxxxxx; 1989a
						Excreta	regular intervals	
						Tissues	at sacrifice	
	Hens	chlorophenyl-U-^{14}C and dioxyphenyl-1-^{14}C	10	0.74 (Chlorophenyl Label) 0.81 (Dioxyphenyl Label)	5	Eggs	Twice daily	A53203; xxxxx,. xxxxxxxxx; 1994a
						Excreta	Once daily	
						Tissues	at sacrifice	

Summary of plant metabolism studies reported in the EU

Fenoxaprop-ethyl (Hoe 033171) is mainly excreted (almost 98.1 % for the chlorophenyl-label and 96.4 % for the dioxyphenyl-label) when administered to hens at a rate of approx. 0.8 mg/kg bw/day for five consecutive days. The administered dose corresponded to a dietary concentration of 9 mg/kg feed. Residues in edible tissues and eggs were low , the principal route of metabolism is, similar to other species, the de-esterification to the free acid Hoe 053022, followed by cleavage of the ether linkage between the two rings forming on the one hand the metabolite Hoe 054014 (chlorobenzoxzolone) and other hand Hoe 020686 (hydroxyphenoxypropionic acid = HOPP acid). The metabolite Hoe 040356 was identified in egg yolks only. For the proposed metabolic pathway see Figure B.7.2.2-8.



Conclusion on metabolism in livestock

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

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

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

	Endpoints
Animals covered	Lactating goats
	Laying hens

Time needed to reach a plateau concentration	Not reached throughout the duration of the metabolism studies (3 days-lactating goat, 5 days-laying hens)
Animal residue definition for monitoring	not required
Animal residue definition for risk assessment	not required
Conversion factor	Not necessary
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)

** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

*** If metabolism in rat and ruminant are not similar

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

No new data are submitted in the framework of this application. The studies were evaluated and accepted during registration of CHR/H/FETEC 110 EC (Fenoxinn 110 EC – authorization number: R - 145/2016).

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of CHR/H/FETEC-PART B 110 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, Rye, Barley grain	EFSA Scientific Report (2007) 121, 1-76	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.083 kg as/ha, BBCH 10-32, outdoor E: 12x < 0.02 RA: 12x < 0.02	N/A				
	Overall supporting data for cGAP	N-EU	E: 12x < 0.02 RA: 12x < 0.02	<0.02	<0.02		0.1	Yes
Wheat, Rye, Barley straw	EFSA Scientific	N-EU	GAP on which MRL/EU a.s. assessment is based: 2 x 0.083 kg as/ha, BBCH 10-32, outdoor	N/A				

	Report (2007) 121, 1-76		E: 12x < 0.05 RA: 12x < 0.05					
	Overall supporting data for cGAP	N-EU	E: 12x < 0.05 RA: 12x < 0.05	<0.05	<0.05		0.1	Yes

* Source of EU MRL: 2017/1016

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on cereals are considered acceptable, for outdoor uses.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.
CHR/H/FETEC 110 EC – Part B can be use in tank mix with Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG/Draco 50 SG containing 500 g/kg tribenuron-methyl (renewal authorization: R - 19/2021o in 13.05.2021 r; MRL for cereals = 0.01 mg/kg) or Galaper 200 EC/Fluroherb 200 EC/Herbistar 200 EC, containing 200 g/L fluroxypyr (renewal authorization: R – 696/2017d in 27.12.2017 r ; MRL for cereals – 0.1 mg/kg). All residue for tribenuron-methyl and fluroxypyr were below MRL value in cerelas for both Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG/Draco 50 SG and for Galaper 200 EC/Fluroherb 200 EC/Herbistar 200 EC.

Accepted GAP for Tristar 50 SG/Trimax 50 SG/Triben Super 50 SG/Draco 50 SG (renewal authorization: R - 19/2021o in 13.05.2021 r.). No quantifiable tribenuron methyl residues (<0.003 mg/kg) were found in cereal grains at the time of harvest.

1	2	3	4	5	6	7	8	9	10	11	12	13	14
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)
					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, CZ, SK, RO, HU, LV	Winter cereals	F	Dicotyledonous weed species	Spray, medium sprayer	Spring BBCH 26-32	a) 1 b) 1	NA	a) 0.030 kg/ha b) 0.030 kg/ha	a) 0.015 kg a.s./ha b) 0.015 kg a.s./ha	200 - 300	n/a	
2	PL, CZ, SK, RO, HU, LV	Winter cereals	F	Dicotyledonous weed species	Spray, medium sprayer	Spring BBCH 26-32	a) 1 b) 1	NA	a) 0.040 kg/ha b) 0.040 kg/ha	a) 0.020 kg a.s./ha b) 0.020 kg a.s./ha	200 - 300	n/a	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/or situation (crop destination / purpose of crop)**	**F, Fn, FpnG, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application** Method / Kind	**Application** Timing / Growth stage of crop & season	**Application** Max. number a) per use b) per crop / season	**Application** Min. interval between applications (days)	**Application rate** kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	**Application rate** g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	**Application rate** Water L/ha min / max	**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
3	PL, CZ, SK, RO, HU, LV	Winter cereals	F	Dicotyledonous weed species	Spray, medium sprayer	Spring BBCH 26-32	a) 1 b) 1	NA	a) 0.025 kg/ha CHR/H/1TR + 0.035 kg/ha Galaper 200 EC* b) b) 0.025 kg/ha 4CHR/H/1TR + 0.035 kg/ha Galaper 200 EC*	a) 0.0125 kg a.s./ha tribenuron-methyl + 0.07 kg a.s/ha fluroksypyr b) b) 0.0125 kg a.s./ha tribenuron-methyl + 0.07 kg a.s/ha fluroksypyr	200 - 300	n/a	
4	PL, CZ, SK, RO, HU, LV	Winter cereals	F	Dicotyledonous weed species	Spray, medium sprayer	Spring BBCH 26-32	a) 1 b) 1	NA	a) 0.030 kg/ha b) 0.030 kg/ha	a) 0.015 kg a.s./ha b) 0.015 kg a.s./ha	200 - 300	n/a	
5	PL, CZ, SK, RO, HU,	Winter	F	Dicotyledonous weed	Spray, medium sprayer	Spring BBCH 26-32	a) 1 b) 1	NA	a) 0.040 kg/ha b) 0.040 kg/ha	a) 0.020 kg a.s./ha b) 0.020 kg a.s./ha	200 - 300	n/a	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F, Fn, FpnG, 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)
					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		
	LV	cereals		species									
6	PL, CZ, SK, RO, HU, LV	Winter cereals	F	Dicotyledonous weed species	Spray, medium sprayer	Spring BBCH 26-32	a) 1 b) 1	NA	c) 0.025 kg/ha CHR/H/1TR + 0.035 kg/ha Galaper 200 EC* d) b) 0.025 kg/ha CHR/H/1TR + 0.035 kg/ha Galaper 200 EC*	c) 0.0125 kg a.s./ha tribenuronmethyl + 0.07 kg a.s/ha fluroksypyr d) b) 0.0125 kg a.s./ha tribenuronmethyl + 0.07 kg a.s/ha fluroksypyr	200 - 300	n/a	Use wasn't a subject of the evaluation in the section B9
7	PL, CZ, SK, RO, HU, LV	Sprig cereals	F	Dicotyledonous weed species	Spray, medium sprayer	Spring BBCH 20-31	a) 1 b) 1	NA	a) 0.025 kg/ha b) 0.025 kg/ha	a) 0.0125 kg a.s./ha b) 0.0125 kg a.s./ha	200 - 300	n/a	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
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)
					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		
8	PL, CZ, SK, RO, HU, LV	Sprig cereals	F	Dicotyledonous weed species	Spray, medium sprayer	Spring BBCH 20-31	a) 1 b) 1	NA	a) 0.030 kg/ha b) 0.030 kg/ha	a) 0.015 kg a.s./ha b) 0.015 kg a.s./ha	200 - 300	n/a	

GAP for Galaper 200 EC/Fluroherb 200 EC/Herbistar 200 EC (renewal authorization: R – 696/2017d in 27.12.2017 r). Residue for fluroxypyr were also evaluated during inclusion on Annex 1 in DAR of fluroxypyr.

Crop and/or situation	**Member State or Country**	**Product name**	**F G or I**	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days)	**Remarks:**
(a)			(b)	(c)	Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	(l)	(m)
HORVS Spring barley *Hordeum vulgare*	PL	Galaper 200 EC* + Galmet 20 SG	F	dicotyledonous weeds	EC + SG	200g/l + 200g/kg	Foliar spray, spray medium	BBCH 21-30	1	N/A	0,0167 - 0,04 + 0,0013 - 0,002	200-300	0,050 – 0,080 + 0,004	N/A	

TRZAW Winter wheat *Triticum aestivum*	PL	Galaper 200 EC*	F	dicot-yle-donous weeds	EC	200 g/l	spray me-dium	BBCH 26-32	1	N/A	0,04-0,1	200-300	0,12 – 0,2	N/A	
TRZAW Winter wheat *Triticum aestivum*	PL	Galaper 200 EC* + Galmet 20 SG	F	dicot-yle-donous weeds	EC	200 g/l	spray me-dium	BBCH 26-32	1	N/A	0,0267 – 0,06 + 0,0013 – 0,002	200-300	0,08-0,12 + 0,04	N/A	
TRZAW Winter wheat *Triticum aestivum*	PL	GAL-APER 200 EC * + TRI-MAX 50 SG***	F	di-cot-yle-don ous we eds	EC + SG	200 g/l + 500 g/kg	spray me-diu m	BBCH 26-32	1	N/A	0,023 – 0,035 + 0,0041 – 0,00625	200-300	0,070 + 0,0125	N/A	
TTLWI Winter Triticale *Triticosecale Wittm. ex A. Camus*	PL	Galaper 200 EC*	F	dicot-yle-donous weeds	EC	200 g/l	Foliar spray, spray me-dium	BBCH 24-31 spring	1	N/A	0,04 – 0,1	200-300	0,12 - 0,20	N/A	
TTLWI Winter Triticale *Triticosecale Wittm. ex A. Camus*	PL	Galaper 200 EC* + Galmet 20 SG	F	dicot-yle-donous weeds	EC + SG	200 g/l + 200 g/kg	Foliar spray, spray me-dium	BBCH 24-31 spring	1	N/A	0,0267 – 0,06 + 0,002 – 0,0013	200-300	0,08 - 0,12 + 0,004	N/A	

TTLWI Winter Triticale *Triticosecale Wittm. ex A. Camus*	PL	GALAPER 200 EC * + TRIMAX 50 SG** *	F	dicotyledonous weeds	EC + SG	200 g/l + 500 g/kg	spray medium	BBCH 26-32	1	N/A	0,023 – 0,035 + 0,0041 – 0,00625	200-300	0,070 + 0,0125	N/A	
TTLWI Winter Triticale *Triticosecale Wittm. ex A. Camus*	PL	GALAPER 200 EC * + TOTO 75 SG **** + Partner+	F	dicotyledonous weeds	EC + SG	200 g/l + 750 g/kg	spray medium	BBCH 26-31	1	N/A	0,016 – 0,025 + 0,0175 – 0,0262	200-300	0,050 + 0,0525	N/A	
SECCW Rye Secale cereale (winter)	PL	Galaper 200 EC*	F	dicotyledonous weeds	EC	200 g/l	Foliar spray, spray medium	BBCH 26-31 spring	1	N/A	0,04 – 0,1	200-300	0,12 - 0,20	N/A	
SECCW Rye Secale cereale (winter)	PL	Galaper 200 EC* + Galmet 20 SG	F	dicotyledonous weeds	EC + SG	200 g/l + 200 g/kg	Foliar spray, spray medium	BBCH 24-30 spring	1	N/A	0,0267 – 0,06 + 0,002 – 0,0013	200-300	0,08 - 0,12 + 0,004	N/A	
SECCW Rye Secale	PL	GALAPER 200 EC * +	F	dicotyledon	EC + SG	200 g/l + 750	spray medium	BBCH 26-31	1	N/A	0,016 – 0,025 + 0,01	200-300	0,050 + 0,0525	N/A	

ce-reale (win ter)		TOTO 75 SG **** + Part-ner+		ous we eds		g/k g					75 – 0,02 62				
Winter cere-als: TRZA W Winter wheat *Triti-cum aes-tivum* HORV WWin ter barley *hordeu m vul-gare (win-ter)*	RO , HU , SK	GALA-PER 200 EC*	F	dicot-yle-donou s weeds	EC	200 g/l	Fo-liar spray , spray me-dium	BBC H 26-31	1	N/A	0,04 - 0,1	200 - 300	0,12 – 0,20	N/A	
Win-ter ce-reals: TRZA W Win-ter wheat *Triti-cum aes-tivum* HOR VWW inter barley *horde um vul-gare (win-ter)*	RO , HU , SK	GALA-PER 200 EC* + GAL-MET 20 SG *	F	dicot-yle-donou s weeds	EC + SG	200 g/l + 200 g/kg	Fo-liar spray , spray me-dium	BBC H 26-31	1	N/A	0,0267 - 0,04 + 0,002 – 0,0013	200 - 300	0,08 + 0,004	N/A	
HOR VS Spring barley *Horde um*	PL, CZ	Galaper 200 EC	F	dicot-yle-donou s weeds	EC	200g/ l	Fo-liar spray , spray me-dium	BBC H 12 -39	1	N/A	0,026 – 0,07	200 – 300	0,08 – 0,14	N/A	

vul-gare															
HORVS Spring barley *Hordeum vul-gare*	PL, CZ	Galaper 200 EC + Tri-max 50 SG	F	dicot-yle-donous weeds	EC + SG	200g/l + 500g/kg	Fo-liar spray, spray me-dium	BBCH 30 -39	1	N/A	0,026 – 0,04 + 0,005 – 0,0075	200 – 300	0,08 + 0,015	N/A	
Maize *Zea mays* (ZEA MX)	PL, CZ	Galaper 200 EC	F	dicot-yle-donous weeds	EC	200g/l	Fo-liar spray, spray me-dium	BBCH 12-16	1	N/A	0,053 – 0,1	200 – 300	0,16 – 0,2	N/A	
Maize *Zea mays* (ZEA MX)	PL, CZ	Galaper 200 EC + CHR/H/TIF + CHR/H/MEZ	F	dicot-yle-donous weeds	EC + OD + SE	200g/l + 40g/l + 200g/l	Fo-liar spray, spray me-dium	BBCH 12-16	1	N/A	0,053 – 0,1 + 0,003 – 0,005 + 0,033 – 0,05	200 – 300	0,16 – 0,2 + 0,010 + 0,100	N/A	

The studies (including uses with mention above tank mix) were evaluated and accepted during registration of CHR/H/FETEC 110 EC (Fenoxinn 110 EC – authorization number: R - 145/2016).

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Dietary burden calculation has been made at EU level in the framework of the peer review, EFSA Scientific Report (2007) 121, 1-76.

A ruminant feeding study was conducted with animals fed with a mixture of the racemic substance fenoxaprop-ethyl and chlorobenzoxazolone. This study shows that up to a dietary burden of 0.2 mg fenoxaprop-ethyl equivalent/kg feed, total residues in edible ruminant commodities are below the LOQ level (0.01 mg/kg).

Since all residues for CHR/H/FETEC-PART B 110 EC in cereals are below LOQ there is no need to perform risk assessment for dietary burden. There will no risk for domestic animals feeding grains in accord to the label. The studies were evaluated and accepted during registration of CHR/H/FETEC 110 EC (Fenoxinn 110 EC – authorization number: R - 145/2016).

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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

The study is not required considering that nonsignificant residues may occur in the edible animal tissues taking into account the residue levels in potential feeding stuffs. The studies were evaluated and accepted during registration of CHR/H/FETEC 110 EC (Fenoxinn 110 EC – authorization number: R - 145/2016).

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

No significant residues, i.e. >0.1 mg/kg, were found in grain and therefore processing studies are not required. No further studies have been performed.

7.2.5.1 Available data for all crops under consideration

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

7.2.5.2 Conclusion on processing studies

No data were submitted. Processing data are not required.

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. The studies were evaluated and accepted during registration of CHR/H/FETEC 110 EC (Fenoxinn 110 EC – authorization number: R - 145/2016).
The nature of residues in succeeding crops has been evaluated and described in DAR of fenoxaprop-P-ethyl under B.7.9 and it has been concluded that significant residues are not expected to be present in rotational crops when fenoxaprop-P-ethyl is used according to the representative GAP. Details are presented below.

Summary of plant metabolism studies reported in the EU

According to KCP 6.6.2.1/01 report, Buerkle L. et al (1987a) concluded that total radioactive residues in plants sown 30 days and one year after application of radiolabelled Hoe 046360 to bare soil under outdoor conditions were very low or even below the limits of detection for all crops at all time points investigated. The measurements in soil samples showed that the parent compound Hoe 046360 was rapidly degraded in soil since on day 0 (start of the experiment) only the hydrolysed free acid Hoe 088406 and the metabolite chlorobenzoxazolone Hoe 054014 were detectable at levels of 0.04 and 0.02 mg/kg soil, respectively, and did not leach to soil layers deeper than 10 cm. The transition factors (plant residues/soil residues) were low indicating that no uptake of radioactivity into the soil matter took place at a relevant level.

According to KCP 6.6.2.2/01report Schwalbe-Fehl M.. et al. (1985a) concluded that there were no significant differences between the heterocyclic part and the phenoxy moiety found indicating the good degradability of Hoe 033171 in plant material and soil. Residue concentrations in plants sown 120 days after application were mostly below the LOQ for all crops tested and at all time points investigated. Residue concentrations in soil samples at harvest time were also below the LOQ.

The possible intake of soil residues via succeeding crops was investigated by two studies using radiolabeled Fenoxaprop-P-ethyl (chlorophenyl-U-14C) and Fenoxaprop-ethyl (dioxyphenyl-1-14C and chlorophenyl-U-14C). Total radioactive residues in plants, sown 30 days, 120 days and one year after application were very low or even below the limits of quantification (LOQ) for all crops tested (leafy vegetables, root vegetables and cereals) at all time points investigated. Residues at low concentrations were found only in soil layers up to 5 cm. but there was no evidence either of residue uptake or accumulation by plants or soil indicating a rapid metabolization of Fenoxaprop-P-ethyl (Hoe 046360) and its racemic compound Fenoxaprop-ethyl (Hoe 033171), respectively. It can be concluded that the application of Fenoxaprop-P-ethyl according to the intended use will not lead to detectable residues in succeeding crops.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application. The studies were evaluated and accepted during registration of CHR/H/FETEC 110 EC (Fenoxinn 110 EC – authorization number: R - 145/2016).
According to the rotational crop studies described under B.7.9.1 of DAR, it can be concluded that, even at higher application rates, residues in rotational crops are below the limit of quantification achieveable in routine monitoring (LOQ= 0.02mg/kg). The residues determined in soil, after rotational crops were planted, were low and there was no evidence of an uptake or accumulation of residues by plants. The substance is not translocated into deeper soil layers. As there is no potential of Fenoxaprop residues for u take into plants or accumulation in soil, field trials in rotational crops are regarded to be not necessary.

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/H/FETEC-PART B 110 EC. Therefore, other special studies are not needed.

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

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

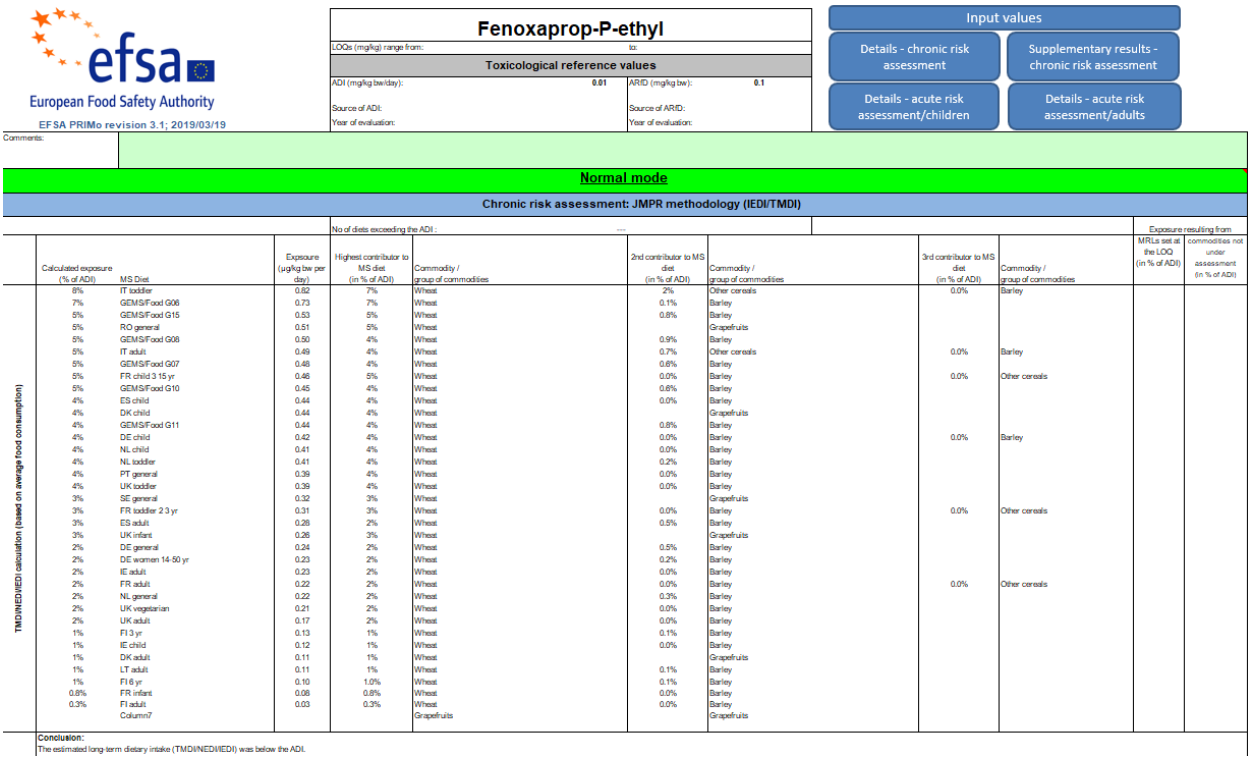
7.2.8.1 Input values for the consumer risk assessment

Table 7.2-9: Input values for the consumer risk assessment

Commodity	MRL values	
	Input value (mg/kg)	Comment
Barley	0.1	Reg. (EC) No 149/2008 (MRL value)
Wheat	0.1	Reg. (EC) No 149/2008 (MRL value)
Triticale	0.1	Reg. (EC) No 149/2008 (MRL value)
Swine	0.05	Reg. (EC) No 149/2008 (MRL value)
Bovine (meat, fat, edible offals)	0.05	Reg. (EC) No 149/2008 (MRL value)
Bovine (liver, kidney)	0.1	Reg. (EC) No 149/2008 (MRL value)
Sheep	0.05	Reg. (EC) No 149/2008 (MRL value)
Goat	0.05	Reg. (EC) No 149/2008 (MRL value)
Equine	0.05	Reg. (EC) No 149/2008 (MRL value)
Poultry	0.05	Reg. (EC) No 149/2008 (MRL value)
Milk (of cattle, sheep, goat, horse)	0.05	Reg. (EC) No 149/2008 (MRL value)
Eggs (of chicken, duck, goose, quail)	0.05	Reg. (EC) No 149/2008 (MRL value)

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.
Consumer risk assessment were performed using EFSA PRIMo rev. 3.0; 2017/12/11.
The calculation of the TMDI was performed taking into account all the crops to which the fenoxaprop-P-ethyl may be applied.



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

Fenoxaprop-P-ethyl

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.1
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
8%	IT toddler	0.82	7%	Wheat	2%	Other cereals	0.0%	Barley		
7%	GEMS/Food G06	0.73	7%	Wheat	0.1%	Barley				
5%	GEMS/Food G15	0.53	5%	Wheat	0.8%	Barley				
5%	RO general	0.51	5%	Wheat		Grapefruits				
5%	GEMS/Food G08	0.50	4%	Wheat	0.9%	Barley				
5%	IT adult	0.49	4%	Wheat	0.7%	Other cereals	0.0%	Barley		
5%	GEMS/Food G07	0.48	4%	Wheat	0.6%	Barley				
5%	FR child 3 15 yr	0.46	5%	Wheat	0.0%	Barley	0.0%	Other cereals		
5%	GEMS/Food G10	0.45	4%	Wheat	0.6%	Barley				
4%	ES child	0.44	4%	Wheat	0.0%	Barley				
4%	DK child	0.44	4%	Wheat		Grapefruits				
4%	GEMS/Food G11	0.44	4%	Wheat	0.8%	Barley				
4%	DE child	0.42	4%	Wheat	0.0%	Barley	0.0%	Barley		
4%	NL child	0.41	4%	Wheat	0.0%	Barley				
4%	NL toddler	0.41	4%	Wheat	0.2%	Barley				
4%	PT general	0.39	4%	Wheat	0.0%	Barley				
4%	UK toddler	0.39	4%	Wheat	0.0%	Barley				
3%	SE general	0.32	3%	Wheat		Grapefruits				
3%	FR toddler 2 3 yr	0.31	3%	Wheat	0.0%	Barley	0.0%	Other cereals		
3%	ES adult	0.28	2%	Wheat	0.5%	Barley				
3%	UK infant	0.26	3%	Wheat		Grapefruits				
2%	DE general	0.24	2%	Wheat	0.5%	Barley				
2%	DE women 14-50 yr	0.23	2%	Wheat	0.2%	Barley				
2%	IE adult	0.23	2%	Wheat	0.0%	Barley				
2%	FR adult	0.22	2%	Wheat	0.0%	Barley	0.0%	Other cereals		
2%	NL general	0.22	2%	Wheat	0.3%	Barley				
2%	UK vegetarian	0.21	2%	Wheat	0.0%	Barley				
2%	UK adult	0.17	2%	Wheat	0.0%	Barley				
1%	FI 3 yr	0.13	1%	Wheat	0.1%	Barley				
1%	IE child	0.12	1%	Wheat	0.0%	Barley				
1%	DK adult	0.11	1%	Wheat		Grapefruits				
1%	LT adult	0.11	1%	Wheat	0.1%	Barley				
1%	FI 6 yr	0.10	1.0%	Wheat	0.1%	Barley				
0.8%	FR infant	0.08	0.8%	Wheat	0.0%	Barley				
0.3%	FI adult	0.03	0.3%	Wheat	0.0%	Barley				
	Column7			Grapefruits		Grapefruits				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

Table 7.2-10: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	8 % (based on IT toddler)
IESTI (% ARfD) according to EFSA PRIMo*	1 % (based on wheat for children)
NTMDI (% ADI) **	N/A
NEDI (% ADI)**	N/A
NESTI (% ARfD) **	N/A

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

The proposed uses of fenoxaprop-P-ethyl in the formulation CHR/H/FETEC-PART B 110 EC do not represent unacceptable acute and chronic risks for the consumer.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

Austria, 2005. Draft Assessment Report (DAR) Initial risk assessment provided by the rapporteur Member State Austria for the existing active substance.

EFSA (European Food Safety Authority), 2007. Conclusion regarding the peer review of the pesticide risk assessment of the active substance. EFSA Scientific Report (2007) 121.

European Comission, 2008. COMMISSION REGULATION (EC) No 149/2008 of 29 January 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I thereto (Text with EEA relevance).

SANCO/3777/08, 2007. Review report for the active substance fenoxaprop-P. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 14 March 2008 in view of the incl sion of fenoxaprop-P in Annex I of Directive 91/414/EEC.

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	Verte-brate study Y/N	Owner

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	Verte-brate study Y/N	Owner
KCP 6/01	Fuchsbichler G.	1993b	Storage stability in wheat and validation of analytical method AL 58/86. Hoe 046360. Hoe 088406 and Hoe 054014 Universitaet Muenchen; Document No: A51681 GLP I GEP Unpublished	N	BCS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 6/02	Ver Hey Margaret E.	1992a	Determination of the residue in barley grain and straw.Storage stability of Hoe 033171 or Hoe 046360 and their metabolites Hoe 053022 and Hoe 054014 Analytical Development corporation; Document No: A49224 GLP / GEP Unpublished	N	BCS
KCP 6.1.1/01	Schwalbe-Fehl M.. Schmidt E.. Koecher H.	1987b	Metabolism and degradation kinetics in wheat (Triticum aestivum). Hoe 033171 -14C Hoechst AG; GBC Analytisches Laboratorium Hoechst AG; Pflanzenschutz Forschung Biologie Document No: A36855 GLP I GEP Yes Unpublished	N	BCS
KCP 6.1.1/02	Wink O.. Kuenzler K.. Wuerz S.	1987a	Identification and characterization of the water-soluble conjugates in wheat. Hoe 033171 -14C Hoechst AG; GBC-Analytisches Laboratorium Document No: A36657 GLP / GEP Yes Unpublished	N	BCS
KCP 6.1.1/03	Schwalbe-Fehl M.. Schmidt E.. Koecher H.	1986a	Residue determinations in wheat (Triticum aestivum) after application of 183 g active ingredient/ha in presence of Hoe 070542. Fenoxaprop-ethyl. Hoe 033171-14C Hoechst AG; GBC-Analytisches Laboratorium Hoechst AG; Pflanzenschutz Forschung Biologie Document No: A34525 GLP / GEP Yes Unpublished	N	BCS
KCP 6.1.1/05	Wink O.. Kuenzler	1987a	Residue determination in wheat (Triticum aestivum) after application of 110 g active ingredient/ha (and soil) Hoe 046360- chlorophenyl-U-14C Hoechst AG; GBC-Analytisches Laboratorium Hoechst AG;	N	BCS

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	Verte-brate study Y/N	Owner
	K.. Lemke G.		Pflanzenschutz Forschung Biologie Document No: A35778 GLP / GEP Yes Unpublished		
KCP 6.1.1/06	Wink O.. Kuenzler K.. Lemke G.	1986a	Racemization in soy beans and wheat of Hoe 046360-chlorophenyl-U-14C Hoechst AG; GBC-Analytisches Laboratorium Document No: A35943 GLP / GEP Yes Unpublished	N	BCS
KCP 6.1.1/07	Buerkle L.W.	2000e	Identification of residues in wheat (Triticum aestivum) following treatment with 14CFenoxaprop- P-ethyl at a rate of 90 g as./ha Code: (U-14C-chlorophenyl)-AE F04636 Aventis CropScience GmbH. DEU; Oekochemie. Frankfurt Document No: C009798 GLP / GEP Yes Unpublished	N	BCS
KCP 6.1.2/01	Buerkle W.L.. Becker A.	1997a	Code: Hoe 046360 00 ZE98 0004 Chlorophenyl-U-14C-Hoe 046360 Influence of the Safener Hoe 107892 on the Metabolism of the Radiolabeled Herbicide Fenoxaprop-Pethyl. Hoe 046360. in Barley (Hordeum vulgare) Hoechst Schering AgrEvo GmbH; Environmental Sciences Frankfurt Document No: A58851 GLP I GEP Yes Unpublished	N	BCS
KCP 6.1.3.1/01	Wink O.. Kuenzler	1988a	Metabolism and kinetics in rice plants (Oryza sativa) under field conditions. Hoe 046360- chlorphenyl-U-14C Hoechst AG; GBC-Analytisches Laboratorium Hoechst AG; Pflanzenschutz Forschung Biologie	N	BCS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
	K.. Lemke G.. Haberkorn B.. Mueller H.J.		Document No: A38627 GLP / GEP Yes Unpublished		
KCP 6.1.3.2/01	Buettner B.. Kuenzler K.. Lemke G.. Mueller H.J.	1988a	Degradation behaviour in/on rice plants (Oryza sativa) under field conditions. Hoe 046360-dioxyphenyl-1-14C Hoechst AG; GBC-Analyfisches Laboratorium Hoechst AG; Pflanzenschutz Forschung Biologie Document No: A40366 GLP I GEP Yes Un ublished	N	BCS
KCP 6.2/01	xxxxxxxxxx	1989o	Metabolism in the lactating goat following repeated oral administrationxxxxxxxxxxxxxxxxxxxxxxxxx; Document No: A41369 GLP I GEP Yes Un ublished	Y	BCS
KCP 6.2/02	xxxxxxxxxx	1990b	Metabolism in the lactating goat following repeated oral administration. Reply to EPAMemorandum (Subject: PP 9F 3714. EPA Reg.No.8340-GI.). Fenoxaprop-ethyl in or on wheat. CT1D 040889. xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx Document No: A42690 GLP I GEP Unpublished	Y	BCS
KCP 6.2/04	xxxxxxxxxxxx	1987a	Ruminant feeding study. Code: Hoe 033171 Hoechst AG; xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx Document No: A36705	Y	BCS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			GLP / GEP Yes Unpublished		
KCP 6.2/05	xxxxxxxxxxxxxxx	1989a	Distribution and excretion after repeated oraladministration to laying hen of 14C-Hoe 033171 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx; Document No: A40877 GLP / GEP Yes Unpublished	Y	BCS
KCP 6.2/06	xxxxxxxxxxxxxx	1994a	Nature of residue in laying hens of 14CFenoxaprop- ethyl xxxxxxxxxxxxxxxxxxxxxxxx; Document No: A53203 GLP / GEP Yes Unpublished	Y	BCS
KCP 6.3.1/01	Sochor H.	1993 bo	Report on plant protection residue trial Hoe 046360 24EW14 A201 Universitaet Muenchen; Document No: A50817 GLP / GEP Unpublished	N	BCS
KCP 6.3.1/02	Sochor H.	1993 bn	Report on plant protection residue trial Hoe 046360 24EW14 A201 Universitaet Muenchen; Document No: A50818 GLP I GEP Unpublished _	N	BCS
KCP 6.3.2/02	Sochor H.	1993 bm	Report on plant protection residue trial Hoe 046360 24 EW14 A201 Universitaet Muenchen; Document No: A50836 GLP / GEP	N	BCS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
			Unpublished		
KCP 6.3.2/03	Sochor H.. Idstein H.	1993 a	Report on plant protection residue trial Hoe 046360 24 EW14 A201 Universitaet Muenchen; Document No: A50837 GLP / GEP Unpublished	N	BCS
KCP 6.3.1/03	Helgers A.. Idstein H.. Junker H.	1996 a	Fenoxaprop-P-ethyl and Hoe 107892 oil in water emulsion 55 and 30 g/I Code: Hoe 46360 24 EW08 A802 Determination of residues of Hoe 046360 and Hoe 107892 to establish a maximum residue level following one application in different wheat and durum wheat varieties under field conditions in southern Europe Hoechst Schering AgrEvo GmbH; Residues and User Safety. Frankfurt Document No: A57042 GLP / GEP Yes Unpublished	N	BCS
KCP 6.6.2.1/01	Buerkle W.L.. Wink O.. Koecher H.	1987 a	Confined accumulation study on rotational crops sown 30 days and one year after application of 0.11 kg as/ha Hoe 046360-14C Hoechst AG; GBC-Analytisches Laboratorium Hoechst AG; Pflanzenschutz Forschung Biologie Document No: A37484 GLP / GEP Yes Unpublished	N	BCS
KCP 6.6.2.2/01	Schwalbe-Fehl M.. Steinau M.. Mueller H.J.	1985 a	Confined accumulation study on rotational crops planted 111 days after treatment of the first crop Hoe 033171-14C Hoechst AG; GBC-Analytisches Laboratorium Hoechst AG; Pflanzenschutz Forschung Biologie Document No: A31992	N	BCS

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

List of data submitted by the applicant and not relied on

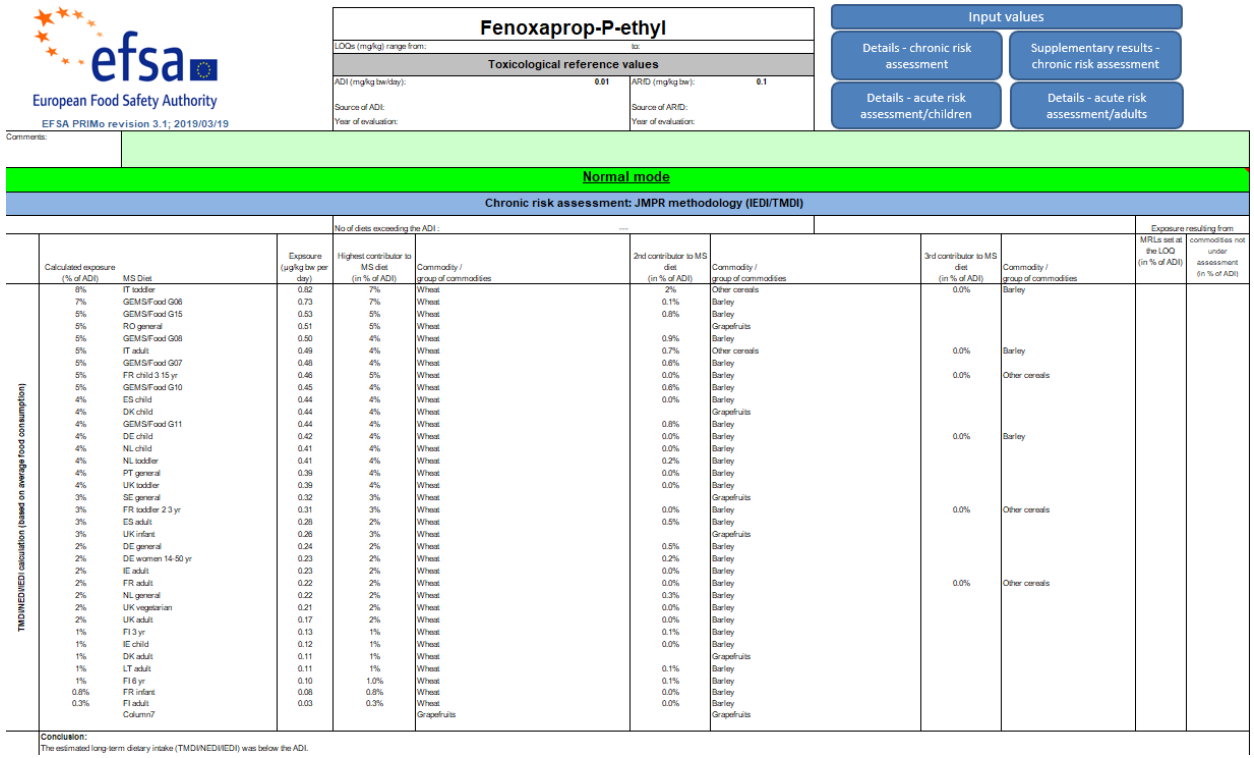
Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner

Appendix 2 Detailed evaluation of the additional studies relied upon

No new or additional studies were performed.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations



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Fenoxaprop-P-ethyl

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.01	ARfD (mg/kg bw):	0.1
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

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

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
6%	IT toddler	0.62	7%	Wheat	2%	Other cereals	0.0%	Barley		
7%	GEMS/Food G06	0.73	7%	Wheat	0.1%	Barley				
5%	GEMS/Food G15	0.53	5%	Wheat	0.8%	Barley				
5%	RO general	0.51	5%	Wheat		Grapefruits				
5%	GEMS/Food G08	0.50	4%	Wheat	0.9%	Barley				
5%	IT adult	0.49	4%	Wheat	0.7%	Other cereals	0.0%	Barley		
5%	GEMS/Food G07	0.48	4%	Wheat	0.6%	Barley				
5%	FR child 3 15 yr	0.46	5%	Wheat	0.0%	Barley	0.0%	Other cereals		
5%	GEMS/Food G10	0.45	4%	Wheat	0.6%	Barley				
4%	ES child	0.44	4%	Wheat	0.0%	Barley				
4%	DK child	0.44	4%	Wheat		Grapefruits				
4%	GEMS/Food G11	0.44	4%	Wheat	0.8%	Barley				
4%	DE child	0.42	4%	Wheat	0.0%	Barley	0.0%	Barley		
4%	NL child	0.41	4%	Wheat	0.0%	Barley				
4%	NL toddler	0.41	4%	Wheat	0.2%	Barley				
4%	PT general	0.39	4%	Wheat	0.0%	Barley				
4%	UK toddler	0.39	4%	Wheat	0.0%	Barley				
3%	SE general	0.32	3%	Wheat		Grapefruits				
3%	FR toddler 2 3 yr	0.31	3%	Wheat	0.0%	Barley	0.0%	Other cereals		
3%	ES adult	0.26	2%	Wheat	0.5%	Barley				
3%	UK infant	0.26	3%	Wheat		Grapefruits				
2%	DE general	0.24	2%	Wheat	0.5%	Barley				
2%	DE women 14-50 yr	0.23	2%	Wheat	0.2%	Barley				
2%	IE adult	0.23	2%	Wheat	0.0%	Barley				
2%	FR adult	0.22	2%	Wheat	0.0%	Barley	0.0%	Other cereals		
2%	NL general	0.22	2%	Wheat	0.3%	Barley				
2%	UK vegetarian	0.21	2%	Wheat	0.0%	Barley				
2%	UK adult	0.17	2%	Wheat	0.0%	Barley				
1%	FI 3 yr	0.13	1%	Wheat	0.1%	Barley				
1%	IE child	0.12	1%	Wheat	0.0%	Barley				
1%	DK adult	0.11	1%	Wheat		Grapefruits				
1%	LT adult	0.11	1%	Wheat	0.1%	Barley				
1%	FI 6 yr	0.10	1.0%	Wheat	0.1%	Barley				
0.8%	FR infant	0.08	0.8%	Wheat	0.0%	Barley				
0.3%	FI adult	0.03	0.3%	Wheat	0.0%	Barley				
	Column7			Grapefruits		Grapefruits				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

A 3.2 IESTI calculations - Raw and processed commodities

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat	0.1 / 0.1	1.4
0.6%	Barley	0.1 / 0.1	0.56

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.8%	Wheat	0.1 / 0.1	0.84
0.5%	Barley	0.1 / 0.1	0.48

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat	0.1 / 0.1	1.4
0.6%	Barley	0.1 / 0.1	0.56

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.8%	Wheat	0.1 / 0.1	0.84
0.5%	Barley	0.1 / 0.1	0.48

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

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat / milling (flour)	0.1 / 0.1	1.2
0.6%	Wheat / milling (wholemeal)-t	0.1 / 0.1	0.55
0.4%	Barley / cooked	0.1 / 0.1	0.36
0.2%	Barley / milling (flour)	0.1 / 0.1	0.18
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Barley / beer	0.1 / 0.02	0.72
0.4%	Wheat / bread/pizza	0.1 / 0.1	0.44
0.4%	Wheat / pasta	0.1 / 0.1	0.38
0.3%	Wheat / bread (wholemeal)	0.1 / 0.1	0.35
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat / milling (flour)	0.1 / 0.1	1.2
0.6%	Wheat / milling (wholemeal)-	0.1 / 0.1	0.55
0.4%	Barley / cooked	0.1 / 0.1	0.36
0.2%	Barley / milling (flour)	0.1 / 0.1	0.18
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Barley / beer	0.1 / 0.02	0.72
0.4%	Wheat / bread/pizza	0.1 / 0.1	0.44
0.4%	Wheat / pasta	0.1 / 0.1	0.38
0.3%	Wheat / bread (wholemeal)	0.1 / 0.1	0.35
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Appendix 4 Additional information provided by the applicant

No new or additional studies were performed.