European Commission

Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009

FENOXAPROP-P-ETHYL

Volume 1

Rapporteur Member State: Austria
Co-Rapporteur Member State: Finland

Version History

When	What
2005/April	Initial DAR
2018/March	DRAR

Table of contents

1. STATEMENT OF SUBJECT MATTER AND PURPOSE FOR WHICH THIS REPORT HAS BEEN PREPARED AND BACKGROUND INFORMATION ON THE APPLICATION 7

1.1. CONTEXT IN WHICH THIS DRAFT ASSESSMENT REPORT WAS PREPARED 7

1.1.1. Purpose for which the draft assessment report was prepared 7
1.1.2. Arrangements between rapporteur Member State and co-rapporteur Member State 7
1.1.3. EU Regulatory history for use in Plant Protection Products 7
1.1.4. Evaluations carried out under other regulatory contexts 9

1.2. APPLICANT INFORMATION 9

1.2.1. Name and address of applicant(s) for approval of the active substance 9
1.2.2. Producer or producers of the active substance 9
1.2.3. Information relating to the collective provision of dossiers 9

1.3. IDENTITY OF THE ACTIVE SUBSTANCE 10

1.4. INFORMATION ON THE PLANT PROTECTION PRODUCT 11

1.5. DETAILED USES OF THE PLANT PROTECTION PRODUCT 14

1.5.1. Details of representative uses 14
1.5.2. Further information on representative uses 17
1.5.3. Details of other uses applied for to support the setting of MRLs for uses beyond the representative uses 17
1.5.4. Overview on authorisations in EU Member States 17

2. SUMMARY OF ACTIVE SUBSTANCE HAZARD AND OF PRODUCT RISK ASSESSMENT 66

2.1. IDENTITY 66

2.2. PHYSICAL AND CHEMICAL PROPERTIES 66

2.2.1. Summary of physical and chemical properties of the active substance 66
2.2.2. Summary of physical and chemical properties of the plant protection product 66

2.3. DATA ON APPLICATION AND EFFICACY 66

2.3.1. Summary of effectiveness 66
2.3.2. Summary of information on the development of resistance 67
2.3.3. Summary of adverse effects on treated crops 67
2.3.4. Summary of observations on other undesirable or unintended side-effects 67

2.4. FURTHER INFORMATION 67

2.4.1. Summary of methods and precautions concerning handling, storage, transport or fire 67
2.4.2. Summary of procedures for destruction or decontamination 67
2.4.3. Summary of emergency measures in case of an accident 67

2.5. METHODS OF ANALYSIS 68

2.5.1. Methods used for the generation of pre-authorisation data 68
2.5.2. Methods for post control and monitoring purposes 68

2.6. EFFECTS ON HUMAN AND ANIMAL HEALTH 69

2.6.1. Summary of absorption, distribution and excretion in mammals 69
2.6.2. Summary of acute toxicity 71
2.6.3. Summary of short-term toxicity 73
2.6.4. Summary of genotoxicity 78
2.6.5. Summary of long-term toxicity and carcinogenicity 79
2.6.6. Summary of reproductive toxicity 82
2.6.7. Summary of neurotoxicity 86

2.6.8. Summary of further toxicological studies on the active substance ... 86
2.6.9. Summary of toxicological data on impurities and metabolites ... 89
2.6.10. Summary of medical data and information ... 89
2.6.11. Toxicological end point for assessment of risk following long-term dietary exposure - ADI ... 90
2.6.12. Toxicological end point for assessment of risk following acute dietary exposure - ARfD (acute reference dose) ... 90
2.6.13. Toxicological end point for assessment of occupational, bystander and residents risks – AOEL ... 90
2.6.14. Toxicological end point for assessment of acute occupational, bystander and residents risks – AAOEL ... 90
2.6.15. Summary of product exposure and risk assessment ... 91

2.7. RESIDUE ... 92

2.7.1. Summary of storage stability of residues ... 92
2.7.2. Summary of metabolism, distribution and expression of residues in plants, poultry, lactating ruminants, pigs and fish ... 92
2.7.3. Definition of the residue ... 97
2.7.4. Summary of residue trials in plants and identification of critical GAP ... 99
2.7.5. Summary of feeding studies in poultry, ruminants, pigs and fish ... 101
2.7.6. Summary of effects of processing ... 103
2.7.7. Summary of residues in rotational crops ... 103
2.7.8. Summary of other studies ... 104
2.7.9. Estimation of the potential and actual exposure through diet and other sources ... 104
2.7.10. Proposed MRLs and compliance with existing MRLs ... 107
2.7.11. Proposed import tolerances and compliance with existing import tolerances ... 107

2.8. FATE AND BEHAVIOUR IN THE ENVIRONMENT ... 108

2.8.1. Summary of fate and behaviour in soil ... 108
2.8.2. Summary of fate and behaviour in water and sediment ... 115
2.8.3. Summary of fate and behaviour in air ... 122
2.8.4. Summary of monitoring data concerning fate and behaviour of the active substance, metabolites, degradation and reaction products ... 122
2.8.5. Definition of the residues in the environment requiring further assessment ... 122
2.8.6. Summary of exposure calculations and product assessment ... 123

2.9. EFFECTS ON NON-TARGET SPECIES ... 123

2.9.1. Summary of effects on birds and other terrestrial vertebrates ... 123
2.9.2. Summary of effects on aquatic organisms ... 124
2.9.3. Summary of effects on arthropods ... 129
2.9.4. Summary of effects on non-target soil meso- and macrofauna ... 133
2.9.5. Summary of effects on soil nitrogen transformation ... 134
2.9.6. Summary of effects on terrestrial non-target higher plants ... 134
2.9.7. Summary of effects on other terrestrial organisms (flora and fauna) ... 135
2.9.8. Summary of effects on biological methods for sewage treatment ... 135
2.9.9. Summary of product exposure and risk assessment ... 135

2.10. CLASSIFICATION AND LABELLING ... 153

2.11. RELEVANCE OF METABOLITES IN GROUNDWATER ... 155

2.11.1. STEP 1: Exclusion of degradation products of no concern ... 156
2.11.2. STEP 2: Quantification of potential groundwater contamination ... 156
2.11.3. STEP 3: Hazard assessment – identification of relevant metabolites ... 156
2.11.4. STEP 4: Exposure assessment – threshold of concern approach ... 156
2.11.5. STEP 5: Refined risk assessment ... 156
2.11.6. Overall conclusion ... 156

2.12. CONSIDERATION OF ISOMERIC COMPOSITION IN THE RISK ASSESSMENT ... 156

2.12.1. Identity and physical chemical properties ... 156
2.12.2. Methods of analysis ... 156
2.12.3. Mammalian toxicity ... 157

2.12.4. Operator, Worker, Bystander and Resident exposure 157
2.12.5. Residues and Consumer risk assessment 157
2.12.6. Environmental fate 157
2.12.7. Ecotoxciology 157

2.13. RESIDUE DEFINITIONS 157

2.13.1. Definition of residues for exposure/risk assessment 157
2.13.2. Definition of residues for monitoring 158

3. PROPOSED DECISION WITH RESPECT TO THE APPLICATION 160

3.1. BACKGROUND TO THE PROPOSED DECISION 160

3.1.1. Proposal on acceptability against the decision making criteria – Article 4 and annex II of regulation (EC) No 1107/2009 160
3.1.2. Proposal – Candidate for substitution 169
3.1.3. Proposal – Low risk active substance 171
3.1.4. List of studies to be generated, still ongoing or available but not peer reviewed 172
3.1.5. Issues that could not be finalised 175
3.1.6. Critical areas of concern 175
3.1.7. Overview table of the concerns identified for each representative use considered 176
3.1.8. Area(s) where expert consultation is considered necessary 177
3.1.9. Critical issues on which the Co RMS did not agree with the assessment by the RMS 177

3.2. PROPOSED DECISION 178

3.3. RATIONAL FOR THE CONDITIONS AND RESTRICTIONS TO BE ASSOCIATED WITH THE APPORVAL OR AUTHORISATION(S), AS APPROPRIATE 178

3.3.1. Particular conditions proposed to be taken into account to manage the risks identified 178

3.4. APPENDICES 179

3.5. REFERENCE LIST 182

Level 1

Fenoxaprop-P-ethyl

1. STATEMENT OF SUBJECT MATTER AND PURPOSE FOR WHICH THIS REPORT HAS BEEN PREPARED AND BACKGROUND INFORMATION ON THE APPLICATION

1.1. CONTEXT IN WHICH THIS DRAFT ASSESSMENT REPORT WAS PREPARED

1.1.1. Purpose for which the draft assessment report was prepared

Fenoxaprop-P-ethyl was originally included in Annex I of the EU Council Directive 91/414/EEC with Commission Directive 2008/66/EC (entry into force on 30 June 2008). The active substance was subsequently approved under Regulation (EC) 1107/2009 via Implementing Regulation (EU) 540/2011. In accordance with Commission Regulation (EU) 844/2012 of 18 September 2012, the Task Force Fenoxaprop-P-ethyl (representing Bayer CropScience and FMC Agricultural Solutions submitted a joint dossier to support the renewal of the approval of Fenoxaprop-P-ethyl. Austria acting as the Rapporteur Member State (RMS) evaluated all aspects of the renewal dossiers via a Draft Renewal Assessment Report (DRAR). Co-RMS Finland decided to participate in the first bilateral peer review but to provide the comments for the official peer review.

This DRAR provides a discussion of relevant new studies and information submitted and evaluated since the first approval of Fenoxaprop-P-ethyl in 2008. Regarding studies submitted for the original approval mostly re-wording was conducted and additional information was included in DRAR where considered necessary for better overview. Partially, new endpoints were derived. The validity of studies in view of updated OECD guidelines was proven.

Fenoxaprop-P-ethyl was included in ATP07 (Regulation (EC) 1221/2015) of Regulation (EC) 1272/2008 and was classified as Skin Sens. 1 (H317), STOT RE 2 (H373), Aquatic Acute (H400) and Aquatic Chronic (H410). The RMS paid special attention to the new criteria for classification and labelling according to Regulation (EC) 1272/2008. Regarding ecotoxicity, no new proposal for classification and labelling has been established (H400 and H410 could be further supported). According to the assessment for the renewal of this active substance, additional classification as Acute Tox 4 (H302) is proposed based on a new study.

1.1.2. Arrangements between rapporteur Member State and co-rapporteur Member State

According to an agreement reached by the respective designated authorities, the RMS Austria conducted the full evaluation and prepared the DRAR. Co-RMS Finland decided to participate in the first bilateral peer review but to provide the comments for the official peer review.

1.1.3. EU Regulatory history for use in Plant Protection Products

Commission Regulation (EC) No 451/2000 laying down the detailed rules for the implementation of the second and third stages of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 1490/2002, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Fenoxaprop-P is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EC) No 451/2000, Bayer CropScience AG notified to the Commission of their wish to secure the inclusion of the active substance fenoxaprop-P in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EC) No 451/2000, the Commission, designated Austria as rapporteur Member State to carry out the assessment of (AS) on the basis of the dossiers submitted by the notifier. In Regulation (EC) No 1490/2002 the Commission specified furthermore that the deadline for the notifier with regard to the submission to the rapporteur Member States of the dossiers required under Article 7(2) of Regulation (EC) No 1490/2002, as well as for other parties with regard to further technical and scientific information was 30 November 2003.

Bayer CropScience AG submitted by the deadline a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore Bayer CropScience was considered to be the sole data submitter.

In accordance with the provisions of Article 10(1) of Regulation (EC) No 1490/2002, Austria submitted on 2 May 2005 to the EFSA the report of their examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of fenoxaprop-P in Annex I to the Directive. Moreover, in accordance with the provisions of Article 10(2) of Regulation (EC) 1490/2002, the Commission and the Member States received also the summary dossier on fenoxaprop-P from the notifier.

In accordance with the provisions of Article 11 of Regulation (EC) No 1490/2002, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by Bayer CropScience AG being the sole data submitter, on 22 December 2005 by making it available. The EFSA organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review).

In accordance with the provisions of Article 11 (4) of Regulation 1490/2002 the EFSA sent to the Commission its conclusion on the risk assessment [Conclusions regarding the peer review of the pesticide risk assessment of the active substance fenoxaprop-P (EFSA Scientific Report (2007) 121, 1-76): https://www.efsa.europa.eu/en/efsajournal/pub/rn-121).

In accordance with the provisions of Article 12 of Regulation (EC) No 1490/2002, the Commission referred on 14 March 2008 a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 14 March 2008 (Fenoxaprop-P, SANCO/3777/08-rev.1).

In agreement with Article 3 of Regulation (EC) No 844/2012 Task Force Fenoxaprop-p (representing Bayer CropScience and Cheminova), submitted a joint application for renewal to Austria as RMS and Finland as Co-RMS by the deadline of 31 December 2015. The application was considered complete.

Task Force Fenoxaprop-p submitted the supplementary active substance dossier by the deadline for submission (30 June 2016). As required by Article 8 of Regulation (EC) No 844/2012 RMS checked the supplementary dossier for its completeness. It was concluded that the supplementary dossier completely fulfils the requirements set out in Article 7 of the Regulation (EC) No 844/2012.

1.1.4. Evaluations carried out under other regulatory contexts

Fenoxaprop-p-ethyl is used only as herbicide and not regulated by other EU legislations (e.g. biocides, flavourings, food additives, cosmetics).

An US EPA and PMRA evaluation has been conducted.

Fenoxaprop-p has not been considered by the JMPR.

No FAO specification is available.

Fenoxaprop-p-ethyl is currently included in Annex VI of Regulation (EC) No 1272/2008 with Index No 607-707-00-9 (CAS No: 71283-80-2) as skin Sens 1, H317, STOT RE 2, H373 (kidney), Aquatic Acute and Chronic 1, H400 and 410.

1.2. APPLICANT INFORMATION

1.2.1. Name and address of applicant(s) for approval of the active substance

Name:	Bayer CropScience AG
Address:	Alfred-Nobel-Strasse 50 40789 Monheim Germany
Contact:	[redacted] Bayer CropScience AG Alfred-Nobel-Strasse 50 D-40789 Monheim Germany
Telephone number:	[redacted]
Fax number:	+[redacted]

Name:	Cheminova A/S
Address:	P.O. Box 9, DK-7620 Lemvig, Denmark
Contact:	[redacted]
Telephone number:	[redacted]
E-mail:	[redacted]

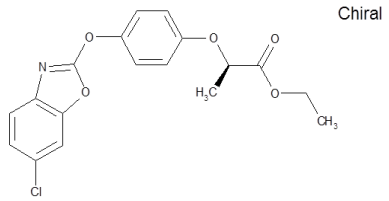
1.2.2. Producer or producers of the active substance

Confidential information, see Annex C.

1.2.3. Information relating to the collective provision of dossiers

For the renewal of fenoxaprop-P-ethyl a Task Force has been established between Bayer CropScience AG and Cheminova A/S and a joint CA dossier as well as company specific CP dossiers have been submitted.

1.3. IDENTITY OF THE ACTIVE SUBSTANCE

1.3.1. Common name proposed or ISO-accepted and synonyms	**Fenoxaprop-P (ISO)** Variant: Fenoxaprop-P-ethyl (unless otherwise stated the data relate to the variant Fenoxaprop-P-ethyl)
1.3.2. Chemical name (IUPAC and CA nomenclature)	
IUPAC	ethyl (2*R*)-2-{4-[(6-chloro-1,3-benzoxazol-2-yl)oxy] phenoxy}propanoate
CA	propanoic acid, 2-[4-[(6-chloro-2-benzoxazolyl)oxy] phenoxy]-, ethyl ester, (2*R*)-
1.3.3. Producer's development code number	**Bayer CropScience (BCS)**: BCS-AI29180; AE F046360; Hoe 046360 **Cheminova A/S**: 480-01
1.3.4. CAS, EEC and CIPAC numbers	
CAS	71283-80-2
EEC	not allocated
CIPAC	484.202
1.3.5. Molecular and structural formula, molecular mass	
Molecular formula	$C_{18}H_{16}ClNO_5$
Structural formula	
Molecular mass	361.8 u
1.3.6. Method of manufacture (synthesis pathway) of the active substance	CONFIDENTIAL information – refer to Volume 4 (individual Volume 4 for each member of the task force)
1.3.7. Specification of purity of the active substance in g/kg	Reference specification (**BCS**): 920 g/kg **BCS**: 930 g/kg **Cheminova**: 985 g/kg
1.3.8. Identity and content of additives (such as stabilisers) and impurities	
1.3.8.1. *Additives*	CONFIDENTIAL information – refer to Volume 4 (individual Volume 4 for each member of the task force)
1.3.8.2. *Significant impurities*	CONFIDENTIAL information – refer to Volume 4 (individual Volume 4 for each member of the task force)
1.3.8.3. *Relevant impurities*	CONFIDENTIAL information – refer to Volume 4 (individual Volume 4 for each member of the task force)
1.3.9. Analytical profile of batches	CONFIDENTIAL information – refer to Volume 4 (individual Volume 4 for each member of the task force)

1.4. INFORMATION ON THE PLANT PROTECTION PRODUCT

Puma S 69 EW

1.4.1. Applicant	Name:	Bayer CropScience AG
	Address:	Alfred-Nobel-Strasse 50 40789 Monheim Germany
	Contact:	[redacted] Bayer CropScience AG Alfred-Nobel-Strasse 50 D-40789 Monheim Germany
	Telephone number:	[redacted]
	Fax number:	[redacted]
1.4.2. Producer of the plant protection product	Name:	Bayer S.A.S. Bayer CropScience
	Address:	16, rue Jean-Marie Leclair CS 90106 69266 Lyon Cedex 09 France
	Contact:	As applicant
1.4.3. Trade name or proposed trade name and producer's development code number of the plant protection product	Puma ExtraTM; Puma SuperTM; Ralon SuperTM; Primera SuperTM; Puma UniversalTM; Event SuperTM; Code number: Specification 102000011507, UVP 06471331, FPP+MPR EW 144 (69+75 g/L), AE F0463460 24 EW14 B0, AE F0463460 24 EW14 A7, AE F0463460 24 EW14 A2, Hoe 046360 24 EW14 A2	
1.4.4. Detailed quantitative and qualitative information on the composition of the plant protection product		
1.4.4.1. Composition of the plant protection product	Fenoxaprop-P-ethyl 69 g/L	
1.4.4.2. Information on the active substances		

Type	Name/Code Number	Variant
ISO common name	Fenoxaprop-P	none
CAS No.	113158-40-0	71283-80-2
CIPAC No.	484	484.202
EC No.	not allocated	not allocated
Salt, ester anion or cation present		Fenoxaprop-P-ethyl

1.4.4.3. Information on safeners, synergists and co-formulants	CONFIDENTIAL information, refer to Volume 4
1.4.5. Type and code of the plant protection product	Emulsion, oil in water [EW]

1.4.6. Function	Herbicide
1.4.7. Field of use envisaged	soft wheat, durum wheat, rye, triticale (BBCH 11-39) and barley (BBCH 12-32), post-emergence application against grass weeds
1.4.8. Effects on harmful organisms	Systemic; Inhibition of the enzyme acetyl-CoA carboxylase.

CHA 4960:

1.4.1. Applicant	Name:	Cheminova A/S
	Address:	P.O. Box 9, DK-7620 Lemvig, Denmark
	Contact:	[redacted]
	Telephone number:	[redacted])
	E-mail:	[redacted]
1.4.2. Producer of the plant protection product	Name:	Cheminova A/S
	Address:	P.O. Box 9, DK-7620 Lemvig, Denmark
	Contact:	[redacted]
	Telephone number:	[redacted]
	E-mail:	[redacted]
1.4.3. Trade name or proposed trade name and producer's development code number of the plant protection product	Trade names: e.g. FOXTROT Code number: CHA 4960	
1.4.4. Detailed quantitative and qualitative information on the composition of the plant protection product		
1.4.4.1. Composition of the plant protection product	Fenoxaprop-P-ethyl 69 g/L	

1.4.4.2. Information on the active substances

Type	Name/Code Number	Variant
ISO common name	Fenoxaprop-P	none
CAS No.	113158-40-0	71283-80-2
CIPAC No.	484	484.202
EC No.	not allocated	not allocated
Salt, ester anion or cation present		Fenoxaprop-P-ethyl

1.4.4.3. Information on safeners, synergists and co-formulants	CONFIDENTIAL information – please refer to Volume 4
1.4.5. Type and code of the plant protection product	Oil-in-water emulsion [Code: EW]
1.4.6. Function	Herbicide
1.4.7. Field of use envisaged	soft wheat, durum wheat, rye, triticale (BBCH 11-39) and barley (BBCH 12-32), post-emergence application against grass weeds
1.4.8. Effects on harmful organisms	Systemic; Inhibition of the enzyme acetyl-CoA carboxylase.

1.5. DETAILED USES OF THE PLANT PROTECTION PRODUCT

1.5.1. Details of representative uses

PUMA S 69 EW [Fenoxaprop-P-ethyl + Mefenpyr-diethyl EW 144 (69+75 g/L)]

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and 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		
wheat (s+w) durum wheat rye, w.-rye triticale	Europe	**PUMA S69 EW** [Fenoxaprop-P-ethyl + Mefenpyr-diethyl EW 144 (69+75 g/L)]	F	grass weed species	EW	(1) 69 (2) 75	Ground-boom sprayer	BBCH 11-39 (autumn or spring)	1	-	(1) 0.007 - 0.083 (2) 0.0075 - 0.090	100 -400	(1) 0.028 0.083 (2) 0.030. 0.090	F*	Dose rate: **max. 1.2 1 L product/ha** F*: PHI is covered by the normal vegetation period between last application and harvest
barley (s+w)	Europe	**PUMA S69 EW** [Fenoxaprop-P-ethyl + Mefenpyr-diethyl EW 144 (69+75 g/L)]	F	grass weed species	EW	(1) 69 (2) 75	Ground-boom sprayer	BBCH 12-32 (autumn or spring)	1	-	(1) 0.007 - 0.083 (2) 0.0075 - 0.090	100 - 400	(1) 0.028 0.083 (2) 0.030. 0.090	F*	Dose rate: **max. 1.2 L product/ha** F*: PHI is covered by the normal vegetation period between last application and harvest

* For uses where the column „Remarks“ in marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

CHA 4960 (Fenoxaprop-P-ethyl 69 g/L EW)

Crop and/or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applica-tions (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
wheat (s+w), durum wheat (S+W) rye, triticale	Europe	**CHA 4960** (Fenoxaprop-P-ethyl 69 g/L EW)	F	Monocotyledonous weeds		69g/L	Ground-boom sprayer	BBCH 11-39 (autumn or spring)	1	-	1) 0.010 - 0.083 (2) 0.0053 - 0.041	100 - 400	(1) 0.041 - 0.083 (2) 0.021 - 0.041	F*	Dose rate: **max. 1.2 L product/ha**
barley (s+w)	Europe	**CHA 4960** (Fenoxaprop-P-ethyl 69 g/L EW)	F	Monocotyledonous weeds		69g/L	Ground-boom sprayer	BBCH 11-32 (autumn or spring)	1	-	(1) 0.010 - 0.069 (2) 0.0053 - 0.035	100 - 400	(1) 0.041 - 0.069 (2) 0.021 - 0.035	F*	Dose rate: **max. 1.0 L product/ha**

(1) fenoxaprop-P-ethyl 69 g/L (2) cloquintocet-mexyl 34,5 g/L F*: PHI is covered by the normal vegetation period between last application and harvest

1.5.2. Further information on representative uses

Please refer to section 1.5.1.

1.5.3. Details of other uses applied for to support the setting of MRLs for uses beyond the representative uses

No other uses applied for to support the setting of MRLs beyond the representative uses.

1.5.4. Overview on authorisations in EU Member States

PUMA S 69 EW

Details of the currently authorized uses (GAPs) for the representative formulation fenoxaprop-P-ethyl + mefenpyr-diethyl EW 144 (69+75 g/L) and its registration numbers in the territory of the EU are listed in the following tables. There are no known deviations from the registered uses.

Country	Trade Name	Registration No.
Austria	PUMA EXTRA	2586
Bulgaria	PUMA SUPER 7,5 EW	0565/29.09.2009
Czech Republic	DUKE	4251-6
	PUMA EXTRA	4251-5
Denmark	PRIMERA SUPER	18-432
Estonia	PUMA UNIVERSAL	0189/27.01.00.
Finland	PUMA EXTRA	1702
Germany	RALON SUPER	024259-00 (limited to 31.12.2016)
Greece	RALON SUPER 6,9 EW	70046
Hungary	PUMA EXTRA	35277/2001
Italy	RALON SUPER	14395
Latvia	PUMA UNIVERSAL	0131
Lithuania	PUMA UNIVERSAL	0144H/05
Netherlands	Puma Extra EW, PUMA EXTRA EW	12379 N
Norway	PUMA EXTRA	2014.8
Poland	FANTOM 069 EW	R-106/2014
	PUMA UNIWERSAL 069 EW	R-107/2014
Slovakia	PUMA EXTRA	97-11-0366
Spain	RALON SUPER	24809
Sweden	EVENT SUPER	4222

Crop and/ or situation (a)	EU zone/ country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (BBCH) (j)	number (k)	interval between appl.	kg as/hL min max	water L/ha min max	kg as/ha min max		
Barley, spring Rye, winter Triticale Wheat, durum Wheat, spring	Austria	PUMA EXTRA	F	AVEFA ALOMY APESV	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From BBCH 13 to B 30 (old Code)	1		(1) 0.021 - 0.041 (2) 0.022 - 0.045	200 - 400	(1) 0.083 (2) 0.09		
Barley, winter	Austria	PUMA EXTRA	F	ALOMY APESV AVEFA	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 13 to 29	1		(1) 0.017 - 0.034 (2) 0.019 - 0.038	200 - 400	(1) 0.069 (2) 0.075		
Lawn, turf	Austria	PUMA EXTRA	F	SETSS	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 13 to 25	1		(1) 0.014 - 0.021 (2) 0.015 - 0.022	400 - 600	(1) 0.083 (2) 0.09		
Spelt Wheat, winter	Austria	PUMA EXTRA	F	ALOMY APESV AVEFA	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From BBCH 13 to B 31 (old code)	1		(1) 0.021 - 0.041 (2) 0.022 - 0.045	200 - 400	(1) 0.083 (2) 0.09		
Barley	Bulgaria	PUMA SUPER 7,5 EW	F	AVESS GGGAN	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 13 to 39	1		(1) 0.034 (2) 0.038	200 - 300	(1) 0.069 (2) 0.075		
Wheat	Bulgaria	PUMA SUPER 7,5 EW	F	AVESS GGGAN	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From B 13 (old Code) to B 39 (old Code)	1		(1) 0.034 (2) 0.038	200 - 300	(1) 0.069 (2) 0.075	60	

Crop and/ or situation (a)	EU zone/ country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (BBCH) (j)	number (k)	interval between appl.	kg as/hL min max	water L/ha min max	kg as/ha min max		
Barley, spring	Czech Republic	DUKE PUMA EXTRA	F	APESV ALOMY AVEFA GGGAN	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 13 to 29	1		(1) 0.018 - 0.034 (2) 0.02 - 0.038	200 - 300	(1) 0.055 - 0.069 (2) 0.06 - 0.075		doserate 0,8 l/ha at weeds in BBCH 13-15 doserate 1 l/ha at weeds in BBCH 21-29 PHI: AT
Grass (seed production)	Czech Republic	PUMA EXTRA	F	AVEFA GGGAN	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From B 29 (old Code) to B 31 (old Code)	1		(1) 0.034 (2) 0.038	200 - 300	(1) 0.069 (2) 0.075		
Rye, winter Triticale, winter triticale	Czech Republic	DUKE PUMA EXTRA	F	AVEFA APESV ALOMY GGGAN	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 13 to 31	1		(1) 0.018 - 0.034 (2) 0.02 - 0.038	200 - 300	(1) 0.055 - 0.069 (2) 0.06 - 0.075		doserate 0,8 l/ha at weeds in BBCH 13-15 doserate 1 l/ha at weeds in BBCH 21-29 PHI: AT
Ryegrass	Czech Republic	DUKE PUMA EXTRA	F	AVEFA GGGAN	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 29 to After tillering / formation of side shoots	1		(1) 0.018 - 0.034 (2) 0.02 - 0.038	200 - 300 l/ha	(1) 0.055 - 0.069 (2) 0.06 - 0.075		
Wheat, spring Wheat, winter	Czech Republic	DUKE PUMA EXTRA	F	ALOMY APESV AVEFA GGGAN	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 13 to 32	1		(1) 0.018 - 0.034 (2) 0.02 - 0.038	200 - 300	(1) 0.055 - 0.069 (2) 0.06 - 0.075		doserate 0,8 l/ha at weeds in BBCH 13-15 doserate 1 l/ha at weeds inBBCH 21-29 PHI: AT

Crop and/ or situation (a)	EU zone/ country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (BBCH) (j)	number (k)	interval between appl.	kg as/hL min max	water L/ha min max	kg as/ha min max		
Barley, spring Wheat, spring	Denmark	PRIMER A SUPER	F	ALOMY AVEFA	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From main shoot leaf development - After tillering / formation of side shoots to BBCH 30	1		(1) 0.031 - 0.038 (2) 0.033 - 0.042	180 l/ha	(1) 0.055 - 0.069 (2) 0.06 - 0.075	70	PHI depends on what the crop should be used for. Spring barley not to be traeted after BBCH 30
Barley, winter Rye Triticale Wheat, winter	Denmark	PRIMER A SUPER	F	AVEFA APESV ALOMY	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From Spring treatment to BBCH 30	1		(1) 0.031 - 0.038 (2) 0.033 - 0.042	180 l/ha	(1) 0.055 - 0.069 (2) 0.06 - 0.075	70	winter wheat no to be treated after BBCH 39 others no to be treated after BBCH 30
Barley, winter Rye Triticale Wheat, winter	Denmark	PRIMER A SUPER	F	ALOMY APESV	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From Fall (autumn) treatment to BBCH 30	1		(1) 0.015 (2) 0.017	180 l/ha	(1) 0.028 (2) 0.03	70	winter wheat no to be treated after BBCH 39 others no to be treated after BBCH 30

Crop and/ or situation (a)	EU zone/ country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (BBCH) (j)	number (k)	interval between appl.	kg as/hL min max	water L/ha min max	kg as/ha min max		
Barley, spring Wheat, spring	Estonia	PUMA UNIVERSAL	F	ALOMY APESV AVEFA ECHCE SETSS	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 13 to 32	1		(1) 0.018 - 0.034 (2) 0.02 - 0.038	200 - 300	(1) 0.055 - 0.069 (2) 0.06 - 0.075		
Barley, winter	Estonia	PUMA UNIVERSAL	F		EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 30	1		(1) 0.018 - 0.034 (2) 0.02 - 0.038	200 - 300	(1) 0.055 - 0.069 (2) 0.06 - 0.075		
Rye Triticale Wheat, winter	Estonia	PUMA UNIVERSAL	F	ALOMY APESV AVEFA ECHCE SETSS	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 13 to 32	1		(1) 0.023 - 0.041 (2) 0.025 - 0.045	200 - 300	(1) 0.069 - 0.083 (2) 0.075 - 0.09		
Barley Wheat, spring	Finland	PUMA EXTRA	F	AVEFA	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 14 to 30	1		(1) 0.017 - 0.041 (2) 0.019 - 0.045	200 - 400	(1) 0.069 - 0.083 (2) 0.075 - 0.09		
Barley Wheat, spring	Finland	PUMA EXTRA	F	APESV	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From B 14 (old Code) to B 30 (old Code)	1		(1) 0.014 - 0.041 (2) 0.015 - 0.045	200 - 400	(1) 0.055 - 0.083 (2) 0.06 - 0.09		
Rye Triticale Wheat, winter	Finland	PUMA EXTRA	F	APESV AVEFA	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From Spring treatment - Postemergence ; weeds in cotyledon stage to BBCH 30	1		(1) 0.014 - 0.041 (2) 0.015 - 0.045	200 - 400	(1) 0.055 - 0.083 (2) 0.06 - 0.09		

Crop and/ or situation (a)	EU zone/ country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (BBCH) (j)	number (k)	interval between appl.	kg as/hL min max	water L/ha min max	kg as/ha min max		
Wheat, winter	Greece	RALON SUPER 6,9 EW	F	ALOSS APESV AVESS PHASS POATR SETSS	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 10 to 39	1		(1) 0.023 - 0.083 (2) 0.025 - 0.09	100 - 300	(1) 0.069 - 0.083 (2) 0.075 - 0.09		Application when weeds are at the stage of 2 true leaves, leaf pairs or whorls unfolded and until 2 node stage (BBCH 12-32). For phalaris application until the middle of the tillering formation.
Barley Rye Triticale Wheat, winter	Hungary	PUMA EXTRA	F	GGGAN	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 13 to 30	1		(1) 0.022 - 0.034 (2) 0.024 - 0.038	200 - 250	(1) 0.055 - 0.069 (2) 0.06 - 0.075	56	aerial application/-50 l/ha water
Barley Wheat, durum Wheat, soft	Italy	RALON SUPER	F	ALOMY APESV AVESS PHASS POATR	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 21 to 32	1		(1) 0.017 - 0.041 (2) 0.019 - 0.045	200 - 400	(1) 0.069 - 0.083 (2) 0.075 - 0.09		
Barley, spring Wheat, spring	Latvia	PUMA UNIVERSAL	F	ALOMY APESV AVEFA ECHCE SETSS	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 13 to 32	1		(1) 0.018 - 0.034 (2) 0.02 - 0.038	200 - 300	(1) 0.055 - 0.069 (2) 0.06 - 0.075		
Barley, winter Rye Triticale Wheat, winter	Latvia	PUMA UNIVERSAL	F	ALOMY APESV AVEFA ECHCE SETSS	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 13 to 32	1		(1) 0.023 - 0.041 (2) 0.025 - 0.045	200 - 300	(1) 0.069 - 0.083 (2) 0.075 - 0.09		

Crop and/ or situation (a)	EU zone/ country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (BBCH) (j)	number (k)	interval between appl.	kg as/hL min max	water L/ha min max	kg as/ha min max		
Barley, spring Triticale, summer triticale Triticale, winter triticale Wheat, spring	Lithuania	PUMA UNIVERSAL	F	ALOMY APESV AVEFA ECHCE SETSS AGRRE POAAN FESSS LOLSS	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 13 to 32	1		(1) 0.018 - 0.034 (2) 0.02 - 0.038	200 - 300	(1) 0.055 - 0.069 (2) 0.06 - 0.075		
Barley, winter	Lithuania	PUMA UNIVERSAL	F	APESV AVEFA ALOMY AGRRE POAAN FESSS LOLSS	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 13 to 30	1		(1) 0.018 - 0.034 (2) 0.02 - 0.038	200 - 300	(1) 0.055 - 0.069 (2) 0.06 - 0.075		
Rye Triticale, winter triticale Wheat, winter	Lithuania	PUMA UNIVERSAL	F	ALOMY APESV AVEFA ECHCE SETSS	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 13 to 32	1		(1) 0.023 - 0.041 (2) 0.025 - 0.045	200 - 300	(1) 0.069 - 0.083 (2) 0.075 - 0.09		

Crop and/ or situation (a)	EU zone/ country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (BBCH) (j)	number (k)	interval between appl.	kg as/hL min max	water L/ha min max	kg as/ha min max		
Barley, spring Barley, winter Rye, spring Rye, winter Spelt Triticale	Netherlands	PUMA EXTRA EW	F	ALOMY APESV AVEFA	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 12 to 32	1		(1) 0.014 - 0.041 (2) 0.015 - 0.045	200 - 400	(1) 0.055 - 0.083 (2) 0.06 - 0.09		
Fescue, reed	Netherlands	PUMA EXTRA EW	F	GGGAN	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 21 to 30	1		(1) 0.021 - 0.041 (2) 0.022 - 0.045	200 - 400	(1 0.083 (2) 0.09		*Festuca arundinacea*. Only for seed production Against annual grasses
Lawn, turf	Netherlands	PUMA EXTRA EW	F	GGGAN	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 21 to 30	1		(1) 0.014 - 0.041 (2) 0.015 - 0.045	200 - 400	(1) 0.055 - 0.083 (2) 0.06 - 0.09		
Ryegrass, perennial	Netherlands	PUMA EXTRA EW	F	GGGAN	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 21 to 30	1		(1) 0.021 - 0.041 (2) 0.022 - 0.045	200 - 400	(1) 0.083 (2) 0.09		Only for seed production Against annual grasses
Wheat, spring Wheat, winter	Netherlands	PUMA EXTRA EW	F	ALOMY APESV AVEFA	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 12 to 32	1		(1) 0.014 - 0.041 (2) 0.015 - 0.045	200 - 400	(1) 0.055 - 0.083 (2) 0.06 - 0.09		mixing is possible but not with all herbicides
Barley Rye Triticale Wheat	Norway	PUMA EXTRA		AVEFA PANSS	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From At main shoot leaf development to After tillering / formation of side shoots	1		(1) 0.023 - 0.0552 (2) 0.025 - 0.06	150 - 300	(1) 0.069 - 0.0828 (2) 0.075 - 0.09		

Crop and/ or situation (a)	EU zone/ country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (BBCH) (j)	number (k)	interval between appl.	kg as/hL min max	water L/ha min max	kg as/ha min max		
Barley, spring Wheat, winter	Poland	FANTOM 069 EW PUMA UNIWER SAL 069 EW	F	ALOMY APESV AVEFA ECHCA	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From B 12 (old Code)	1		(1) 0.018 - 0.041 (2) 0.02 - 0.045	200 - 300	(1) 0.055 - 0.083 (2) 0.06 - 0.09		winter wheat - 1-1,2 l/ha; mixture with Sekator 125 OD or Granstar 75 WG barley spring - 0,8-1 l/ha; mixture with Sekator 125 OD or Granstar 75 WG, or Chwastox Turbo 340 SL
Barley, spring Wheat, spring	Slovakia	PUMA EXTRA	F	AVEFA	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From Postemergence spring to Postemergence weeds	1		(1) 0.018 - 0.046 (2) 0.02 - 0.05	150 - 300	(1) 0.055 - 0.069 (2) 0.06 - 0.075		
Rye	Slovakia	PUMA EXTRA	F	ALOMY APESV	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From Postemergence spring to Postemergence weeds	1		(1) 0.023 - 0.046 (2) 0.025 - 0.05	150 - 300	(1) 0.069 - 0.069 (2) 0.075 - 0.075		
Wheat, winter	Slovakia	PUMA EXTRA	F	ALOMY APESV	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From Postemergence spring to Postemergence weeds	1		(1) 0.023 - 0.046 (2) 0.025 - 0.05	150 - 300	(1) 0.069 (2 0.075		
Wheat, winter	Slovakia	PUMA EXTRA	F	AVEFA	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From Postemergence spring to Postemergence weeds	1		(1) 0.018 - 0.046 (2) 0.02 - 0.05	150 - 300	(1) 0.055 - 0.069 (2) 0.06 - 0.075		

Crop and/ or situation (a)	EU zone/ country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (BBCH) (j)	number (k)	interval between appl.	kg as/hL min max	water L/ha min max	kg as/ha min max		
Barley Rye Triticale Wheat	Spain	RALON SUPER	F	ALOSS AVESS PHASS	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	weeds at postemergence (low dose) until the end of tillering (high dose)	1		(1) 0.014 - 0.046 (2) 0.015 - 0.05	180 - 400	(1) 0.055 - 0.083 (2) 0.06 - 0.09		Registered timing: weeds at postemergence, from the 2-3 leaves stage (using 0.8 – 1 L/ha) until the end of tillering (using 1 – 1.2 L/ha).
Barley, spring Barley, winter	Sweden	EVENT SUPER	F	ALOMY APESV	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 13 to 30	1		(1) 0.01 - 0.046 (2) 0.011 - 0.05	150 - 400	(1) 0.041 - 0.069 (2) 0.045 - 0.075		Autumn treatment
Rye Triticale	Sweden	EVENT SUPER	F	ALOMY APESV AVEFA	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From main shoot leaf development to BBCH 30	1		(1) 0.014 - 0.046 (2) 0.015 - 0.05	150 - 400	(1) 0.055 - 0.069 (2) 0.06 - 0.075		
Wheat, winter	Sweden	EVENT SUPER	F	ALOMY APESV AVEFA	EW	(1)fenoxaprop-P-ethyl 69g/l (2)mefenpyr-diethyl 75g/l	Spraying	From 13 to 37	1		(1) 0.014 - 0.055 (2) 0.015 - 0.06	150 - 400	(1) 0.055 - 0.083 (2) 0.06 - 0.09		

CHA 4960

List of authorised uses and extent of use in the EU

Austria (CHA 4960) – Foxtrot (Reg. No.: 3418)

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		

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	AT	winter wheat	F	*annual monocots*	spraying	post emergence, autumn or spring, BBCH 12 (two leaves) up to BBCH 31 (1st node) of the grass weeds	1	-	1,2 l/ha	a) 0.0828 kg as/ha b) 0.0828 kg as/ha	200 – 400 l/ha	-	
2	AT	spring wheat	F	*annual monocots*	spraying	post emergence, BBCH 12 (two leaves) up to BBCH 31 (1st node) of the grass weeds	1	-	1,2 l/ha	a) 0.0828 kg as/ha b) 0.0828 kg as/ha	200 – 400 l/ha	-	
3	AT	winter barley	F	*annual monocots*	spraying	post emergence, autumn or spring, BBCH 12 (two leaves) up to BBCH 31 (1st node) of the grass weeds	1	-	1,0 l/ha	a) 0.069 kg as/ha b) 0.069 kg as/ha	200 – 400 l/ha	-	
4	AT	spring barley	F	*annual monocots*	spraying	post emergence, BBCH 12 (two leaves) up to BBCH 31 (1st node) of the grass weeds	1	-	1,0 l/ha	a) 0.069 kg as/ha b) 0.069 kg as/ha	200 – 400 l/ha	-	

Belgium (CHA 4960) – Foxtrot (Reg. No.: 9705P/B)

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	BE	Winter barley	F	*Weeds** Annual Graminea	High volume spraying	Weeds: BBCH 12-30 Crop: BBCH 13-31	1	n.a.	1 L	0.069 kg	200-600	BBCH 31	
2	BE	Spring barley	F	*Weeds** Annual Graminea	High volume spraying	Weeds: BBCH 12-30 Crop: BBCH 13-31	1	n.a.	1 L	0.069 kg	200-600	BBCH 31	
3	BE	Winter wheat	F	*Weeds** Annual Graminea	High volume spraying	Weeds: BBCH 12-30 Crop: BBCH 13-31	1	n.a.	1 L	0.069 kg	200-600	BBCH 31	
4	BE	Spring wheat	F	*Weeds** Annual Graminea	High volume spraying	Weeds: BBCH 12-30 Crop: BBCH 13-31	1	n.a.	1 L	0.069 kg	200-600	BBCH 31	
5	BE	Rye	F	*Weeds** Annual Graminea	High volume spraying	Weeds: BBCH 12-30 Crop: BBCH 13-31	1	n.a.	1 L	0.069 kg	200-600	BBCH 31	
6	BE	Triticale	F	*Weeds** Annual Graminea	High volume spraying	Weeds: BBCH 12-30 Crop: BBCH 13-31	1	n.a.	1 L	0.069 kg	200-600	BBCH 31	

Bulgaria (CHA 4960) – Foxtrot 69 EW (Reg. No.: 0518)

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	BG	Winter wheat	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides*	Overall, post emergence	BBCH 13-37	1	n.a.	1.0 L	0.69 kg	200	n.r.	+ adjuvant (Renol) Autumn + spring
2	BG	Winter barley	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides*	Overall, post emergence	BBCH 13-30	1	n.a.	1.0 L	0.069 kg	200	n.r.	+ adjuvant (Renol) Spring

Croatia (CHA 4960) – Foxtrot 69 EW (Reg. No.: UP/I-320-20/15-01/178)

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	HR	Winter wheat	F	*Avena Fatua*	Overall, post emergence	BBCH 12-39	1	n.a.	0.75 L	0.0522 kg a.i./ha	200-400	n.r.	Autumn or spring Weed growth stage BBCH 12-23 (adjuvant can be added)
2	HR	Winter wheat	F	*Apera spica-venti*	Overall, post emergence	BBCH 12-39	1	n.a.	1.2 L	0.0828 kg a.i./ha	200-400	n.r.	Autumn or spring Weed growth stage BBCH 12-25 (adjuvant can be added)
3	HR	Winter wheat	F	*Phalaris paradoxa*	Overall, post emergence	BBCH 12-39	1	n.a.	1.0 L	0.069 kg a.i./ha	200-400	n.r.	Autumn or spring Weed growth stage BBCH 12-23 (adjuvant can be added)
4	HR	Winter wheat	F	*Poa trivialis*	Overall, post emergence	BBCH 12-39	1	n.a.	1.2 L	0.0828 kg a.i./ha	200-400	n.r.	Autumn or spring Weed growth stage BBCH 12-31 (adjuvant can be added)
5	HR	Spring wheat	F	*Avena Fatua*	Overall, post emergence	BBCH 12-39	1	n.a.	0.75 L	0.0522 kg a.i./ha	200-400	n.r.	Autumn or spring Weed growth stage BBCH 12-23 (adjuvant can be added)

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		
6	HR	Spring wheat	F	*Apera spica-venti*	Overall, post emergence	BBCH 12-39	1	n.a.	1.2 L	0.0828 kg a.i./ha	200-400	n.r.	Autumn or spring Weed growth stage BBCH 12-25 (adjuvant can be added)
7	HR	Spring wheat	F	*Phalaris paradoxa*	Overall, post emergence	BBCH 12-39	1	n.a.	1.0 L	0.069 kg a.i./ha	200-400	n.r.	Autumn or spring Weed growth stage BBCH 12-23 (adjuvant can be added)
8	HR	Spring wheat	F	*Poa trivialis*	Overall, post emergence	BBCH 12-39	1	n.a.	1.2 L	0.0828 kg a.i./ha	200-400	n.r.	Autumn or spring Weed growth stage BBCH 12-31 (adjuvant can be added)
9	HR	Winter barley	F	*Avena Fatua*	Overall, post emergence	BBCH 12-31	1	n.a.	0.75 L	0.0522 kg a.i./ha	200-400	n.r.	Autumn or spring Weed growth stage BBCH 12-23
10	HR	Winter barley	F	*Apera spica-venti*	Overall, post emergence	BBCH 12-31	1	n.a.	1.0 L	0.069 kg a.i./ha	200-400	n.r.	Autumn or spring Weed growth stage BBCH 12-25
11	HR	Winter barley	F	*Phalaris paradoxa* *Poa trivialis*	Overall, post emergence	BBCH 12-31	1	n.a.	1.0 L	0.069 kg a.i./ha	200-400	n.r.	Autumn or spring Weed growth stage BBCH 12-23
12	HR	Spring barley	F	*Avena Fatua*	Overall, post emergence	BBCH 12-31	1	n.a.	0.75 L	0.0522 kg a.i./ha	200-400	n.r.	Autumn or spring Weed growth stage BBCH 12-23

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		
13	HR	Spring barley	F	*Apera spica-venti*	Overall, post emergence	BBCH 12-31	1	n.a.	1.0 L	0.069 kg a.i./ha	200-400	n.r.	Autumn or spring Weed growth stage BBCH 12-25
14	HR	Spring barley	F	*Phalaris paradoxa* *Poa trivialis*	Overall, post emergence	BBCH 12-31	1	n.a.	1.0 L	0.069 kg a.i./ha	200-400	n.r.	Autumn or spring Weed growth stage BBCH 12-23

Czech Republic (CHA 4960) – Foxtrot (Reg. No.: 4852-0)

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	CZ	Winter wheat	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides*	Overall, post-emergence	BBCH 13-32	1	n.a.	1 L	0.0552 – 0.069 kg	200	n.r.	Spring + Adjuvant in dry conditions (methyl-ester 1 L/ha)
2	CZ	Spring wheat	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides*	Overall, post-emergence	BBCH 13-32	1	n.a.	1 L	0.0552 – 0.069 kg	200	n.r.	Spring
3	CZ	Winter barley	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides*	Overall, post-emergence	BBCH 13-31	1	n.a.	1 L	0.0552 – 0.069 kg	200	n.r.	Spring + Adjuvant in dry conditions (methyl-ester 1 L/ha)
4	CZ	Spring barley	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides*	Overall, post-emergence	BBCH 13-29	1	n.a.	1 L	0.0552 – 0.069 kg	200	n.r.	Spring
5	CZ	Rye	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides*	Overall, post-emergence	BBCH 13-31	1	n.a.	1 L	0.0552 – 0.069 kg	200	n.r.	Spring + Adjuvant in dry conditions (methyl-ester 1 L/ha)

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		
6	CZ	Triticale	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides*	Overall, post-emergence	BBCH 13-31	1	n.a.	1 L	0.0552 – 0.069 kg	200	n.r.	Spring + Adjuvant in dry conditions (methyl-ester 1 L/ha)

Denmark (CHA 4960) – Foxtrot (Reg. No.: 11-31)

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	DK	Winter wheat	F	*Apera spica-venti* *Alopecurus myosuroides*	Overall, post-emergence	Autumn BBCH 11-30	1	-	0.4-1L/ha a) 1L b) 1L	29-69 g/ha a) 69 b) 69	150-200	-	Low rate for weeds in BBCH 12-25. Oil can be added.
2	DK	Rye	F	*Apera spica-venti* *Alopecurus myosuroides*	Overall, post-emergence	Autumn BBCH 11-30	1	-	0.4-1L/ha a) 1L b) 1L	29-69 g/ha a) 69 b) 69	150-200	-	Low rate for weeds in BBCH 12-25. Oil can be added.
3	DK	Triticale	F	*Apera spica-venti* *Alopecurus myosuroides*	Overall, post-emergence	Autumn BBCH 11-30	1	-	0.4-1L/ha a) 1L b) 1L	29-69 g/ha a) 69 b) 69	150-200	-	Low rate for weeds in BBCH 12-25. Oil can be added.
4	DK	Winter wheat	F	*Apera spica-venti* *Alopecurus myosuroides* *Avena fatua*	Overall, post-emergence	Spring BBCH 11-39	1	-	0.8-1L/ha a) 1L b) 1L	55-69 g/ha a) 69 b) 69	150-200	-	Low rate for weeds in BBCH 12-25. Oil can be added.
5	DK	Winter barley	F	*Apera spica-venti* *Alopecurus myosuroides* *Avena fatua*	Overall, post-emergence	Spring BBCH 11-30	1	-	0.8-1L/ha a) 1L b) 1L	55-69 g/ha a) 69 b) 69	150-200	-	Low rate for weeds in BBCH 12-25. Oil can be added.
6	DK	Rye	F	*Apera spica-venti* *Alopecurus myosuroides* *Avena fatua*	Overall, post-emergence	Spring BBCH 11-30	1	-	0.8-1L/ha a) 1L b) 1L	55-69 g/ha a) 69 b) 69	150-200	-	Low rate for weeds in BBCH 12-25. Oil can be added.
7	DK	Triticale	F	*Apera spica-venti* *Alopecurus myosuroides*	Overall, post-emergence	Spring BBCH 11-30	1	-	0.8-1L/ha a) 1L b) 1L	55-69 g/ha a) 69 b) 69	150-200	-	Low rate for weeds in BBCH 12-25. Oil can be added.

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		
				Avena fatua									
8	DK	Spring barley (with and without undersown clover)	F	*Apera spica-venti* *Alopecurus myosuroides* *Avena fatua*	Overall, post-emergence	Spring BBCH 14-30	1	-	0.8-1L/ha a) 1L b) 1L	55-69 g/ha a) 69 b) 69	150-200	-	Low rate for weeds in BBCH 12-25. Oil can be added.
9	DK	Spring wheat	F	*Apera spica-venti* *Alopecurus myosuroides* *Avena fatua*	Overall, post-emergence	Spring BBCH 11-30	1	-	0.8-1L/ha a) 1L b) 1L	55-69 g/ha a) 69 b) 69	150-200	-	Low rate for weeds in BBCH 12-25. Oil can be added.
10	DK	Fallow land	F	*Avena fatua*	Overall, post-emergence	Spring	1	-	1L/ha a) 1L b) 1L	69 g/ha a) 69 b) 69	150-200	-	Oil can be added

Estonia (CHA 4960) – Foxtrot (Reg. No.: 0462/09.05.12)

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	EE	Winter wheat	F	*Avena fatua* *Apera spica-venti* *Aloprcurus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	Spring or autumn BBCH 13-32	1	-	a) 1.2 L b) 1.2 L	a) 83 g b) 83 g	200	-	Weeds at BBCH 12-29
2	EE	Winter barley	F	*Avena fatua* *Apera spica-venti* *Aloprcurus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	Spring BBCH 13-32	1	-	a) 1 L b) 1 L	a) 69 g b) 69 g	200	-	Weeds at BBCH 12-29
3	EE	Rye	F	*Avena fatua* *Apera spica-venti* *Aloprcurus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	Spring or autumn BBCH 13-32	1	-	a) 1.2 L b) 1.2 L	a) 83 g b) 83 g	200	-	Weeds at BBCH 12-29

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		
4	EE	Triticale	F	*Avena fatua* *Apera spica-venti* *Aloprcurus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	Spring or autumn BBCH 13-32	1	-	a) 1.2 L b) 1.2 L	a) 83 g b) 83 g	200	-	Weeds at BBCH 12-29
5	EE	Spring wheat	F	*Avena fatua* *Apera spica-venti* *Aloprcurus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	Spring BBCH 13-32	1	-	a) 1 L b) 1 L	a) 69 g b) 69 g	200	-	Weeds at BBCH 12-29
6	EE	Spring barley	F	*Avena fatua* *Apera spica-venti* *Aloprcurus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	Spring BBCH 13-32	1	-	a) 1 L b) 1 L	a) 69 g b) 69 g	200	-	Weeds at BBCH 12-29

Finland (CHA 4960) – Foxtrot (Reg. No.: 3229)

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	FI	Winter wheat	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides*	Overall, post emergence	BBCH 13-37	1	n.a.	1.2 L	0.0828 kg	200	n.r.	+ Wetter Spring or autumn use
2	FI	Spring wheat	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides*	Overall, post emergence	BBCH 13-32	1	n.a.	1 L	0.069 kg	200	n.r.	+ Wetter Spring use
3	FI	Spring barley	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides*	Overall, post emergence	BBCH 13-30	1	n.a.	1 L	0.069 kg	200	n.r.	+ Wetter Spring use
4	FI	Winter barley	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides*	Overall, post emergence	BBCH 13-30	1	n.a.	1 L	0.069 kg	200	n.r.	+ Wetter Spring use
5	FI	Rye	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides*	Overall, post emergence	BBCH 13-30	1	n.a.	1 L	0.069 kg	200	n.r.	+ Wetter Spring or autumn use
6	FI	Triticale	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides*	Overall, post emergence	BBCH 13-30	1	n.a.	1 L	0.069 kg	200	n.r.	+ Wetter Spring or autumn use

France (CHA 4960) – Fenova Super (Reg. No.: 2110077)

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	FR	Winter barley	F	*Weeds** Annual Graminea	High volume spraying	BBCH 13-32	1	n.a.	1 L	0.069 kg	200-600	BBCH 32	
2	FR	Spring barley	F	*Weeds** Annual Graminea	High volume spraying	BBCH 13-32	1	n.a.	1 L	0.069 kg	200-600	BBCH 32	
3	FR	Winter wheat (common)	F	*Weeds** Annual Graminea	High volume spraying	BBCH 13-32	1	n.a.	1,2 L	0.0828 kg	200-600	BBCH 32	
4	FR	Winter wheat (durum)	F	*Weeds** Annual Graminea	High volume spraying	BBCH 13-32	1	n.a.	1,2 L	0.0828 kg	200-600	BBCH 32	
5	FR	Spring wheat (common)	F	*Weeds** Annual Graminea	High volume spraying	BBCH 13-32	1	n.a.	1 L	0.069 kg	200-600	BBCH 32	
6	FR	Spring wheat (durum)	F	*Weeds** Annual Graminea	High volume spraying	BBCH 13-32	1	n.a.	1 L	0.069 kg	200-600	BBCH 32	
7	FR	Spelt	F	*Weeds** Annual Graminea	High volume spraying	BBCH 13-32	1	n.a.	1 L	0.069 kg	200-600	BBCH 32	
8	FR	Rye	F	*Weeds** Annual Graminea	High volume spraying	BBCH 13-32	1	n.a.	1,2 L	0.0828 kg	200-600	BBCH 32	
9	FR	Triticale	F	*Weeds** Annual Graminea	High volume	BBCH 13-32	1	n.a.	1,2 L	0.0828 kg	200-600	BBCH 32	

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		
					spraying								
10	FR	Seed crops: forage grasses and turf grasses	F	*Weeds** Annual Graminea	High volume spraying	BBCH 13-32	1	n.a.	1 L	0.069 kg	200-600	BBCH 32	

Greece (CHA 4960) – Foxtrot 6,9 EW (Reg. No.: 70049) / Tetramor 6.9 EW (Reg. No.: 70.052) / Fenova Super (Reg. No.: 70.057)

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	GR	Wheat Hard and Soft	F	*Avena spp.* *Alopecurus spp.* *Apera spica-venti* *Poa trivialis* *Setaria spp.*	Overall, post emergence	BBCH 10-32	1	n.a.	1L	0,069 kg	100-300	n.r.	Weed growth stage BBCH 12-29 Application rate of Cloquintocet-mexyl: max. 0.0345kg /ha per crop/season
2	GR	Wheat Hard and Soft	F	*Avena spp.* *Alopecurus spp.* *Apera spica-venti* *Poa trivialis* *Setaria spp.*	Overall, post emergence	BBCH 10-32	1	n.a.	1.2 L	0.0828 kg	100-300	n.r.	Weed growth stage BBCH 29-32 Application rate of Cloquintocet-mexyl: max. 0.0414kg /ha per crop/season
3	GR	Wheat Hard and Soft	F	*Phalaris sp.*	Overall, post emergence	BBCH 10-32	1	n.a.	1.2 L	0.0828 kg	100-300	n.r.	Weed growth stage BBCH 12-29 Application rate of Cloquintocet-mexyl: max. 0.0414kg /ha per crop/season
4	GR	Barley	F	*Avena spp.* *Alopecurus spp.* *Apera spica-venti* *Poa trivialis* *Setaria spp.*	Overall, post emergence	BBCH 10-32	1	n.a.	1 L	0.069 kg	100-300	n.r.	Weed growth stage BBCH 12-29 Application rate of Cloquintocet-mexyl: max. 0.0345kg /ha per crop/season
5	GR	Barley	F	*Phalaris sp.*	Overall, post	BBCH 10-32	1	n.a.	1 L	0.069 kg	100-300	n.r.	Weed growth stage BBCH 12-19

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		
					emergence								Application rate of Cloquintocet-mexyl: max. 0.0345kg /ha per crop/season

Hungary (CHA 4960) – Foxtrot EW (Reg. No.: 04.2/101-1/2016)

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	HU	Winter wheat	F	*Avena fatua* *Alopecurus myosuroides*	Overall, post emergence	BBCH 13-30	1	n.a.	0.8-1 L	0.0552-0.069 kg	200-250	n.r.	
2	HU	Winter barley	F	*Avena fatua* *Alopecurus myosuroides*	Overall, post emergence	BBCH 13-30	1	n.a.	0.8-1 L	0.0552-0.069 kg	200-250	n-r.	

Ireland (CHA 4960) – Foxtrot EW (Reg. No.: 03858)

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	IE	Winter wheat	F	*Avena fatua* *Alopecucus myosuroides*	Overall, post emergence	BBCH 12-39	1	n.a.	0.8 L	0.0552 kg	200-300	n.r.	Autumn or spring Weed growth stage BBCH 12-23 (adjuvant can be added)
2	IE	Winter wheat	F	*Avena fatua* *Alopecucus myosuroides*	Overall, post emergence	BBCH 12-39	1	n.a.	1 L	0.069 kg	200-300	n.r.	Autumn or spring Weed growth stage BBCH 12-31 (adjuvant can be added)
3	IE	Winter wheat	F	*Avena fatua* *Alopecucus myosuroides*	Overall, post emergence	BBCH 12-39	1	n.a.	1.2 L	0.0828 kg	200-300	n.r.	Autumn or spring Weed growth stage BBCH 12-39 (adjuvant can be added)
4	IE	Winter wheat	F	*Phalaris paradoxa* *Poa trivialis*	Overall, post emergence	BBCH 12-39	1	n.a.	1 L	0.069 kg	200-300	n.r.	Autumn or spring Weed growth stage BBCH 12-23 (adjuvant can be added)
5	IE	Winter wheat	F	*Phalaris paradoxa* *Poa trivialis*	Overall, post emergence	BBCH 12-39	1	n.a.	1.2 L	0.0828 kg	200-300	n.r.	Autumn or spring Weed growth stage BBCH 12-31 (adjuvant can be added)

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		
6	IE	Spring wheat	F	*Avena fatua* *Alopecucus myosuroides*	Overall, post emergence	BBCH 12-39	1	n.a.	0.8 L	0.0552 kg	200-300	n.r.	Spring Weed growth stage BBCH 12-23 (adjuvant can be added)
7	IE	Spring wheat	F	*Avena fatua* *Alopecucus myosuroides*	Overall, post emergence	BBCH 12-39	1	n.a.	1 L	0.069 kg	200-300	n.r.	Spring Weed growth stage BBCH 12-31 (adjuvant can be added)
8	IE	Spring wheat	F	*Avena fatua* *Alopecucus myosuroides*	Overall, post emergence	BBCH 12-39	1	n.a.	1.2 L	0.0828 kg	200-300	n.r.	Spring Weed growth stage BBCH 12-39 (adjuvant can be added)
9	IE	Spring wheat	F	*Phalaris paradoxa* *Poa trvialis*	Overall, post emergence	BBCH 12-39	1	n.a.	1 L	0.069 kg	200-300	n.r.	Spring Weed growth stage BBCH 12-23 (adjuvant can be added)
10	IE	Spring wheat	F	*Phalaris paradoxa* *Poa trvialis*	Overall, post emergence	BBCH 12-39	1	n.a.	1.2 L	0.0828 kg	200-300	n.r.	Spring Weed growth stage BBCH 12-31 (adjuvant can be added)
11	IE	Winter barley	F	*Avena fatua* *Alopecucus myosuroides*	Overall, post emergence	BBCH 12-31	1	n.a.	0.8 L	0.0552 kg	200-300	n.r.	Autumn or spring Weed growth stage BBCH 12-23
12	IE	Winter barley	F	*Avena fatua*	Overall,	BBCH 12-31	1	n.a.	1 L	0.069 kg	200-	n.r.	Autumn or spring

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		
				Alopecucus myosuroides	post emergence						300		Weed growth stage BBCH 12-31
13	IE	Winter barley	F	*Phalaris paradoxa* *Poa trivialis*	Overall, post emergence	BBCH 12-31	1	n.a.	1 L	0.069 kg	200-300	n.r.	Autumn or spring Weed growth stage BBCH 12-23
14	IE	Spring barley	F	*Avena fatua* *Alopecucus myosuroides*	Overall, post emergence	BBCH 12-31	1	n.a.	0.8 L	0.552 kg	200-300	n.r.	Spring Weed growth stage BBCH 12-23
15	IE	Spring barley	F	*Avena fatua* *Alopecucus myosuroides*	Overall, post emergence	BBCH 12-31	1	n.a.	1 L	0.069 kg	200-300	n.r.	Spring Weed growth stage BBCH 12-31
16	IE	Spring barley	F	*Phalaris paradoxa* *Poa trivialis*	Overall, post emergence	BBCH 12-31	1	n.a.	1 L	0.069 kg	200-300	n.r.	Spring Weed growth stage BBCH 12-23

Italy (CHA 4960) – Foxtrot (Reg. No.: 14878) / Starprop (Reg. No.: 12960)

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	IT	Wheat Hard and Soft	F	*Avena spp.*, *Poa trivialis*, *Apera spica-venti*	Overall, post emergence	BBCH 13-32	1	n.a.	1.2 L	0.0828 kg	200-400	n.r.	Weed growth stage until BBCH 32
2	IT	Wheat Hard and Soft	F	*Avena spp.*, *Poa trivialis*, *Apera spica-venti*	Overall, post emergence	BBCH 13-32	1	n.a.	0.8 L	0.0552 kg	200-400	n.r.	Weed growth stage BBCH 12-21
3	IT	Wheat Hard and Soft	F	*Alopecucus myosuroides*	Overall, post emergence	BBCH 13-32	1	n.a.	1.0 L	0.0690 kg	200-400	n.r.	Weed growth stage BBCH 12-32
4	IT	Wheat Hard and Soft	F	*Alopecucus myosuroides*	Overall, post emergence	BBCH 13-32	1	n.a.	0.6 L	0.0414 kg	200-400	n.r.	Weed growth stage BBCH 12-21
5	IT	Barley	F	*Avena spp.*, *Poa trivialis*, *Apera spica-venti*	Overall, post emergence	BBCH 13-30	1	n.a.	1.0 L	0.0690 kg	200-400	n.r.	Weed growth stage BBCH 12-32
6	IT	Barley	F	*Avena spp.*, *Poa trivialis*, *Apera spica-venti*	Overall, post emergence	BBCH 13-30	1	n.a.	0.8 L	0.0552 kg	200-400	n.r.	Weed growth stage BBCH 12-21
7	IT	Barley	F	*Alopecucus myosuroides*	Overall, post emergence	BBCH 13-32	1	n.a.	1,0 L	0.0690 kg	200-400	n.r.	Weed growth stage BBCH 12-32
8	IT	Barley	F	*Alopecucus myosuroides*	Overall, post emergence	BBCH 13-32	1	n.a.	0,6 L	0.0414 kg	200-400	n.r.	Weed growth stage BBCH 12-21
9	IT	Wheat Hard and Soft	F	*Phalaris sp*	Overall, post emergence	BBCH 13-32	1	n.a.	1.2 L	0.0828 kg	200-400	n.r.	Weed growth stage BBCH 19-29
10	IT	Wheat Hard and Soft	F	*Phalaris sp*	Overall, post emergence	BBCH 13-32	1	n.a.	0.8 L	0.0552 kg	200-400	n.r.	Weed growth stage BBCH 12-19

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		
11	IT	Barley	F	*Phalaris sp*	Overall, post emergence	BBCH 13-30	1	n.a.	1 L	0.0690 kg	200-400	n.r.	Weed growth stage BBCH 12-29
12	IT	Barley	F	*Phalaris sp*	Overall, post emergence	BBCH 13-30	1	n.a.	0.8 L	0.0552 kg	200-400	n.r.	Weed growth stage BBCH 12-19

Latvia (CHA 4960) – Foxtrot 69 EW (Reg. No.: 0408)

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	LV	Winter wheat	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	BBCH 13-32	1	n.a.	1.2 L	0.069-0.0828 kg	200	n.r.	Spring Weeds at BBCH 12-29
2	LV	Spring wheat	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	BBCH 13-32	1	n.a.	1 L	0.069 kg	200	n.r.	Spring Weeds at BBCH 12-29
3	LV	Winter barley	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	BBCH 13-32	1	n.a.	1 L	0.069 kg	200	n.r.	Spring Weeds at BBCH 12-29

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		
4	LV	Spring barley	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	BBCH 13-32	1	n.a.	1 L	0.069 kg	200	n.r.	Spring Weeds at BBCH 12-29
5	LV	Rye	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	BBCH 13-32	1	n.a.	1.2 L	0.069-0.0828 kg	200	n.r.	Spring Weeds at BBCH 12-29
6	LV	Triticale	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	BBCH 13-32	1	n.a.	1.2 L	0.069-0.0828 kg	200	n.r.	Spring Weeds at BBCH 12-29

Lithuania (CHA 4960) – Foxtrot 69 EW (Reg. No.: 0448H/12)

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	LT	Winter wheat	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	BBCH 13-32	1	n.a.	a) 1.2 L a) 1.2 L	a) 83 g b) 83 g	200-300	n.r.	Spring Weeds at BBCH 12-29
2	LT	Spring wheat	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	BBCH 13-32	1	n.a.	1 L	0.069 kg	200-300	n.r.	Spring Weeds at BBCH 12-29
3	LT	Winter barley	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	BBCH 13-32	1	n.a.	1 L	0.069 kg	200-300	n.r.	Spring Weeds at BBCH 12-29

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		
4	LT	Spring barley	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	BBCH 13-32	1	n.a.	1 L	0.069 kg	200-300	n.r.	Spring Weeds at BBCH 12-29
5	LT	Rye	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	BBCH 13-32	1	n.a.	1.2 L	0.069-0.0828 kg	200-300	n.r.	Spring Weeds at BBCH 12-29
6	LT	Triticale	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides* *Echinochloa crus-galli* *Setaria sp.* *Lolium sp.*	Overall, post emergence	BBCH 13-32	1	n.a.	1.2 L	0.069-0.0828 kg	200-300	n.r.	Spring Weeds at BBCH 12-29

Luxembourg (CHA 4960) – Foxtrot (Reg. No.: L01988-091)

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	LU	Winter barley	F	*Weeds** Annual Graminea	High volume spraying	BBCH 13-31	1	n.a.	1 L	0.069 kg	200-600	BBCH 31	
2	LU	Spring barley	F	*Weeds** Annual Graminea	High volume spraying	BBCH 13-31	1	n.a.	1 L	0.069 kg	200-600	BBCH 31	
3	LU	Winter wheat	F	*Weeds** Annual Graminea	High volume spraying	BBCH 13-31	1	n.a.	1 L	0.069 kg	200-600	BBCH 31	
4	LU	Spring wheat	F	*Weeds** Annual Graminea	High volume spraying	BBCH 13-31	1	n.a.	1 L	0.069 kg	200-600	BBCH 31	
5	LU	Rye (spring and winter)	F	*Weeds** Annual Graminea	High volume spraying	BBCH 13-31	1	n.a.	1 L	0.069 kg	200-600	BBCH 31	
6	LU	Triticale (spring and winter)	F	*Weeds** Annual Graminea	High volume spraying	BBCH 13-31	1	n.a.	1 L	0.069 kg	200-600	BBCH 31	

Poland (CHA 4960) – Foxtrot 069 EW (Reg. No.: R-153/2014) / Rumba 069 EW (Reg. No.: R-184-2014) / Norton 069 EW (Reg. No.: R-183-2014)

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	Winter wheat	F	*Apera spica-venti*	Overall, post emergence	BBCH 12-29	1	n.a.	1.2 L	0.069-0.0828 kg	200-300	n.r.	* 0.5 l/ha +Atpolan 80 EC Adjuvant + lower rate dose
2	PL	Winter Triticale	F	*Apera spica-venti*	Overall, post emergence	BBCH 12-29	1	n.a.	1.2 L	0.069-0.0828 kg	200-300	n.r.	* 0.5 l/ha +Atpolan 80 EC Adjuvant + lower rate dose
3	PL	Spring barley	F	*Avena fatua* *Echinochloa crus-galli*	Overall, post emergence	BBCH 20-30	1	n.a.	1 L	0.055-0.069 kg	200-300	n.r.	* 0.5 l/ha +Atpolan 80 EC Adjuvant + lower rate dose
4	PL	Spring wheat	F	*Avena fatua* *Echinochloa crus-galli*	Overall, post emergence	BBCH 20-30	1	n.a.	1 L	0.055-0.069 kg	200-300	n.r.	* 0.5 l/ha +Atpolan 80 EC Adjuvant + lower rate dose

Portugal (CHA 4960) – Foxtrot (Reg. No.: 0535) / Fenova Super (Reg. No.: 0538)

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	PT	Wheat Hard and Soft	F	*Avena spp* *Alopecucus myosuroides* *Phalaris spp*	Overall, post emergence	BBCH 12-29	1	n.a.	1.2 L	0.0552-0.0828 kg	200-300	n.r.	Dose: 0.8-1.2 L/ha Weed growth stage BBCH 12 – 21 for Phalaris and BBCH 12-29 for the rest
2	PT	Barley	F	*Avena spp* *Alopecucus myosuroides* *Phalaris spp*	Overall, post emergence	BBCH 12-29	1	n.a.	1.2 L	0.0552-0.0828 kg	200-300	n.r.	Dose: 0.8-1.2 L/ha Weed growth stage BBCH 12 – 21 for Phalaris and BBCH 12-29 for the rest
3	PT	Rye	F	*Avena spp* *Alopecucus myosuroides* *Phalaris spp*	Overall, post emergence	BBCH 12-29	1	n.a.	1.2 L	0.0552-0.0828 kg	200-300	n.r.	Dose: 0.8-1.2 L/ha Weed growth stage BBCH 12 – 21 for Phalaris and BBCH 12-29 for the rest
4	PT	Triticale	F	*Avena spp* *Alopecucus myosuroides* *Phalaris spp*	Overall, post emergence	BBCH 12-29	1	n.a.	1.2 L	0.0552-0.0828 kg	200-300	n.r.	Dose: 0.8-1.2 L/ha Weed growth stage BBCH 12 – 21 for Phalaris and BBCH 12-29 for the rest

Romania (CHA 4960) – Foxtrot 69 EW (Reg. No.: 2772)

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	RO	Winter wheat Hard and Soft	F	*Avena fatua* *Apera spica-venti* *Annual grass weed*	Overall, post emergence	BBCH 12-32	1	n.a.	0.9 L	0.0621 kg	200-300	n.r.	Weed growth stage BBCH 12–30 Adjuvant recommended for dry conditions or high weed populations
2	RO	Winter wheat Hard and Soft	F	*Avena fatua* *Apera spica-venti* *Annual grass weed*	Overall, post emergence	BBCH 12-32	1	n.a.	1.1 L	0.0759 kg	200-300	n.r.	Weed growth stage BBCH 30 + Adjuvant recommended for dry conditions or high weed populations

Slovakia (CHA 4960) – Foxtrot (Reg. No.: 14-11-1488)

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	SK	Winter wheat	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides*	Overall, post emergence	BBCH 13-32	1	n.a.	1 L	0.0552-0.069 kg	200	n.r.	Spring + Adjuvant in dry conditions (methyl-ester 1 L/ha)
2	SK	Spring wheat	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides*	Overall, post emergence	BBCH 13-32	1	n.a.	1 L	0.0552-0.069 kg	200	n.r.	Spring + Adjuvant in dry conditions (methyl-ester 1 L/ha)
3	SK	Winter barley	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides*	Overall, post emergence	BBCH 13-29	1	n.a.	1 L	0.0552-0.069 kg	200	n.r.	Spring + Adjuvant in dry conditions (methyl-ester 1 L/ha)
4	SK	Spring barley	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides*	Overall, post emergence	BBCH 13-31	1	n.a.	1 L	0.0552-0.069 kg	200	n.r.	Spring
5	SK	Rye	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides*	Overall, post emergence	BBCH 13-31	1	n.a.	1 L	0.0552-0.069 kg	200	n.r.	Spring + Adjuvant in dry conditions (methyl-ester 1 L/ha)
6	SK	Triticale	F	*Avena fatua* *Apera spica-venti* *Alopecucus myosuroides*	Overall, post emergence	BBCH 13-31	1	n.a.	1 L	0.0552-0.069 kg	200	n.r.	Spring + Adjuvant in dry conditions (methyl-ester 1 L/ha)

Spain (CHA 4960) – Fenova Super (Reg. No.: 24.998) / Arsol (Reg. No.: 25.076)

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	ES	Wheat Hard and Soft	F	*Avena spp* *Alopecucus myosuroides* *Phalaris spp*	Overall, post emergence	BBCH 13-29	1	n.a.	1 L	0.069 kg	200-300	n.r.	Weeds in post-emergence
2	ES	Barley	F	*Avena spp* *Alopecucus myosuroides* *Phalaris spp*	Overall, post emergence	BBCH 13-29	1	n.a.	1 L	0.069 kg	200-300	n.r.	Weeds in post-emergence
3	ES	Triticale	F	*Avena spp* *Alopecucus myosuroides* *Phalaris spp*	Overall, post emergence	BBCH 13-29	1	n.a.	1 L	0.069 kg	200-300	n.r.	Weeds in post-emergence

Sweden (CHA 4960) – Foxtrot (Reg. No.: 4959)

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	SE	Winter wheat	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides*	Overall, post emergence	BBCH 13-37	1	n.a.	1.2 L	0.0828 kg	200	n.r.	+ adjuvant (Renol) Autumn or spring
2	SE	Spring wheat	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides*	Overall, post emergence	BBCH 13-32	1	n.a.	1 L	0.069 kg	200	n.r.	+ adjuvant (Renol) Spring
3	SE	Winter barley	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides*	Overall, post emergence	Spring BBCH 13-30	1	n.a.	1 L	0.069 kg	200	n.r.	+ adjuvant (Renol) Spring only
4	SE	Spring barley	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides*	Overall, post emergence	Spring BBCH 13-30	1	n.a.	1 L	0.069 kg	200	n.r.	+ adjuvant (Renol) Spring only
5	SE	Rye	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides*	Overall, post emergence	BBCH 13-30	1	n.a.	1 L	0.069 kg	200	n.r.	+ adjuvant (Renol) Autumn or spring
6	SE	Triticale	F	*Avena fatua* *Apera spica-venti* *Alopecurus myosuroides*	Overall, post emergence	BBCH 13-30	1	n.a.	1 L	0.069 kg	200	n.r.	+ adjuvant (Renol) Autumn or spring

UK (CHA 4960) – Foxtrot (Reg. No.: 13243) / Oskar (Reg. No.: 13344)

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	GB	Winter wheat	F	*Avena fatua* *Alopecurus myosuroides*	Overall, post emergence	BBCH 12-39	1	n.a.	0.8 L	0.0552 kg	200-300	n.r.	Autumn or spring Weed growth stage BBCH 12-23 (adjuvant can be added)
2	GB	Winter wheat	F	*Avena fatua* *Alopecurus myosuroides*	Overall, post emergence	BBCH 12-39	1	n.a.	1 L	0.069 kg	200-300	n.r.	Autumn or spring Weed growth stage BBCH 12-31 (adjuvant can be added)
3	GB	Winter wheat	F	*Avena fatua* *Alopecurus myosuroides*	Overall, post emergence	BBCH 12-39	1	n.a.	1.2 L	0.0828 kg	200-300	n.r.	Autumn or spring Weed growth stage BBCH 12-39 (adjuvant can be added)
4	GB	Winter wheat	F	*Phalaris paradoxa* *Poa trivialis*	Overall, post emergence	BBCH 12-39	1	n.a.	1 L	0.069 kg	200-300	n.r.	Autumn or spring Weed growth stage BBCH 12-23 (adjuvant can be added)
5	GB	Winter wheat	F	*Phalaris paradoxa* *Poa trivialis*	Overall, post emergence	BBCH 12-39	1	n.a.	1.2 L	0.0828 kg	200-300	n.r.	Autumn or spring Weed growth stage BBCH 12-31 (adjuvant can be added)
6	GB	Spring wheat	F	*Avena fatua*	Overall,	BBCH 12-39	1	n.a.	0.8 L	0.0552 kg	200-	n.r.	Spring

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		
				Alopecurus myosuroides	post emergence						300		Weed growth stage BBCH 12-23 (adjuvant can be added)
7	GB	Spring wheat	F	*Avena fatua* *Alopecurus myosuroides*	Overall, post emergence	BBCH 12-39	1	n.a.	1 L	0.069 kg	200-300	n.r.	Spring Weed growth stage BBCH 12-31 (adjuvant can be added)
8	GB	Spring wheat	F	*Avena fatua* *Alopecurus myosuroides*	Overall, post emergence	BBCH 12-39	1	n.a.	1.2 L	0.0828 kg	200-300	n.r.	Spring Weed growth stage BBCH 12-39 (adjuvant can be added)
9	GB	Spring wheat	F	*Phalaris paradoxa* *Poa trvialis*	Overall, post emergence	BBCH 12-39	1	n.a.	1 L	0.069 kg	200-300	n.r.	Spring Weed growth stage BBCH 12-23 (adjuvant can be added)
10	GB	Spring wheat	F	*Phalaris paradoxa* *Poa trvialis*	Overall, post emergence	BBCH 12-39	1	n.a.	1.2 L	0.0828 kg	200-300	n.r.	Spring Weed growth stage BBCH 12-31 (adjuvant can be added)
11	GB	Winter barley	F	*Avena fatua* *Alopecurus myosuroides*	Overall, post emergence	BBCH 12-31	1	n.a.	0.8 L	0.0552 kg	200-300	n.r.	Autumn or spring Weed growth stage BBCH 12-23
12	GB	Winter barley	F	*Avena fatua* *Alopecurus*	Overall, post	BBCH 12-31	1	n.a.	1 L	0.069 kg	200-300	n.r.	Autumn or spring Weed growth stage

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		
				myosuroides	emergence								BBCH 12-31
13	GB	Winter barley	F	*Phalaris paradoxa* *Poa trivialis*	Overall, post emergence	BBCH 12-31	1	n.a.	1 L	0.069 kg	200-300	n.r.	Autumn or spring Weed growth stage BBCH 12-23
14	GB	Spring barley	F	*Avena fatua* *Alopecurus myosuroides*	Overall, post emergence	BBCH 12-31	1	n.a.	0.8 L	0.552 kg	200-300	n.r.	Spring Weed growth stage BBCH 12-23
15	GB	Spring barley	F	*Avena fatua* *Alopecurus myosuroides*	Overall, post emergence	BBCH 12-31	1	n.a.	1 L	0.069 kg	200-300	n.r.	Spring Weed growth stage BBCH 12-31
16	GB	Spring barley	F	*Phalaris paradoxa* *Poa trivialis*	Overall, post emergence	BBCH 12-31	1	n.a.	1 L	0.069 kg	200-300	n.r.	Spring Weed growth stage BBCH 12-23

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

Level 2

Fenoxaprop-P-ethyl

2. SUMMARY OF ACTIVE SUBSTANCE HAZARD AND OF PRODUCT RISK ASSESSMENT

2.1. IDENTITY

All points of the date requirements regarding Section 1 have been addressed and the information supplied is acceptable. The technical specifications for all producers (Bayer CropScience and Cheminova) are provided in respective confidential parts (Volume 4). All active substances are produced at commercial stage and are considered equivalent to the reference source (BCS) included in Annex I of the DAR 2005.

2.2. PHYSICAL AND CHEMICAL PROPERTIES

2.2.1. Summary of physical and chemical properties of the active substance

Fenoxaprop-P-ethyl, substance pure, is a white solid, practically odourless with a melting point of 90 °C and decomposition occurs above 330°C. The appearance of the as technical material differs from batch to batch; yellowish flakes, coarse powder or solidified melt. Technical fenoxaprop-P-ethyl has a weak aromatic smell. Vapour pressure measured at 20 °C is 6.5×10^{-6} Pa. The Henry's constant at 20 °C was calculated to be 5.5×10^{-3} $Pa\cdot m^3\cdot mol^{-1}$. The solubility in water of approximately 0.4 mg/L was determined at pH 4, 7 and 10 at 20 °C. The substance is soluble in organic solvents with solubility of > 400 g/L in acetone, toluene, dichloromethane and dimethylsulfoxide. The lowest solubility (7 g/L) was observed in n-hexane. The log K_{ow} value is 4.58. The active substance is not flammable, auto-flammable or explosive and has no oxidising properties.

2.2.2. Summary of physical and chemical properties of the plant protection product

Puma S 69 EW

The appearance of the product is that of a light-beige opaque liquid with an aromatic or medium musty odour. It is not explosive, has no oxidising properties. It has flash point above 100 °C and an auto ignition temperature of 435 °C. In aqueous solution, it has a pH value around 7.5. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in COEX/PA, HDPE/PA and HDPE/EV. Its technical characteristics are acceptable for an EW formulation.

CHA 4960:

The appearance of the product is that of an opaque white liquid, with a weak aromatic odour. It is not explosive, has no oxidising properties. It has no auto-ignition temperature below 400°C. In aqueous solution, it has a pH value around 6.5 – 7.3. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored as recommended. Its technical characteristics are acceptable for an oil emulsion in water (EW) formulation.
The label should contain the recommendation "Shake well before use".

2.3. DATA ON APPLICATION AND EFFICACY

PUMA S69 EW [FPP+MPR EW 144 (69+75 g/L)] and CHA 4960 [Fenoxaprop-P-ethyl 69 g/l EW] are the representative formulations used for re-approval of fenoxaprop-P-ethyl.
The representative uses for the renewal of Fenoxaprop-p-ethyl are intended to be applied post-emergence in soft wheat, durum wheat, rye, triticale (BBCH 11-39) and barley (BBCH 12-32) for the control of grass weeds (max. 1x1.2 l PPP/ha).

2.3.1. Summary of effectiveness

Fenoxaprop-P-ethyl belongs to the class of aryloxyphenoxypropionate chemicals. It is a selective herbicide with systemic distribution in the plant to inhibit fatty acid synthesis (ACCase). Fenoxaprop P-ethyl is applied as a post-emergence herbicide for the control of: *Avena spp., Apera spica venti, Alopecurus myosuroides, Echinochloa crus galli* and other annual grass weeds in wheat soft and durum, barley, triticale spelt and rye.

A summary table of achieved control (efficacy % against targets representative of proposed uses at the proposed dose), as required according to SANCO/10054/2013-rev.3, 11 July 2013 (Appendix I) is not available.

2.3.2. Summary of information on the development of resistance

In the action mechanism classification of the HRAC, the products "FPP + MPR EW 144 (69+75 g/L)" and "CHA 4960 (Fenoxaprop-P-ethyl 69 g/l EW)" are listed in group A - Inhibition of acetyl CoA carboxylase (ACCase). As some naturally occurring weed biotypes resistant to ACCase herbicides may exist through normal genetic variability in any weed population the resistant individuals will not be controlled and can eventually dominate the weed population if these herbicides are used repeatedly. To avoid and/or delay the development of resistance in the field several use patterns are recommended to be followed. This includes avoidance of the use of products containing fenoxaprop-P-ethyl on fields with known population of suspected to be resistant, use of fenoxaprop-P-ethyl containing products in tank mixture with other mode of action than fenoxaprop-P-ethyl and/or alternating with other mode of action the within the whole crop rotation. Always use of recommended use rate to ensure maximum efficacy to avoid increase of seedbank of local weed varieties and includes also other agriculture measurements to reduce weed pressure (wide and divers crop rotation, ploughing cultivation etc.).

The inherent risk-related to the active substance is considered high due to 34 resistance cases against Fenoxaprop-p-ethyl in Europe (www.weedscienc.om, 03-04-2017).

Major target weeds of winter and spring cereals are *Apera spica venti*, *Alopecurus myosuroides*, *Poa annua*, *Bromus* species for winter cereals and especially *Avena fatua* in spring cereals. Following confirmed resistance cases (resistance to Fenoxaprop-p-ethyl) were observed in Europe: *Apera spica venti* (3 cases), *Alopecurus myosuroides* (18 cases), *Poa annua* and *Bromus specis* (0 cases), *Avena fatua* (8 cases).
The inherent risk related to target weeds is considered high.

Overall, it can be concluded that the overall risk of resistance development (Fenoxaprop-p-ethyl) is high in Europe.

2.3.3. Summary of adverse effects on treated crops

According to the applicant, no adverse effects on treated crops have been observed when the representative formulations FPP + MPR EW 144 (69+75 g/L) (Bayer CropScience) or CHA 4960 (Fenoxaprop-P-ethyl 69 g/l EW) (Cheminova) are applied according to good agricultural practice.

A summary of crop safety (x specific crop safety trials with N doses and 2N doses, maximum % phytotoxicity), as required according to SANCO/10054/2013-rev.3, 11 July 2013 (Appendix I) is not available.

2.3.4. Summary of observations on other undesirable or unintended side-effects

No other undesirable or unintended side-effects have been observed when the representative FPP + MPR EW 144 (69+75 g/L) (Bayer CropScience) or CHA 4960 (Fenoxaprop-P-ethyl 69 g/l EW) (Cheminova) are applied according to good agricultural practice.

According to SANCO/10054/2013-rev.3, 11 July 2013 (Appendix I), a brief summary of any testing on impacts on succeeding or adjacent crops should be available for Fenoxaprop-P-ethyl.

2.4. FURTHER INFORMATION

2.4.1. Summary of methods and precautions concerning handling, storage, transport or fire

For information on active substance please see Volume 3CA, B4.

For information on representative formulations please see Volume 3CP, B4.

2.4.2. Summary of procedures for destruction or decontamination

For information on active substance please see Volume 3CA, B4.

For information on representative formulations please see Volume 3CP, B4.

2.4.3. Summary of emergency measures in case of an accident

For information on active substance please see Volume 3CA, B4.

For information on representative formulations please see Volume 3CP, B4.

2.5. METHODS OF ANALYSIS

2.5.1. Methods used for the generation of pre-authorisation data

Adequate methods are available for the analysis of the technical compound and risk assessment analysis.

2.5.2. Methods for post control and monitoring purposes

Adequate methods are available to monitor the respective current residue definition in plant material, soil, drinking water, surface water, air, and body fluids. A summary of adequate enforcement methods are given in the table below:

Matrix group / crop group	**Analyte**	**LOQ**	**Methods**		
			Primary method	**Confirmatory method**	**Independent lab validation**
Grain = Dry commodity (high protein/high starch content) Tomato = Commodity with high water content Olive = Commodity with high oil content Citrus = Commodity with high acid content	AE F46360 [1]: >**AE F054014** (one transition) AE F088406 [2] >**AE F054014** (one transition) **AE F054014** [3] >**AE F054014** (two transitions)	0.01 mg/kg	**Freitag, T.;** LC-MS/MS AE F46360 [1]: >AE F054014 (one transition) AE F088406 [2] >AE F054014 (one transition) AE F054014 [3] >AE F054014 (two transitions	**Not necessary**	**Class, T.; 2004** LC-MS/MS
Whole Milk Muscle Kidney Liver Fat Whole Egg	AE F46360 [1]: >**AE F054014** (two transitions) AE F088406 [2] >**AE F054014** (two transitions) **AE F054014** [3] >**AE F054014** (two transitions)	0.01 mg/kg	**Lakaschus, S.; Amann, S.; 2011** LC-MS/MS two transitions	**not necessary**	**Konrad, St.; Neuland, M.; 2011** LC-MS/MS
Soil (silt loam, sandy loam)	AE F033171 [4] AE F053022 [5] AE F054014 [3]	0.01 mg/kg	**Freitag T., (2007)** LC-MS/MS two transitions	**not necessary**	**not necessary**
Water (surface)	AE F046360 [1] AE F088406 [2]	0.05 µg/L	**Braune, M.; 2013** LC-MS/MS two transitions	**not necessary**	**Thies, S.; 2015** LC-MS/MS two transitions
Air	AE F46360 [1] AE F088406 [2]	1.0 µg/m^3	**Bacher R. (2005)** LC-MS/ two transitions	**not necessary**	**not necessary**

Matrix group / crop group	Analyte	LOQ	Methods		
			Primary method	**Confirmatory method**	**Independent lab validation**
Body fluids Urine, blood	AE F46360 [1]: >**AE F054014** (two transitions) AE F088406 [2] >**AE F054014** (two transitions) **AE F054014** [3] >**AE F054014** (two transitions)	0.01 mg/kg	**Burton, D.** LC-MS/MS two transitions	**not necessary**	**not necessary**
Body tissues				**not necessary**	**not necessary**

[1] AE F046360 Fenoxaprop-P-ethyl not enantio-selective detected

[2] AE F088406 Fenoxaprop-P (free acid) not enantio-selective detected

[3] AE F054014 6-chloro-2,3-dihydro-benzoxazol-2-one

[4] AE F33171 Fenoxaprop-ethyl

[5] AE F053022 Fenoxaprop

2.6. EFFECTS ON HUMAN AND ANIMAL HEALTH

In chapter B.6 “Toxicology and metabolism” a great number of studies on the active ingredient (Fenoxaprop-P-ethyl; Hoe 046360 or AE F046360) and the racemic mixture (Fenoxaprop-ethyl; Hoe 033171 or AE F033171) are presented and discussed. The complete evaluation of the data for the racemic mixture Fenoxaprop-ethyl was necessary for bridging the results of the carcinogenicity and multigeneration studies, as no such studies have been conducted with the active ingredient Fenoxaprop-P-ethyl. For every toxicological endpoint, results of studies performed with the racemic mixture are presented subsequently to the studies conducted with the active ingredient. Summaries of the data for both substances as well as a comparison of the results were conducted for every endpoint.

2.6.1. Summary of absorption, distribution and excretion in mammals

Biokinetics and metabolism were investigated in the rat. No new data were submitted to address ADME endpoints.

Absorption

The absorption of fenoxaprop-P-ethyl in male and female rats was rapid as the test substance was already found in the blood 15 min after single oral administration. The maximum concentration was reached 6-8 hours after application. In a study with a single dose of 2 mg/kg bw, maximum blood levels of 3.88 ±0.66 and 4.38 ±0.14µg equivalents fenoxaprop-P-ethyl/g in males and females respectively were determined after a single dose of 10 mg/kg bw, maximum blood levels of 19.86 ±1.62 and 23.27 ±4.02 /µg equivalents fenoxaprop-P-ethyl/g in males and females, respectively. The blood level curve was biphasic with half-lives of 9-11 hours for the initial phase and 68-75 hours for the terminal phase. The highest concentrations at the end (7 d after treatment) of a repeated-dose study with a 14-day administration and a radioactive dose on day 15 in males and females respectively were measured in the kidneys (0.19 and 0.24 /µg equivalents/g) and in the blood (0.18 and 0.16 /µg equivalents/g). The minimum rate of absorption (urinary excretion including cage washes and residues in tissues/organs (excluding faeces)) was generally higher in females than in males and reached at least 40% of the administered dose.

Distribution

Following oral administration of 2 or 10 mg/kg, radioactivity was widely distributed into the investigated organs and tissues. However, the overall concentrations from the tissues analysed 7 days after treatment were rather low with 0.7 to 2 % of the total applied dose after single and also after repeated dosing. The highest concentrations

were found in the kidneys, blood, fatty tissues (subcutaneous, retroperitoneal) and the liver. In a study with single administration of 10 mg/kg bw, liver, kidneys and blood had the highest radioactivity concentrations with ranges of 0.4 to 1.5 mg a.i. equivalents/kg. Intravenous administration of 2 mg/kg bw showed similar results.

Elimination

After oral application, female rats generally excreted higher amounts of radioactivity via urine (51-65 %) than via faeces (33-42 %), which was independent from dose level (2 or 10 mg/kg) or application frequency (single or repeated dose). In contrast, male rats generally excreted lower amounts of orally applied radioactivity with the urine (35-54 %) than with faeces (41-54 %), with the exception of repeated dose application when higher amounts of radioactivity were excreted in the urine (54 %) than in the faeces (41 %). When the test substances were administered via intravenous injection, higher amounts of radioactivity were excreted renally (50-59 %) as via faeces (29-40 %) in both sexes. More than approximately 75 % of the administered dose was excreted within a time period of 48 hours, independent from route of application, dose level or sex.

Metabolism

No unchanged parent compound was found in the urine after oral administration of 10 mg/kg bw. The major metabolite in the urine of males was the mercapturic acid derivative of 6-chloro-2,3-dihydrobenzoxazol-2-one. In the urine of females, also the mercapturic acid derivative of 6-chloro-2,3-dihydro-benzoxazol-2-one and the free acid from the parent compound appeared in a ratio of approximately 1:1. On average, 10 % of the applied dose was present in the faeces in the form of the intact parent compound. Another major metabolite in the faeces was the free acid, contributing to 9.5-13.5 % of the administered dose. Some other minor metabolites and their sulphate or glucuronic acid conjugates were found in the urine and faeces. The amounts of metabolites in blood, liver and kidneys were about 0.1-0.3 % of the applied dose. The metabolites had the same structures as found in the excreta.

Comparative *in vitro* metabolism

In the renewal dossier *in vitro* interspecies comparative metabolism data should be provided, according to the data requirement in Regulation (EU) No. 283/2013, even if internationally validated methods and criteria for the interpretation of the results are missing ("Outcome of the pesticides peer review meeting on general recurring issues in mammalian toxicology", EFSA Supporting publication 2016:EN-1074). For this purpose, a new comparative metabolism study has been provided and fenoxaprop-P-ethyl was tested with S9 fractions from mouse, rat, rabbit, dog and human liver.

According to the study results, fenoxaprop-P-ethyl degraded rapidly mostly to the major metabolite M11 (Hoe 054014) in all species. M11 is the sulphate ester of 6-chloro-4-hydroxy-2(3H)-benzoxazolone, where a 13-week oral toxicity study in the rat is available (see section B.6.1.2). Ten of these metabolites (M1, M2, M3, M7, M9, M10, M12, M13, M14, and M16) appeared in all species only in trace levels (below 1 % of the total radioactivity). Further 5 metabolites (M4, M5, M6, M8, M14) occurred in mouse, rat and humans also at levels below 1 % but occasionally appeared in rabbit and/or dog at levels up to 4 % at maximum. No unique human metabolite was identified.

Comparison of the absorption, distribution, metabolism and excretion behaviour of fenoxaprop-P-ethyl and fenoxaprop-ethyl:

A comparison of the metabolism of fenoxaprop-P-ethyl and fenoxaprop-ethyl is given by Schwalbe-Fehl, M.; 1988; M-120271-01-1.

The metabolism and pharmacokinetic behaviour of both compounds was investigated in male and female rats after oral administration of the radiolabelled test substances at two dose levels, i.e. 2 mg/kg bw and 10 mg/kg bw. Fenoxaprop-P-ethyl and fenoxaprop-ethyl were both excreted rapidly. In general, approx. 75% or more of the administered radioactivity were recovered in the excreta of the 0-48 hours sampling interval. Excretion via urine and faeces was in the same order of magnitude. No significant differences in the organ and tissue concentrations could be observed between fenoxaprop-P-ethyl and fenoxaprop-ethyl. Comparison of the metabolism of fenoxaprop-P-ethyl and fenoxaprop-ethyl in rats showed that the pathway of metabolism is identical for both compounds. Therefore, based on the similar absorption, distribution, metabolism and excretion behaviour of both compounds, confirmed by the similar toxicological profile of both, the bridging of toxicity data from the long-term studies and the 2-generation study with fenoxaprop-ethyl to fenoxaprop-P-ethyl is justified.

2.6.2. Summary of acute toxicity

All studies for acute oral, dermal and inhalation toxicity as well as skin irritation, eye irritation and skin sensitization were evaluated in the DAR (May 2005). In addition, an in-vitro phototoxicity study is included in response to updated data requirements under EU Regulation No 283/2013. A summary of all data is presented in **Table 2.6.2-1** and **Table 2.6.2-2**.

Fenoxaprop-P-ethyl is of moderate toxicity via the oral route and of low toxicity via the dermal and inhalation route. The active substance did not show any skin or eye irritating properties and is classified as a skin sensitizer. The *in-vitro* phototoxicity study for fenoxaprop-P-ethyl was demonstrated to present no phototoxic hazard. A summary of all original submitted and evaluated studies (EC review report (SANCO/3777/08-rev.1, 14 December 2007)) as well as newly submitted studies (marked) is presented in the following tables.

Table 2.6.2-1 Summary of acute toxicity studies with fenoxaprop-P-ethyl

Study, reference	Dose levels	Results	Classification: CLP 1272/2008
Acute oral toxicity LD_{50} in rats [redacted]., *1992* A47470, CA 5.2.1/01	2,000; 3,150; 4,000 and 5,000 mg/kg bw	4,000>LD_{50}>3,150 mg/kg bw	No classif.
Acute oral toxicity LD_{50} in mice [redacted]., *1985a* A37268, CA 5.2.1/04	5,000 mg/kg bw	>5,000 mg/kg bw	No classif.
Acute oral toxicity LC_{50} in rats [redacted] *2008* 271 FPE, CA 5.2.1/07	2,000 mg/kg bw and 300 mg/kg bw	2,000>LD_{50}>300 mg/kg bw	**Acute Tox. 4** **H302: harmful if swallowed**
Acute oral toxicity LC_{50} in rats [redacted] *2005* 127 FPE, CA 5.2.1/08	175-2,000 mg/kg bw	1,098 mg/kg bw	**Acute Tox. 4** **H302: harmful if swallowed**
Acute dermal toxicity LD_{50} in rats [redacted] *1985b* A36023, CA 5.2.2/01	2,000 mg/kg bw	>2,000 mg/kg bw	No classif.
Acute inhalation toxicity LC_{50} in rats [redacted] *1991* A46998, CA 5.2.3/01	1.224 mg/L	>1.224 mg/L*	No classif.
Acute inhalation toxicity LC_{50} in rats *Griffiths D.R., 2005* 131 FPE, CA 5.2.3/03	3.4 mg/L	>3.40 mg/L* (supplementary information)	No classif.
Acute skin irritation in rabbits [redacted] *1985d* A36061, CA 5.2.4/01	500 mg	Slight irritant	No classif.
Acute skin irritation in rabbits [redacted] *2005* 125 FPE, CA 5.2.4/03	500 mg	Not irritating	No classif.
Acute eye irritation in rabbits [redacted] *1985e* A36022, CA 5.2.5/01	100 mg	Slight irritant	No classif.
Acute eye irritation in rabbits [redacted] *2005* 124 FPE, CA 5.2.5/03	31 mg	Slight irritant	No classif.
Skin sensitization (MK-GPMT) [redacted] *1986a* A37243, CA 5.2.6/01	5% intradermal, 50% dermal induction	Sensitizing	**Skin Sens. 1** **H317: may cause an allergic skin reaction**
Skin sensitization (Bühler) [redacted] *1986b* A36040, CA 5.2.6/02	50% topical induction, 2, 10 and 25% challenge	Inconclusive	-

Study, reference	Dose levels	Results	Classification: CLP 1272/2008
Skin sensitization (Bühler) [redacted] *1992* A47403, CA 5.2.6/03	75% induction, 75% challenge	Not sensitizing [+]	No classif.
Local Lymph Node in mice [redacted] *2005* 123 FPE, CA 5.2.6/05	10, 25 and 50%	Not sensitizing	No classif.
Cytotoxicity Assay *In-vitro* with BALB/c 3T3 Cells *Wason S., 2014* Nr. 1637600, CA 5.2.7/01	w/o irr: 6.25-200 µg/ml w/ irr: 0.125- 4.0 µg/ml	Non-phototoxic	No classif.

* Highest technically attainable atmosphere concentration
[+] Induction phase non-irritating

The racemate, **fenoxaprop-ethyl** is of low toxicity via the oral, dermal and inhalation route. The racemate did not show any skin or eye irritating properties and is not classified. As no new studies were submitted for fenoxaprop-ethyl, the following table includes all originally submitted and evaluated studies (EC review report (SANCO/3777/08-rev.1, 14 December 2007)).

Table 2.6.2-2 Summary of acute toxicity studies with fenoxaprop-ethyl

Study, reference	Dose levels	Results	Classification: CLP 1272/2008
Acute oral toxicity LD_{50} in male rat [redacted], *1979a* A24696, CA 5.2.1/02	1,600-5,000 mg/kg bw	2,357 mg/kg bw	No classif.
Acute oral toxicity LD_{50} in female rat [redacted] *1979b* A24698, CA 5.2.1/03	2,000-5,000 mg/kg bw	2,500 mg/kg bw	No classif.
Acute oral toxicity LD_{50} in male mouse [redacted], *1979a* A24692, CA 5.2.1/05	3,150-6,300 mg/kg bw	4,670 mg/kg bw	No classif.
Acute oral toxicity LD_{50} in female mouse [redacted], *1979b* A24694, CA 5.2.1/05	2,500-6,300 mg/kg bw	5,490 mg/kg bw	No classif.
Acute dermal toxicity LD_{50} in female rat [redacted], *1978b* A24673, CA 5.2.2/02	2,000 mg/kg bw	>2,000 mg/kg bw	No classif.
Acute dermal toxicity LD_{50} in female rat [redacted], *1979c* A24702, CA 5.2.2/03	2,000 mg/kg bw	>2,000 mg/kg bw	No classif.
Acute inhalation toxicity LC_{50} in rat [redacted] *1982* A24752, CA 5.2.4/01	0.151 and 0.511 mg/L [§]	Mortality: 1 / 24 [§]	No classif
Acute skin irritation in rabbit [redacted] *1979d* A24688, CA 5.2.4/02	500 mg	Slight irritant	No classif.
Acute eye irritation in rabbit *(reference as in skin irritation study)*	100 mg	Slight irritant	No classif.
Skin Sensitization (Bühler) [redacted], *1982* A30110, CA 5.2.6/04	10% topical induction, 5% challenge	Not sensitizing [x] (supplementary information)	-

[§] Highest concentration tested: 0.511 mg/L
[x] Number of animals low

2.6.3. Summary of short-term toxicity

All required data were evaluated during the first Annex I review of fenoxaprop-p and were presented in the fenoxaprop monograph (Vol.3, Annex B, Section B6, Point B.6.3, August 2005) and addenda to the monograph (January 2007). The 90-day (13-week) rat and dog studies are required according to data requirements under Regulation (EC) No. 1107/2009. These studies were considered in general compliance with test guidelines and fit for purpose. Percentages to the values of untreated group were calculated and differences were added to the result tables.
4- and 13-week shorter term toxicity studies with fenoxaprop-P-ethyl were conducted in rats, mice and dogs. However, 4-week studies were regarded as supplementary information only.
In addition to the studies already submitted and reviewed, a 21-day dermal toxicity study in the rat was conducted (2014) for data registration requirements outside the E.U. Fenoxaprop-P-ethyl is currently classified as STOT RE 2 H373 (kidneys).
A summary of all data is presented in **Table 2.6.3-1** and **Table 2.6.3-2**.

Fenoxaprop-P-ethyl

Rats: Fenoxaprop-P-ethyl induced comparable effects in the 28 day dose finding study and the 13 week feeding studies in Wistar rats. Reductions of body weights were found at doses of 640 ppm and above and were more distinct in males than in females. Severe toxicity was observed in all animals receiving 5,210 ppm in the 28 day study leading to an interim kill in extremis. Slight, but not biologically significant effects on haematology were observed in both sexes. In clinical chemistry, the most striking effects were observed on lipid metabolism and liver enzymes at 80 ppm and above in both sexes. Total cholesterol, HDL-cholesterol and HDL-phospholipid levels were decreased while triglyceride levels were increased. Regarding liver enzymes, ALP and LDH levels were increased. Additional investigations on mixed function oxidase, catalase and glutathione in liver revealed a distinct increase at 1,280 ppm. Slight effects on plasma electrolytes were noted in both sexes, with decreased calcium and increased sodium levels at 80 ppm and above. All these effects were reversible after a 4 week recovery period. Slight to moderate ketonuria and urobilinogenuria were noted for males at mid and high doses. Also bilirubinuria were observed at the high dose in males. However, both findings were within the normal range of biological variation. Organ weight analysis demonstrated effects on liver and kidney with increases in relative and/or absolute organ weights at dose levels of 80 ppm and above. In the 13 week study, effects on the target organs were obvious also at macroscopic examination where enlargements of liver (both sexes, 640 ppm) and kidneys (females, 80 and 640 ppm) were noticed. Furthermore, histopathology revealed centrilobular hypertrophy in the 640 ppm dose group.

The oral short-term toxicity NOAEL of Fenoxaprop-P-ethyl in rats is considered to be 10 ppm (equivalent to 0.7 mg/kg bw/d in males and 0.8 mg/kg bw/d in females).

Other routes: Similar effects (organ weight changes, lipid metabolism) were observed in the repeated subchronic inhalation study as well as the subchronic dermal study, where additionally dry/chapped skin and/or fine/coarse scales were noted. Inhalative and dermal short-term toxicity NOAELs were determined as 0.015 mg/L and 20 mg/kg bw/d, respectively.

Mice: Fenoxaprop-P-ethyl was tested in a 28 day dose finding study and a 13 week feeding study in NMRI mice. An increase in body weight was observed in the 28 day study at the highest dose level of 1280 ppm in females, which was discussed to be caused by the markedly increased liver weight in these animals. Haematology was not performed in the 28 day study and only marginal effects were noticed in the highest dose group (640 ppm) of the 13 week study. Clinical chemistry evaluations in both studies revealed marked effects on lipid metabolism and liver enzymes at concentrations of 320 ppm and above. Phospholipids and total cholesterol were decreased in males while total cholesterol was increased in females. Liver enzymes (ASAT, ALAT and ALP) and total protein and albumin levels were increased in males and females at 640 ppm and above. Additional investigations on mixed function oxidase, catalase and glutathione in liver indicated induction of peroxisome proliferation through markedly increased catalase starting from 80 ppm in males and from 320 ppm and onwards in females. An increase of urea in females at 640 ppm suggested changes in kidney function. Absolute and/or relative liver weights were increased in males and females starting at a dose level of 80 ppm. For kidney weights, clear effects were evident at 640 ppm and above. In the 13 week study, macroscopic examination showed enlarged livers (males, females) and irregular kidney surface (females) at 640 ppm. Effects on liver and kidney were also confirmed at histopathological evaluation in both studies. In the liver, hepatocellular hypertrophy, single cell

necrosis and increased mitotic activity were observed at 320 ppm and above and were more pronounced in males than in females. In kidneys, tubular injury was more marked in females than in males and was noted starting at doses of 80 ppm.

The oral short-term toxicity NOAEL of Fenoxaprop-P-ethyl in mice is considered to be 10 ppm (equivalent to 1.4 mg/kg bw/d in males and 2.0 mg/kg bw/d in females).

Dogs: Two studies were conducted in Beagle dogs. The 28 day feeding study served as a dose finding study and employed only 1 animal per sex per dose group that is why no statistical analysis could be performed. No obvious treatment-related effects could be found in this study. The 13 week feeding study which was performed according to EPA Guideline is valid and acceptable and showed the following results: a decrease in body weight gain was only observed at the highest dose of 2000 ppm in males. Some liver toxicity was demonstrated by increased ASAT and LDH levels in males at 2000 ppm. Also, total protein levels were increased in this dose group. Relative liver weight was increased in females at 2000 ppm. However, no statistically significant changes were noted at organ weight analysis. No treatment-related effects were seen at macroscopical and microscopical examination.

The oral short-term toxicity NOAEL of Fenoxaprop-P-ethyl in dogs is considered to be 400 ppm (equivalent to 15.6 mg/kg bw/d in males and 16.2 mg/kg bw/d in females).

Table 2.6.3-1 Summary of short-term toxicity studies, fenoxaprop-P-ethyl

Study, reference	Dose levels	NOAEL	Main effects/target organs
Oral 28-day studies			
28 days oral Wistar rat [redacted] *1987a*, A36568, CA 5.3.1/01 Addendum [redacted].., *1990*, A42820, CA 5.3.1/02 Supplement [redacted], *1987b* A36955, CA 5.8.2/01	0, 20, 80, 320, 1280 and 5120 ppm / diet (equivalent to 0, 2, 6, 26, 95 and 126 mg/kg bw/d in males; 0, 2, 6, 28, 94 and 144 mg/kg bw in females)	20 ppm (♂ and ♀: 2 mg/kg bw/d) Supplementary information only	- haematology, clinical chemistry and urinalysis findings - increase of catalase levels at 1,280 ppm
28 days oral NMRI mice [redacted]., *1987b* A36557, CA 5.3.1/04 Supplements [redacted] *1987c* A36958, CA 5.8.2/03 [redacted] [redacted] *1987d* A36960, CA 5.8.2/04	0, 20, 80, 320 and 640 ppm / diet (equivalent to 0, 3, 14, 56 and 260 mg/kg bw/d in males; 0, 4, 16, 61 and 280 mg/kg bw/d in females)	80 ppm (♂: 14 mg/kg bw/d; ♀: 16 mg/kg bw/d) Supplementary information only	- clinical chemistry findings - increased organ weights (liver, kidney) - histopathological findings (tubular injury, hepatocellular hypertrophy, single cell necrosis, mitotic hepatocytes) - increased catalase in ♂ at 80 ppm and in ♀ at 320 ppm onwards - at 640 ppm: induction of N-demethylase in ♀; increased CP450 levels observed in ♂; increase in catalase activity; decreased testis weight
28 days oral Beagle dog [redacted] *1987a*, A36558, CA 5.3.1/07 Supplement [redacted] *1987c*, A36597, CA 5.8.2/05	0, 80, 320 and 1280 ppm / diet (equivalent to 0, 3.3, 13.0 and 67.9 mg/kg bw/d in males; 0, 3.7, 14.9 and 56.1 mg/kg bw/d in females)	NOAEL could not be established Supplementary information only	No treatment-related effects could be identified in any of the dose groups (only 1 animal/sex/group).
Oral 90-day studies			

Study, reference	Dose levels	NOAEL	Main effects/target organs
13 weeks oral Wistar rat [redacted] *1987* A36566, CA 5.3.2/01 [redacted] [redacted] *1987* A36954, CA 5.8.2/02	0, 10, 80 and 640 ppm / diet (equivalent to 0, 0.7, 5.8 and 49.0 mg/kg bw/d in males; 0, 0.8, 6.3 and 51.8 mg/kg bw/d in females)	10 ppm (♂: 0.7 mg/kg bw/d; ♀: 0.8 mg/kg bw/d)	- haematology, clinical chemistry and urinalysis findings - increased organ weights (liver, kidney) - macroscopically enlarged kidneys - at 640 ppm: changes in glutathione levels, slight increase in CP450; in ♂: increased activity of catalase
13 weeks oral NMRI mouse [redacted] *1987a* A36567, CA 5.3.2/05	0, 10, 80 and 640 ppm / diet (equivalent to 0, 1.4, 11.9, 100.8 mg/kg bw/d in males; 0, 2.0, 16.5 and 122.4 mg/kg bw/d in females)	10 ppm (♂: 1.4 mg/kg bw/d; ♀: 2.0 mg/kg bw/d)	- increased organ weights (liver) - histopathological findings (tubular injury)
13 weeks oral Beagle dog [redacted] *1987b*, A36617, CA 5.3.2/07 Supplement [redacted] *1987d*, A36959, CA 5.8.2/06	0, 80, 400 and 2000 ppm / diet (equivalent to 0, 3.0, 15.6 and 77.7 mg/kg bw/d in males; 0, 3.2, 16.2 and 83.4 mg/kg bw/d in females)	400 ppm (♂: 15.6 mg/kg bw/d; ♀: 16.2 mg/kg bw/d)	- decreased body weight gain - clinical chemistry findings - N-demethylase decreased in ♂ at 2,000 ppm
Other routes			
28 day inhalation Wistar rat [redacted] *1989* A40799, CA 5.3.3/01	0, 0.015, 0.07 and 0.3 mg/L air	0.015 mg/L	- haematology and clinical chemistry findings - increased organ weights (liver)
21 day dermal application Wistar rat [redacted] *1988* A40800, CA 5.3.3/02	0, 10, 20, 100 and 500 mg/kg bw/d	20 mg/kg bw/d	- dry/chapped skin, fine/coarse scales - haematology and clinical chemistry findings - increased organ weights (liver, kidney)

Fenoxaprop-ethyl

Rats: Fenoxaprop-ethyl was tested in a 32-day and a 3-month-feeding study in Wistar rats. Excessive toxicity was found at a dose level of 5000 ppm in the 32-day study leading to a premature sacrifice of these animals. A reduction in body weight gain was observed at a dose level of 1250 ppm in the 32-day study but not at the highest dose (320 ppm) in the 3-month-study. Slight haematological effects were only observed in the 3-month study at 320 ppm (decreased haemoglobin and erythrocyte levels). Changes in lipid status were observed in both studies at doses of 20 ppm and above (decreased cholesterol and total lipids). Signs of hepatotoxicity were demonstrated by increased ALP levels at 320 ppm and above. In both studies elevated relative liver weights were observed at doses of 315 ppm and higher. This finding was accompanied with an enlargement of hepatocytes, with effects being more marked in males than in females. Also, relative kidney weights were increased at doses of 80 ppm and above.

The oral short-term toxicity NOAEL of Fenoxaprop-ethyl in rats is considered to be 20 ppm (equivalent to 1.57 mg/kg bw/d in males and 1.74 mg/kg bw/d in females).

Mice: A 32-day and a 30-day feeding study in NMRI mice were conducted because no NOAEL could be defined in the 32-day study as effects were already observed at the lowest dose level of 80 ppm. Furthermore, a 3-month feeding study in NMRI mice was done to establish a MTD for a chronic toxicity study and to further investigate the mechanistic action of Fenoxaprop-ethyl in hepatocytes. Again, no NOAEL could be established as effects were evident at the lowest dose level of 320 ppm in this 3-month study. 5000ppm Fenoxaprop-ethyl led to excessive toxicity and subsequently to an interim sacrifice of animals in the 32-day feeding study. An increased body weight was observed after 3 months at 640 ppm and higher, which was discussed to be a result of markedly increased liver weight in these dose groups. Haematological effects were observed at doses of 320 ppm and/or

above including a decrease in haemoglobin, erythrocytes and thrombocytes, and an increase in MCV, reticulocytes and leucocytes. Clinical chemistry revealed effects on the lipid status (increased total lipids and cholesterol at 20 and/or 80 ppm; increased triglycerides at 640 ppm and above), and on bilirubin (increased at 320 ppm and above), total protein (increased at 640 ppm and above) and albumin (increased at 1280 ppm). Elevated levels of liver enzymes (315 ppm and above) were indicative of hepatotoxicity. An increase of relative liver weight was already observed at a dose level of 20 ppm and increased markedly with dose. Histopathological examination of the livers revealed enlargement of hepatocytes starting at a dose level of 20 ppm. At higher dose levels (320 ppm and above), also single cell necrosis and an increased rate of mitosis were observed. Liver peroxisome proliferation was confirmed by electron microscopy and special biochemical investigations in the 3-month study. Kidneys weights were increased at 315 ppm and above which was accompanied by tubular necrosis. Furthermore, increased erythropoiesis was noted at histopathological investigations of the spleen (320 ppm and higher) with an increased spleen weight at 1280 ppm in males only. Also in males only, adrenals weight was increased at 320 ppm and above without correlating histopathological findings.

The oral short-term toxicity NOAEL of Fenoxaprop-ethyl in mice is considered to be 10 ppm (equivalent to 1.82 mg/kg bw/d in males and 1.85 mg/kg bw/d in females).

Dogs: Three feeding studies were conducted in Beagle dogs: a 30-day dose finding study (supplementary information only due to limited study design, 2 dogs/sex/group), a 3-month study and a 1-year study. The dogs of the highest dose group (2,000 ppm) in the 30-day dose finding study had to be sacrificed prematurely due to excessive toxicity. These dogs showed signs of intoxication at macroscopic (liver: lobular marking, clay-brownish discoloration; lymph nodes: enlargement) and microscopic examination (fatty degeneration of the liver, atrophy of splenic corpuscles, acute lymphadenitis, haemorrhages of the adrenal cortex, thymus atrophy and changes of the cerebellum). Except in those prematurely killed animals which seemed to have a slightly reduced body weight, no effect on body weight gain was noted in any of the studies. No substance related changes were observed in haematological, clinical chemistry and urinalysis parameters and at liver and renal function tests. In the 30-day dose finding study, adrenals weights seemed to be increased slightly at 400 ppm and distinctly at 2000 ppm. In the 3-month study, relative pituitary weights were increased statistically significant in males at 400 ppm. Furthermore, chronic interstitial pyelonephritis was detected at histopathological investigation of males and females of the 80 and 400 ppm dose groups. In the 1-year study, dose-related but statistically not significant increases were observed starting from 3 ppm in relative prostate weight in males, absolute and relative uterus weight and absolute and relative ovaries weight in females. The applicant submitted a position paper with detailed reasoning and historical control data, which did not fulfil the criteria set out in Regulation (EC) No 283/2013. However, due to high variability in organ weights and as no histopathological changes were observed these effects were considered not relevant.

The oral short-term toxicity NOAEL of Fenoxaprop-ethyl in dogs is considered to be 16 ppm (♂: 1.2 ♀: 1.0 mg/kg bw/d).

Table 2.6.3-2 Summary of short-term toxicity studies, fenoxaprop-ethyl

Study, reference	Dose levels	NOAEL	Main effects/target organs
Oral 28-day studies			
32 days oral Wistar rat [redacted] *1980a* A26171, CA 5.3.1/03	0, 80, 315, 1250 and 5000 ppm / diet (values in mg/kg bw/d are not presented in the study report)	< 80 ppm (approximately ♂: 9.44 mg/kg bw/d ♀: 9.36 mg/kg bw/d)	- clinical chemistry findings (decreased cholesterol, total lipids, phosphorus (♂ only), uric acid, potassium; increased ALP - increased organ weights (kidney)
32 days oral NMRI mouse [redacted] *1980b* A26168, CA 5.3.1/05	0, 80, 315, 1250 and 5000 ppm / diet (equivalent to 0, 14.6, 56.7, 215.0 and 556.7 mg/kg bw/d in males; 0, 14.9, 58.6, 222.7 and 463.6 mg/kg bw/d in females).	< 80 ppm (♂: 14.6 mg/kg bw/d; ♀: 14.9 mg/kg bw/d)	- increased organ weights (liver) - histopathological findings (liver)

Study, reference	Dose levels	NOAEL	Main effects/target organs
30 days oral NMRI mouse [redacted] *1981* A26169, CA 5.3.1/06	0, 5, 10, 20 and 80 ppm / diet (equivalent to 0, 0.87, 1.82, 3.52 and 14.35 mg/kg bw/d in males; 0, 0.96, 1.85, 3.52 or 15.35 mg/kg bw/d in females)	10 ppm (♂: 1.82 mg/kg bw/d; ♀: 1.85 mg/kg bw/d)	- clinical chemistry findings - increased organ weights (liver) - histopathological findings (liver)
30 days oral Beagle dog [redacted] *1980* A25657, CA 5.3.1/08 Supplement [redacted], *1986* A32691, CA 5.3.1/09	0, 80, 400 and 2000 ppm / diet (values in mg/kg bw/d are not presented in the study report)	<u>Supplementary information only,</u> <u>dose finding study with two animals per group</u>	- excessive toxicity at 2000 ppm leading to premature sacrifice - haematology and clinical chemistry findings - increased organ weights (adrenals) - histopathology findings (various organs)
Oral 90-day studies			
3 months oral Wistar rat [redacted] *1981* A35788, CA 5.3.2/02 Addendum [redacted] *1986* A32697, CA 5.3.2/03 Addendum [redacted] 1986 A32985, CA 5.3.2/04	0, 20, 80 and 320 ppm / diet (equivalent to 0, 1.57, 6.29 and 25.27 mg/kg bw/d in males; 0, 1.74, 6.93 and 27.53 mg/kg bw/d in females)	20 ppm (♂: 1.57 mg/kg bw/d; ♀: 1.74 mg/kg bw/d)	- clinical chemistry findings - increased organ weights (adrenals)
13 weeks oral NMRI mouse [redacted] *1993a* A50244, CA 5.3.2/06	0, 320, 640 and 1280 ppm / diet (equivalent to 0, 51.6, 100.7 and 211.9 mg/kg bw/d in males; 0, 54.4, 113.8 or 230.0 mg/kg bw/d in females)	< 320 ppm (♂: 51.6 mg/kg bw/d; ♀: 54.4 mg/kg bw/d)	- haematology findings - clinical chemistry findings - increased organ weights (liver, kidney, spleen, adrenals) - histopathological findings (liver, kidney, spleen) - electron microscopy and special biochemistry findings (peroxisome proliferation)
3 months oral Beagle dog [redacted] *1981a* A24131, CA 5.3.2/08 Supplement [redacted] *1986* A32690, CA 5.3.2/09	0, 16, 80 and 400 ppm / diet (equivalent to 0, 1.2, 5.4 and 28.2 mg/kg bw/d in males; 0, 1.0, 4.9 and 25.6 mg/kg bw/d in females)	16 ppm (♂: 1.2 ♀: 1.0 mg/kg bw/d)	at 400 ppm: Relative pituitary weights were increased statistically significantly in males, however not dose-related Biologically significant but not dose-related Females - absolute and relative liver weight - absolute kidney weight - absolute and relative ovary weights - relative thyroid weights in all dose groups Males: - absolute pituitary weights - histopathology findings (interstitial pyelonephritis)
Other studies			

Study, reference	Dose levels	NOAEL	Main effects/target organs
1 year oral Beagle dog [redacted] *1984* A29692, CA 5.3.2/10	0, 3, 15 and 75 ppm / diet (equivalent to 0, 0.2, 1.0 and 5.0 mg/kg bw/d in males; 0, 0.2, 0.8 and 4.4 mg/kg bw/d in females)	75 ppm (♂: 5.0 ♀: 4.4 mg/kg bw/d)	dose-related but statistically not significant changes: Males: slight ⇩ relative prostate weight Females: - ⇩ triglycerides - ⇧ total lipids (starting from mid dose:) - ⇧ abs. and relative uterus weight - ⇧ abs. and relative ovaries weight

2.6.4. Summary of genotoxicity

Data on the genotoxicity of fenoxaprop-P-ethyl and fenoxaprop-ethyl were previously submitted and evaluated in the context of the original E.U review of this active substance, resulting in the first approval of fenoxaprop-P. All data were considered acceptable and fenoxaprop-P was concluded to be non-genotoxic based on weight of evidence analysis across the package of studies.
Five new in-vitro studies were undertaken for fenoxaprop-P-ethyl and are included in this renewal application. A summary of all essential data is presented in **Table 2.6.4-1** and **Table 2.6.4-2** (newly submitted data marked).

Fenoxaprop-P-ethyl was tested in a battery of in vitro and in vivo genotoxicity tests. All experiments were performed according to GLP and, if available, to OECD, EPA or EEC study guidelines. None of the vitro tests including gene mutation, chromosome aberration and DNA repair tests indicated genotoxicity of Fenoxaprop-P-ethyl. These results were confirmed in an in vivo micronucleus assay in NMRI mice. In conclusion, there was no indication that Fenoxaprop-P-ethyl induced genotoxicity in vitro or in vivo.

Table 2.6.4-1 Summary of genotoxicity testing with fenoxaprop-P-ethyl

Study, reference	Dose range	Results
In vitro-studies		
Reverse mutation assay (S. typhimurium and E. coli strains) *Müller W., 1994* A53077, CA 5.4.1/01	0; 4; 20; 100; 500; 2,500 and 5,000 µg/plate (dissolved in DMSO)	Negative (+/- S9-mix)
S. typhimurium reverse mutation assay, *Sokolowski, A., 2015* 1698300, CA 5.4.1/13	0; 3; 10; 33; 100; 333; 1,000; 2,500 and 5,000 µg/plate (dissolved in DMSO)	Negative (+/- S9-mix)
S. typhimurium reverse mutation assay *Thompson, P.W., 2005* 132 FPE, CA 5.4.1/14	0; 50; 150; 500 and 1,500 µg/plate (dissolved in DMSO)	Negative (+/- S9-mix)
Reverse mutation assay using bacteria (S. typhimurium and E. coli) *Donath, C., 2011* 396 FPE, CA 5.4.1/15	0; 10.0*; 31.6; 100; 316*; 1,000; 2,500; 5,000 µg/plate (dissolved in DMSO)	Negative (+/- S9-mix)
Forward mutation assay in S. pombe *Edwards C.N., 1986a* A34056, CA 5.4.1/03	0; 2.5; 5; 10; 20 and 40 µg/ml (dissolved in DMSO)	Negative (+/- S9-mix)
Gene mutation assay in Chinese hamster V79 cells *Seeberg A.H., 1986* A34057, CA 5.4.1/05	0; 6.25; 12.5; 25; 50 and 100 µg/ml (dissolved in DMSO)	Negative (+/- S9-mix)
L5178Y TK +/- Mouse Lymphoma assay *Flanders, L., 2006* 175 FPE, CA 5.4.1/16	I: 0-450 µg/ml (+/- S9) II: 0-300 µg/ml (-S9), 0-225 µg/ml (+S9) III: 0-275 µg/ml (-S9), 0-287.5 µg/ml (+S9)	Negative (+/- S9-mix)
Chromosome aberration test in human lymphocytes *Mosesso P., 1987* A35218, CA 5.4.1/06	0; 50; 79 and 125 µg/ml (dissolved in DMSO)	Negative (+/- S9-mix)

Study, reference	Dose range	Results
Chromosome aberration test in human lymphocytes in vitro *Wright, N.P., 2006* 178 FPE, CA 5.4.1/17	I: 0-678.75 (-S9), 0-1,357.5 µg/ml (+S9) II: 0-452.9 (-S9), 0-1,810 µg/ml (+S9) III: 3 groups, 0-905/1,131.25 µg/ml (+/-S9)	Negative (+/- S9-mix)
Mitotic gene conversion in S. cerevisiae *Edwards C.N., 1986b* A34058, CA 5.4.1/08	0; 1.25; 2.5; 5; 10 and 20 µg/ml (dissolved in DMSO)	Negative (+/- S9-mix)
In vitro UDS test in primary rat hepatocytes *Cifone M.A., 1986* A34916, CA 5.4.1/11	0; 2.51; 5.02; 10; 25.1; 50.2; 100; 201 and 301 µg/ml (dissolved in DMSO)	Negative (supplementary information)
In vitro UDS test in mammalian cells *Müller W., 1995* A54045, CA 5.4.1/12	0; 0.1; 0.3; 1; 3; 10; 30 and 100 µg/ml (dissolved in DMSO)	Negative (+/- S9-mix)
In vivo studies		
Oral micronucleus test in NMRI mice [redacted], *1986* A34297, CA 5.4.2/01	0; 1,000; 2,000 and 4,000 mg/kg bw (dissolved in sesame oil)	Negative

* additional concentrations in the second experiment (pre-incubation method)

Fenoxaprop-ethyl was tested in a battery of in vitro and in vivo genotoxicity tests including gene mutation, chromosome aberration, DNA repair and micronucleus tests. All experiments were performed according to GLP and, if available, were designed to meet OECD, EPA or EEC study guidelines. However, all of the in vitro studies lack a second, independent repeat experiment which confirms the results obtained in the genotoxicity testing. For this reason, all the in vitro studies are of limited validity. On the other hand, the in vivo micronucleus assay with NMRI mice was conducted according to OECD, EPA or EEC guidelines and can be considered scientific valid and acceptable. All the in vitro and in vivo genotoxicity tests performed with Fenoxaprop-ethyl did not show any genotoxic potential of Fenoxaprop-ethyl. Taken together, it can be assumed that Fenoxaprop-ethyl is not genotoxic in vitro or in vivo.

Table 2.6.4-2 Summary of genotoxicity studies with fenoxaprop-ethyl

Study, reference	Dose range	Results
In vitro-studies		
Reverse mutation assay (S. typhimurium and E. coli strains) *Jung et al., 1982* CA 5.4.1/02	0, 4, 20, 100, 500, 2500 and 5000 µg/plate (dissolved in DMSO)	Negative (+/- S9-mix) (supplementary information)
Forward mutation assay in S. pombe *Mellano D., Mondino A., 1982a* CA 5.4.1/04	0, 125, 250, 500 and 1000 µg/ml (dissolved in DMSO)	Negative (+/- S9-mix)
Chromosome aberration test in human lymphocytes *Mellano D., Mondino A., 1982b* CA 5.4.1/07	0, 1, 10, 100 and 1000 µg/ml (dissolved in DMSO)	Negative (+/- S9-mix)
Mitotic gene conversion in S. cerevisiae *Mellano D., Mondino A., 1982c* CA 5.4.1/09	0, 125, 250, 500 and 1000 µg/ml (dissolved in DMSO)	Negative (+/- S9-mix)
In vitro UDS test in mammalian cells *Mellano D., Mondino A., 1982d* CA 5.4.1/10	0, 5, 50 and 500 µg/ml (dissolved in DMSO)	Negative (+/- S9-mix)
In vivo-studies		
Oral micronucleus test in NMRI mice [redacted] *1986* CA 5.4.2/02	0, 750, 1500 and 3000 mg/kg bw (dissolved in sesame oil)	Negative

2.6.5. Summary of long-term toxicity and carcinogenicity

The long term toxicity and carcinogenicity studies were performed with fenoxaprop-ethyl from which the information on long term toxicity and carcinogenicity was bridged to fenoxaprop-P-ethyl.

Therefore, an important aspect of the toxicological studies, including acute and subchronic toxicity, embryotoxicity and mutagenicity, was to establish whether there were differences between the toxicological profiles of fenoxaprop-P-ethyl and fenoxaprop-ethyl. For this reason the study designs of the subchronic (4-week and 13-week) feeding studies in rats, mice and dogs and of the embryotoxicity studies in rats and rabbits with fenoxaprop-P-ethyl corresponded closely to the studies with fenoxaprop-ethyl. A comparison was provided by [redacted] (A40415, 1989).

This comparative toxicological evaluation summarizes the results of the toxicological studies performed with both compounds to assess whether they differ in their toxicological profiles or not. Both compounds exhibited only slight toxic properties following acute oral and dermal treatment in rats and mice. Inhalational exposure to rats over a period of 4 hours yielded and LC_{50} concentration higher than 604 mg/m^3 of fenoxaprop-ethyl and 511 mg/m^3 of fenoxaprop-P-ethyl, which were the highest technically feasible concentrations. The LD_{50} values and the clinical signs of intoxication of both compounds corresponded closely, particularly in the rat. Neither of the compounds showed mutagenic potential in a variety of tests with different end-points. Repeated-dose (4-week) and subchronic (3-month) feeding studies in rat, mouse and dog indicated that the toxicological profiles of both compounds were identical indicating that also in the longer-term studies similar profiles can be expected. Also testing for prenatal development in rats and rabbits indicated that both compounds had an identical toxicological profile in both dams and in embryos and foetuses.

Based on this comparison of the toxicological data of fenoxaprop-P-ethyl and fenoxaprop-ethyl, it is concluded that the toxicological profile of fenoxaprop-P-ethyl is identical to that of fenoxaprop-ethyl. There was nothing within the available datasets to indicate any differences of toxicological significance between fenoxaprop-P-ethyl and fenoxaprop-ethyl. Thus from a toxicological point of view, it is considered justified to base the evaluation of chronic toxicity and oncogenicity and the calculation of the ADI for fenoxaprop-P-ethyl on the long-term studies with fenoxaprop-ethyl.

A summary of all data is presented in **Table 2.6.5-1**.

Fenoxaprop-ethyl

Rats: A long term toxicity / carcinogenicity study was performed in Wistar rats. Animals were sacrificed after 6, 12, 24 or 28 months, and in additional investigations hepatic enzyme levels, liver and kidney function and residues in the animal carcass were determined. During the whole study, changes in the lipid status were noticed in form of decreased total cholesterol and total lipid levels, which appeared consistently at the highest dose level of 180 ppm. Slight reductions of liver weights were observed after 24 and 28 months in male rats. Effects on kidneys (increased relative weights and calcification) were seen only at the interim sacrifice after 6 months in rats receiving 180 ppm. Adrenals were affected only at the 12 month sacrifice: an increase of organ weight together with distension of the sinuses of the zona reticularis and medulla was observed in the 180 ppm group. No carcinogenicity was observed in this study. Investigation of hepatic enzymes showed no clear evidence for peroxisomal proliferation. The overall NOAEL for long term toxicity in Wistar rats is considered to be 30 ppm (equivalent to 1.6 mg/kg bw/d in males and 2.0 mg/kg bw/d in females).

Mice: Two carcinogenicity studies were conducted in NMRI mice. As no treatment-related effects could be observed at doses of 2.5, 10 and 40 ppm in the first study, higher doses (40, 115, 320 ppm) were tested in a second study. In the high dose study, Fenoxaprop-ethyl caused carcinogenicity in the liver of rats. Hepatocellular tumours (predominantely adenomas) were observed in 30 % of the male animals receiving 320 ppm. The rates of tumours in females at 320 ppm and males at 115 ppm were low when compared to controls therefore a relation to treatment remained unclear. Hepatocellular hypertrophy and degenerative liver lesions were noted with dose-related incidences and severities predominantely in males at 115 and 320 ppm. Peroxisome proliferation is discussed as a non-genotoxic mechanism for the hepatocellular carcinogenesis, which is highly species-specific for rodents. Kidney weights were slightly increased in both sexes of the 320 ppm group, however without any histological correlate. In conclusion, the NOAEL for NMRI mice in both carcinogenicity studies is considered to be 40 ppm (equivalent to 5.67 mg/kg bw/d for males and 6.83 mg/kg bw/d for females).

Dogs: The long term toxicity of Fenoxaprop-ethyl was tested in a 2 year study in Beagle dogs. In this study, slight decreases in bodyweight were observed at the high dose in both sexes, in males additionally at the mid dose, however did not follow a dose relation. Dose-related reductions in organ weights of thyroid (relative to bw) in males and ovaries in females (absolute and relative to bw) were observed. The study authors stated that these effects were a result of inadequate exsanguinations. The applicant submitted a position paper with detailed reasoning and historical control data, which did not fulfil the criteria set out in Regulation (EC) No 283/2013. However, statistically significant changes in the organ weights of thyroid and ovaries were observed at the high

dose only (75 ppm), and no histopathological changes occurred. As also a high variability in organ weights was noted, these effects were not considered as relevant.
Therefore the NOAEL for long term toxicity in Beagle dogs is considered to be 15 ppm (equivalent to 1.1 mg/kg bw/d in males and 0.9 mg/kg bw/d in females).

Table 2.6.5-1 Results summary of chronic toxicity and carcinogenicity studies with fenoxaprop-ethyl

Study, reference	Dose levels	NOAEL	LOAEL	Effects observed at the LOAEL
28 months chronic toxicity and carcinogenicity study in rats [redacted]. *1985a* A31880, CA 5.5/30 Combined chronic toxicity and carcinogenicity study in rats. Part II [redacted] *1985b, 1987* A31878, CA 5.5/6	0, 5, 30 and 180 ppm fenoxaprop-ethyl (0-0.3-1.6-9.4 mg/kg bw/d for males and 0-0.3-2.0-11.9 mg/kg bw/d for females)	30 ppm ♂: 9.4 ♀: 2.0 mg/kg bw/d	180 ppm ♂: 9.4 ♀: 11.9 mg/kg bw/d	Changes in lipid status (decreased cholesterol, total lipids) Organ weight changes and histopathological findings at different times of investigation, 6 months: increased kidney weight, increased calcification and hyperplasia of the pelvic region of the kidneys, 12 month: increased adrenals weight: distension of the sinuses of the zona reticularis and of medulla of adrenal, 24 and 28 months: decreased liver weight, no carcinogenicity observed. No significant differences between treated and control animals.
Chronic study in rats -interim kill after 6 months [redacted]., *1983a* A30803, CA 5.5/1	0, 5, 30 and 180 ppm fenoxaprop-ethyl in diet (0-0.3-2.0-11.9 mg/kg bw/d for males and 0-0.4-2.5-14.6 mg/kg bw/d for females)	30 ppm ♂: 2.01 ♀: 2.45 mg/kg bw/d	180 ppm ♂: 11.88 ♀: 14.58 mg/kg bw/d	Lipid changes (cholesterol reduced), liver weight increase
Chronic study in rats -interim kill after 12 months [redacted] *1983b* A29693, CA 5.5/2 Supplement: Determination of hepatic enzyme levels [redacted]*; 1984* A29694, CA 5.5/3	0, 5, 30 and 180 ppm fenoxaprop-ethyl in diet (0-0.3-1.7-10.2 mg/kg bw/d for males and 0-0.4-2.1-13.3 mg/kg bw/d for females)	30 ppm ♂: 1.7 ♀: 2.1 mg/kg bw/d	180 ppm ♂: 10.2 ♀: 13.3 mg/kg bw/d	In the adrenals frequent occurrences of more pronounced sinus dilatation in the zona reticularis and the medulla, but without tissue lesions
		>180 ppm	>180 ppm	The biochemical examinations showed that feeding of Hoe 33171 in concentrations of 5, 30 or 180 ppm over a 12-months period did not lead to an induction of foreign substance metabolism or to peroxisome proliferation. Moreover, histological examination of the livers showed that no organ changes resulted from feeding of Hoe 33171.
24 months study in rats [redacted] *1984a* A30807, CA 5.5/4 Supplement: Determination of residues in organs and tissues [redacted] *1985* A30804, CA 5.5/5	0, 5, 30 and 180 ppm fenoxaprop-ethyl in diet (0-0.3-1.6-9.4 mg/kg bw/d for males and 0-0.3-2.0-11.9 mg/kg bw/d for females)	30 ppm ♂: 1.58 ♀: 2.0 mg/kg bw/d	180 ppm ♂: 9.43 ♀: 11.87 mg/kg bw/d	Liver weight increase
				The residue examinations showed that feeding of 5, 30 or 180 ppm Hoe 33171 resulted in dose-related residues in organs and tissues of rats. However, there was no accumulation of residues over a period of time. No differences were observed between males and females.

Study, reference	Dose levels	NOAEL	LOAEL	Effects observed at the LOAEL
24 months carcinogenicity study in NMRI mice [redacted] *1985c* A30816, CA 5.5/7	0, 2.5, 10 and 40 ppm fenoxaprop-ethyl (0-0.34-1.38-5.48 mg/kg bw/d for males, 0-0.40-1.61-6.54 mg/kg bw/d for females)	40 ppm ♂: 5.48 ♀: 6.54 mg/kg bw/d	-	-
Chronic study in mice -interim kill after 12 months [redacted] *1983c* A29695, CA 5.5/8 Supplement: Determination of hepatic enzyme levels [redacted] *1984b* A29696, CA 5.5/9	0, 2.5, 10 and 40 ppm fenoxaprop-ethyl in diet (0-0.35-1.30-5.54 mg/kg bw/d for males, 0-0.43-1.63-6.59 mg/kg bw/d for females)	10 ppm ♂: 1.30 ♀: 1.63 mg/kg bw/d	40 ppm ♂: 5.54 ♀: 6.59 mg/kg bw/d	Kidney weight increases (absolute and relative) in both sexes, without histological correlate
		>40 ppm	>40 ppm	No induction of foreign substance metabolism or peroxisomal proliferation. Moreover, histological examination of the livers showed that no organic changes were due to feeding of Hoe 33171.
24 months carcinogenicity study in NMRI mice [redacted] *1996* A57500, CA 5.5/13 Supplement: Histophotographs [redacted] *1996* A58176, CA 5.5/14	0, 40, 115 and 320 ppm fenoxaprop-ethyl 0, 40, 115 and 320 ppm fenoxaprop-ethyl (0-5.67-16.59-44.63 mg/kg bw/d for males, 0-6.83-19.44-53.68 mg/kg bw/d for females)	40 ppm ♂: 5.67 ♀: 6.83 mg/kg bw/d	115 ppm ♂: 16.59 ♀: 19.44 mg/kg bw/d	Swollen abdomen, increased liver and kidney weights, liver and adrenals enlargement, hepatocellular hypertrophy, single cell necrosis, pigment in macrophages, lipofuscin deposits, liver foci, liver adenomas and carcinomas
Repeated 2 year oral study in beagle dogs [redacted] *1985* A31854, CA 5.3.2/11 Supplement [redacted] *1987* A37042, CA 5.3.2/12	0, 3, 15 and 75 ppm fenoxaprop-ethyl in diet (0-0.2-1.1-5.2 mg/kg bw/d for males, 0-0.18-0.9-4.6 mg/kg bw/d for females)	15 ppm ♂: 1.1 ♀: 0.9 mg/kg bw/d	75 ppm ♂: 5.2 ♀: 4.6 mg/kg bw/d	75ppm: ⇩ bodyweight in ♀ ⇩ haematological parameters ⇧ clinical chemistry ⇧ thyroid weight (relative to bw) in ♂ ⇧ ovaries weight (abs.+rel. to bw) in ♀

2.6.6. Summary of reproductive toxicity

For fenoxaprop-P-ethyl developmental toxicity studies conducted in rats and rabbits were reported. For fenoxaprop-ethyl a multi-generation study in rats, developmental toxicity studies in rats, mice and monkeys were available. As the short-term and developmental toxicological profile of fenoxaprop-ethyl were similar to that of fenoxaprop-P-ethyl, the multigeneration study of fenoxaprop-ethyl was used for the evaluation of the reproductive toxicity of fenoxaprop-P-ethyl.

These studies were evaluated during the first Annex I review of fenoxaprop-P-ethyl. They were presented in the monograph (Vol.3, Annex B, Section B6. Point B.6.6, August 2007). The overall data package for assessment of reproductive toxicity was considered in general compliance with test guidelines and appropriate to address data requirements under Regulation (EC) No. 1107/2009.

The summary of all essential data, relevant to support the renewal application of fenoxaprop-P-ethyl, is presented in the following sections as well as Table 2.6.6-1 and Table 2.6.6-2.

Fenoxaprop-P-ethyl

No multigeneration study has been performed with Fenoxaprop-P-ethyl.
Teratogenicity studies with Fenoxaprop-P-ethyl have been carried out in rats and rabbits. Furthermore, a study on embryotoxicity and postnatal development was conducted in rats. All of the studies were performed according to GLP, and, when applicable, close to international guidelines though that was not stated in the study reports.
In the embryotoxicity study in Wistar rats, maternal toxicity was observed at the highest dose of 100 mg/kg bw/d as evidenced by decreased food consumption and decreased body weight gain. Also, placental weight and heart weight were reduced. These findings were confirmed in the embryo- and postnatal toxicity study in Wister rats, when a decrease in food consumption, a decrease in body weight and a slightly increased duration of gravidity was noted at 100 mg/kg. Fetal toxicity was demonstrated by embryonic death, reduced pup weight and pup length at 100 mg/kg. An increased rate of weak or non-ossification of at least 1 cranial bone was already observed at 32 mg/kg bw/d which was considered a fetotoxic effect. However, no effect on offspring was observed in the embryo- and postnatal toxicity study. In conclusion, the NOAEL was 32 mg/kg bw/d for maternal toxicity and 10 mg/kg bw/d for fetal toxicity. No teratogenicity was observed in these studies.

An embryotoxicity study in Himalayan rabbits also showed maternal toxicity at the dose level of 100 mg/kg resulting in decreased food consumption, decreased body weight gain during treatment period, and slightly increased kidney weights. With respect to fetotoxicity, the only effect observed was an increase of the incidence of a 13th rib in the 100 mg/kg group which was also slightly above the historical control value. A NOAEL for both maternal and fetal toxicity of 32 mg/kg bw/d was established. No teratogenicity was observed in this study.

According to Annex VI of the EC Council Directive 67/548/EEC, no classification or labelling of Fenoxaprop-P-ethyl regarding developmental toxicity is required.

Table 2.6.6-1 Summary table of developmental toxicity studies with fenoxaprop-P-ethyl

Study, reference	Dose levels	NOAEL	Main effects/target organs
Developmental toxicity study in rats (Wistar) [redacted]., *1985a,* A33810 CA 5.6.2/01 Supplements [redacted] *1988°* A37496, CA 5.6.2/02 *Baeder et al., 1990°* A42779, CA 5.6.2/03	0, 10, 32 and 100 mg/kg bw/d oral gavage on gestation days 7 – 16	Maternal NOAEL: 32 mg/kg bw/d Fetal NOAEL: 10 mg/kg bw/d	Maternal toxicity: - decreased food consumption - decreased body weight - reduced placentae weight - reduced heart weight Fetal toxicity: - embryonic death - reduced pup weight - reduced pup length - skeletal findings (delayed or non-ossification)
Embryotoxicity and postnatal development study in rats (Wistar) [redacted] *1987a,* Doc. No. A35687 CA 5.6.2/07 Supplement [redacted], *1990°* A42781, CA 5.6.2/08	0, 10, 32 and 100 mg/kg bw/d oral gavage on gestation days 7 - 16	Maternal NOAEL: 32 mg/kg bw/d Offspring NOAEL: 100 mg/kg bw/d	Maternal toxicity: - decreased food consumption - decreased body weight - slightly increased duration of gravidity Offspring toxicity: -

Study, reference	Dose levels	NOAEL	Main effects/target organs
Developmental toxicity study in rabbits (Himalayan) [redacted] *1986a;* A33302 CA 5.6.2/10 Supplement [redacted] *1990* A42780, CA 5.6.2/11	0, 10, 32 and 100 mg/kg bw/d oral gavage on gestation days 7 - 19	Maternal NOAEL: 32 mg/kg bw/d Fetal NOAEL: 32 mg/kg bw/d	Maternal toxicity: - decreased food consumption - decreased body weight gain during treatment period - slightly increased kidney weight Fetal toxicity: - slightly increased incidence of a 13th rib

Fenoxaprop-ethyl

A multigeneration study according to GLP and EPA guideline has been conducted in Wistar rats. In this study there were no effect on reproduction parameters, fertility or offspring development observed even at the highest concentration used (180 ppm, equivalent to 8.77 – 35.98 mg/kg bw/d). Systemic toxicity was observed in both parents and offspring. Significant organ weight changes of the target organs liver and kidney were observed as well as changes in clinical chemistry parameters. These effects appeared predominantely and coincidentally at the highest dose group in parents and offspring. Furthermore, a slightly reduced body weight gain was noted in offspring during the period of lactation in the highest dose group. In conclusion, the NOAEL was 180 ppm (equivalent to 8.77 – 35.98 mg/kg bw/d) for reproduction and 30 ppm (1.42 – 6.06 mg/kg bw/d) for parental and offspring systemic toxicity.

Teratogenicity of Fenoxaprop-ethyl was studied in a range of studies in rats, rabbits, mice and monkeys. Furthermore, a study on embryotoxicity and postnatal development was conducted in rats. All of the studies were performed according to GLP, and, when applicable, close to international guidelines though that was not stated in most of the study reports. With the exception of the study in monkeys, all studies are scientific valid and acceptable.
The developmental study in Wistar rats showed maternal toxicity at the highest dose level of 100 mg/kg. Clinical signs (piloerection) and a decrease in food consumption and body weight were noted in the dams. Results of the embryo- and postnatal toxicity study in Wistar rats confirm these findings, as similar maternal toxic effects like decreased food consumption and body weight were observed at the same dose level. Fetotoxicity was demonstrated by empty implantation sites, reduced pup weight and length, and a slightly delayed ossification observed at 100 mg/kg. Diaphragmatic hernia occurred in control and treatment animals; no relation to treatment was considered as the incidences were within the historical control range. Deformities of the head which were found in one fetus at 32 mg/kg and three fetuses at 100 mg/kg could not be repeated in an additional 100 mg/kg dose group. In the embryo- and postnatal toxicity study embryonic death was also observed as one dam showed only implantation sites. However, postnatal development was not affected by treatment with Fenoxaprop-ethyl. Taken together, a NOAEL of 32 mg/kg bw/d can be established for maternal and fetal toxicity in the rat. No teratogenicity was observed.

Two developmental toxicity studies with different dose levels have been performed in Himalayan rabbits. In the first study the dose levels were 12.5, 50 and 200 mg/kg, and in the second study 2, 10 and 50 mg/kg. At the highest dose level of 200 mg/kg, maternal toxicity was observed resulting in a reduced number of dams with live fetuses, an increase of abortions and early resorptions, and a macroscopic enlargement and increased organ weight of liver and spleen. A decreased number of resorption sites and of live fetuses per dam was observed at 50 mg/kg in the second rabbit study. These effects showed no statistical significant difference compared to concurrent controls but were outside the range of previous studies. Additionally, a decrease in food consumption, a reduction of body weight during the treatment period, and a decreased defecation were noted at 50 and 200 mg/kg. Embryonic death, reduced pup weight and reduced pup length were observed at 200 mg/kg, as well as an increased incidence of a 13th rib, all demonstrating embryotoxicity at this dose level. Furthermore, the incidence of diaphragmatic hernias was increased at 200 mg/kg (3 of 28 fetuses, 10.7 %). A single case of diaphragmatic hernia was also observed in the second rabbit study at 50 mg/kg (1 of 40 fetuses, 2.5 %). According to the RAC opinion and the CLH report, maternal mortality at 200 mg/kg is considered excessive as it was greater than 10% (13.3%). According to the Guidance on the Application of the CLP Criteria, the data for that dose level 'shall not be considered for further evaluation'.
In conclusion, in the first study, maternal NOAEL could be set at 12.5 mg/kg bw/d while the foetal NOAEL was 50 mg/kg bw/d. In the second study, the NOAEL for maternal and fetal toxicity was 10 mg/kg bw/d.

An embryotoxicity study was also performed in CD-1 mice. In this study, the only effect of maternal toxicity was an increased liver weight at 50 mg/kg. No fetotoxicity or teratogenicity were observed. The NOAEL for maternal toxicity is 10 mg/kg bw/d, while the NOAEL for fetal toxicity is 50 mg/kg bw/d.

A developmental toxicity study in Cynomolgus monkeys is of limited validity as no concurrent controls were used and the historical control data showed high variations. Furthermore, the high dose employed in this study (50 mg/kg) was severely toxic to the dams leading to mortality and abortions. As a result of maternal toxicity, only three fetuses were available in this dose group for evaluation of fetotoxicity or teratogenicity. Further maternal toxicity effects observed were slight diarrhoea and / or a reduction of food intake in both dose groups (10 and 50 mg/kg). Also, clinical chemistry was affected showing a reduction in lipid parameters during the treatment period in all treated dams. In fetuses, relatively high rates of undeveloped or uneven thickening of the ribs were observed in both dose groups. Taken together, it is not possible to finally evaluate this study for maternal and fetal toxicity and teratogenicity. Therefore, no NOAELs were established.

Table 2.6.6-2 Summary table of reproduction and developmental toxicity studies with fenoxaprop-ethyl

Study, reference	Dose levels	NOAEL	Main effects/target organs
Multi-generation study in rats (Wistar) [redacted] *1986a*, A32781, CA 5.6.1/01 [redacted] *1986b* A33840, CA 5.6.1/02	0, 5, 30 and 180 ppm during prepairing, pairing, postmating, gestation and lactation (0-0.24-1.42-8.77 mg/kg bw/d for males)	Reproduction NOAEL: 180 ppm (8.77 - 35.98 mg/kg bw/d)	-
		Systemic parental NOAEL: 30 ppm (1.42 - 6.06 mg/kg bw/d)	- organ weight changes (liver, kidney) - clinical chemistry parameters
		Systemic offspring NOAEL: 30 ppm (1.42 - 6.06 mg/kg bw/d)	- reduced bw gain during lactation - organ weight changes (liver, kidney) - clinical chemistry parameters
Developmental study in rats (Wistar) [redacted] *1982a*, A26170 CA 5.6.2/04 Supplements [redacted] *1986* A32696, CA 5.6.2/05 [redacted] *1989* A41709, CA 5.6.2/06	0, 10, 32 and 100 mg/kg bw/d oral gavage on gestation days 7 - 16	Maternal NOAEL: 32 mg/kg bw/d Fetal NOAEL: 32 mg/kg bw/d	Maternal toxicity: - clinical signs (piloerection) - decreased food consumption - decreased body weight Fetal toxicity: - embryonic death - reduced pup weight - reduced pup length - slightly delayed ossification
Embryotoxicity and postnatal development study in rats (Wistar) [redacted] *1986b*, A35783 CA 5.6.2/09	0, 10, 32 and 100 mg/kg bw/d oral gavage on gestation days 7 - 16	Maternal NOAEL: 32 mg/kg bw/d Offspring NOAEL: 32 mg/kg bw/d	Maternal toxicity: - decreased food consumption - decreased body weight Offspring toxicity: - embryonic death
Developmental toxicity study in mice (CD-1) [redacted] *1983;* Doc. No. A30282 CA 5.6.2/17	0, 2, 10 and 50 mg/kg bw/d oral gavage on gestation days 6 - 15	Maternal NOAEL: 10 mg/kg bw/d Fetal NOAEL: 50 mg/kg bw/d	Maternal toxicity: - increased liver weight Fetal toxicity: -

Study, reference	Dose levels	NOAEL	Main effects/target organs
Developmental toxicity study in rabbits (Himalayan) [redacted] *1982b;* A24756 CA 5.6.2/12 Supplements [redacted] *1986* A32692, CA 5.6.2/13 [redacted] *1989* A41707, CA 5.6.2/14	0, 12.5, 50 and 200 mg/kg bw/d oral gavage on gestation days 7 - 19	Maternal NOAEL: 12.5 mg/kg bw/d Fetal NOAEL: 50 mg/kg bw/d Teratogenicity NOAEL: 50 mg/kg bw/d	Maternal toxicity: - decreased food consumption - stagnant body weight gain during treatment period - decreased defecation only at 200 mg/kg: - reduced number of dams with live fetuses - increased abortions and early resorptions - macroscopic enlargement and increased organ weight of liver and spleen Fetal toxicity: - embryonic death - reduced pup weight - reduced pup length - increased incidence of a 13th rib Teratogenicity: - diaphragm hernias
Developmental toxicity study in rabbits (Himalayan) [redacted] *1983;* A29690 CA 5.6.2/15 Supplement *Baeder C., Langer K.H., 1986* A32695, CA 5.6.2/16	0, 2, 10 and 50 mg/kg bw/d oral gavage on gestation days 7 - 19	Maternal NOAEL: 10 mg/kg bw/d Fetal NOAEL: 10 mg/kg bw/d	Maternal toxicity: - decreased food consumption - decreased defecation - slightly increased number of resorptions sites Fetal toxicity: - reduced number of live fetuses/dam
Developmental toxicity study in Cynomolgus monkeys (Macaca fascicularis) [redacted] *1984* A29702 CA 5.6.2/18 Supplement [redacted] *1984* A38394, CA 5.6.2/19	10 and 50 mg/kg bw/d, historical control data oral gavage on gestation days 20 - 50	No NOAELs could be established due to limited study design. The study is of supplementary information only.	

2.6.7. Summary of neurotoxicity

No studies to address neurotoxicity of neither fenoxaprop-P-ethyl nor fenoxaprop-ethyl were submitted for the renewal of fenoxaprop-P-ethyl as there was no evidence of neurotoxicity was seen in any of the conducted studies.

2.6.8. Summary of further toxicological studies on the active substance

Supplementary studies

Supplementary studies on the active studies were submitted for the renewal of this dossier, containing the previously evaluated three intraperitoneal studies in rat and the repeated dose toxicity study with combined administration of fenoxaprop-P-ethyl and the safener Hoe 107892, as well as a newly submitted immunotoxicity study that was conducted with fenoxaprop-P-ethyl to support registration in the USA. The study results are shortly summarized in the **Table 2.6.8-1** and **Table 2.6.8-2** (newly submitted studies in marked).

Table 2.6.8-1 Summary table of supplementary studies on fenoxaprop-P-ethyl

Study, reference	Dose levels	Endpoint	Main effects/target organs
Acute intraperitoneal toxicity study in male and female rats [redacted] *1985,* Doc. No. A37244 CA 5.8.2/08	♂: 1000, 1600 and 2000 ♀: 1000, 2000 mg/kg bw i.p. injection	♂ LD_{50} = 1,490 ♀ LD_{50} > 2,000 mg/kg bw (supplementary information)	After treatment: Reduced spontaneous activity, contracted flanks, ataxic gait and mucous faeces in both sexes. Observation period: Clinical signs like squatting position, prone or lateral position, high-legged and uncoordinated gait, crawling locomotion
Combined repeated dose toxicity study with fenoxaprop-P-ethyl and the safener Hoe 107892 [redacted] *1996;* Doc. No. A57200 CA 5.8.2/07	Hoe046340 + Hoe107892: 0 + 0, 10 + 5, 80 + 40, 640 + 320 ppm in diet	NOAEL: 10 + 5 ppm (♂: 0.74 + 0.37 ♀: 0.81 + 0.41 mg/kg bw/d)	640 + 320 ppm: reduction of food consumption and bw, findings in haematology 80 + 40ppm: effects on the liver (lipid parameter, liver enzyme activity, ketonuria, increased organ weight, discoloration and cellular hypertrophy)
28-day immunotoxicity study in the female rat [redacted] *2011* Doc. No. SA 10132 CA 5.8.2/11	0, 70, 210 und 630 pm (equiv. 5.5, 16, 47 mg/kg bw/day)	Not immunotoxic up to 630 ppm (47 mg/kg bw/day)	No SRBC-specific IgM change, no effects on spleen or thymus weight.

Table 2.6.8-2 Summary table of supplementary studies on fenoxaprop-ethyl

Study, reference	Dose levels	Endpoint	Main effects/target organs
Acute intraperitoneal toxicity study in male rats [redacted] *1979* Doc. No. A24681 CA 5.8.2/09	500, 800, 1250, 2000, 3150, 5000 mg/kg bw i.p. injection	LD_{50} = 739 mg/kg bw (supplementary information)	Clinical signs like squatting, horripilation, abdominal position and passiveness. ⇩ bodyweight 7 days after treatment Light-brown discolouring of parts of liver and suprarenal glands.
Acute intraperitoneal toxicity study in female rats [redacted] *1979,* Doc. No. A24690 CA 5.8.2/10	315, 500, 800, 1250, 2000, 3150 mg/kg bw i.p. injection	LD_{50} = 864 mg/kg bw (supplementary information)	Clinical signs like squatting, horripilation, abdominal position and passiveness. ⇩ bodyweight 7 days after treatment Partly light-brown discolouring of liver.

Studies on endocrine disruption

No targeted in vitro or in vivo screening studies to assess the endocrine disrupting potential of fenoxaprop-P-ethyl (or fenoxaprop-ethyl) have been submitted.
According to the OECD No. 150 Guidance Document on standardized test guidelines for evaluating chemicals for endocrine disruption (ENV/JM/MONO(2012)22) the following information from *in vivo* studies indicate possible ED effects:

- Repeated dose 28-day oral toxicity study in rodents (OECD 407)
- Repeated dose 90-day oral toxicity studies (OECD 408)
- 2-generation reproduction toxicity study (OECD 416)
- Pre-natal developmental toxicity study (OECD 414)

A short summary of study results (including those where ED relevant parameters were altered) is given in Table 2.6.8-3 and Table 2.6.8-4.
Organ weights (i.e. testis, adrenals and thyroid) relevant for potential endocrine disruption were not consistently altered by fenoxaprop-P-ethyl nor by fenoxaprop-ethyl. Some effects were observed on thyroid weight in males and the weights of ovaries and uterus in females in the 2-year and 1-year dog studies. The applicant addressed

these effects in a position paper (Bomann 2017) and provided detailed information and historical control data, which however did not fulfill the criteria as set out in Commission Regulation (EU) No 283/2013.
RMS concluded that, although changes in endocrine active organ weights were observed in the 1-year and 2-year dog studies, it is to be noted that no histopathological changes were observed. No hormonal measurements were conducted in any of the studies. Furthermore the effects on ovaries and uterus were not consistently changed in rat studies, which conclude that these effects were not of biological relevance. The changes were not consistent throughout the studies. Additionally, no effects on the thyroid were observed in any of the rodent studies, where this would have been expected since rodents are considered more sensitive for thyroid effects.
Additionally, a summary of ToxCast and Tox21 Activity Data was available in the position paper, according to which no evidence of ED potential was seen.
No consistent evidence exists that fenoxaprop-P-ethyl has an effect on the endocrine system. Fenoxaprop-P-ethyl also does not fulfil the interim criteria for endocrine disruptors stated in the Regulation (EC) No. 1107.

Table 2.6.8-3 Summary of ED relevant results for fenoxaprop-P-ethyl

Study	Results	Accepted / Deviations
Fenoxaprop-P-ethyl: Repeated dose 28-day oral toxicity in rats [redacted] *1987a* **OECD 407**	No effects on adrenals, thyroids and testis. ⇧ liver weight (absolute + relative to bodyweight)	Supplementary. Limited organ weight and histopathology.
Fenoxaprop-P-ethyl: Repeated dose 28-day oral toxicity study in mice [redacted] *1987b* **OECD 407**	No effects on adrenals and thyroids. ⇩ testis weight at h.d. (absolute + relative) Liver: ⇧ weight (absolute + relative to bodyweight) and histopathological findings	Supplementary. Limited organ weight and histopathology. No haematology and urinalysis.
Fenoxaprop-P-ethyl: 13-week feeding study in rats [redacted] *1987* **OECD 408**	No effect on ovaries, uterus, thyroids, adrenals and pituitary gland. ⇧ testis weight (relative) at week 13 at h.d. ⇧ liver weight (absolute + relative) at week 13 at high dose	Yes. Missing BUN measurement. Limited pathology and organ weight analysis.
Fenoxaprop-P-ethyl: 40-days inhalation study in rats (28 appliations) with recovery period [redacted] *1989* **OECD 412**	No effects on ovaries, uterus, epididymides, prostate, seminal vesicles, thyroid, adrenals and pituitary. ⇩ testis weight (absolute) at 41d at high dose ⇧ liver weight (absolute + relative)	Yes. Animal slightly younger. Limited pathology and organ weight analysis. Dry exposure conditions.

Table 2.6.8-4 Summary of ED relevant results for fenoxaprop-ethyl

Study	Results	Accepted / Deviations
Fenoxaprop-ethyl: Range-finding test in a 32-day study in rats [redacted] *1980a* **No guideline (study design similar to OECD 407)**	No effects on ovaries, uterus, prostate, epididymis, seminal vesicles, thyroids and pituitary gland. ⇧ testis weight at h.d. (relative to bodyweight) ⇧ liver weight (relative to bodyweight) ⇩ adrenals weight in ♀ at h.d. (abs.+rel. to bw)	Yes.
Fenoxaprop-ethyl: Repeated 32-day oral administration to mice [redacted] *1980b* **No guideline (study design similar to OECD 407)**	No effects on ovaries, uterus, prostate, epididymides, testis, seminal vesicles, thyroids, adrenals and pituitary. Liver: ⇩ weight in ♂ (abs. + rel.); ⇧ weight in ♀ (absolute + relative to bw); histopathological changes at h.d. (incl. enlargement of liver cells)	Yes.
Fenoxaprop-ethyl: 30-day oral administration study in mice [redacted] *1981* **No guideline (study design similar to OECD 407)**	No effects on ovaries, uterus, testis, epididymis, prostate, seminal vesicles, thyroid, adrenals, pituitary. Liver: ⇩weight in ♂ (abs. + rel.); ⇧ weight in ♀ (abs. + rel.); histopathological changes at high doses	Yes.

Fenoxaprop-ethyl: Repeated-dose 30-days oral toxicity study in dogs. [redacted] *1980* **No guideline**	No effects on ovaries, uterus, testis, prostate and pituitary gland. Liver: Lobular marking and fatty degeneration Thyroid: hyperplasia of lymph follicles Adrenals: ⇧ weight, haemorrhages of the cortex	Supplementary. Only two animals per dose group. No analysis of t.s. for concentration, stability and homogeneity.
Fenoxaprop-ethyl: 13-week feeding study in rats [redacted] *1981* **No guideline (study design similar to OECD 408)**	No effects on ovaries, uterus and pituitary glands. Liver: ⇧ weight in ♂ at h.d. (absolute + relative); enlarged liver cells at h.d. (at first sacrif.) ⇧ thyroid weight in ♂ (absolute + relative) ⇧ adrenals weight in ♀ (absolute + relative)	Yes.
Fenoxaprop-ethyl: 13-week dietary study in mice [redacted], *1993a* **EPA GD 82-1**	No effects on ovaries, uterus, vagina, testis, prostate, epididymides, seminal vesicles, thyroid, mammary glands and pituitary glands. ⇧ adrenals in ♂ (absolute + relative) Liver: ⇧ weight (absolute + relative); histopathological findings (hypertrophy, necrosis, ⇧ mitosis)	Yes. Limited histopathology and organ weight.
Fenoxaprop-ethyl: Multiple generation study in rats [redacted], *1986* **EPA GD 83-3**	No changes in vaginal opening. No effects on uterus, ovaries, testes, prostate and seminal vesicles. ⇧ bodyweight at lactation (F2a: high dose)	Yes. Anogenital distance, oestrus cyclicity and preputial separation not assessed.

As there was no evidence on primary endocrine disrupting effects in the conducted in vivo studies, fenoxaprop-P-ethyl was considered as unlikely to have endocrine disrupting properties.

2.6.9. Summary of toxicological data on impurities and metabolites

One new study on the major metabolite 6-Chlorobenzoxazolone was submitted for the renewal of this dossier.
6-Chlorobenzoxazolone was tested in a 13-week dietary toxicity study in the rat at dose levels of 0, 5, 15 and 45 mg/kg bw/d. A suppression of bodyweight gain was observed for all treated males and high dose females. After a treatment-free recovery period of 28 days in the high dose groups, a compensatory increase was seen for both sexes. The NOAEL was determined to be close to 45 mg/kg bw/day.

2.6.10. Summary of medical data and information

Information on medical data was supplied in one previously evaluated and three newly submitted reports and in Tier 2, Annex II, Section 3 Summary. Additionally, one peer-reviewed open literature reference was added.
Since the production start in 1989 ([redacted]) workers were examined periodically for possible health damage. No substance-related changes have been indicated by clinical or laboratory examinations. No dermal allergic reactions were reported for fenoxaprop-P-ethyl, while one case of a reversible skin rash was observed by direct skin exposure of the racemate, fenoxaprop-ethyl.
In the production site of Bayer CropScience [redacted], 5-6 employees per shift were monitored in the production period of 1985-2016. No accidents were reported during the time. Medical examinations starting from 2007 revealed no unwanted effects with regards to full blood count, liver enyzmes, urine sediment and lung function. In the production site [redacted], 47 employees handling the product during the production period of 2008-2016 were monitored for health effects. The company reported that all relative workers had passed the medical examination.
A publication from the year 2009 reported about 86 intentional poisoning cases in Sri Lanka. The mixture was a plant protection product containing fenoxaprop-P-ethyl as the main active ingredient, along with ethoxysulfuron and the safener isoxadifen-ethyl. No details on the dose levels are available. No mortalities occurred. Symptoms were mostly epigastric pain and vomiting, with some of the patients having decreased consciousness levels, which recovered after 22 hours the latest.

2.6.11. Toxicological end point for assessment of risk following long-term dietary exposure - ADI

The new data submitted for the renewal of fenoxaprop-P-ethyl do not change derivation of ADI. Therefore, the ADI established by the European Commission (SANCO/3777/08-rev.1, 2007) during the original EU review of fenoxaprop-P-ethyl is still valid. At that time it was considered whether the NOAEL (1.6mg/kg bw/day) of the 2y rat study would be more appropriate because the findings in the 2-year repeated oral dog study were considered marginal. As the values were in the same range, the calculation of the ADI was based on the lowest NOAEL derived from the 2-year repeated oral study in the dog (supported by the 2-year and multigeneration rat studies) by applying a safety factor of 100. The lowest NOAEL in this study was 1.1mg/kg bw/d (2-year, dog).

ADI = 1 mg/kg bw/d / 100 = **0.01 mg/kg bw/day**

2.6.12. Toxicological end point for assessment of risk following acute dietary exposure - ARfD (acute reference dose)

During the original EU review of fenoxaprop-P-ethyl, an ARfD was considered relevant for the active substance due to harmful effects after oral exposure (SANCO/3777/08-rev.1, 2007). At that time RMS did not propose an ARfD due to the low toxicological profile of fenoxaprop-P-ethyl. However, some MSs proposed to set an ARfD based on a precautionary approach to cover the low incidence of a diaphragmatic hernia in rabbit studies. Furthermore classification for Acute Tox 4, according to a new acute oral toxicity study, is proposed. An assessment on the new data according to the criteria of the Guidance for the setting of an Acute Reference Dose (ARfD) (7199/VI/99 rev. 5) shows that the test results do not have impact on the ARfD as determined already. The ARfD is based on the foetal NOAEL of approximately 10 mg/kg bw/d from the developmental study in rats (see Volume 3CA B6, section 6.6.2.1). A safety factor of 100 is applied to the endpoint.

ARfD = 10 mg/kg bw/d / 100 = **0.1 mg/kg bw/day**

2.6.13. Toxicological end point for assessment of occupational, bystander and residents risks – AOEL

The new data submitted for the renewal of fenoxaprop-P-ethyl do not change derivation of AOEL. Therefore, the AOEL established by the European Commission (SANCO/3777/08-rev.1, 2007) during the original EU review of fenoxaprop-P-ethyl is still valid. At that time it was proposed by the RMS to base the AOEL on the NOAEL of 1.4 mg/kg bw/day from the multigeneration study in rats, supported by the 2 y dog study. It was agreed to use the multigeneration on its own. The calculation of the AOEL was based on the lowest relevant NOAEL derived from the rat multi-generation study in the rat (supported by the 2-year dog study) by applying a safety factor of 100. The lowest NOAEL is 1.42 mg/kg bw/d and a correction factor for oral absorption is not needed.

AOEL = 1.42 mg/kg bw/d / 100 = **0.014 mg/kg bw/day**

2.6.14. Toxicological end point for assessment of acute occupational, bystander and residents **risks – AAOEL**

No AAOEL was set during the original EU review of fenoxaprop-P-ethyl.
The EU Commission noted that for the acute risk assessment for bystanders, the derivation of the corresponding toxicological reference value (AAOEL) is still outstanding. Consideration of acute exposure should only be made where an AAOEL has been established during an approval or renewal evaluation, i.e. acute risks should be assessed where an appropriate harmonised EU value has been agreed. This applies to Fenoxaprop-P-ethyl, as dossier submission was in June 2016. (COMMISSION GUIDANCE DOCUMENT (2015) Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products SANTE-10832-2015 29 May 2015.)

The AAOEL could be based on the foetal NOAEL of approximately 10 mg/kg bw/d from the developmental study in rats, as was the case for the ARfD. A safety factor of 100 is applied to the endpoint.

AAOEL = 10 mg/kg bw/d / 100 = **0.1 mg/kg bw/day**

2.6.15. Summary of product exposure and risk assessment

Exposure estimates were assessed for the products PUMA S 69 EW and CHA 4960 for the critical GAP of 1.2 L/ha product application (0.083 kg/ha fenoxaprop-P-ethyl) on cereals with tractor boom sprayer. Exact calculations can be found in the respective Vol 3 CP parts of this dossier.

Operator exposure to PUMA S 69 EW

Exposure estimates using the EFSA model for the proposed uses were lower than the AOEL without the use of PPE (work wear – arms, body and legs covered).

Bystander and resident exposure to PUMA S 69 EW

Resident exposure was assessed with the EFSA model, while for the bystander exposure the model after Martin *et al*. was used. Both models showed no unacceptable risk to any bystander or residential exposure after accidental short-term exposure to product formulation.

Worker exposure to PUMA S 69 EW

Estimations of worker exposure were conducted with the EFSA model, according to which no unacceptable risk is anticipated during re-entry for crop inspection if no gloves are worn (only work wear – arms, body and legs covered). As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

Operator exposure to CHA 4960

Exposure estimates using the EFSA model for the proposed uses were lower than the AOEL without the use of PPE (work wear – arms, body and legs covered).

Bystander and resident exposure to CHA 4960

Resident exposure was assessed with the EFSA model, while for the bystander exposure the model after Martin *et al*. was used. Both models showed no unacceptable risk to any bystander or residential exposure after accidental short-term exposure to product formulation.

Worker exposure to CHA 4960

Estimations of worker exposure were conducted with the EFSA model, according to which no unacceptable risk is anticipated during re-entry for crop inspection if no gloves are worn (only work wear – arms, body and legs covered). As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

2.7. RESIDUE

2.7.1. Summary of storage stability of residues

No new storage stability study has been submitted for the purpose of renewal of the active substance approval.

Storage stability of fenoxaprop-P-ethyl and its racemic compound fenoxaprop-ethyl in cereal matrices (wheat grain, barely grain and straw) has previously been included in the submission for Annex I inclusion under 91/414/EEC and was deemed acceptable following evaluation and peer review at EU level. Storage stability was demonstrated for 24 month (wheat grain) and 14 month (barley grain, straw) for the parent compound and its metabolites.

Plant products (Category)	**Commodity**	**T** (°C)	**Stability** (Month/year)				
			AE F046360 (p-enantiomer)	AE F033171 (racemic a.s.)	AE F088406 (p-acid)	AE F053022 (racemic acid)	AE F054014
High starch content	Wheat grain	-20	24 month		24 month		24 month
	Barley grain	-30	14 month	14 month		14 month	14 month
	Barley straw	-30	14 month	14 month		14 month	14 month
Other	Not considered necessary						

The data on the stability of residues in crops are sufficient to cover the storage period in the residue studies provided in support of representative uses. No degradation is expected to occur during storage and all the trials are considered as valid with respect to the freezer storage data.

Storage stability in animal commodities was not deemed necessary for Annex I conclusion under 91/414/EEC. For the purpose of renewal of a.s. approval the GAP was extended to BBCH 39 and therefore the potential transfer of residues into food of animal origin became relevant. Storage stability for poultry muscle, liver and egg was demonstrated for at least 12 month.

Animal	**Animal commodity**	**T** (°C)	**Stability** (Month/Year)		
			AE F033171 (racemic a.s.)	AE F053022 (racemic acid)	AE F054014
Poultry	Muscle	-23	12 month	12 month	12 month
	Liver	-23	12 month	12 month	12 month
	Milk	-	-	-	-
	Egg	-23	12 month	12 month	12 month

The study is considered suitable to cover the storage periods in the animal feeding study.

2.7.2. Summary of metabolism, distribution and expression of residues in plants, poultry, lactating ruminants, pigs and fish

2.7.2.1. Plants

One new metabolism study in spring wheat conducted with [^{14}C]-Fenoxaprop-P-ethyl has been submitted for the purpose of renewal of the active substance approval. The study was commissioned by Cheminova. The study provides more up to date data while confirming the metabolic profile observed and reported in the DAR (2005).

Studies in wheat, barley, soybean and rice have previously been included in the submission for Annex I inclusion under 91/414/EEC to elucidate the metabolism of fenoxaprop-P-ethyl in plants. The studies were deemed acceptable following evaluation and peer review at EU level. A summary of the new data and the original submitted data which were considered for the purpose of renewal is presented in the following table.

Table 2.7.2-1 Summary of fenoxaprop metabolism studies in plants

Crop/ crop group	Active substance	Label	Application rate	Sampling intervals	Harvested samples	Reference (DRAR)
New submitted study for the purpose of renewal of the active substance approval.						
Wheat/ Cereals	Hoe 046360	Chlorophenyl-^{14}C	1x 143 g as/ha BBCH 23-24	29 DAT	forage	KCA 6.2.1/13 (B.7.2.1.1)
		dioxyphenyl-1-^{14}C	1x 149 g as/ha BBCH 23-24	106 DAT	grain, straw	
Originally submitted and evaluated studies (DAR, 2005) to be considered for purpose of renewal						
Wheat/ Cereals	Hoe 046360	Chlorophenyl-^{14}C	1x 110 g as/ha, early tillering	0, 15 DAT	Whole plant	KCA 6.2.1/04 (B.7.2.1.2)
				30, 60 DAT	Shoots, ears	
				109 DAT	husks, straw, grain	
Wheat/ Cereals	Hoe 046360	Chlorophenyl-^{14}C	1x 90 g as/ha, 3-leaf stage	1, 7 DAT	Whole plant	KCA 6.2.1/12 (B.7.2.1.3)
Wheat/ Cereals	Hoe 033171	Chlorophenyl-^{14}C	1x 183 g as/ha, early tillering	0, 10, 37 DAT	Whole plant	KCA 6.2.1/08 (B.7.2.1.4)
				59 DAT	Whole plant, shoots, ears	
				83, 109 DAT	Husks, straw, grain	
Wheat/ Cereals	Hoe 033171	Chlorophenyl-^{14}C	1x 180 g as/ha, early tillering	2, 4, 21, 27, 96 hours 10 DAT	Wheat shoots	KCA 6.2.1/03 6.2.1/10 (B.7.2.1.5)
						KCA 6.2.1/09 (B.7.2.1.5)
Barley/ Cereals	Hoe 046360	Chlorophenyl-^{14}C	2- leaf stage (nutrient solution)	2, 4, 6, 24, 48, 72, 144 hours	Freshly cut barley shoots	KCA 6.2.1/02 (B.7.2.1.6)
			1x 90 g as/ha 2-3 leaf stage	3, 23, 47, 71, 141 hours	Intact barley shoots	
Rice/ Cereals	Hoe 046360	Chlorophenyl-^{14}C	1x 90 g as/ha 5-6 leaf stage	2, 6, 7, 9, 13, 17 DAT	Whole rice plants	KCA 6.2.1/01 (B.7.2.1.7)
				22, 36, 63, 84, 112 DAT	Leaves, newly grown, stems, panicles, grains	
Rice/ Cereals	Hoe 046360	dioxyphenyl-1-^{14}C	1x 90 g as/ha 5-6 leaf stage	2, 6, 7, 9, 13, 17 DAT	Whole rice plants	KCA 6.2.1/11 (B.7.2.1.8)
				22, 36, 63, 84, 112 DAT	Directly affected leaves, newly grown, stems, panicles, grains	
Soya bean/ wheat	Hoe 046360	Chlorophenyl-^{14}C	1x 110 g as/ha 1st leaflet developed 2-3 leaf stage	5, 12 DAT	Directly affected leaves	KCA 6.2.1/05 (B.7.2.1.9)

DAT= days after treatment

Metabolism in plants evaluated in the DAR (2005) was conducted on wheat (4), barley (1), rice (2) and soybean (1). The plant metabolism studies were conducted with fenoxaprop-P-ethyl AE F046360 as well as with the racemic substance fenoxaprop-ethyl AE F033171. The substances were labelled either in the chlorophenyl ring or the dioxyphenyl ring to provide complete information on the degradation profile.

A new study submitted for the purpose of renewal of a.s. approval elucidated the metabolism of fenoxaprop-P-ethyl in wheat following post-emergence application at a nominal rate of 138 g as/ha (~1.7N) in the presence of the safener cloquintocet-mexyl.

Foliar applied residues of fenoxaprop-P-ethyl (AEF 046360) or its racemic compound fenoxaprop-ethyl (AE F033171) on cereals can be readily metabolised such that no significant residues of the respective parent remain in forage, straw or grain. Identification and characterisation of at least 90% of the total radioactive residue (TRR) in each raw agricultural commodity (RAC) of the treated crops was not possible, but adequate attempts were made to present the components and to characterise them. The findings in all studies were consistent.

Shortly after application the parent compound in plant undergoes ester hydrolysis forming the free acid fenoxaprop-P (AE F088406, or AE F053022 for the racemic mixture), which is still herbicidally active. Subsequent cleavage of the ether bond between the benzoxazolone- and the phenoxy- part of the compound leads to the non chiral chlorobenzoxazolone AE F054014 and glutathionate conjugation of the benzoxazolone. The study with the dioxyphenyl-label on rice (refer to Vol 3, B.7.2.1.8) showed, that via cleavage of the ether bond also HOPP-acid (AE F096918) was formed.

These metabolic reactions were not influenced by the chirality of the molecule and are therefore identical for the racemat (AE F033171) or its optically active form fenoxaprop-P-ethyl Hoe 046360. To sum up

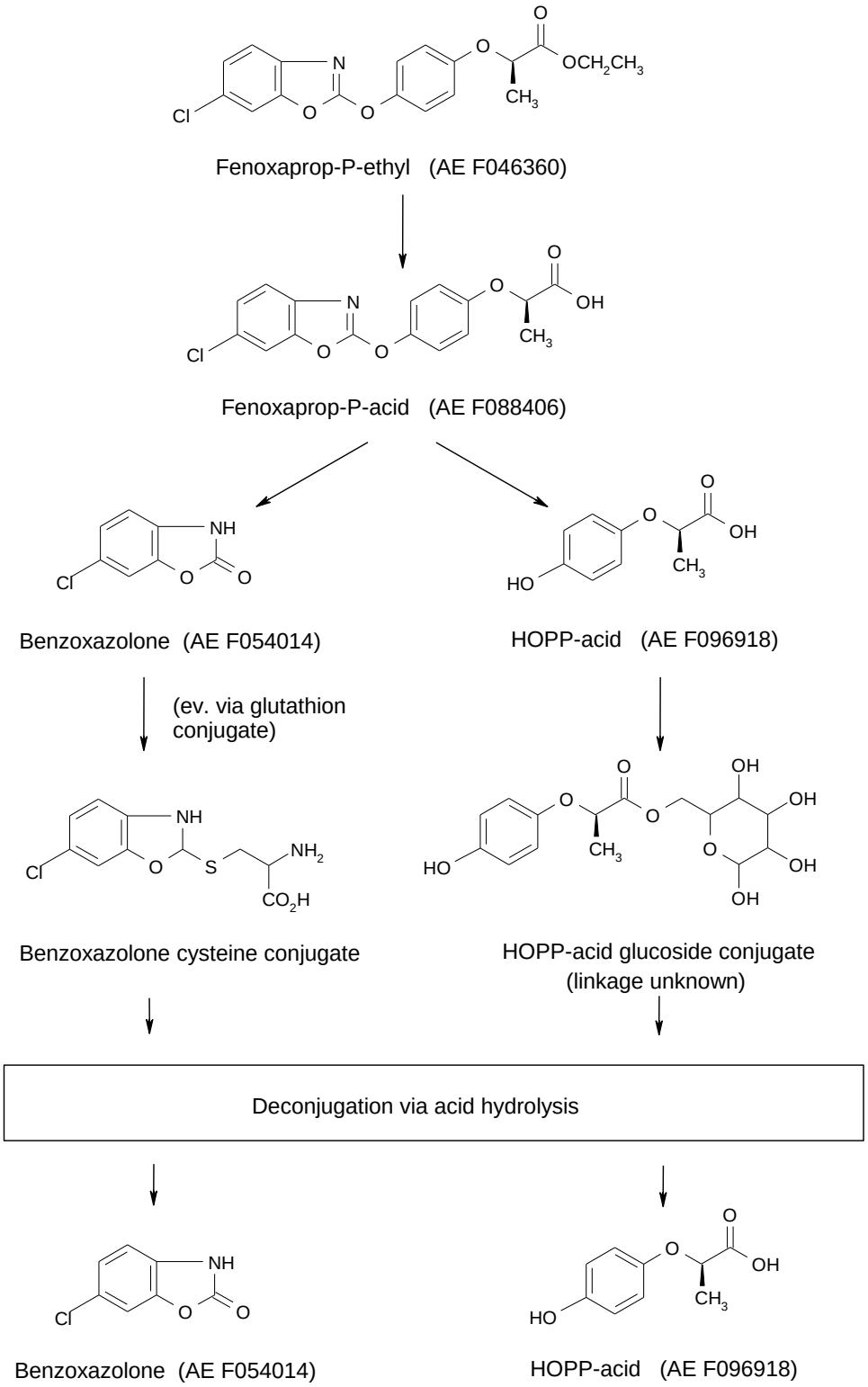
(1) hydrolysis of the ethyl ester group forming the free acid AE F088406, the D(+)- enantiomer of the racemic version AE F053022
(2) phenyl ether cleavage forming AE F054014 [6-chloro-2,3-dihydro-benzoxazol-2- one]
(3) conjugation of AE F054014 by glutathionate and additionally by glycosides.

A study on soya bean and wheat demonstrated that there was no racemization observed for the parent compound fenoxaprop-P-ethyl or it’s rapidly formed main metabolite fenoxaprop-P acid (AE F088406).

The new metabolism study on wheat also confirms the postulated independency of the route of metabolisation from the presence of a safener.

Since the findings in all studies were consistent a common metabolic pathway for all investigated crops can be proposed (see figure below).

Figure 2.7.2-1 Proposed metabolism scheme of fenoxaprop-P-ethyl residues in cereals



2.7.2.2. Livestock

No new metabolism study in livestock was submitted for the purpose of renewal of the active substance approval.
Studies on laying hens, cow and lactating goats have previously been included in the submission for Annex I inclusion under 91/414/EEC to elucidate the metabolism of fenoxaprop-P-ethyl in livestock. The studies were deemed acceptable following evaluation and peer review at EU level. A summary of the original submitted data which were considered for the purpose of renewal is presented in the following table.

Table 2.7.2-2 Summary of fenoxaprop metabolism studies in livestock

Species	Active substance	Label	Dose rate Duration	Matrices	Sampling	Reference (DRAR)
Originally submitted and evaluated studies (DAR, 2005) to be considered for purpose of renewal						
Laying hen	Hoe 033171	Chlorophenyl-^{14}C	0.41 mg/kg bw/day 5 days	Eggs,	2x daily	KCA 6.2.2/01 (B.7.2.2.1)
				Excreta	1x daily Depuration (7d): 4, 8, 24 hours after last dose	
				Liver, Kidney, Muscle, Fat, Stomach, Heart, Brain, Skin, Ovary, Spleen, Blood, Plasma	After sacrifice (8 hours, 72 hours, 7 days after last dose)	
Laying hen	Hoe 033171	Chlorophenyl-^{14}C	0.74 mg/kg bw/day 5 days	Eggs	2x daily (pooled)	KCA 6.2.2/02 (B.7.2.2.2)
				Excreta	1x daily	
				Liver, Muscle, Fat, Blood, Heart, Kidney, Skin, GI tract	After sacrifice (6 hours after last dose)	
		dioxyphenyl-1-^{14}C	0.81 mg/kg bw/day 5 days			
Lactating goat	Hoe 033171	Chlorophenyl-^{14}C	5.5 mg/kg bw/day 3 days	Milk	2x daily	KCA 6.2.3/01 (B.7.2.2.3) KCA 6.2.3/02 (B.7.2.2.3)
				Excreta	1x daily	
				Liver, Kidney, Muscle, Fat	After sacrifice within 24 hours after last dose	
Cow	Hoe 033171	Chlorophenyl-^{14}C	0.1 mg/kg bw/day 3 days	Milk	2x daily	KCA 6.2.3/03 (B.7.2.2.4)
				Faeces	1x daily	
				Urine	3x daily, 1x daily	
				Liver, Kidney, Muscle, Fat	After sacrifice within 24 hours after last dose	

The animal metabolism was studied in the DAR (2005) on laying hen (2) and lactating ruminants (2) with the ^{14}C-labeled racemic compound Hoe 033171 (Fenoxprop-ethyl). The metabolism in the rat and additionally even in plants showed no obvious difference in the metabolic behaviour for both the racemic compound Hoe 033171 and the P-enatiomer Hoe 046360; therefore no animal metabolismus studies with the P-enantiomer have been required.

In **poultry** following repeated oral administration to laying hens at a nominal dose level of either 0.81 mg/kg/day via capsule and 0.41 mg/kg bw by crop infusion, the majority of the administered radioactivity (91-98%) was excreted, eggs contained maximum 0.3 % of the radioactivity. No parent compound Hoe 033171 was detected in any tissue. Mayor residue component in all tissues and egg yolk (residue in egg white too low for identification) was the chlorobenzoxazolone (AE F054014) followed by fenoxaprop acid AE F053022 (racemic mixture of AE F088406). Total radioactive residues in the tissues were low with the highest residues found in the organs associated with excretion; the gastrointestinal tract (0.69 to 1.43 mg/kg), the kidney (0.30 to 0.64 mg/kg) and the liver (0.08 to 0.18 mg/kg). Residues in eggs were also low with equal or less than 0.01 mg/kg.

In **ruminants** Fenoxaprop- ethyl (Hoe 033171) is excreted mainly via faeces and urine (87 % of administered dose) following repeated oral administration via capsule to a lactating goat at a nominal dose level of 5.5 mg/kg/day. The parent Hoe 033171 is evidently rapidly metabolised following absorption since unchanged pesticide was not detected in urine or tissues. Mayor residue component in all tissues and milk was the chlorobenzoxazolone (AE F054014) followed by fenoxaprop acid (AE F053022; racemic mixture of AE F088406). Residues in polar (muscle) and lipophilic (fat) tissues as well as in the organs of excretion (kidney, liver) are low (fat 0.12 %, muscle 0.42 %, kidney 0.15 % and liver 0.25 % of the administered dose). Thus it is unlikely that accumulation of residues, derived from Hoe 033171 and its degradation products, has occurred.

As a conclusion, the lactating ruminant and poultry metabolism studies both indicate that the metabolism of fenoxaprop-P-ethyl in livestock involves hydrolysis into fenoxaprop acid and further cleavage of the ether bond forming chlorobenzoxazolone (Hoe 054014) and HOPP acid (Hoe 020686). This is in agreement with the findings of the rat metabolism study where hydrolysis to fenoxaprop-P is also the primary step of the metabolic pathway. As the principle metabolic steps are consistent in rat, hen and goat no studies are required on the metabolism in pigs.

A **fish** metabolism study is considered not necessary. The log P_{OW} of Fenoxaprop-P-ethyl is 4.58 however Fenoxaprop-P-ethyl residues in cereal grain are all below the LOQ of 0.01 mg/kg. Additionally, it is considered that no green material or forages nor straw will be part of the fish diet. The dietary burden of fenoxaprop-P-ethyl derived residues in fish feed is therefore considered negligible. Moreover residues in cereal harvest commodities consist of the metabolites fenoxaprop-P-acid (AE F088406) and chlorobenzoxazolone (AE F054014) and their conjugates. The log P_{OW} values of fenoxaprop-P-ethyl acid and benzoxazolone are far below 3 in acidic as well as in basic solutions.

2.7.3. Definition of the residue

2.7.3.1. Plant

One new metabolism study in spring wheat conducted with [^{14}C]-Fenoxaprop-P-ethyl has been submitted for the purpose of renewal of the active substance approval. The study confirm the results of the metabolism studies on wheat, barley, soybean and rice have previously evaluated for Annex I inclusion under 91/414/EEC. The studies were deemed acceptable following evaluation and peer review at EU level.

The plant metabolism studies were conducted with fenoxaprop-P-ethyl AE F046360 as well as with the racemic substance fenoxaprop-ethyl AE F033171. The substances were labelled either in the chlorophenyl ring or the dioxyphenyl ring to provide complete information on the degradation profile.

There is no obvious difference in the metabolic behaviour of the racemic compound and the P-enantiomer. In both cases the active substance in plant undergoes ester hydrolysis forming the free acid fenoxaprop-P (AE F088406, or AE F053022 for the racemic mixture), which is still herbicidally active. Further metabolism proceeds through cleavage of the ether-linkage between the benzoxazolone and the phenoxy- moieties of the substance from 2 to 7 days after application. Major constituent of the residue after this cleavage are chlorbenzoxazolone (AE F054014) and HOPP-acid (AE F09618) as free or conjugated forms. The rat metabolism proceeds through the same major steps as plant metabolism and it can be considered that the plant metabolism is covered by the toxicological studies conducted with the parent compound either fenoxaprop-P-ethyl or fenoxaprop-ethyl.

The validated analytical methods for residues derived from fenoxaprop-P-ethyl start with a hydrolysis step which converts the active ingredient, the free acid fenoxaprop-p as well as other metabolites or conjugates still containing the chlorobenzoxazolone moiety to chlorobenzoxazolone (AE F054014). This common moiety approach was chosen because most of the aged residues of fenoxaprop-P-ethyl were determined to be conjugated. After harsh hydrolysis the predominant residue in plant matrices could be identified as chlorobenzoxazolone (AE F054014).
For the purpose of renewal of the active substance approval a new analytical method for plant matrices *"Modification M001 to method 00874 for the determination of residues of AE F046360, AE F088406, and AE F054014 in/on matrices of plant origin by HPLC-MS/MS (Method and validation)* (please refer to B.5.2.1) has been submitted. The method determines the sum (total residue) of AE F046360, AE F088406 and AE F054014. The analytical target is AE F054014. The method 00874/M001 is considered applicable as a residue analytical method as well as for enforcement purposes.

According to OECD Guidance on the definition of residue (ENV/JM/MONO(2009)30) the residue definition for monitoring/MRL enforcement (RD-Mo) should focus on those residue components suitable as analyte of multi-residue methods, as well as suitable as general marker compound in food commodities concerned.

Considering that there is no obvious difference in the metabolic behaviour of the racemic compound fenoxaprop-ethyl and the P-enantiomer and that the parent compound and its free acid form cannot be considered as valid indicator of the residue situation at harvest. The requirement of an enantio-selective method of analysis is not reasonable since the analytical target is 6-chloro-2,3- dihydrobenzoxazol-2-one (AE F054014).

The residue definition for monitoring and risk assessment for the purpose of renewal of the active substance approval is proposed as outlined in the table below compared to the residue definition as decided during 91/414 peer review (EFSA, 2007).

Table 2.7.3-1 Existing and proposed residue definitions for fenoxaprop-P-ethyl in plants

	Residue defintion	
	EFSA conclusion [EFSA Scientific Report (2007) 121, 1-76]	**Proposal for purpose of renewal**
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.	Sum of fenoxaprop-ethyl and all metabolites converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-ethyl. There is no obvious difference in the metabolic behaviour of the racemic compound fenoxaprop-ethyl and the P-enantiomer. Since the parent compound and its free acid form cannot be considered as valid indicator of the residue situation at harvest, the requirement of an enantio-selective method of analysis is not reasonable. The analytical target is the non enantioselective compound 6-chloro-2,3- dihydrobenzoxazol-2-one.
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	Sum of fenoxaprop-P-ethyl and all metabolites converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-P-ethyl.
Conversion factor (monitoring to risk assessment)	None	Not relevant The analytical method determines the sum (total residue) of fenoxaprop-P-ethyl (parent), fenoxaprop-P (acid) and 6-chloro-2,3-dihydrobenzoxazol-2-one (AE F054014). The analytical target is AE F054014.

2.7.3.2. Livestock

No new metabolism study in livestock was submitted for the purpose of renewal of the active substance approval. Studies on laying hens, cow and lactating goats have previously evaluated in the submission for Annex I inclusion under 91/414/EEC and deemed acceptable following peer review at EU level.

The metabolism studies were conducted with the radiolabeled racemic compound fenoxaprop-ethyl (AE F033171) only. The comparison with the rat metabolism showed an identical pathway for both the racemic compound AE F033171 and the P-enatiomer AE F046360, thus no metabolism studies with the P-enantiomer have been required.

Fenoxaprop-ethyl (AE F033171) or its degradation products were excreted almost completely by farm animals showing no accumulating behaviour following repeated administration to ruminants or poultry. There were also no signs for a significant transfer of residues into eggs, milk or tissues.

The metabolism of fenoxaprop-P-ethyl in livestock involves hydrolysis into fenoxaprop acid and further cleavage of the ether bond forming chlorobenzoxazolone (AE F054014) and HOPP acid (AE F020686) This is in agreement with the findings of the rat metabolism study where hydrolysis to fenoxaprop-P is also the primary step of the metabolic pathway. The principle metabolic steps are consistent in rat, hen and goat.

During the EU review for Annex I inclusion under 91/414/EEC no residue definition for livestock was considered necessary.

For the purpose of renewal of the active substance approval a new analytical method for animal matrices *Validation of analytical BCS method 01316 for the determination of residues of fenoxaprop-P-ethyl and its metabolites fenoxaprop-P and AE F054014 (using LC-MS/MS in animal tissues: liver, kidney, muscle, milk, egg, fat)" (*please refer to B.5.2.1) has been submitted. Specimen material was extracted under acidic organic conditions. At these conditions fenoxaprop-P-ethyl (AE F046360) and fenoxaprop P acid (AE F088406) are converted into benzoxazolone AE F054014 (6-chloro-2,3- dihydrobenzoxazol-2-one). After clean up the residue extract was then analysed for residues of AE F054014 by HPLC-MS/MS for two mass transitions.

With respect to the no-residue situation in grain and the low uptake of fenoxaprop residues by lactating cows from straw of treated cereals it is justified to determine AE F054014 as the only analytical target for monitoring purposes. Considering that the parent compound and its free acid form cannot be considered as valid indicator, the requirement of an enantio-selective method of analysis is not reasonable since the analytical target is 6-chloro-2,3- dihydrobenzoxazol-2-one. Therefore the residue definition for monitoring and risk assessment for the purpose of renewal of the active substance approval is proposed as outlined in the table below compared to the residue definition as decided during 91/414 peer review (EFSA, 2007).

Table 2.7.3-2 Existing and proposed residue definitions for fenoxaprop-P-ethyl in livestock

	Residue defintion	
	EFSA conclusion **[EFSA Scientific Report (2007) 121, 1-76]**	**Proposal for purpose of renewal**
Residue definition for monitoring	Not required	Sum of fenoxaprop-ethyl and all metabolites converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-ethyl. The parent compound and its free acid form cannot be considered as valid indicator for monitoring since the analytical target is the non enantioselective compound 6-chloro-2,3- dihydrobenzoxazol-2-one. The requirement of an enantio-selective method of analysis is not reasonable.
Residue definition for risk assessment	Not required	Sum of fenoxaprop-P-ethyl and all metabolites converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-P-ethyl.
Conversion factor (monitoring to risk assessment)	None	Not relevant The analytical method determines the sum (total residue) of fenoxaprop-P-ethyl (parent), fenoxaprop-P (acid) and 6-chloro-2,3- dihydrobenzoxazol-2-one (AE F054014). Analytical target is the non enantioselective compound 6-chloro-2,3- dihydrobenzoxazol-2-one.

2.7.4. Summary of residue trials in plants and identification of critical GAP

The magnitude of residues on treated cereal crops has previously been investigated in a number of supervised residue trial studies on wheat, barley and rye. These trials were included within the submission for Annex I inclusion under 91/414/EEC and were deemed acceptable following evaluation and peer review at EU level (Review Report SANCO/3778/2007). The representative uses and critical GAPs of fenoxaprop-P-ethyl for the purpose of renewal of the active substance approval are outlined in the table below.

Table 2.7.4-1 Critical EU GAPs for fenoxaprop-P-ethyl

Type of GAP	Crop	Region	Application details			PHI (d)	Reference
			Method growth stage	No of applications	Max. Rate (kg as/ha)		
Renewal	Wheat, durum wheat, rye, triticale	NEU SEU	spraying BBCH 11-39	1	0.083	F	Dossier for renewal of the a.s.
	Barley	NEU SEU	spraying BBCH 12-32	1	0.083	F	
DAR, 2005	Wheat (s+w), durum wheat, raye, w-rye, tricale, barley (s+w)	NEU SEU	spraying BBCH 10-32	1	0.083	F	EFSA Scientific Report (2007) 121, 1-76

F= preharvest interval is determined by the vegetation period of the crop

Fenoxaprop-P-ethyl (Hoe 046360) was applied post-emergence to annual grass weeds from the two-leaf stage up to tillering in cereals (wheat, rye and barley). The Fenoxaprop-P-ethyl based oil in water formulation (69 g/L active substance) contain 75 g/L of the safener Mefenpyr-diethyl (Hoe 107892), which is absorbed by the foliage in a similar manner as the herbicide itself. The safener enhances the rate of Fenoxaprop-P-ethyl metabolism via the free acid Fenoxaprop-P to water soluble, non phytotoxic products without changing the metabolic pathway.

A sufficient number of residue trials on cereals (wheat, durum wheat, barley and rye) for both the northern and the southern Europe are available. A total of 26 residue trials (8x NEU, 18x SEU) with application rates between 62-83 g as/ha (within ± 25%) are available supporting BBCH 37-41. To support applications up to BBCH 32 a total of 18 residue trials (14x NEU, 4x SEU) with an application rates of 83 – 87 g as/ha were provided.

The new trials were analysed according to the same method principle but with lower LOQs. No residues in **cereal grain** samples could be determined neither in the residue trials for the EU review (<0.02 mg/kg, LOQ) nor in the newly submitted trials (<0.01 mg/kg, LOQ). Residues in **cereal straw** applied up to growth stage BBCH 32 were below the LOQ of 0.05 mg/kg. Straw residues with trials applied up to BBCH 39 showed residues between 0.1 and 0.89 mg/kg.
According to Guidance Document « *Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs* » (Sanco 7525/VI/95, Rev. 10.2, September 2016) extrapolation from wheat to barley, rye and triticale is considered acceptable since application was before forming of the edible part (before BBCH 51). An overview on the available residue trials is given in the tables below.

Table 2.7.4-2 Overview on residue trials covering the supported GAP (1x 83 g as/ha) for BBCH 37-41

Crop	Zone	No of trials	Rate	Growth stage	Residue levels	HR	STMR	Reference
			g as/ha	BBCH	mg/kg	mg/kg	mg/kg	
Wheat grain	NEU	8	75-83	39-41	8x < 0.01*	< 0.01*	< 0.01*	KCA 6.3.1/15, KCA 6.3.1/16
Wheat straw					0.14, 0.2, 0.25, 0.27, 2x 0.34, 0.45, 0.7	0.70	0.31	
	Total	**8**						
Wheat grain	SEU	11	83-87	37-41	11x < 0.02*	< 0.02*	< 0.02*	DAR, 2005
Wheat straw					0.10, 0.11, 0.20, 0.22, 0.23, 0.27, 0.57, 0.58, 0.73, 0.74, 0.89	0.89	0.27	
Wheat grain	SEU	7	83, 62 (1x)	39	7x < 0.01*	< 0.01*	< 0.01*	KCA 6.3.1/17, KCA 6.3.1/18
Wheat straw					0.18, 0.23, 0.27, 0.28, 0.29, 0.30, 0.42	0.42	0.28	
	Total	**18**						

*.. LOQ

Table 2.7.4-3 Overview on residue trials covering the supported GAP (1x 83 g as/ha) for BBCH 32

Crop	Zone	No of trials	Rate	Growth stage	Residue levels	HR	STMR	Reference
			g as/ha	BBCH	mg/kg	mg/kg	mg/kg	
Wheat grain	NEU	7	83-87	29-31	7x <0.02*	< 0.02*	< 0.02*	DAR, 2005
Wheat straw					7x <0.05*	< 0.05*	< 0.05*	
Barley grain	NEU	3	87	29-31	3x <0.02*	< 0.02*	< 0.02*	
Barley straw					3x <0.05*	< 0.05*	< 0.05*	
Rye grain	NEU	4	87	29-31	4x <0.02*	< 0.02*	< 0.02*	
Rye straw					4x <0.05*	< 0.05*	< 0.05*	
	Total	**14**						
Wheat grain	SEU	2	83	29-31	2x <0.02*	< 0.02*	< 0.02*	DAR, 2005
Wheat straw					2x <0.05*	< 0.05*	< 0.05*	
Wheat grain	SEU	2	83	29-31	2x <0.02*	< 0.02*	< 0.02*	
Wheat straw					2x <0.05*	< 0.05*	< 0.05*	
	Total	**4**						

*.. LOQ

2.7.5. Summary of feeding studies in poultry, ruminants, pigs and fish

Livestock dietary burden is calculated using the EFSA dietary burden calculator 2017. The potential levels of fenoxaprop-P-ethyl residues in the total diet of livestock were estimated based on median and highest residue levels observed in these commodities during supervised field trials conducted according to the respective critical GAPs (1x 0.083 kg as/ha).

Table 2.7.5-1 Input values for the dietary burden calculation

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Barley straw	0.05	STMR	0.05	HR
Rye straw[#]	0.28	STMR	0.89	HR
Wheat, triticale straw	0.28	STMR	0.89	HR
Barley grain	0.02	STMR	0.02	HR
Rye grain[#]	0.01	STMR	0.01	HR
Wheat, triticale grain	0.01	STMR	0.01	HR

[#]...extrapolated from wheat

Table 2.7.5-2 Results of the dietary burden calculation

Animals	Median dietary burden	Maxiumum dietary burden	Above trigger value	Maximum dietary burden	Highest contributing commodities
	mg/kg bw	mg/kg bw	0.004 mg/kg bw	mg/kg DM	
Beef cattle	0.002	0.005	Yes	0.22	Wheat straw
Dairy cattle	0.003	0.008	Yes	0.22	Wheat straw
Ram/Ewe	0.005	0.014	Yes	0.40	Wheat straw
Lamb	0.006	0.018	Yes	0.43	Wheat straw

Animals	Median dietary burden	Maxiumum dietary burden	Above trigger value	Maximum dietary burden	Highest contributing commodities
	mg/kg bw	mg/kg bw	0.004 mg/kg bw	mg/kg DM	
Pig (breeding)	0.001	0.001	No	0.02	Barley grain
Pig (finishing)	0.001	0.001	No	0.02	Barley grain
Poultry broiler	0.001	0.001	No	0.02	Wheat gluten meal
Poultry layer	0.004	0.008	Yes	0.12	Wheat straw
Turkey	0.001	0.001	No	0.02	Wheat gluten meal

The maximum expected dietary burden of fenoxaprop-p-ethyl derived residues was above the EU trigger level of 0.004 mg/kg bw/day in 5 species. Therefore there is a requirement to consider livestock feeding studies and the potential transfer of residues into food of animal origin for the supported uses of fenoxaprop-P-ethyl.

One new feeding study in laying hens conducted with [^{14}C]-Fenoxaprop-P-ethyl has been submitted for the purpose of renewal of the active substance approval.

The feeding study on laying hens was performed with dose levels which covered the maximum estimated laying hens feed intake. Four groups of laying hens received gelatine capsules containing fenoxaprop-P-ethyl at dose levels of 0.2 mg/bird (1X), 0.6 mg/bird (3X) and 2.0 mg/bird (10X) once daily for at least 28 consecutive days until study termination or depuration. The samples taken were pooled from each subgroup with a sub-sample (5 g) taken from this pooled sample for analysis by LC-MS/MS.

Residues in eggs at the 1X level all remained below the LOQ of 0.01 mg/kg. With the 3X level a plateau at LOQ was reached between day 7 and day 14. With the 10X level the plateau was reached within the second week at 0.055 mg/kg.

In tissues, the highest residues occurred in the liver (0.15 – 1.30 mg/kg); lower residues were found in abdominal (0.01 – 0.24 mg/kg) and subcutaneous fat (< 0.01 – 0.16 mg/kg) and the lowest residue concentrations occurred in muscle with levels between < LOQ (0.01mg/kg) and 0.11 mg/kg.

Following withdrawal of dosing residues of fenoxaprop-P-ethyl rapidly declined to levels below the LOQ within 7 days in eggs, liver and muscle. Remaining residues at Day 10 of the depuration phase were detected in subcutaneous fat (0.022 mg/kg) and abdominal fat (0.10 mg/kg), respectively.

Table 2.7.5-3 Summary of highest values for Fenoxaprop-P-ethyl equivalents in tissues (mg/kg)

Group	Dose		No of birds	Depuration Period (Days)	Tissues			
No	mg/ bird	mg/ kg bw[1]			Liver	Muscle	Abdominal fat	Subcutaneous fat
1	-	-	4	0	ND	ND	ND	ND
2 (1X)	0.2	0.11	12	0	0.146	< LOQ	0.012	< LOQ
3 (3X)	0.6	0.33	12	0	0.463	0.025	0.041	0.040
4 (10X)	2	1.11	12	0	1.30	0.112	0.236	0.163
4a (10 X D)	2	1.11	4	3	0.035	0.011	0.14	0.037
			4	7	0.011	<LOQ	0.20	0.024
			4	10	<LOQ	<LOQ	0.10	0.022

4a= Depuration [1]… based on a mean body weight of 1.82 kg ND= < 0.001 mg/kg LOQ= < 0.01 mg/kg

For the supported uses of fenoxaprop-P-ethyl on cereals the estimated highest residues in poultry at 1N rate are below the LOQ of 0.01 mg/kg in eggs or any edible tissues, except for liver where the residue level (0.011 mg/kg) is slightly above the LOQ. Poultry metabolism studies showed that the majority of the administered radioactivity (91-98%) was excreted, no significant residues are expected in animal tissues or milk after application according to the recommended GAP.

A **ruminant feeding study** on lactating cows has previously been included in the submission for Annex I inclusion under 91/414/EEC. The study was deemed acceptable following evaluation and peer review at EU

level. As shown in plant metabolism studies and in a broad scale of field crop residue studies the active ingredient Hoe 033171 is degraded rapidly. The racemic compound Hoe 033171 and its metabolite chlorobenzoxazolone (Hoe 054014) were fed in equal amounts to lactating cows at 3 dose levels. One group of 3 cows (1X) received 3 mg and two groups of 4 cows each received 9 mg (3X) and 30 mg (10X) per substance per animal for 28 consecutive days.

In the *1x dose group* (3 mg Hoe 033171 + 3 mg 054014/cow/day) no detectable residues were determined in milk (mean values), fat, kidney and blood. Residues in muscle and liver were slightly above the LOQ (in one of three animals).
In the *3x dose group* (9 mg Hoe 033171 + 9 mg 054014/cow/day) a mean residue level of 0.01 mg/L in milk and a maxium residue level of 0.05 mg/kg in liver was detected. Residues in fat, blood and kidney were below or at the LOQ of 0.01 mg/kg.

In the *10x dose group* (30 mg Hoe 033171 + 30 mg 054014/cow/day) a mean residue level of 0.02 mg/L was detected in milk and a maxium residue level of 0.09 mg/kg in kidney and of 0.2 mg/kg in liver. Residues in muscle and fat were below or at the LOQ (in one of three animals).

Considering the renal and faecal excretion in lactating goats (87% of the administered dose), it can be concluded that residues of Fenoxaprop-ethyl and its metabolites are rapidly excreted in cows and do not show any tendancy to accumulate. Thus for the supported uses of fenoxaprop-P-ethyl on cereals it is not expected that residues, which are significantly higher than the LOQ of 0.01 mg/kg will occur in edible tissues or milk.

2.7.6. Summary of effects of processing

Since the supported uses of fenoxaprop-P-ethyl on cereals do not result in significant residues in the raw agricultural commodities (RAC) at harvest (all residues in grains are < 0.01 mg/kg) and no significant transfer to food of animal origin is expected, studies to specifically investigate the processing nature of residue for fenoxaprop-P-ethyl are considered not required.

2.7.7. Summary of residues in rotational crops

Two metabolism studies in rotational crops have previously been included in the submission for Annex I inclusion under 91/414/EEC. The studies were deemed acceptable following evaluation and peer review at EU level. A summary of the original submitted data which were considered for the purpose of renewal is presented in the following table.

Table 2.7.7-1 Summary of fenoxaprop metabolism studies in rotational crops

Rotational crops	Active substance	Label	Application rate	PBI	Reference
Originally submitted and evaluated studies (DAR, 2005) to be considered for purpose of renewal					
Leafy vegetables (Spinach, lettuce) root vegetables (radish, carrots), cereals (wheat, buckwheat)	Hoe 046360	Chlorophenyl-^{14}C	1x 0.113 kg as/ha, bare soil	30days, 1year	Bürkle, W.L.; Wink O., Köcher, H.; 1987 KCA 6.6.1/01 (B.7.6.1.1)
Leafy vegetables (Spinach) root vegetables (red beets), cereals (wheat)	Hoe 033171	Chlorophenyl-^{14}C	0.11 kg as/ha, rice plants (5-6 leaf stage)	111days	Schwalbe-Fehl M. ; Steinau M. ; Mueller H.J.; 1985a KCA 6.6.1/02 (B.7.6.1.2)
		Dioxyphenyl-1-^{14}C	0.07 kg as/ha, rice plants (5-6 leaf stage)		

The two studies lead to the conclusion that 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) of the radioactive method for all crops tested (leafy vegetables, root vegetables and cereals) at all time points investigated. Residues in edible commodities intended for human consumption were all below 0.01 mg/kg. Only in straw a residue of 0.022 mg/kg could be detected, but with high background radioactivity (LOQ 0.014 mg/kg). Therefor no metabolite identification was performed. Residues in soil layers up to 5 cm were only found at low concentrations but there was no evidence either of residue uptake or accumulation by plants or soil indicating a

rapid metabolisation of fenoxaprop-P-ethyl (AE F046360) and its racemic mixture fenoxaprop-ethyl (AE F033171), respectively. The application of fenoxaprop-P-ethyl according to the intended use will not lead to detectable residues in succeeding crops.

2.7.8. Summary of other studies

For the evaluation of residues in pollen and bee products for human consumption, the relevant question regarding bee attractiveness is not whether or not the crop is occasionally visited by bees, but if the crop is foraged by honey bees to an extent of economic relevance. Cereals are crops that are visited by honey bees for potential pollen and/or nectar collection. However Fenoxaprop-p-ethyl is applied on cereals early in the growing season (latest at BBCH 39), thus no residues are expected in pollen and bee products.

2.7.9. Estimation of the potential and actual exposure through diet and other sources

The acute and chronic consumer dietary risk resulting from the representative uses on wheat (durum wheat, triticale), rye and barley was carried out by means of the *EFSA chronic acute RA model rev.2* and the following proposed toxicological endpoints.

Table 2.7.9-1 Proposed toxicological reference values for the dietary risk assessment of fenoxaprop-P-ethyl

Reference value	**Value**	**Study relied upon**	**Safety factor**
ADI	0.01 mg/kg bw/day	a 2-year repeated oral study in the dog (fenoxaprop-ethyl), supported by the 2-year and multigeneration rat studies	100
ARfD	0.1 mg/kg bw	a developmental study in rats (fenoxaprop-P-ethyl)	100

For the estimation of the chronic consumer exposure calculation, the calculated MRL values for the representative crops were used for TMDI calculation. In case of products of animal origin, the currently established MRLs in the Reg. 396/2005 were used as input values. The acute risk assessment was carried out using the highest residue from the supervised residue trials.

Table 2.7.9-2 Summary of the critical residue data for fenoxaprop-P-ethyl in mg/kg

Crop	**MRL**	**HR**	**STMR**	**comment**
Wheat	0.01*	< 0.01	< 0.01	based on 8 residue trials from NEU and 7 residue trials from SEU

The highest TMDI (Theoretical Maximum Daily Intakes) was calculated for the FR toddler, accounting for 22% of the ADI. For this diet, the highest contributor is milk and cream with 19.8% of the ADI. The highest calculated value of the ARfD is 1.9% for milk and milk products: cattle

On the basis of these calculations, it is concluded that the representative uses of fenoxaprop-P-ethyl supported in the framework of renewal of a.s. approval on cereals (wheat, durum wheat, triticale, rye and barley) are acceptable with regard to consumer dietary exposure.

EFSA model (PRIMo) for chronic and acute risk assessment - rev. 2 for TMDI calculation for the representative uses

FENOXAPROP-P

Status of the active substance:	**approved**	Code no.	
LOQ (mg/kg bw):	0,01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,01**	ARfD (mg/kg bw):	**0,1**
Source of ADI:	**DRAR**	Source of ARfD:	**DRAR**
Year of evaluation:	**2017**	Year of evaluation:	**2017**

Prepare workbook for refined calculations

Undo refined calculations

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

	TMDI (range) in % of ADI minimum - maximum
	22
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	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	pTMRLs at LOQ (in % of ADI)
21,9	FR toddler	19,8	Milk and cream,	0,7	Bovine: Meat	0,5	Birds' eggs	0,3
20,6	UK Infant	19,4	Milk and cream,	0,7	Birds' eggs	0,3	Wheat	0,3
17,4	NL child	14,7	Milk and cream,	0,8	Swine	0,6	Bovine: Meat	0,5
13,8	FR infant	12,9	Milk and cream,	0,3	Bovine: Meat	0,3	Poultry -chicken, geese, duck,	0,1
11,4	UK Toddler	10,3	Milk and cream,	0,4	Birds' eggs	0,4	Wheat	0,4
9,3	DK child	6,3	Milk and cream,	1,1	Swine	0,6	Wheat	1,0
9,3	ES child	6,3	Milk and cream,	0,7	Bovine: Meat	0,7	Swine	0,4
8,9	DE child	7,1	Milk and cream,	0,6	Birds' eggs	0,4	Wheat	0,5
7,0	SE general population 90th percentile	6,2	Milk and cream,	0,4	Birds' eggs	0,3	Wheat	0,3
5,1	WHO regional European diet	2,4	Milk and cream,	0,7	Swine	0,5	Bovine: Meat	0,3
4,8	NL general	3,3	Milk and cream,	0,5	Swine	0,4	Bovine: Meat	0,2
4,6	WHO Cluster diet B	1,6	Milk and cream,	0,9	Wheat	0,5	Poultry -chicken, geese, duck,	0,9
4,3	WHO cluster diet D	2,5	Milk and cream,	0,7	Wheat	0,3	Bovine: Meat	0,7
4,3	ES adult	2,5	Milk and cream,	0,4	Swine	0,4	Bovine: Meat	0,2
4,2	WHO Cluster diet F	2,0	Milk and cream,	0,6	Swine	0,4	Bovine: Meat	0,4
4,1	DK adult	2,7	Milk and cream,	0,5	Swine	0,3	Bovine: Meat	0,3
3,9	WHO cluster diet E	1,5	Milk and cream,	0,5	Poultry -chicken, geese, duck,	0,4	Swine	0,4
3,5	IE adult	1,4	Milk and cream,	0,5	Swine	0,4	Sheep	0,2
3,5	FI adult	2,8	Milk and cream,	0,2	Swine	0,1	Poultry -chicken, geese, duck,	0,2
3,2	LT adult	2,0	Milk and cream,	0,6	Swine	0,2	Birds' eggs	0,2
2,6	FR all population	1,3	Milk and cream,	0,3	Wheat	0,3	Poultry -chicken, geese, duck,	0,3
2,1	UK Adult	1,5	Milk and cream,	0,2	Poultry -chicken, geese, duck,	0,2	Wheat	0,2
2,0	UK vegetarian	1,6	Milk and cream,	0,2	Wheat	0,2	Birds' eggs	0,2
0,7	IT kids/toddler	0,7	Wheat	0,0	Barley		FRUIT (FRESH OR FROZEN)	0,7
0,4	IT adult	0,4	Wheat	0,0	Barley		FRUIT (FRESH OR FROZEN)	0,4
0,4	PT General population	0,4	Wheat	0,0	Rye	0,0	Barley	0,4
	PL general population		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of FENOXAPROP-P is unlikely to present a public health concern.

EFSA model (PRIMo) for chronic and acute acute risk assessment - rev. 2 for IESTI calculation for representative uses

The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities

Acute risk assessment /children						Acute risk assessment / adults / general population					
No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	****)**
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
1,9	Milk and milk products: Cattle	0,015 / -	1,9	Milk and milk	0,015 / -	0,3	Milk and milk	0,015 / -	0,3	Milk and milk products: Cattle	0,015 / -
0,6	Birds' eggs	0,05 / -	0,6	Birds' eggs	0,05 / -	0,2	Birds' eggs	0,05 / -	0,2	Birds' eggs	0,05 / -
0,5	Milk and milk products: Goat	0,02 / -	0,5	Milk and milk	0,02 / -	0,1	Bovine: Edible offal	0,05 / -	0,1	Bovine: Edible offal	0,05 / -
0,4	Bovine: Edible offal	0,05 / -	0,4	Bovine: Edible	0,05 / -	0,1	Barley	0,02 / -	0,1	Barley	0,02 / -
0,3	Horse: Meat	0,05 / -	0,3	Horse: Meat	0,05 / -	0,1	Milk and milk	0,02 / -	0,1	Milk and milk products: Goat	0,02 / -
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded:		---				**No of commodities for which ARfD/ADI is exceeded:**		---			
		*****)**						*****)**			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
0,1	Wheat flour	0,01 / -				0,0	Bread/pizza	0,01 / -			

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL
***) pTMRL: provisional temporary MRL for unprocessed commodity

2.7.10. Proposed MRLs and compliance with existing MRLs

A summary of the currently published EU MRLs in the Regulation 396/2005 for the crops under consideration (wheat, durum wheat, triticale, rye and barley) are summarized in the table below.

Table 2.7.10-1 EU MRLs for fenoxaprop-P-ethyl according to Regulation 396/2005

Food commodity	**Code**	**Current EU MRLs established in Reg. (EC) 396/05[1] (mg/kg)**	**Proposed EU MRLs for representative GAP (mg/kg)**	**Justification**
CEREALS	0500000			
barley	0500010	0.1	0.01*	Extrapolated from wheat [2]
rye	0500070	0.1	0.01*	Extrapolated from wheat [2]
wheat	0500090	0.1	0.01*	15 new residue trials (8x NEU, 7x SEU) provided
Others (triticale)	0500990	0.1	0.01*	Extrapolated from wheat [2]

[1]…Reg. (EC) No 149/2008
[2]…SANCO 7525/VI/95 Rev.10.2 (23.09.2016)

2.7.11. Proposed import tolerances and compliance with existing import tolerances

No import tolerances were intended in the framework of the renewal process.

2.8. FATE AND BEHAVIOUR IN THE ENVIRONMENT

2.8.1. Summary of fate and behaviour in soil

The degradation of fenoxaprop-P-ethyl (AE F046360) under **aerobic soil conditions** proceeds via fast microbial-induced hydrolysis of the ester functional group to form the herbicidal active metabolite fenoxaprop-P-acid (AE F088406). This ester hydrolysis is followed by cleavage at the 'central' heterocyclic ether bond to result in formation of chlorobenzoxazolone (AE F054014) and, in principle, of its counterpart HOPP-acid (AE F096918). However, as indicated by additional dedicated degradation studies (Fitzmaurice, 2010; Stroech & Junge, 2014), HOPP-acid (AE F096918) is degraded almost spontaneously in aerobic soil once formed and the compound is thus too short-living to occur at significant levels in corresponding aerobic soil degradation tests. Cleavage of fenoxaprop-P-acid (AE F088406) at the 'non-central' ether bond (i.e. split at the alkyl ether-phenyl moiety) resulted in the formation of the phenolic metabolite (AE F040356) observed as a minor pathway (< 5 % AR) in the route of degradation in aerobic soil. Formation of non-extractable residues (NER) was significant, particularly for the chlorophenyl label. At study end NER accounted for 63.5 - 68.7 % AR in studies lasting for 37 days and 49.4 - 70.1 % AR in studies lasting for 100 days. Formation of NER for the phenoxy label was somewhat lower with finally 37.6 - 51.3 % AR in studies lasting for 37 days. Formation of CO_2 was significant as well, at study end 8.4 - 16.6 % (37 days studies) and 9.7 - 32.5 % AR (100 days studies), respectively, were observed for the chlorophenyl label. Formation of CO_2 for the phenoxy label accounted for 33.5 - 49.6 % AR (37 days studies only). One study (Buerkle at al., 1986) conducted with racemic fenoxaprop-ethyl (AE F033171) basically gave the same results, but is considered as supplemental information only in this context. An additional study (Buettner et al., 2992) investigating fenoxaprop-P-ethyl (AE F046360) in one soil at 10 and 21 °C is not considered reliable owing to significant data scatter.

In principle, the route of degradation in **anaerobic soil** does not differ from the degradation pathway in aerobic soils. However, HOPP-acid (AE F096918) was found at significant amounts indicating that this metabolite may be considered rather stable under anaerobic soil conditions. As indicated above, HOPP-acid (AE F096918) is degraded spontaneously under aerobic soil conditions. In one anaerobic soil degradation study (Voelkel, 2001a), an unknown metabolite fraction ('M8') exceeded 5 % AR at two consecutive sampling points (max. 6.2 % at 120 DAT, declining thereafter) thus triggering identification and an exposure assessment according to Regulation (EU) No 283/2013. This is currently not the case (data gap). However, as 'M8' appears only in samplings following 45 days of continuous strict anaerobic conditions, the RMS AT considers significant amounts of 'M8' unlikely to occur under real outdoor conditions. Similar to aerobic conditions, formation for NER was significant with 63.9 - 76.4 % AR and 26.5 % AR for the chlorophenyl and phenoxy label, respectively (study end, approx. 120 days). Formation of CO_2 was low for the chlorophenyl label (0.6 - 3.9 % AR) but significant for the phenoxy label (22.7 % AR). It is noted that in one of these anaerobic soil degradation experiments racemic fenoxaprop-ethyl (AE F033171) was applied.

The route of **degradation on irradiated soil surfaces** has been investigated under laboratory conditions in one sterilized and dry soil at 25 °C following application of chlorophenyl labelled racemic fenoxaprop-ethyl (AE F033171). Fenoxaprop-ethyl (AE F033171) was degraded slowly under the conditions of the test when being compared to results of tests performed with microbial active and moist soils. Following continuous irradiation for 120 hours photolytic degradation was found to proceed via formation of non-extractable residues (NER, maximum 7.4 % AR after 120 hours) and CO_2 (maximum of 12.1 % AR after 120 hours). No formation of (racemic) fenoxaprop-acid (AE F053022) was observed in the course of the study. Chlorobenzoxazolone (AE F054014) was observed at maximum amounts of 6.8 % AR. Minor unknown metabolites were observed at levels of 6.4 % AR at maximum, at one sampling time only, thus neither triggering identification nor exposure assessment according to Regulation (EU) No 283/2013. The RMS AT notes that the soil photodegradation study has some deficits as it only investigates racemic fenoxaprop-ethyl (AE F033171) on dry and sterilized soil layers. However, considering the overall fast degradation of fenoxaprop-P-ethyl (AE F046360) in aerobic and anaerobic soils, a significant impact of irradiation on the overall dissipation of fenoxaprop-P-ethyl (AE F046360) in terrestrial systems is not expected at all.

Figure B.2.8.1-1: Proposed route of degradation of fenoxaprop-P-ethyl (AE F046360) in <u>aerobic</u> soil

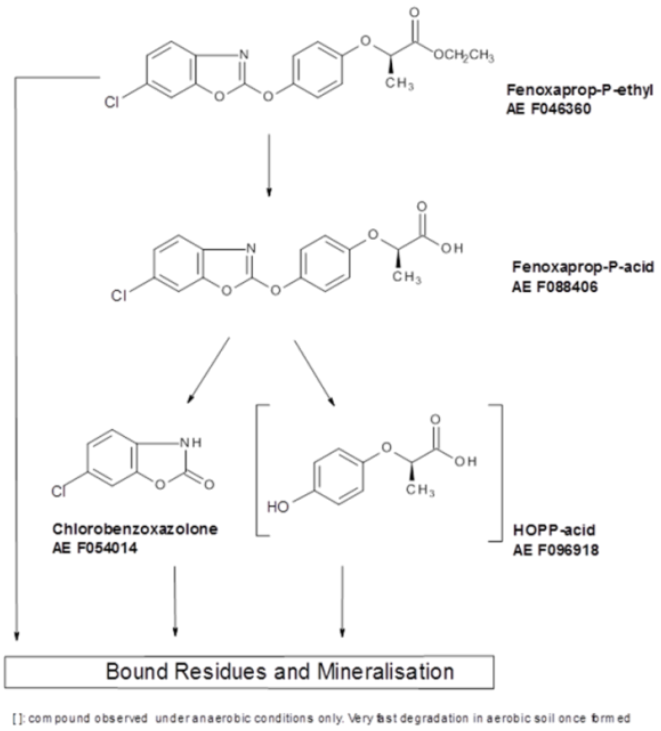


Figure B.2.8.1-2: Proposed route of degradation of fenoxaprop-P-ethyl (AE F046360) in <u>anaerobic</u> soil (2-(4-hydroxy-phenoxy)-propionic acid = HOPP acid (AE F096918))

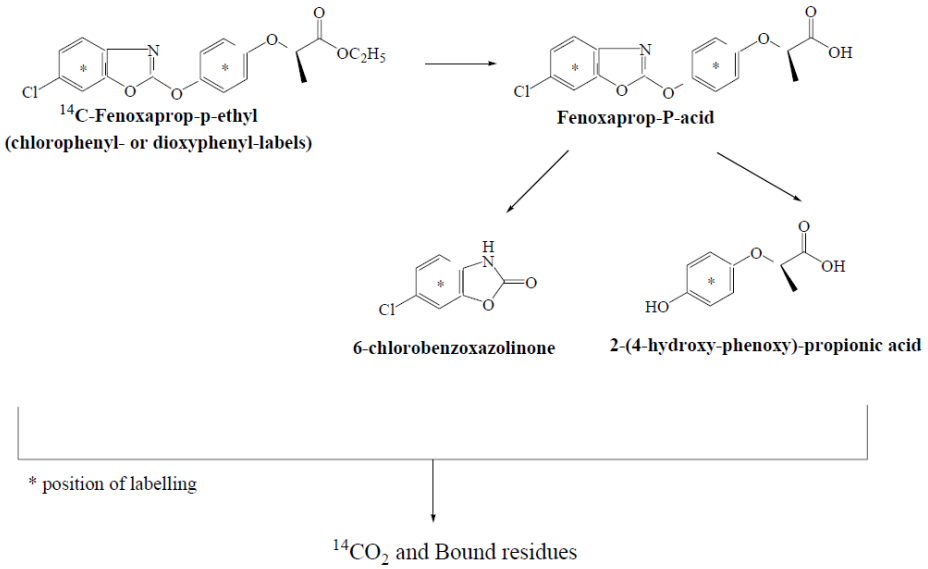


Table B.2.8.1-1: Summary on maximum occurrence (% AR) of identified and non-identified (unknown) metabolites in laboratory soil route studies conducted with fenoxaprop-P-ethyl (AE F046360) (metabolites shaded in grey require an exposure assessment in soil, groundwater and surface water)

Compound	Aerobic	Anaerobic	Soil photolysis
Fenoxaprop-P-acid (AE F088406)	85.8[(a)]	94.8[(a)]	no
Chlorobenzoxazolone (AE F054014)	19.1	7.5	6.8[(b)]
HOPP-acid (AE F096918)	no	74.1[(c)]	ni
Phenol metabolite (AE F040356)	1.2	2.2	ni
Unknowns	4.3	6.2[(d)]	6.4[(e)]

ni denotes not investigated
no denotes not observed (but investigated)
(a) Arithmetic mean of ClPh and Ph label applied to the same soil
(b) Racemic fenoxaprop-ethyl (AE F033171) applied (no study available with non-racemic fenoxaprop-P-ethyl (AE F046360)
(c) Racemic mixture (AE F020686) of HOPP-acid (AE F096918) observed after application of racemic fenoxaprop-ethyl (AE F033171); HOPP acid (AE F096918) max. 49.2 % of AR in one study with non-racemic fenoxaprop-P-ethyl (AE F046360) applied
(d) Metabolite fraction 'M8' exceeding 5 % AR at two consecutive sampling points (Voelkel, 2008a), other unknown metabolite fractions max. 5.4 % AR (at one sampling point only)
(e) At one sampling point only

The rate of degradation in soil of fenoxaprop-P-ethyl (AE F046360) and metabolites has been assessed in laboratory studies and is summarised in the tables below.

Table B.2.8.1-2 Summary on aerobic degradation rates for <u>fenoxaprop-P-ethyl (AE F046360)</u> in laboratory studies - <u>trigger & modelling endpoints</u>

Soil name	Soil type (USDA)	Label	*p*H ($CaCl_2$)	T (°C)	Water content (% MWHC)	*DegT 50* (d)	*DegT 90* (d)	*DegT50* (d) 20 °C, *p*F2	χ^2 err. (%)	Kinetic model	Reference
LS 2.2	Loamy sand	ClPh	5.8	22	40	0.35	1.2	0.33	12.7	SFO	Stumpf & Dambach (1988)
SL V	Sandy loam	ClPh	5.6	22	40	0.33	1.1	0.28	11.0	SFO	
SL 2	Silt loam	ClPh	5.2	22	40	0.25	3.0	0.70[(a)]	6.5	FOMC	
SL S	Sandy loam	ClPh	5.2	22	40	0.42	5.9	1.4[(a)]	7.7	FOMC	
Pikeville	Sandy loam	ClPh	5.2	20	26	0.32	7.0	1.2[(a)]	5.5	FOMC	Shepherd (2012)
Porterville	Loamy sand	ClPh	6.9	20	57	0.22	0.71	0.20	10.6	SFO	
Sanger	Sandy loam	ClPh	6.2	20	42	0.13	1.2	0.26[(a)]	2.4	FOMC	
Springfield	Silt loam	ClPh	6.6	20	74	0.07	0.24	0.07	7.3	SFO	
Pikeville	Sandy loam	Ph	5.2	20	26	0.35	5.2	0.86[(a)]	12.8	FOMC	Shepherd & Ripperger (2012)
Porterville	Loamy sand	Ph	6.9	20	57	0.14	1.0	0.27[(a)]	6.0	FOMC	
Sanger	Sandy loam	Ph	6.2	20	42	0.24	0.78	0.17	10.8	SFO	
Springfield	Silt loam	Ph	6.6	20	74	0.08	0.25	0.07	8.6	SFO	
				Maximum (n = 8)[(b)]		**0.42**	**5.9**	**-**		FOMC[(c)]	
				Geometric mean (n = 8)[(b)]		**-**	**-**	**0.36**		SFO	
				pH-dependency: y/n		**y[(d)]**					

(a) Based on non-normalized FOMC-DT90 divided by 3.32
(b) Different labels in Shepherd (2012) and Shepherd & Ripperger (2012) averaged (geometric mean) before averaging different soils or calculating maximum
(c) FOMC $\alpha = 0.771$, $\beta = 0.305$
(d) Refer to text below

Table B.2.8.1-3 Summary on aerobic degradation rates for <u>fenoxaprop-P-acid (AE F088406)</u> in laboratory studies - <u>trigger and modelling endpoints</u>

Soil name	Soil type (USDA)	Label	*p*H ($Ca-Cl_2$)	T (°C)	WC (% MWHC)	*DegT 50* (d)	*DegT 90* (d)	*ff* (-)	*DegT50* (d) 20 °C, *p*F2	χ^2 err. (%)	Kinetic model	Ref.
LS 2.2	Loamy sand	ClPh	5.8	22	40	12.6	41.7	0.95	12.1	13.4	$P_{SFO} \rightarrow M_{SFO}$	1)
SL V	Sandy loam	ClPh	5.6	22	40	4.3	14.1	0.90	3.5	5.0	$P_{SFO} \rightarrow M_{SFO}$	
SL 2	Silt loam	ClPh	5.2	22	40	3.0	9.8	0.66	2.3	6.0	$P_{FOMC} \rightarrow M_{SFO}$	
SL S	Sandy loam	ClPh	5.2	22	40	4.0	13.2	0.79	3.0	12.8	$P_{FOMC} \rightarrow M_{SFO}$	
Pikeville	Sandy loam	ClPh	5.2	20	26	4.5	14.9	0.76	2.5	10.0	$P_{FOMC} \rightarrow M_{SFO}$	2)

Porterville	Loamy sand	ClPh	6.9	20	57	16.7	55.4	0.93	15.5	2.7	P_{SFO}→M_{SFO}	
Sanger	Sandy loam	ClPh	6.2	20	42	10.0	33.2	0.93	7.3	5.9	P_{FOMC}→M_{SFO}	
Springfield	Silt loam	ClPh	6.6	20	74	8.1	26.9	0.88	7.5	6.4	P_{SFO}→M_{SFO}	
Pikeville	Sandy loam	Ph	5.2	20	26	4.4	14.7	0.84	2.4	10.5	P_{FOMC}→M_{SFO}	3)
Porterville	Loamy sand	Ph	6.9	20	57	16.2	54.0	0.95	15.0	1.5	P_{FOMC}→M_{SFO}	
Sanger	Sandy loam	Ph	6.2	20	42	7.7	25.5	0.90	5.6	6.7	P_{SFO}→M_{SFO}	
Springfield	Silt loam	Ph	6.6	20	74	4.5	14.9	0.86	4.2	10.9	P_{SFO}→M_{SFO}	
					Maximum (n = 8)[(a)]	**16.4**	**54.7**	**-**	**15.2**	**-**		
					Geometric mean (n = 8)[(a)]	**-**	**-**	**-**	**5.0**	**-**		
					Arithmetic mean (n = 8)[(b)]	**-**	**-**	**0.85**	**-**	**-**		
					***p*H-dependency: y/n**	**y[(c)]**						

Ref. 1) Stumpf & Dambach (1988)
Ref. 2) Shepherd (2012)
Ref. 3) Shepherd & Ripperger (2012)
(a) Different labels in Shepherd (2012) and Shepherd & Ripperger averaged (geometric mean) before averaging different soils
(b) Different labels in Shepherd (2012) and Shepherd & Ripperger averaged (arithmetic mean) before averaging different soils
(c) Refer to text below.

Table B.2.8.1-4 Summary on aerobic degradation rates for chlorobenzoxazolone (AE F054014) in laboratory studies - trigger and modelling endpoints

Soil name	Soil type (USDA)	Label	*p*H ($CaCl_2$)	T (°C)	WC (% MWHC)	*DegT 50* (d)	*DegT 90* (d)	*ff* (-)	*DegT50* (d) 20 °C, *p*F2	χ^2 err. (%)	Kinetic model	Ref.
LS 2.2	Loamy sand	ClPh	5.8	22	40	7.7	25.4	na	7.3	17.0	SFO[(a)]	1)
SL V	Sandy loam	ClPh	5.6	22	40	23.8	79.2	na	23.8	24.3	SFO[(a)]	
SL 2	Silt loam	ClPh	5.2	22	40	17.9	59.6	na	14.0	6.0	SFO[(a)]	
SL S	Sandy loam	ClPh	5.2	22	40	8.5	28.1	na	6.5	20.0	SFO[(a)]	
Pikeville	Sandy loam	ClPh	5.2	20	26	56.6	188	na	31.0	4.4	SFO[(a)]	2)
Porterville	Loamy sand	ClPh	6.9	20	57	Low occurrence (< 2 % AR)						
Sanger	Sandy loam	ClPh	6.2	20	42	Low occurrence (< 5 % AR)						
Springfield	Silt loam	ClPh	6.6	20	74	Low occurrence (< 3 % AR)						
					Maximum (n = 5)	**56.6**	**188**	**-**	**-**			
					Geometric mean (n = 5)	**-**	**-**	**-**	**13.7**			
					Arithmetic mean (n = 5)	**-**	**-**	**na**	**-**			
					***p*H-dependency: y/n**	**n[(b)]**						

(a) Decline fit
(b) No *p*H dependent degradation can be deduced from the available degradation rate data set. However, OECD 106 batch studies indicate that chlorobenzoxazolone is less stable under more alkaline conditions (refer to text below)
Ref. 1) Stumpf & Dambach (1988)
Ref. 2) Shepherd & Ripperger (2012)

Table B.2.8.1-5 Summary on aerobic degradation rates for HOPP-acid (AE F096918) in laboratory studies - trigger and modelling endpoints

Soil name	Soil type (USDA)	Label	*p*H ($CaCl_2$)	T (°C)	WC (% MWHC)	*DegT 50* (d)	*DegT 90* (d)	*ff* (-)	*DegT50* (d) 20 °C, pF2	χ^2 err. (%)	Kinetic model	Ref.
Farditch	Loam	Ph	5.8	20	45	0.01	0.03	na	0.01	8.5	SFO[(a)]	1)
Longwoods	Sandy loam	Ph	7.4	20	24	0.01	0.03	na	0.01	4.1	SFO[(a)]	
Lockington	Sandy clay loam	Ph	5.7	20	41	0.01	0.03	na	0.01	3.9	SFO[(a)]	
Wurmwiese	Loam	Ph	5.2	20	34	0.01	0.03	na	0.01	0.3	SFO[(a)]	2)
AXXa	Sandy loam	Ph	6.9	20	29	0.01	0.04	na	0.01	0.9	SFO[(a)]	
Hoefchen	Silt loam	Ph	6.3	20	32	0.01	0.04	na	0.01	0.3	SFO[(a)]	
Dollendorf	Clay loam	Ph	7.3	20	45	0.01	0.04	na	0.01	0.5	SFO[(a)]	
					Maximum (n = 7)	**0.01**	**0.04**	**-**	**-**			
					Geometric mean (n = 7)	**-**	**-**	**-**	**0.01**			
					Arithmetic mean (n = 7)	**-**	**-**	**na**	**-**			
					***p*H-dependency: y/n**	**n**						

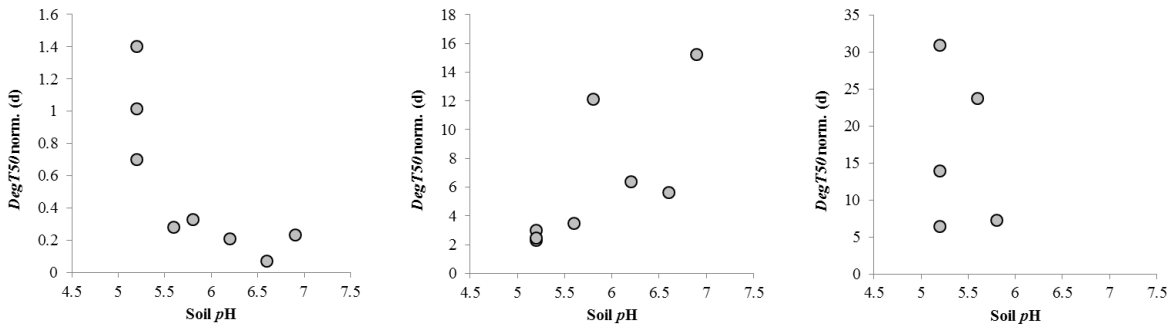
na denotes not applicable
(a) Metabolite applied
Ref. 1) Fitzmaurice (2010)
Ref. 2) Stroech & Junge (2014)

The RMS AT notes that with the exception of HOPP-acid (AE F096918) lab degradation studies do not cover alkaline soils at all. This is considered particularly critical in case of fenoxaprop-P-acid (AE F088406) as degradation rates available for acidic and neutral soils (see figure below) as well as data from batch sorption studies conducted with fenoxaprop-P-acid (AE F088406) (Rupprecht, 1999; Voelkel, 2008a) indicate that fenoxaprop-P-acid (AE F088406) is more stable to degradation in alkaline soils. Unless degradation rates are available for alkaline soils as well, the RMS AT therefore recommends applying the worst case *DegT50* of fenoxaprop-P-acid (AE F088406) observed in acidic and neutral soils in the environmental exposure assessment for conservative reasons.

Degradation rates available for the parent fenoxaprop-P-ethyl (AE F046360) in acidic and neutral soils indicate some *p*H-dependent degradation as well, with possibly faster degradation in more alkaline soils (see figure below). This observation is somewhat in contrast to results from (abiotic) hydrolysis, where fenoxaprop-P-ethyl (AE F046360) was most stable under neutral conditions (*p*H 7). As degradation of fenoxaprop-P-ethyl (AE F046360) is fast in any case (*DegT50* ≤ 1.4 days) the RMS AT does not consider it necessary applying a more conservative approach in this case.

OECD 106 batch experiments conducted with chlorobenzoxazolone (AE F054014) (Allan, 2004; Voelkel, 2008b) indicate that chlorobenzoxazolone (AE F054014) is less stable under alkaline soil conditions. Thus degradation rates available for acidic soils only (*p*H in $CaCl_2$ ≤ 5.8) are considered sufficiently conservative for the groundwater and aquatic exposure assessment.

Degradation rates (at reference conditions) in relation to the soil *p*H are given in Figure B.8.1.2.1.5-1.



Fenoxaprop-P-ethyl (AE F046360) **Fenoxaprop-P-acid (AE F088406)** **Chlorobenzoxazolone (AE F054014)**

Figure B.2.8.1-3: **Normalized *DegT50 vs* soil *p*H for fenoxaprop-P-ethyl (AE F046360) and metabolites (different labels from Shepherd, 2012, and Shepherd & Ripperger, 2012, averaged)**

The rate of degradation of fenoxaprop-P-ethyl (AE F046360) in **anaerobic soil** is rapid as well (*DegT50* of 0.35 and 0.37 days in two soils). Degradation of the herbicidal active metabolite fenoxaprop-P-acid (AE F088406) is somewhat lower under anaerobic conditions compared to aerobic conditions (*DegT50* of 35.7 and 43.7 days in two soils).

The rate of degradation of racemic fenoxaprop-ethyl (AE F033171), used as a surrogate for fenoxaprop-P-ethyl (AE F046360), **under conditions of photolysis** on a (sterile) soil surface is relatively slow (*DegT50* of 62.5 days under environmental conditions, 52 °N). On overall, photolysis is not considered to significantly contribute to the overall dissipation of fenoxaprop-P-ethyl (AE F046360) in terrestrial systems.

Field dissipation studies with formulated fenoxaprop-P-ethyl (AE F046360) were conducted in the US (two studies) and in Canada (two studies, one of them with repeated application over 3 years). Results from the Canadian field trials are expressed on basis of parent equivalents only, thus these two studies are considered non-reliable. In the two studies conducted in the US (one peanut and one soybean field trial) amounts of fenoxaprop-P-ethyl (AE F046360) in soil close to the LOQ do not allow calculating dissipation half-lives for the parent. Dissipation half-lives for fenoxaprop-P-acid (AE F088406) re-calculated by the RMS AT were 8.8 days in Wilson County, NC (peanut field) and 7.2 days in Iowa (soybeans), thus well in line with observations made in the laboratory studies. Results from these two field studies are considered supplemental information only.

The **adsorption** of fenoxaprop-P-ethyl (AE F046360), fenoxaprop-P-acid (AE F088406) and chlorobenzoxazolone (AE F054014) in soil has been assessed in OECD guideline 106 batch studies and is summarised in the tables below. Batch sorption studies with HOPP-acid (AE F096918) failed due to the instability of HOPP-acid (AE F096918) observed in these test systems.

Due to the instability of the test items as well as significant formation of non-extractable residues (NER) observed in batch sorption studies conducted with fenoxaprop-P-ethyl (AE F046360), fenoxaprop-P-acid (AE F088406) and chlorobenzoxazolone (AE F054014) parental mass balances were in most cases below 90 % recommended by OECD guideline 106 in order to allow the *indirect* method to be applied for the determination of Freundlich isotherm constants. Despite of the low mass balance, advanced Freundlich isotherm experiments were conducted by the study authors applying the *indirect* method throughout, thus calculating the mass of test item adsorbed on basis of the test item in the liquid phase only. In view of insufficient test item mass balance the RMS AT considers the obtained results on Freundlich isotherms obtained in these experiments non-reliable.

It may be noted that formation of NER in OECD 106 batch experiments with fenoxaprop-P-ethyl (AE F046360) and its main metabolites is not unexpected to occur, as NER in soil degradation experiments conducted with fenoxaprop-P-ethyl (AE F046360) were generally high accounting for up to 17.3 % AR already one day after application. Applying the *indirect* method, NER are implicitly assumed to equally contribute to the equilibrium sorption, which is not defendable from a scientific point of view.

In contrast to the advanced tests (Freundlich isotherm experiments), the RMS AT considers results from the preliminary experiments (usually conducted at the highest test concentration, only) applying the *direct* method adequate to calculate distribution coefficients (K_d/K_{oc}) on basis of the test item recovered (i.e. in the liquid phase and in the soil extract). As these results are based on one concertation only, linear sorption ($1/n = 1$) is assumed by default.

In Reynolds (1993), investigating fenoxaprop-P-ethyl (AE F046360), fenoxaprop-P-acid (AE F088406) and chlorobenzoxazolone (AE F054014), no pre-equilibrium phase (i.e. shaking of soil with pure $CaCl_2$ solution overnight) was accounted for. In principle this invalidates this study with respect to recommendations given in OECD guideline 106. However, soil adsorption tests according to OECD guideline 106 with fenoxaprop-P-ethyl (AE F046360) will always be somehow limited due to the instability of fenoxaprop-P-ethyl (AE F046360) in these test systems. In this respect, the RMS AT considers results obtained in Reynolds (1993) sufficiently robust to at least give an estimate of the sorption coefficient of fenoxaprop-P-ethyl (AE F046360) in soils even without pre-equilibrium phase. However, results of Reynolds (1993) are not considered further in case of fenoxaprop-P-acid (AE F088406) and chlorobenzoxazolone (AE F054014) as dedicated batch sorption studies with an adequate pre-equilibration phase are available for these two metabolites. It may be added, that despite missing pre-equilibrium phase, results from Reynolds (1993) are nevertheless well in line with results from valid soil sorption studies.

Table B.2.8.1-6 Summary on soil adsorption of fenoxaprop-P-ethyl (AE F046360)

Soil name	Soil type (USDA)	OC (%)	*p*H[(a)]	K_d (L/kg)	K_{oc} (L/kg)	K_f (L/kg)	K_{foc} (L/kg)	1/*n* (-)	Reference
Arizona	Clay	0.23	7.6	12.8	5419	na	na	1.0[(b)]	Reynolds (1993)[(c)]
Mississippi	Silty clay loam	0.81	6.5	212	26207	na	na	1.0[(b)]	
Maryland	Sandy loam	2.55	6.4	443	17352	na	na	1.0[(b)]	
Michigan	Clay loam	2.65	6.8	176	6667	na	na	1.0[(b)]	
		Arithmetic mean (n = 4)		-	-	-	-	**1.0**	
		Geometric mean (n = 4)		**121**	**11322**	-	-	-	
		pH-dependency: y/n		n					

na denotes not applicable (one test concentration only); note that results on Freundlich isotherms are not considered reliable by the RMS AT
(a) Matrix not specified
(b) Default assuming linear adsorption (one test concentration only)
(c) This sorption study was conducted without a pre-equilibration phase thus leaving some uncertainty regarding the reliability of the obtained K_d/K_{oc} values

Table B.2.8.1-7 Summary on soil adsorption of fenoxaprop-P-acid (AE F088406)

Soil name	Soil type (USDA)	OC (%)	*p*H ($CaCl_2$)	K_d (L/kg)	K_{oc} (L/kg)	K_f (L/kg)	K_{foc} (L/kg)	1/*n* (-)	Reference
EFS-6	Sandy loam	2.64	7.3	6.91	262	na	na	1.0[a]	Rupprecht (1999)
EFS-8	Sand	0.53	4.7	2.32	438	na	na	1.0[a]	
EFS-16	Silty clay loam	1.67	7.1	2.58	154	na	na	1.0[a]	
EFS-24	Sand	0.81	6.4	1.20	148	na	na	1.0[a]	
EFS-29	Loam	1.43	7.5	3.95	276	na	na	1.0[a]	
EFS-38	Clay loam	1.99	7.4	3.14	158	na	na	1.0[a]	
EFS-54[b]	Sandy loam	2.07	4.5	21.9	1058	na	na	1.0[a]	
	Arithmetic mean (all soil, n = 7)			**-**	**-**	**-**	**-**	**1.0**	
	Geometric mean (all soil, n = 7)			**3.89**	**276**	**-**	**-**	**-**	
	Geometric mean (neutral and alkaline soils, n = 5)			**3.05**	**192**				
	pH-dependency: y/n			y[c]					

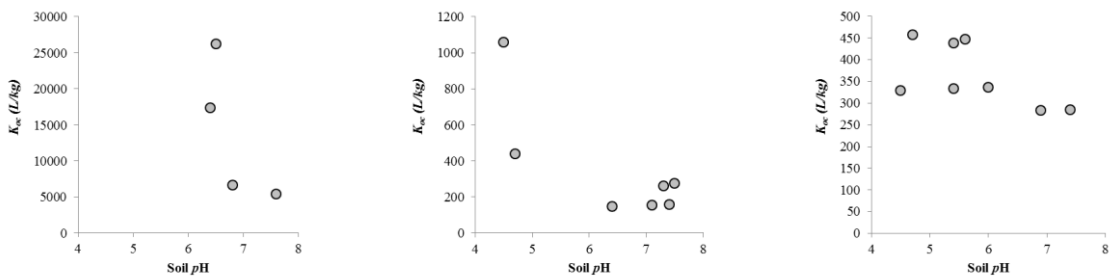
na denotes not applicable (one test concentration only); note that results on Freundlich isotherms are not considered reliable by the RMS AT
(a) Default assuming linear adsorption (one test concentration only)
(b) Sediment
(c) Refer to text below

Table B.2.8.1-8 Summary on soil adsorption of chlorobenzoxazolone (AE F054014)

Soil name	Soil type (USDA)	OC (%)	*p*H ($CaCl_2$)	K_d (L/kg)	K_{oc} (L/kg)	K_f (L/kg)	K_{foc} (L/kg)	1/*n* (-)	Reference
EFS-8	Loamy sand	0.53	4.7	2.43	458	na	na	1.0[a]	Allan (2004)
EFS-25	Sandy loam	1.84	5.4	6.12	333	na	na	1.0[a]	
EFS-35	Silty loam	1.52	5.4	6.66	438	na	na	1.0[a]	
EFS-54[b]	Sandy loam	2.07	4.5	6.84	330	na	na	1.0[a]	
EFS-66	Loamy sand	1.95	6.0	6.55	336	na	na	1.0[a]	
Attenschwiller	Silt loam	1.10	7.4	3.26	285	na	na	1.0[a]	Voelkel (2008b)
Speyer 6S	Clay	1.90	6.9	6.59	284	na	na	1.0[a]	
Speyer 2.2	Loamy sand	2.36	5.6	10.8	448	na	na	1.0[a]	
	Arithmetic mean (n = 8)			**-**	**-**	**-**		**1.0**	
	Geometric mean (n = 8)			**5.64**	**358**	**-**	**-**	**-**	
	pH-dependency: y/n				n				

na denotes not applicable (one test concentration only), note that results on Freundlich isotherms are not considered reliable by the RMS AT
(a) Default assuming linear adsorption (one test concentration only)
(b) Sediment

The RMS AT investigated a possible relationship between sorption coefficient (K_{oc}) and soil *p*H for fenoxaprop-P-ethyl (AE F046360), fenoxaprop-P-acid (AE F088406) and chlorobenzoxazolone (AE F054014) more in detail (Figure B.8.1.4.4-1). No such relationship was observed for fenoxaprop-P-ethyl (AE F046360) and chlorobenzoxazolone (AE F054014). In case of fenoxaprop-P-acid (AE F088406), sorption in the two fairly acidic soils (*p*H ≤ 4.7) was higher in comparison to the more neutral and alkaline soils. In view of fenoxaprop-P-acid (AE F088406), being an organic acid, *p*H-dependent sorption may *a priori* be expected (depending on the protonation status). For reasons of conservativeness, the RMS AT therefore recommends omitting sorption results of the two rather acidic soils for calculating the average K_{oc} of fenoxaprop-P-acid (AE F088406) to be used in the exposure assessment.



Fenoxaprop-P-ethyl (AE F046360) **Fenoxaprop-P-acid (AE F088406)** **Chlorobenzoxazolone (AE F054014)**

Figure B.2.8.1-4: Soil sorption (K_{oc}) *vs* soil *p*H for fenoxaprop-P-ethyl (AE F046360) and metabolites

Data resulting from two **soil column leaching** studies are regarded as qualitative information on mobility in soil only, broadly reflecting the behaviour of fenoxaprop-P-ethyl (AE F046360) and its metabolites observed in dedicated soil degradation and batch sorption experiments.

2.8.2. Summary of fate and behaviour in water and sediment

Abiotic hydrolysis of fenoxaprop-P-ethyl (AE F046360) was studies in several studies. Although test conditions are highly standardized (following OECD guideline 111), hydrolysis rates obtained and metabolite formation observed were somehow different in these studies, particularly at *p*H 7. On overall, fenoxaprop-P-ethyl (AE F046360) shows significant degradation under conditions of abiotic hydrolysis depending on the *p*H and, probably, on the buffer used in the hydrolysis experiment. As already noted in OECD guideline 111, the buffer system used may influence the rate of hydrolysis. At *p*H 4 and 25 °C, hydrolysis half-life of fenoxaprop-P-ethyl (AE F046360) was in a range from 2.1 - 4.3 days (three studies). At *p*H 5 and 25 °C hydrolysis half-life was in a range from 19.1 - 34.0 days (two studies). At *p*H 9 and 25 °C hydrolysis half-life of fenoxaprop-P-ethyl (AE F046360) was in a range from 0.5 - 0.9 days (three studies). At *p*H 7, however, results on hydrolysis are quite inconsistent with half-lives in a range from 8.6 - 111 days (three studies applying either phosphate or TRIS buffer). On request by the RMS AT, the notifier could not give a sound explanation for inconsistent results obtained under conditions of hydrolysis, particularly at *p*H 7.

In a dedicated hydrolysis study with unlabelled fenoxaprop-P-acid (AE F088406) half-lives at 25 °C were 27.4, 189 and 35 days at *p*H 5, 7 and 9, respectively (interpolated from experiments conducted at 50, 55 and 65 °C). Additional hydrolysis half-lives of fenoxaprop-P-acid (AE F088406) obtained in parent dosed studies (pathway fits) conducted at 25 °C were 2.5 days at *p*H 4 and 143 days at *p*H 9 (chlorophenyl label only).

At *p*H 4 (25 °C), hydrolysis of fenoxaprop-P-ethyl (AE F046360) is considered to be mainly driven by cleavage of the parent molecule at the central ether bond releasing chlorobenzoxazolone (AE F054014, max. 102.4 % AR) and its counterpart AE F029062 (max. 101.2 % AR). HOPP-acid (AE F029062, max. 1.4 % AR), the de-alkylated form of AE F029062, was hardly formed at this *p*H value. In one of the three hydrolysis studies fenoxaprop-P-acid (AE F088406) was found in significant amounts as well (max. 22.2 % AR) indicating that de-alkylation of fenoxaprop-P-ethyl (AE F046360) may also occur at this *p*H value under certain test conditions.

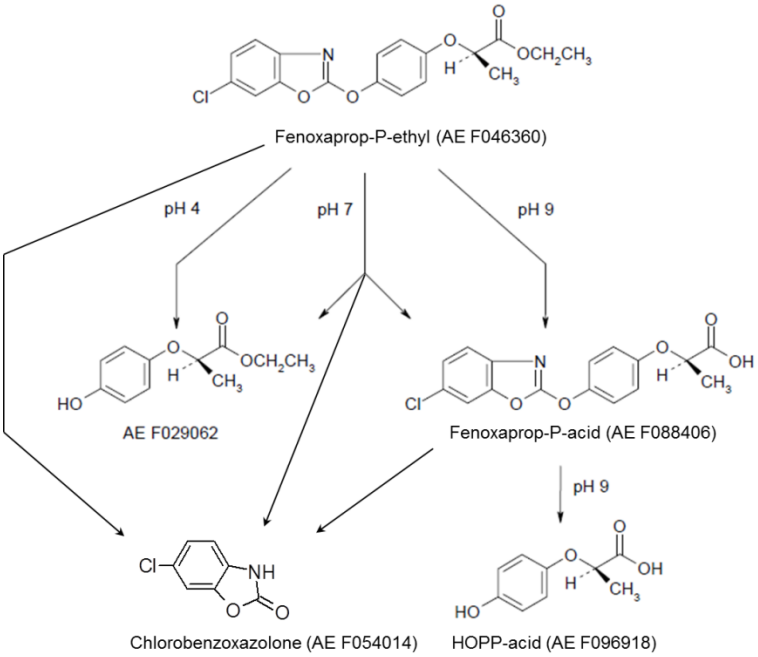
At *p*H 7 (25 °C), hydrolysis of fenoxaprop-P-ethyl (AE F046360) is considered to be governed by both, de-alkylation of the parent releasing fenoxaprop-P-acid (AE F0488406, max. 84.4 % AR) and by cleavage of the parent at the central ether bond releasing chlorobenzoxazolone (AE F054014, max. 27.9 % AR) and AE F029062 (max. 3.2 % AR). HOPP-acid (AE F096918) was not detected at this *p*H value indicating that fenoxaprop-P-acid (AE F088406) and AE F029062 are fairly stable under conditions of abiotic hydrolysis at *p*H 7.

At *p*H 9 (25 °C), de-alkylation of fenoxaprop-P-ethyl (AE F046360) releasing fenoxaprop-P-acid (AE F088406, max. 95.9 % AR) is considered the main driving force for hydrolysis. Fenoxaprop-P-acid (AE F088406) is further degraded by cleavage at the central ether bond to release chlorobenzoxazolone (AE F054014, max. 24.5 % AR) and HOPP-acid (AE F096918, max. 14.2 % AR). Formation of AE F029062 (max. 2.1 % AR) was insignificant at *p*H 9.

In two dedicated studies chlorobenzoxazolone (AE F054014) was shown to be stable at conditions of abiotic hydrolysis at *p*H 5, 7 and 9.

Metabolite AE F029062, a cleavage product of fenoxaprop-P-ethyl (AE F046360) under conditions of abiotic hydrolysis observed in significant amounts at *p*H 4 and *p*H 7 was neither observed in aerobic degradation studies in surface water nor in water/sediment studies. Thus, metabolite AE F029062 is considered not to occur in biotic aquatic systems.

Figure B.2.7.3.2-1: Proposed route of degradation of fenoxaprop-P-ethyl (AE F046360) under conditions of abiotic hydrolysis



Under conditions of **direct photochemical degradation** conducted in sterile buffer solutions at *p*H 5 (chlorophenyl label) and *p*H 7 (chlorophenyl and phenoxy label) fenoxaprop-P-ethyl (AE F046360) degraded into numerous metabolite fractions, none of them exceeding 10 % AR with the exception of fenoxaprop-P-ethyl-dechloro-hydroxy (BCS-CY11271) observed at max. 17.7 % AR at *p*H 7 in one study only. Metabolites observed at low levels at *p*H 7 were fenoxaprop-P-acid (AE F088406, max. 2.4 % AR), chlorobenzoxazolone (AE F054014, max. 1.8 % AR), HOPP-acid (AE F096918, max. 2.1 % AR), phenol metabolite (AE F040356, max. 5.9 % AR), AE F029062 (max. 3.3 % AR) and AE F031886 (max. 1.4 % AR). Metabolites identified at *p*H 5 were chlorobenzoxazolone (AE F054014, max. 6.4 % AR), phenol metabolite (AE F040356, max. 4.2 % AR) and hydroxybenzoxazolone (AE 0316854, max. 5.5 % AR). It is believed that unidentified, highly polar metabolite fractions formed under conditions of direct photochemical degradation mainly consist of short-chain aliphatic carboxylic acids, two of them definitely identified as malonic acid and succinic acid. Amounts of CO_2 formed at study end were 6.2 % AR (chlorophenyl label, 7 days) at *p*H 5, and 6.6 % AR (phenoxy label, 1.66 days) and 0.8 % AR (chlorophenyl label, 7 days) at *p*H 7, respectively.

Experimental net photolysis half-lives of fenoxaprop-P-ethyl (AE F046360) obtained were 14.6 days at *p*H 5, and 0.3 and 17.8 days, respectively, for the phenoxy and chlorophenyl labelled parent at *p*H 7. On request by the RMS AT, the notifier could not give a sound explanation for the deviating photolysis results of the two labels observed at *p*H 7 in two separate studies (and different laboratories). Related to natural sunlight conditions this gives a photolytic half-life of 85.7 days at *p*H 5 in Schwab (1993), and 0.7 and 17.8 days, respectively, at *p*H 7 (Fitzmaurice, 2008; Fletcher & Gilbert, 2008). Keeping in mind the overall fast degradation of fenoxaprop-P-ethyl (AE F046360) in non-irritated aquatic systems, photolysis is considered of minor importance in the overall dissipation of fenoxaprop-P-ethyl (AE F046360) in the aquatic environment.

Two photolysis studies (both *p*H 7) were also conducted with chlorobenzoxazolone (AE F054014). Numerous unknown metabolites were observed in both studies at significant amounts, beside CO_2 (max. 38.0 % AR at study end) and hydroxybenzoxazolone (AE 0316854, max. 26.6 % AR), considered to at least partly comprise short-chain aliphatic carboxylic compounds. Experimental photolysis half-lives values of chlorobenzoxazolone (AE F054014) obtained in these two studies were 1.3 and 0.11 days, corresponding to 7.0 days in summer (40 °N) in one study and 0.25 days of natural sunlight at 30 - 40 °N in the other study. Direct photolysis processes may therefore contribute to the elimination of chlorobenzoxazolone (AE F054014) from the aquatic environment (chlorobenzoxazolone (AE F054014) is considered rather persistent in aquatic systems under non-irradiated conditions).

The quantum yield (Φ) of fenoxaprop-P-ethyl (AE F046360) was determined in two studies at two different *p*H values, with 5.11×10^{-6} at a *p*H 5 in the first study (Schwab, 1993) and 0.04 at a *p*H 7 in the second study (Fletcher & Gilbert, 2008). It may be noted that in Fletcher & Gilbert (2008) no actinometer was applied, instead the quantum yield was directly calculated on basis of the absorbance (extinction coefficient) measured from 290 to 800 nm (as described in OECD guideline 316).

The quantum yield of the metabolite chlorobenzoxazolone (AE F054014) was determined in two studies as well (both studies conducted at *p*H 7), with Φ = 0.00565 in the first (Burgener, 1999) and 0.151 in the second study (Adam, 2008). There is no obvious reason for the difference observed, except that the actinometer used in both studies was different.

Indirect photochemical degradation of fenoxaprop-P-ethyl (AE F046360) was investigated in one study in irradiated non-sterile surface water (*p*H 9, chlorophenyl label). Major metabolites observed were fenoxaprop-P-acid (AE F088406, max. 56.6 % AR) and highly polar peaks accounting for max. 41.5 % AR in total, likely consisting of short-chain aliphatic carboxylic acids. As no dedicated experiment/analysis was performed to further elucidate these polar fractions, it remains unclear whether individual substances covered by these polar fractions exceed 10 % of AR on individual basis. Chlorobenzoxazolone (AE F054014) and the phenol metabolite (AE F040356) were observed at 3.5 and 4.3 % AR, respectively. CO_2 at study end (144 hrs) accounted for 6.8 % AR. Experimental *DT50* of fenoxaprop-P-ethyl (AE F046360) under conditions of indirect photolysis in surface water (*p*H 9) was 0.7 days. The impact of indirect photochemical degradation on the dissipation of fenoxaprop-P-ethyl (AE F046360) at *p*H 9 is considered negligible as hydrolysis *DT50* in non-irradiated (dark samples) was already 0.3 days.

Fenoxaprop-P-ethyl (AE F046360) is considered **not ready biodegradable** under the conditions of a CO_2 evolution (Modified Sturm) test.

In two **aerobic mineralisation studies in surface water** (chlorophenyl and phenoxy label, *p*H 8.0 and 9.2, two dose levels) fenoxaprop-P-ethyl (AE F046360) was instantaneously de-alkylated to form fenoxaprop-P-acid (AE F088406, max. 101.4 % AR, low dose). Fenoxaprop-P-acid (AE F088406) was further degraded by cleavage at the central ether bond to release chlorobenzoxazolone (AE F054014, max. 36.8 % AR) and HOPP-acid (AE 096918, max. 21.0 % AR). No other metabolite fractions were found above 5 % AR. Obtained *DT50* values (low dose) for fenoxaprop-P-ethyl (AE F046360) under conditions of the test system were 0.4 and 0.2 days at *p*H 8.0 (chlorophenyl label) and *p*H 9.2 (phenoxy label), respectively. *DT50* values (low dose) for fenoxaprop-P-acid (AE F088406) were 107 days at *p*H 8 and 39.4 days at *p*H 9.2. Amounts of CO_2 formed at study end (62 days, low dose) were negligible in case of the chlorophenyl label but 14.1 % AR for the phenoxy label.

The fate and behaviour of fenoxaprop-P-ethyl (AE F046360) in **aerobic water/sediment** was investigated in total eight water/sediment systems (four studies) partly applying both chlorophenyl and phenoxy labelled parent (*p*H in water from 6.6 - 8.3, in the sediment ($CaCl_2$) from 4.4 - 7.9). Similar to observations made in the aerobic mineralisation studies in surface water, fenoxaprop-P-ethyl (AE F046360) was rapidly de-alkylated in water/sediment systems to release fenoxaprop-P-acid (AE F088406, max. 97.2 % in the total system), which was further degraded by cleavage of the central ether bond to release chlorobenzoxazolone (AE F054014, max. 8.5 %) and HOPP-acid (AE F096918, max. 26.3 % AR). In addition, the phenol metabolite (AE F040356) was formed at maximum levels of 13.1 % AR. In Tarara (2000), an unknown metabolite fraction called 'U-1' exceeded 5 % of AR in more than two consecutive sampling points (maximum 6.0 % AR), thus formally triggering identification and exposure assessment according to Regulation (EU) No 283/2013. However, due to its distinct polar character in chromatography, 'U-1' is not regarded as one single compound. No other metabolite fraction exceeded 5 % AR in the total system at more than one sampling point in any of the studies. Formation of CO_2 was depending on the label investigated and was in the range from 13.8 - 67.9 % AR in studies covering approx. 120 days (three studies) and in the range from 0.9 - 36.6 % AR in one study investigating a 28-days period only. As already observed in soil degradation studies formation of non-extractable residues after application of fenoxaprop-P-ethyl (AE F046360) in water/sediment systems was significant as well reaching max. 67.7 % AR in the 120-days studies and max. 66.1 % AR in the 28-days study. Similar to formation of CO_2, formation of NER depends on the label applied (higher amounts of NER observed with the chlorophenyl label).

The overall degradation pathway of fenoxaprop-P-ethyl (AE F046360) observed in one **anaerobic water/sediment** system at 20 and 7 °C (Voelkel, 2004) was similar to that observed under aerobic conditions. Fenoxaprop-P-ethyl (AE F046360) rapidly degraded under anaerobic conditions as well releasing fenoxaprop-P-acid (AE F088406, max. 100.9 % AR at 20 °C), which further degraded to chlorobenzoxazolone (AE F054014,

max. 2.8 % AR at 20 °C), the phenol metabolite (AE F040256, max. 5.5 % AR) and HOPP-acid (AE F096918, max. 42.0 % AR). It is noted that amounts of HOPP-acid (AE F096918) in this study refer to racemic HOPP-acid (AE F020686) measured after application of racemic fenoxaprop-ethyl (AE F033171). Due to anaerobic conditions applied this study is considered as supplemental information only.

Figure B.2.7.3.2-2: Proposed route of degradation of fenoxaprop-P-ethyl (AE F046360) in aquatic systems

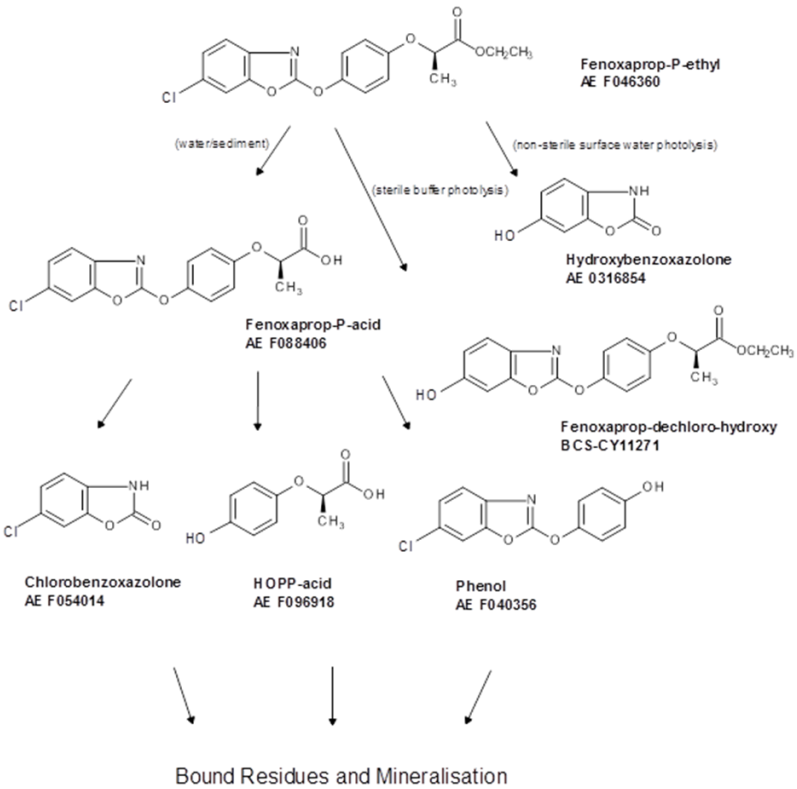


Table B.2.8.2-1 Summary on maximum occurrence (% AR) of identified and non-identified (unknown) metabolites in aquatic laboratory studies conducted with fenoxaprop-P-ethyl (AE F046360) (metabolites shaded in grey require an exposure assessment in surface water)

Compound	Aquatic hydrolysis (20-25 °C)	Direct photolytic degra-dation	Indirect photolytic degra-dation	Aerobic minera-lisation in surface water (low dose)	Water/sediment		
					Water phase	Sed. phase	Total system
Fenoxaprop-P-ethyl (AE F046360)	na	na	na	na	na	34.3[(a)]	na
Fenoxaprop-P-acid (AE F088406)	95.9	2.4	56.6	101.4	97.2	47.9[(a)]	97.2
Chlorobenzoxazolone (AE F054014)	102.4	7.1	3.5	36.8	6.7	8.5	8.5
Phenol metabolite (AE F040356)	-	5.9	4.3	-	-	13.1	13.1
HOPP acid (AE F096918)	14.2	2.1	-	21.0	22.9	3.4	26.3[(b)]
Fenoxaprop-P-ethyl-dechloro-hydroxy (BCS-CY11271)	-	17.7	-	-	-	-	-
Hydroxybenzoxazolone (AE 0316854)	-	5.5	-	-	-	-	-
AE F029062	101.2	3.3	-	-	-	-	-
AE F031886	-	1.4	-	-	-	-	-
AE F064124	1.0	-	-	-	-	-	-
Unknowns	8.9	11.4[(c)]	41.5[(d)]	4.8	ni	ni	6.0[(e)]

ni denotes not investigated by the RMS AT
(a) Arithmetic mean of Ph and ClPh label applied to the same water/sediment system
(b) 42.0 % AR in an anaerobic water/sediment study (measured as racemic HOPP-acid (AE F020686) following application of racemic fenoxaprop-ethyl (AE F033171))

(c) Highly polar fraction M1 observed in buffer solution (*p*H 5) considered to mainly comprising aliphatic short chain carboxylic acids (< 10 % on individual basis)
(d) Sum of highly polar fractions 'M1' (18.6 % AR) and 'M2' (22.9 % AR) observed in irradiated surface water (*p*H 9) considered to mainly comprising aliphatic short chain carboxylic acids. Maximum amounts on individual basis unknown.
(e) Unknown metabolite fraction 'U-1' (above 5 % AR at two consecutive sampling points), considered to be represent multiple polar components; refer to text above

The rate of degradation/dissipation of fenoxaprop-P-ethyl (AE F046360) and its metabolites in laboratory aquatic systems is summarised in the tables below.

Table B.2.8.2-2 Summary on degradation of fenoxaprop-P-ethyl (AE F046360) under conditions of abiotic aquatic hydrolysis at 25 °C

*p*H	Label	Buffer	*DT50* (d)	*DT90* (d)	χ^2 error (%)	Kinetic model	Reference
4	ClPh	Citrate	2.8	9.4	5.0	SFO	Van der Gaauw, 2002
	Ph	Acetate	4.3	14.3	2.3	SFO	Fitzmaurice, 2008
	ClPh	Citrate	2.1	6.8	ns	SFO	Adam, 2008
5	ClPh	Acetate	34.0	113	0.8	SFO	Schwab, 1993[(a)]
	ClPh	Phthalate	19.1	63.5	2.1	SFO	Van der Gaauw, 2002
7	ClPh	Phosphate	23.8	79.1	1.7	SFO	Van der Gaauw, 2002
	Ph	TRIS	111	368	1.3	SFO	Fitzmaurice, 2008
	ClPh	Phosphate	8.6	28.6	ns	SFO	Adam, 2008
9	ClPh	Borate	0.6	1.9	6.1	SFO	Van der Gaauw, 2002
	Ph	Borate	0.9	2.8	3.5	SFO	Fitzmaurice, 2008
	ClPh	Borate	0.7	2.2	ns	SFO	Adam, 2008

(a) Dark control in an aquatic photolysis experiment
ns denotes not stated in the report

Table B.2.8.2-3 Summary on degradation of fenoxaprop-P-ethyl (AE F046360) under conditions of abiotic aquatic hydrolysis at 40 °C

*p*H	Label	Buffer	*DT50* (d)	*DT90* (d)	χ^2 error (%)	Kinetic model	Reference
4	ClPh	Citrate	0.8	2.7	2.7	SFO	Van der Gaauw, 2002
	Ph	Acetate	1.2	4.1	5.3	SFO	Fitzmaurice, 2008
	ClPh	Citrate	0.7	2.3	ns	SFO	Adam, 2008
5	ClPh	Phthalate	6.6	21.8	3.2	SFO	Van der Gaauw, 2002
7	ClPh	Phosphate	5.1	16.8	2.3	SFO	Van der Gaauw, 2002
	Ph	TRIS	37.0	123	1.7	SFO	Fitzmaurice, 2008
	ClPh	Phosphate	6.5	21.7	ns	SFO	Adam, 2008
9	ClPh	Borate	0.2	0.5	2.2	SFO	Van der Gaauw, 2002
	Ph	Borate	0.2	0.6	2.3	SFO	Fitzmaurice, 2008
	ClPh	Borate	0.1	0.4	ns	SFO	Adam, 2008

ns denotes not stated in the report

Table B.2.8.2-4 Summary on degradation of fenoxaprop-P-acid (AE F088406) under conditions of aquatic hydrolysis at 25 °C

*p*H	Label	Buffer	*DT50* (d)	*DT90* (d)	χ^2 error (%)	Kinetic model	Reference
4	ClPh	Citrate	2.5	8.2	ns	SFO	Adam, 2008
5	None	Citrate	27.4[(a)]	90.8[(a)]	na	SFO	Schollmeier & Eyrich, 1993
7	None	Phosphate	189[(a)]	627[(a)]	na	SFO	Schollmeier & Eyrich, 1993
9	None	Borate	35.0[(a)]	116[(a)]	na	SFO	Schollmeier & Eyrich, 1993
	ClPh	Borate	143	474	ns	SFO	Adam, 2008

na denotes not applicable
ns denotes not stated in the report
(a) Interpolated from 50, 55 and 65 °C study applying the Arrhenius equation

Table B.2.8.2-5 Summary on degradation of fenoxaprop-P-acid (AE F088406) under conditions of aquatic hydrolysis at 40 °C

*p*H	Label	Buffer	*DT50* (d)	*DT90* (d)	χ^2 error (%)	Kinetic model	Reference
4	ClPh	Citrate	0.5	1.7	ns	SFO[(a)]	Adam, 2008
5	None	Citrate	6.9[(b)]	22.7[(b)]	na	SFO	Schollmeier & Eyrich, 1993
7	None	Phosphate	38.1[(b)]	127[(b)]	na	SFO	Schollmeier & Eyrich, 1993
	ClPh	Phosphate	24.7	82.1	4.1	SFO[(c)]	Van der Gaauw, 2002
9	None	Borate	5.2[(b)]	17.4[(b)]	na	SFO	Schollmeier & Eyrich, 1993

ClPh	Borate	12.3	40.8	8.8	SFO[c]	Van der Gaauw, 2002
Ph	Borate	16.9	56.0	1.3	SFO	Fitzmaurice, 2008
ClPh	Borate	12.7	42.1	ns	SFO[a]	Adam, 2008

na denotes not applicable
ns denotes not stated in the report
(a) Decline fit
(a) Interpolated from 50, 55 and 65 °C study applying the Arrhenius equation
(c) $P_{SFO} \rightarrow M_{SFO}$ pathway fit

Table B.2.8.2-6 **Summary on net degradation of fenoxaprop-P-ethyl (AE F046360) under conditions of direct and indirect aquatic photolysis**

Test system	Label	Suntest exposure days[a]		Sunlight equivalent days		χ^2 error (%)	Kinetic model	Reference
		DT50 (d)	*DT90* (d)	*DT50* (d)	*DT90* (d)			
*p*H 5 acetate buffer	ClPh	14.6	48.4	85.7[c]	-	-	SFO	Schwab, 1993
*p*H 9 surface water[b]		0.7	2.2	-	-	-	SFO	
*p*H 7 phosphate buffer	Ph	0.3	1.0	0.7[d]	-	-	SFO	Fitzmaurice, 2008
*p*H 7 phosphate buffer	ClPh	17.8	59.0	17.8[e]	-	-	SFO	Fletcher & Gilbert, 2008

(a) Continuous Suntest irradiation
(b) Indirect photolysis
(c) 52 °N in June
(d) 33.3 °N in June
(e) European summer light

Table B.2.8.2-7 **Summary on net degradation of chlorobenzoxazolone (AE 054014) under conditions of aquatic photolysis**

Test system	Suntest exposure days[a]		Sunlight equivalent days		χ^2 error (%)	Kinetic model	Reference
	DT50 (d)	*DT90* (d)	*DT50* (d)	*DT90* (d)			
*p*H 7 phosphate buffer	1.3	4.4	7.0[b]	-	-	SFO	Burgener, 1999
*p*H 7 phosphate buffer	0.11	0.37	0.25[c]	-	-	SFO	Adam, 2008

ns denotes not stated
(a) Continuous Suntest irradiation
(b) Natural summer sunlight at 40 °N
(c) Natural summer sunlight at 30 - 40 °N

Table B.2.8.2-8 **Summary on degradation of fenoxaprop-P-ethyl (AE F046360) in aerobic surface water at 20 °C**

Water/dose	*p*H	Label	*DegT50* water (d)	*DegT90* water (d)	χ^2 error (%)	Kinetic model	Reference
Wiehltalsperre/low dose	8.0	ClPh	0.4	1.4	5.1	SFO	Telscher & Junge, 2016a
Wiehltalsperre/high dose	8.0	ClPh	0.4	1.2	2.6	SFO	
Wiehltalsperre/low dose	9.2	Ph	0.2	0.6	4.6	SFO	Telscher & Junge, 2016b
Wiehltalsperre/high dose	9.2	Ph	0.2	0.8	3.3	SFO	

Table B.2.8.2-9 **Summary on degradation of fenoxaprop-P-acid (AE F088406) in aerobic surface water at 20 °C**

Water/dose	*p*H	Label	*DegT50* water (d)	*DegT90* water (d)	χ^2 error(%)	Kinetic model	Reference
Wiehltalsperre/low dose	8.0	ClPh	107	354	2.5	SFO[a]	Telscher & Junge, 2016a
Wiehltalsperre/high dose	8.0	ClPh	432	> 1000	1.2	SFO[a]	
Wiehltalsperre/low dose	9.2	Ph	39.4	131	5.5	SFO[a]	Telscher & Junge, 2016b
Wiehltalsperre/high dose	9.2	Ph	134	444	2.4	SFO[a]	

(a) Decline fit

Table B.2.8.2-10 **Summary on degradation and dissipation of fenoxaprop-P-ethyl (AE F046360) in the total water/sediment system as well as in the water and sediment phase (aerobic, 20 °C) - trigger & modelling endpoints**

Water / sediment	*p*H wat. /	Label	*DegT50* system	*DegT90* system	Kinetic model	*DissT50* water	Kinetic model	*DissT50* sed.	Kinetic model	Reference

system	sed.[a]		(d)	(d)		(d)		(d)		
Rhine River	7.3 / 7.3	ClPh	0.12	0.40	SFO	0.11	SFO	nr	-	Tarara, 2000
Nidda River	6.8 / 5.1	ClPh	0.11	0.36	SFO	0.09	SFO	0.27	SFO	
Clayton Pond	6.6 / 4.4	Ph	0.17	0.58	SFO	0.17	SFO	na	-	Fitzmaurice, 2004
Roding River	8.0 / 7.2	Ph	0.38	1.2	SFO	0.38	SFO	na	-	
Goose River	8.3 / 7.9	ClPh	0.11	0.38	SFO	0.06	SFO	0.20	SFO	Xu, 2012
		Ph	0.11	0.35	SFO	0.06	SFO	0.13	SFO	
Lawrence Pond	7.8 / 7.4	ClPh	0.05	0.18	SFO	0.04	SFO	nr	-	
		Ph	0.07	0.23	SFO	0.06	SFO	0.05	SFO	
Rhine River	8.0 / 7.4[b]	ClPh	< 1	< 1	-	< 1	-	< 1	-	Mamouni, 2008
		Ph	< 1	< 1	-	< 1	-	< 1	-	
Fröschweiher Pond	7.8 / 7.2[b]	ClPh	< 1	< 1	-	< 1	-	< 1	-	
		Ph	< 1	< 1	-	< 1	-	< 1	-	
Geometric mean (n = 8)[c]			**0.13**	**0.44**		**0.11**		**0.14**		

nr denotes no reliable fit
na denotes not applicable (not observed)
(a) Measure in $CaCl_2$
(b) Matrix not specified
(c) Labels in Xu (2012) and Mamouni (2008) averaged (geometric mean) before averaging different water/sediment systems

Table B.2.8.2-11 Summary on degradation and dissipation of fenoxaprop-P-acid (AE F088406) in the total water/sediment system as well as in the water and sediment phase (aerobic, 20 °C) - trigger & modelling endpoints

Water / sediment system	*p*H wat. / sed.[a]	Label	*DegT50* system (d)	*DegT90* system (d)	Kinetic model	*ff*	*DissT50* water (d)	Kinetic model	*DissT50* sed. (d)	Kinetic model	Reference
Rhine River	7.3 / 7.3	ClPh	13.9	46.2	SFO[b]	1.0	10.7	SFO[c]	16.8	SFO[c]	Tarara, 2000
Nidda River	6.8 / 5.1	ClPh	8.0	26.5	SFO[b]	0.99	4.3	SFO[c]	8.7	SFO[c]	
Clayton Pond	6.6 / 4.4	Ph	39.6	132	SFO[b]	0.96	33.9	SFO[c]	nr	-	Fitzmaurice, 2004
Roding River	8.0 / 7.2	Ph	41.9	139	SFO[b]	1.0	40.5	SFO[c]	nr	-	
Goose River	8.3 / 7.9	ClPh	17.2	57.0	SFO[b]	0.88	7.2[d]	DFOP[c]	19.7	SFO[c]	Xu, 2012
		Ph	17.4	57.8	SFO[b]	0.97	6.7	SFO[c]	19.9	SFO[c]	
Lawrence Pond	7.8 / 7.4	ClPh	18.6	62.0	SFO[b]	0.98	8.4	SFO[c]	9.9	SFO[c]	
		Ph	15.3	50.9	SFO[b]	1.0	8.3	SFO[c]	7.7	SFO[c]	
Rhine River	8.0 / 7.4[e]	ClPh & Ph	13.5	44.7	SFO[c]	na	9.0	SFO[c]	17.7[h]	SFO[c]	Ma-mouni, 2008
Fröschweiher Pond	7.8 / 7.2[e]	ClPh & Ph	15.6	51.9	SFO[c]	na	10.2	SFO[c]	16.6[h]	SFO[c]	
Geometric mean (n = 8)[f]			**18.1**	**60.0**		**-**	**11.6**		**14.0**		
Arithmetic mean (n = 6)[g]			**-**	**-**		**0.98**	**-**		**-**		

nr denotes no reliable fit
(a) Measure in $CaCl_2$
(b) $P_{SFO} \rightarrow M_{SFO}$ pathway fit
(c) Decline fit
(d) DFOP *DT90* / 3.32
(e) Matrix not specified
(f) Labels in Xu (2012) averaged (geometric mean) before averaging different water/sediment systems
(g) Labels in Xu (2012) averaged (arithmetic mean) before averaging different water/sediment systems
(h) Geometric mean of individual decline fits for both replicates

Table B.2.8.2-12 Summary on degradation and dissipation of HOPP-acid (AE F096918) in the total water/sediment system as well as in the water and sediment phase (aerobic, 20 °C) - trigger & modelling endpoints

Water / sediment system	*p*H wat. / sed.[a]	Label	*DegT50* system (d)	*DegT90* system (d)	Kinetic model	*DissT50* water (d)	Kinetic model	*DissT50* sed. (d)	Kinetic model	Reference
Clayton Pond	6.6 / 5.8	Ph	9.8	32.6	SFO[b]	9.9	SFO[b]	nr	na	Fitzmaurice, 2004
Roding River	8.0 / 7.7	Ph	No reliable fit (data scatter)							

(a) Measure in $CaCl_2$
(b) Decline fit

Table B.2.8.2-13 Summary on degradation and dissipation of fenoxaprop-P-ethyl (AE F046360) in the total water/sediment system (anaerobic, 20 °C) - supplemental information

Water /	*p*H	Label	*DegT50*	*DegT90*	Kinetic	*DisT50*	Kinetic	*DisT50*	Kinetic	Reference

sediment system	wat. / sed.		system (d)	system (d)	model	water (d)	model	sed. (d)	model	
Ormalingen	6.8 / 7.5[(a)]	ClPh	0.15	0.51	SFO	nc	nc	nc	nc	Voelkel, 2000

nc denotes not conducted
(a) Matrix not specified

Table B.2.8.2-14 Summary on degradation and dissipation of fenoxaprop-P-acid (AE F088406) in the total water/sediment system (anaerobic, 20 °C) - supplemental information

Water / sediment system	*p*H wat. / sed.	Label	*DegT50* system (d)	*DegT90* system (d)	Kinetic model	*DisT50* water (d)	Kinetic model	*DisT50* sed. (d)	Kinetic model	Reference
Ormalingen	6.8 / 7.5[(a)]	ClPh	55.3	184	SFO[(b)]	nc	nc	nc	nc	Voelkel, 2000

nc denotes not conducted
(a) Matrix not specified
(b) $P_{SFO} \rightarrow M_{SFO}$ pathway fit

2.8.3. Summary of fate and behaviour in air

In view of values for vapour pressure measured being below the triggers of 10^{-4} Pa for soil and of 10^{-5} Pa for plants (FOCUS, 2008) no study on transport of the active substance fenoxaprop-P-ethyl (AE F046360) *via* air is regarded as necessary. The combination of a water solubility of 0.43 mg/L with a vapour pressure of 6.5×10^{-6} Pa (at 20 °C) resulted in a low value for the Henry constant (5.5×10^{-3} Pa × m^3 / mol at 20 °C), indicating non-volatility. Once in the air, half-life in the atmosphere (0.16 days according to Atkinson) is low at all. Consequently, fenoxaprop-P-ethyl (AE F046360) is estimated not to be subject to transport via air.

2.8.4. Summary of monitoring data concerning fate and behaviour of the active substance, metabolites, degradation and reaction products

The Fenoxaprop-P-ethyl Task Force claims that there are no published data from formal monitoring programs available that would indicate a specific concern or findings of fenoxaprop-P-ethyl (AE F046360) and its residues in remote environmental areas not being subject to the intended use.

Without having these data or reports available the RMS AT considers it difficult to judge on their relevance. The applicant is therefore asked to provide public monitoring data (ground water and surface water) available in the EU as far as this feasible. This also includes public report on residues in remote environmental areas which may be available in some of the EU Member States. It may be noted that fenoxaprop-acid (no enantiomer analysis) is regularly included in the public groundwater monitoring at least in Austria (with no concerns here, indeed).

2.8.5. Definition of the residues in the environment requiring further assessment

The residue definitions relevant for risk assessment for each compartment are the following:

Compartment	Residue Definition
Soil	Fenoxaprop-P-ethyl (AE F046360), fenoxaprop-P-acid (AE F088406)[(a)], chlorobenzoxazolone (AE F054014), HOPP-acid (AE F096918)
Groundwater	Fenoxaprop-P-ethyl (AE F046360), fenoxaprop-P-acid (AE F088406)[(a)], chlorobenzoxazolone (AE F054014), HOPP-acid (AE F096918)
Surface Water	Fenoxaprop-P-ethyl (AE F046360), fenoxaprop-P-acid (AE F088406)[(a)], chlorobenzoxazolone (AE F054014), HOPP-acid (AE F096918), phenol metabolite (AE F040356), fenoxaprop-P-ethyl-dechloro-hydroxy (BCS-CY11271)[(b)]
Sediment	Fenoxaprop-P-ethyl (AE F046360), fenoxaprop-P-acid (AE F088406)[(a)], chlorobenzoxazolone (AE F054014), HOPP-acid (AE F096918), phenol metabolite (AE F040356), fenoxaprop-P-ethyl-dechloro-hydroxy (BCS-CY11271)[(b)]
Air	Fenoxaprop-P-ethyl (AE F046360), fenoxaprop-P-acid (AE F088406)[(a)]

(a) Herbicidal active metabolite
(b) Aquatic photolysis

2.8.6. Summary of exposure calculations and product assessment

The **predicted environmental concentrations in soil (PECsoil)** of the active substance fenoxaprop-P-ethyl (AE F046360) and its metabolites fenoxaprop-P-acid (AE F088406), chlorobenzoxazolone (AE F054014) and HOPP-acid (AE F096918) were calculated based on a first tier approach using a Microsoft® Excel spreadsheet, assuming even distribution of the compound in the upper 0 - 5 cm soil layer. A standard soil density of 1.5 g/cm^3 was assumed. The use of fenoxaprop-P-ethyl (AE F046360) in winter and spring cereals was assessed according to Good Agricultural Practice (GAP) under European cropping conditions. The new kinetic evaluations of laboratory studies resulted in a maximum *DegT90* for fenoxaprop-P-ethyl of 7 days; hence the calculation of a PECsoil,plateau is not triggered. For the metabolites fenoxaprop-P-acid (AE F088406), chlorobenzoxazolone (AE F054014) and HOPP-acid (AE F096918), no calculation of a PECsoil,plateau was triggered as well (*DT90* values ≤ 188 days).

Predicted environmental concentrations in groundwater (PECgw) for fenoxaprop-P-ethyl (AE F046360) were calculated for the use in Europe, using the simulation models FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and FOCUS MACRO 5.5.4. PECgw were evaluated as the 80th percentile of the mean annual leachate concentration at 1 m soil depth. Model parameters and scenarios consisting of weather, soil, and crop data were used as proposed by FOCUS (2009, 2014). For fenoxaprop-P-ethyl (AE F046360) and its metabolites fenoxaprop-P-acid (AE F088406), chlorobenzoxazolone (AE F054014) and HOPP-acid (AE F096918), the PECgw was < 0.01 µg/L for all scenarios and the representative uses on winter and spring cereals. Therefore, for fenoxaprop-P-ethyl (AE F046360) and its metabolites fenoxaprop-P-acid (AE F088406), chlorobenzoxazolone (AE F054014) and HOPP-acid (AE F096918) there is no concern for groundwater.

Predicted environmental concentrations of fenoxaprop-P-ethyl (AE F046360) and its metabolites fenoxaprop-P-acid (AE F088406), chlorobenzoxazolone (AE F054014), HOPP-acid (AE F096918), phenol metabolite (AE F040356) and fenoxaprop-P-ethyl-dechloro-hydroxy (BCS-CY11271) **in surface water (PECsw) and sediment (PECsed)** were calculated for the use in Europe, using the tiered FOCUS Surface Water (SW) approach (FOCUS 2001, 2015). All relevant entry routes of a compound into surface water (principally a combination of spray drift and runoff/erosion or drain flow) were considered in these calculations. For the use of Puma S 69 EW (FPP + MPR EW 144, 69 + 75 g/L) and CHA 4960 (Fenoxaprop-P-ethyl 69 EW) as a spray application to winter and spring cereals, FOCUS Steps 1 & 2 calculations were performed for fenoxaprop-P-ethyl (AE F046360) and its relevant metabolites.

Exposure via Air
No PEC calculations were required due to the low volatility and the short half-life in air.

Other routes of exposure
There are no other routes of exposure to be considered if the product is used according to Good Agricultural Practice.

2.9. EFFECTS ON NON-TARGET SPECIES

2.9.1. Summary of effects on birds and other terrestrial vertebrates

Fenoxaprop-P-ethyl has been tested for acute and chronic toxicity in a number of different bird and mammal species under standard laboratory conditions. Risk assessments according to EFSA Guidance Document (2009) with the relevant endpoints listed below show acceptable risk for birds and acceptable risk to mammals for exposure to fenoxaprop-P-ethyl after treatment of winter and spring cereals.

Table 2.9.1-1: Endpoints used in risk assessment for birds and mammals

	Acute endpoint (LD_{50})	Reproductive endpoint (NOAEL)
Birds	> 2000 mg ai/kg bw	265 mg ai/kg bw/d

	> 3776 (extrapolated)	
Mammals	> 1098 mg ai/kg bw	10 mg ai/kg bw/d [a]

[a] based on skeletal ossification.

Endocrine disrupting properties:

Wild mammals

A detailed analysis of all the apical toxicological studies (subchronic, chronic / oncogenicity, reproduction and developmental toxicity) on Fenoxaprop-P-ethyl revealed no evidence of any reproducible endocrine effect. Based on the available toxicological data set, there was no evidence of endocrine disrupting potential of fenoxaprop-P-ethyl in mammals within the in vivo studies. However no mechanistic data is available.

Birds

The population relevant effects of Fenoxaprop-P-ethyl on birds were studied in reproductive toxicity studies on bobwhite quail. No statistically significant effects on adult birds, offspring or reproductive parameters were found at 400 mg Fenoxaprop-P-ethyl/kg diet in bobwhite quails. At the highest tested concentration of 800 mg Fenoxaprop-P-ethyl/kg diet tested in Bobwhite quail there was a slight decrease (ca. 10 %) in food consumption and egg production as compared with the control, which attained statistical significance; however, the overall reproductive toxicity endpoint, i.e. the number of 14-day old chicks per hen, did not show a statistically significant reduction.

Amphibians and Reptiles

Currently no test methods are established to assess the population relevant effects of chemicals to amphibians or reptiles. Under consideration of the overall favourable toxicological profile of Fenoxaprop-P-ethyl in birds and mammals, no adverse effects are to be expected for reptiles and amphibians under field conditions.

Even though, there is no clear evidence on endocrine disruption the available information are not considered sufficient to draw a conclusion on the endocrine disrupting potential of the active substance Fenoxaprop-P-ethyl.

2.9.2. Summary of effects on aquatic organisms

The aquatic risk assessment was conducted according to the EFSA Guidance Document (EFSA, 2013)[1].

Toxicity data are available for the active substance Fenoxaprop-P-ethyl and the EU representative formulations Puma S 69 EW and CHA 4960 and the environmentally relevant metabolites Fenoxaprop-P-acid, Chlorobenzoxazolone, HOPP-acid, Phenol and Fenoxaprop-deschloro.

[1] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 186 pp. doi:10.2903/j.efsa.2013.3290.

Acute and chronic toxicity endpoints of technical and formulated Fenoxxaprop-P-ethyl to aquatic organisms

Test organism	Test substance	Test condition	Time	Endpoint	Test conc.	NOEC [mg a.s./L]	EC_{50}/LC_{50} [mg a.s./L]	Reference
Fish								
Oncorhynchus mykiss Rainbow trout	Fenoxaprop-P-ethyl	Flow-through	96 h	Mortality	mm	0.16	0.39	[redacted] 1999a
Oncorhynchus mykiss Rainbow trout	Fenoxaprop-P-ethyl	Static	96 h	Mortality	n	0.24	0.46	[redacted] 1986a
Lepomis macrochirus Bluegill sunfish	Fenoxaprop-P-ethyl	Flow-through	96 h	Mortality	mm	0.088	0.19	[redacted] 1999b
Pimephales promelas Fathead minnow	Fenoxaprop-P-ethyl	Flow-through	96 h	Mortality	n	0.215	0.466	[redacted] 2011a
Oncorhynchus mykiss Rainbow trout	Puma S 69 EW	Static	96 h	Mortality	n	0.071	0.3	[redacted] 1992a
Cyprinus carpio Mirror carp	Puma S 69 EW	Static	96 h	Mortality	n	0.071	0.27	[redacted] 1992b
Oncorhynchus mykiss Rainbow trout	CHA 4960	Semi-static	96 h	Mortality	mm	0.095	0.17	[redacted] 2005a
Oncorhynchus mykiss Rainbow trout	Fenoxaprop-P-ethyl	Flow-through	ELS (91 d)	Reproduction Growth	mm	0.02832	-	[redacted] 1999d
Pimephales promelas Fathead minnow	Fenoxaprop-P-ethyl	Flow-through	ELS (33 d)	Mortality Growth	n	0.043 0.0719	-	[redacted] 2011b
Aquatic invertebrates								
Daphnia magna Waterflea	Fenoxaprop-P-ethyl	Semi-static	48 h	Immobility	mm	0.8411	> 0.8411	Stachura, J.B. & Ruff, D.F., 1998
Mysidopsis bahia Mysid shrimp	Fenoxaprop-P-ethyl	Flow-through	96 h	Immobility	mm	n.d.	0.109	Murphy, D. & Peters, G. T., 1991
Daphnia magna Waterflea	Puma S 69 EW	Static	48 h	Immobility	mm	0.0401	0.282	Schäfers, C., 2002a
Daphnia magna Waterflea	CHA 4960	Semi-static	48 h	Immobility	n	0.071	0.22	Grade, R. & Wydra, V., 2005
Mysidopsis bahia	Fenoxaprop-P-ethyl	Flow-through	28 d	Reproduction	mm	0.011	-	Boeri, R. L., Magazu, J. P.,

Test organism	Test substance	Test condition	Time	Endpoint	Test conc.	NOEC [mg a.s./L]	EC_{50}/LC_{50} [mg a.s./L]	Reference
Mysid shrimp								& Ward, T. J., 1999
Daphnia magna Waterflea	Puma S 69 EW	Semi-static	21 d	Reproduction	n	0.0875	n.d.	Schäfers, C., 2002b*
Daphnia magna Waterflea	Puma S 69 EW	Semi-static	21 d	Reproduction	n	0.0706	n.d.	Bruns, E., 2006
Daphnia magna Waterflea	CHA 4960	Semi-static	21 d	Reproduction	mm	0.019	n.d.	Kley, A. & Wydra, V., 2010
Sediment dwelling organisms								
Chironomus riparius Midge	Fenoxaprop-P-ethyl	Static	26 d	Emergence Development	n	0.2	-	Memmert, U., 2000
Algae								
Raphidocelis subcapitata Green algae	Fenoxaprop-P-ethyl	Static	72 h	Growth rate Yield	n	0.33	> 0.71	Meister-Werner, A. & Wydra, V., 2009*
Skeletonema costatum Saltwater diatom	Fenoxaprop-P-ethyl	Static	72 h	Growth rate Biomass Yield	n	0.19	12 1.6 1.5	Seyfried, B., 2008*
			96 h	Growth rate Biomass Yield	n	0.19	41 2.2 3.3	
Navicula pelliculosa Diatom	Fenoxaprop-P-ethyl	Static	72 h	Growth rate Yield	mm	0.049	> 0.811 > 0.811	Meister-Werner, A. & Wydra, V., 2008
Anabaena flos-aquae Blue-green algae	Fenoxaprop-P-ethyl	Static Limit Test	72 h	Growth rate Biomass	mm	0.94	> 0.94	Pawlowski, S. & Wydra, V., 2005
Anabaena flos-aquae Blue-green algae	Fenoxaprop-P-ethyl	Static	72 h	Growth rate	mm	0.518	> 0.518	Banman, C.S., Howerton, J.H. & Lam, C.V., 2011a
			96 h	Growth rate	mm	0.518	> 0.518	
R. subcapitata Green algae	Puma S 69 EW	Static	72 h	Growth rate Biomass Yield	mm	0.087 0.041 0.041	0.418 0.231 0.243	Wenzel, A., 2005
D. subspicatus Green algae	CHA 4960	Static	72 h	Growth rate Biomass	mm	0.025 0.012	0.12 0.04	Pawlowski, S., Wydra, V., 2005b
Aquatic macrophytes								
Lemna gibba Duckweed	Fenoxaprop-P-ethyl	Semi-static	14 d	Growth rate (frond number)	n	3.0	> 3.0	Christ, M.T. & Ruff, D.F., 1997*

Test organism	Test substance	Test condition	Time	Endpoint	Test conc.	NOEC [mg a.s./L]	EC_{50}/LC_{50} [mg a.s./L]	Reference
Lemna gibba Duckweed	Fenoxaprop-P-ethyl	Semi-static Limit test	7 d	Growth rate (frond number) Biomass (dry weight)	mm	0.80	>0.80	Pawlowski, S., 2005*
Myriophyllum spicatum Water milfoil	Fenoxaprop-P-ethyl	Semi-static Limit test	14 d	Growth rate Yield	mm	0.0336	> 0.0336	Banman, C.S., Alexander, T.M. & Moore, S., 2013
Lemna gibba Duckweed	CHA 4960	Semi-static	7 d	Growth rate Yield (frond number)	mm	0.026 0.026	0.359 0.166	Pawlowski, S. & Wydra, V., 2006
				Growth rate Yield (dry weight)		0.026 0.026	0.366 0.201	

n…nominal, mm…mean measured, im…initially measured
n.d…. not determined
* Studies are considered valid; however, no reliable endpoint could be determined taken into account the results of the analytical measurements

Endpoints: Toxicity of metabolites to aquatic organisms

Test substance	Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg/L]	EC_{50}/LC_{50} [mg/L]	Reference
Fish								
Fenoxaprop-P acid AE F088406	*Oncorhynchus mykiss* Rainbow trout	Static	96 h	Mortality	mm	68.82	> 68.82	[redacted] 1996
Chlorobenzoxazolone AE F054014	*Oncorhynchus mykiss* Rainbow trout	Semi-static	96 h	Mortality	n	10	> 10	[redacted] 1999c
HOPP-acid AE F0962918	*Oncorhynchus mykiss* Rainbow trout	Semi-static	96 h	Mortality	n	250	353	[redacted] 2004b
Phenol AE F040356	*Oncorhynchus mykiss* Rainbow trout	Semi-static	96 h	Mortality	mm	0.248	0.590	[redacted] 2015
Fenoxaprop-P-ethyl-dechloro-hydroxy BCS-CY11271	*Oncorhynchus mykiss* Rainbow trout	Semi-static	96 h	Mortality	mm	0.307	0.734	[redacted] 2015a
Chlorobenzoxazolone AE F054014	QSAR	-	-	Reproduction	-	0.02832[a]		Vrbka, S., & Christl, H., 2016
Phenol	QSAR	-	-	Reproduction	-	0.02832[a]		Vrbka, S., &

Test substance	Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg/L]	EC_{50}/LC_{50} [mg/L]	Reference
AE F040356								Christl, H., 2016
Aquatic invertebrates								
Fenoxaprop-P acid AE F088406	*Daphnia magna* Waterflea	Static	48 h	Immobility	n	56	126	Heusel, R., 1993a
Chlorobenzoxazolone AE F054014	*Daphnia magna* Waterflea	Semi-static	48 h	Immobility	n	1.3	6.6	Young, B.M. & Ruff, D.F., 1999a
HOPP-acid AE F0962918	*Daphnia magna* Waterflea	Static	48 h	Immobility	n	n.d.	> 200	Schäfers, C., 2004c
HOPP-acid AE F0962918	*Daphnia magna* Waterflea	Static	48 h	Immobility	n	25	86.8	Pupp, A. & Wydra, V., 2008
Phenol AE F040356	*Daphnia magna* Waterflea	Static	48 h	Immobility	mm	0.848	1.75	Börschig, C. & Emnet, P., 2015b
Fenoxaprop-P-ethyl-dechloro-hydroxy BCS-CY11271	*Daphnia magna* Waterflea	Static	48 h	Immobility	mm	9.98	> 9.98	Kuhl, R. & Emnet, P., 2016
Fenoxaprop-P acid AE F088406	*Daphnia magna* Waterflea	Semi-static	21 d	Reproduction Growth	n	1.0	0.49 (EC_{10})	Ebeling, M., Nguyen, D. & Gosch, H., 2002
Chlorobenzoxazolone AE F054014	QSAR	-	-	Reproduction	-	0.011[a]	-	Vrbka, S., & Christl, H., 2016
HOPP-acid AE F0962918	*Daphnia magna* Waterflea	Semi-static	21 d	Reproduction Growth	n	3.2	3.0 (EC_{10})	Schäfers, C., 2004d
Phenol AE F040356	QSAR	-	-	Reproduction	-	0.011[a]	-	Vrbka, S., & Christl, H., 2016
Algae								
Fenoxaprop-P acid AE F088406	*R. subcapitata* Green algae	Static	72 h	Growth rate Biomass Yield	mm	13.72	69.9 35.8 33.9	Heusel, R., 1993b
Chlorobenzoxazolone AE F054014	*R. subcapitata* Green algae	Static	72 h	Growth rate Yield	n	5.1	8.78 8.12	Börschig, C. & Emnet, P., 2016
HOPP-acid AE F0962918	*R. subcapitata* Green algae	Static [a]	72 h	Growth rate Biomass Yield	n	10.0 1.0 3.2	53.4 9.56 14.3	Wenzel, A., 2004
Phenol AE F040356	*R. subcapitata* Green algae	Static	72 h	Growth rate Yield	mm	0.828	> 3.33 3.04	Börschig, C., Emnet, P., 2015c

Test substance	Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg/L]	EC_{50}/LC_{50} [mg/L]	Reference
Fenoxaprop-P-ethyl-dechloro-hydroxy BCS-CY11271	*R. subcapitata* Green algae	Static	72 h	Growth rate Yield	mm	2.74	> 8.73	Kuhl, R., Emnet, P., 2015b
Aquatic macrophytes								
Fenoxaprop-P acid AE F088406	*Lemna gibba* Duckweed	Static	7 d	Growth rate Yield (frond number)	n	10 3.2	> 100 64.1	Hengsberger, A. & Emnet, P., 2015
				Growth rate Yield (dry weight)		32 32	> 100 > 100	
Phenol AE F040356	*Lemna gibba* Duckweed	Semi-static	7 d	Growth rate Yield (frond number)	mm	0.137 0.137	> 2.70 > 2.70	Börschig, C. & Emnet, P., 2015d
				Growth rate Yield (dry weight)		1.21 1.21	> 2.70 > 2.70	
Fenoxaprop-P-ethyl-dechloro-hydroxy BCS-CY11271	*Lemna gibba* Duckweed	Semi-static	7 d	Growth rate Yield (frond number)	mm	2.09 2.09	> 29.4 12.9	Kuhl, R., Emnet, P., 2015c
				Growth rate Yield (dry weight)		2.09 2.09	> 29.4 16.0	

n…nominal, mm…mean measured
n.d…. not determined
[a] Endpoint of the active substance supported by QSAR is used for the risk assessment

2.9.3. Summary of effects on arthropods

Effects on bees

Acute oral and contact toxicity to honey-bees from exposure to the active substance and the representative formulations FPP + MPR EW 144 (69+75 g/L) and CHA 4690.

Test substance	Exposure route	Endpoint	Toxicity	Reference
Fenoxaprop-P-ethyl tech.	Acute oral Acute contact	48 h LD_{50}	> 200 µg ai/bee > 200 µg ai/bee	KIeiner, R., 2000
	Acute oral Acute contact	48 h LD_{50}	> 109.5 µg ai/bee > 100 µg ai/bee	Sekine, T., 2013
	Acute oral Acute contact	48 h LD_{50}	> 108.9 µg ai/bee > 100 µg ai/bee	Schmitzer, S., 2007

Test substance	Exposure route	Endpoint	Toxicity	Reference
FPP+MPR EW 144 (69+75 g/L)	Acute oral Acute contact	48 h LD_{50} 72h LD_{50}	> 211.8 µg prod./bee (>14.61 µg a.s./bee) > 200 µg prod./bee (>13.8 µg a.s./bee)	Schmitzer, S., 2013
CHA 4960	Acute oral Acute contact	48 h LD_{50} 72h LD_{50}	356.1 µg prod./bee 23.9 µg ai/bee 598.6 µg prod./bee 40.1 µg ai/bee	Schmidt, T., 2005

In addition studies on the chronic oral toxicity to adult honey-bees (10 day exposure) and honey-bee brood were conducted.

Test substance	Exposure route	Endpoint	Toxicity	Reference
CHA 4960	Chronic oral	10 d LDD_{50} 10 d NOEDD	10.06 µg ai/bee/d 3.95 µg ai/bee/d	Theis, M., 2017

Effects on honey-bees and honey-bee brood

Test substance	Exposure route	Results	Reference
FPP + MPR EW 144 (69+75) "Ralon Super"	Honey bee brood feeding (Oomen *et al.*, 1992)	Slightly increased termination rate of eggs and old larvae and decreased termination rate of young larvae. No effects on honey bee pupae and larvae were observed. In both, in the test item treatment group and in the control group, post-application adult mortality was on the same level as the corresponding pre-application adult mortality, with the post-application adult mortality in the test item treatment group being only slightly higher. Overall, it can be concluded according to the results of this study that the administration of FPP + MPR EW 144 (69+75 g/L) fortified sugar syrup 0.21 g/L fenoxaprop-P-ethyl to honey bee colonies does neither adversely affect honey bee colonies nor bee brood development.	Schmitzer, S., 2014
FPP + MPR EW 144 "Ralon Super"	Honeybee brood development	Slightly increased termination rate of eggs and young larvae, not significant compared to the control and decreased termination rate of old larvae. No effects on honey bee pupae and larvae were observed. Adult bee mortality in the test item treatment group was slightly lower compared to control. In both, in the test item treatment group and in the control group, post-application adult mortality was on the same level as the corresponding pre-application adult mortality in the test item treatment and control group being only slightly higher. Overall it can be concluded according to the results of this study that the administration of fenoxaprop 69 g/L EW fortified sugar syrup 0.21 g/L fenoxaprop-P-ethyl to honey bee colonies did not adversely affect honey bee colonies or bee brood development.	Taenzler, V. 2016

Effects on non-target arthropods other than bees

Laboratory studies with the standard arthropod species *Aphidius rhopalosiphi* and *Typhlodromus pyri* were submitted with both representative formulations.

Test species	Exposure	Test item	Rate [mL/ha]	Type of effect	Effect [%]	Reference
Aphidius rhopalosiphi (adults)	contact with dried residues on treated glass plates	Puma S 69 EW	75 150 300 600 1200	Corrected mortality / Reproduction	-8.6 / -41.7 -2.9 / -7.9 11.4 / 41.0 37.1* /42.5 85.7* / not assessed	Moll, M. & Groer, 2001
				48 h LR_{50} = 678 mL prod./ha 48 h ER_{50} > 600 mL prod./ha		
Typhlodromus pyri (protonymphs)	contact with dried residues on treated glass plates	Puma S 69 EW	12 48 1200	Corrected mortality / Reproduction	4.1 / 6.6 2.0 / 8.3 36.9 / 87*	Waltersdorfer 2011
				7 days LR_{50} > 1200 mL prod./ha 14 d ER_{50} > 48 mL prod./ha		
Crysoperla carnea	contact with dried residues on treated glass plates	Puma S 69 EW	1200	Corr. Mortality [%]	Eggs/ Female/d	Hatching [%]	Waltersdorfer 2000
				- 9.5	25.3 25.4	84.9 85.6	
				LR_{50} > 1200 mL/ha ER_{50} > 1200 mL/ha		
Aphidius rhopalosiphi (adults)	contact with dried residues on glass plates	CHA 4960	64.4 128.8 257.5 515 1030	Mortality / Reproduction	0.0 / 137 7.5 /108 15.0 / 110 32.5* / 64 92.5* / not assessed	Schmidt T., 2006a
				48 h LR_{50} = 578 g/ha		
Typhlodromus pyri (protonymphs)	contact with dried residues on glass plates	CHA 4960	64.4 128.8 257.5 515 1030	Corrected mortality / Reproduction	8.3 / 81 2.8 / 95 9.7 / 65 52.8* / not assessed 94.4* / not assessed	Schmidt T., 2006b
				7 d LR_{50} = 478 g/ha		

In addition, laboratory studies with three additional arthropod species relevant for the proposed GAP uses were submitted.

Test species	Exposure	Test item	Rate [ml/ha]	Type of effect	Effect	Reference
Aphidius rhopalosiphi	Dried residues on treated plant surfaces (barley plants)	CHA 4960	14.8 44.4 133 400 1200	Corrected mortality / reduction in parasitisation	[%] -3.4 /51.5 -3.4 / 19.8 -3.4 / 24.4 0.0 / 30.4 0.0 / 43.2	Moll M.,2007
				ER_{50} > 1200 ml/ha		
Typhlodromus pyri	Fresh and aged residues on treated plant surfaces (French bean plants)	CHA 4960	1200	Corrected mortality / Effects on reproduction 0 DAT	[%] 6 / 1.6	Fallowfield, L., 2010
				48 h ER_{50} > 1200 ml/ha		
Chrysoperla carnea (larvae)	dried residues on treated leaf surfaces (bean leaves)	CHA 4960	14.8 44.4 133 400 1200	Corrected mortality / larval hatching rate / eggs per femal	Corr. Mortality [%] 14.7 17.6 -5.9 -2.9 2.9 Larval hatching rate [%] 93.5 88.8 87.5 91.0 87.6 Eggs per female [per day] 25.3 20.5 15.5 18.3	Moll M., 2008
				48 h ER_{50} > 1200 ml/ha		

2.9.4. Summary of effects on non-target soil meso- and macrofauna

Table 2.9.4-1: Summary of effects on soil meso- and macrofauna

Species	Substance	Endpoint	Reference
Eisenia fetida	FPP+MPR EW 144 (69+75 g/L)	$EC_{10\ reproduction}$ = 170.015 mg/kg soil dw	Friedrich, S., 2016
	Fenxoaprop-P-ethyl	NOEC ≥ 56 mg/kg soil dry weight	Friedrich, S., 2014
	Fenxoaprop-P-acid	NOEC = 100 mg/kg soil dw	Friedrich, S., 2006
	Chlorobenzoxazolone	NOEC = 89 mg/kg soil dw	Friedrich, S., 2016

Species	Substance	Endpoint	Reference
	HOPP acid	NOEC = 158 mg/kg soil dw	Friedrich, S., 2016
Folsomia candida	FPP+MPR EW 144 (69+75 g/L)	NOEC = 56 mg /kg soil dw	Friedrich, F., 2016
	Fenxoaprop-P-ethyl	NOEC ≥ 1000 mg/kg soil dw	Friedrich, S., 2015
	Fenoxaprop-P-acid	NOEC ≥ 111.6 mg/kg soil dw	Friedrich, S., 2015
	Chlorobenzoxazolone	NOEC ≥ 100 mg/kg soil dw	Friedrich, S., 2016
	HOPP acid	NOEC ≥ 100 mg/kg sdw	Friedrich, S., 2016
Hypoaspis aculeifer	FPP+MPR EW 144 (69+75 g/L)	NOEC = 56 mg/kg sdw	Schulz, L., 2016
	Fenxoaprop-P-ethyl	NOEC ≥ 1000 mg/kg soil dw	Lopez, M. I. L., 2015
	Chlorobenzoxazolone	NOEC ≥ 100 mg/kg sdw	Schulz, L., 2016
	Fenoxaprop-P-acid	NOEC ≥ 111.6 mg/kg soil dw	Schulz, L., 2015

2.9.5. Summary of effects on soil nitrogen transformation

Test substance	Test parameter	Test concentration	Time	Effects (deviation from control)	Reference
FPP+MPR EW 144 (69+75 g/L)	Nitrogen mineralisation	1.69 mg/kg soil dw	28 d	+ 14.4	Schulz, L. 2016
		8.44 mg/kg soil dw		+ 12.1	
CHA 4960	Nitrogen mineralisation	2.75 mg from./kg dry soil	28 days	+1.13	Reis, K.-H, 2005
		13.73 mg/kg soil dw		+1.16	
Fenoxaprop-P-ethyl	Nitrogen mineralisation	0.133 mg /kg dry soil	56 days	+ 0.3	McMurray A., 2002
		0.67 mg /kg dry soil		+ 5.4	
Fenoxaprop-P-ethyl	Nitrogen mineralisation	0.11 mg/kg soil dw	42 days	1.6%	Reis, K.-H.., 2008
		0.55 mg/kg soil dw		-19%	
Fenoxaprop-P-acid	Nitrogen mineralisation	0.1049 mg/kg soil dw	28 days	-3.7	Schulz, L., 2016
		0.5244 mg/kg soil dw		+24.8	
Chlorobenzoxazolone	Nitrogen mineralisation	0.053 mg/kg soil dw	28 days	+2.1	Schulz, L., 2016
		0.263 mg/kg soil dw		-12	
HOPP acid	Nitrogen mineralisation	0.060 mg/kg soil dw	28 days	-6.5	Schulz, L., 2016
		0.3 mg/kg soil dw		+5.3	

According to regulatory requirements the risk is acceptable, if the effect on nitrogen transformation at the maximum PECsoil values is < 25% after 100 days. In no case, deviations from the control exceeded 25% after 28 up to 56 days, indicating low risk to soil microorganisms.

2.9.6. Summary of effects on terrestrial non-target higher plants

Test organisms	Study type	Test duration	Lowest ER_{50} [mL prod./ha]	Most sensitive species	Reference
Terrestrial non-target plants (6 species)	Vegetative vigour (Tier 2)	21 days	ER_{50} = 84.85	Corn (*Zea mays*)	Siemoneit, R., 2005a
Terrestrial non-target plants (6 species)	Seedling emergence (Tier 2)	21 days	ER_{50} > 1000	-	Siemoneit, R., 2005b
Terrestrial non-target plants (10 species)	Vegetative vigour (Tier 2)	21 days	ER_{50} = 108.7*	Corn (*Zea mays*)	Pallett K., Gosch, H. 2005a
Terrestrial non-target plants (9 species)	Seedling emergence (Tier 2)	21 days	ER_{50} > 1200	-	Pallett, K., Gosch, H., 2005b

2.9.7. Summary of effects on other terrestrial organisms (flora and fauna)

In view of the study results presented above no studies on other terrestrial organisms are considered necessary.

2.9.8. Summary of effects on biological methods for sewage treatment

Studies on sewage treatment with Fenoxaprop-P-ethyl resulted in endpoints of EC_{50} greater than 1000 mg a.s./L after 3 hours.

2.9.9. Summary of product exposure and risk assessment

2.9.9.1. *Risk assessment for birds*

FPP+MPR EW 144 (69+75 g/L) & CHA 4960

Crop	Generic focal species	SV_{90}	TER_A	Assessment level
Cereals	Small omnivorous bird	158.8	157	Screening

Crop	Generic focal species	SV_m	TER_{LT}	Assessment level
Cereals	Small omnivorous bird	64.8	10	Screening

2.9.9.2. *Risk assessment for mammals*

FPP+MPR EW 144 (69+75 g/L) & CHA 4960

Crop	Generic focal species	SV_{90}	TER_A	Assessment level
Cereals	Small insectivorous mammal	118.4	112	Screening

Crop	Generic focal species	SV_m	TER_{LT}	Assessment level

Crop	Generic focal species	SV_m	TER_{LT}	Assessment level
Cereals	Small insectivorous mammal “shrew”	4.2	55	Tier 1
	Small insectivorous mammal “shrew”	1.9	125	
	Large herbivorous mammal “lagomorph”	22.3	10.2	
	Small omnivorous mammal “mouse”	7.8	29	
	Small omnivorous mammal “mouse”	3.9	59	

2.9.9.3. *Risk assessment for aquatic organisms*

The risk assessment for aquatic organism was conducted according to the EFSA Aquatic Guidance Document (EFSA Journal 2013;11(7):3290).

PUMA S 69 EW

Fish acute:

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS		Fish, acute					
		Fenoxaprop-P-ethyl RAC = 1.9 µg a.s./L	Fenoxaprop-P-acid RAC = 688.2 µg/L	Chlorobenzoxazolone RAC = 100 µg/L	HOPP-acid RAC = 3530 µg/L	Phenol RAC = 5.9 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 7.34 µg/L
Step 1		**1.31**	0.06	0.025	0.004	0.53	0.65
Step 2	N-EU	0.40	0.012	0.0071	0.000028	0.049	0.018
	S-EU	0.40	0.01	0.0057	0.000028	0.042	0.018

Bold: PEC_{SW}/RAC ratios > 1

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS		Fish, acute					
		Fenoxaprop-P-ethyl RAC = 1.9 µg a.s./L	Fenoxaprop-P-acid RAC = 688.2 µg/L	Chlorobenzoxazolone RAC = 100 µg/L	HOPP-acid RAC = 3530 µg/L	Phenol RAC = 5.9 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 7.34 µg/L
Step 1		**1.31**	0.06	0.025	0.004	0.53	0.65
Step 2	N-EU	0.40	0.0054	0.003	0.000028	0.027	0.018
	S-EU	0.40	0.01	0.0057	0.000028	0.042	0.018

Bold: PEC_{SW}/RAC ratios > 1

Under consideration of FOCUS Step 2 PEC_{sw} values an acceptable acute risk to fish was identified for Fenoxaprop-P-ethyl and the respective metabolites.

Aquatic invertebrates acute:

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS	Aquatic invertebrates, acute					
	Fenoxaprop-P-ethyl RAC = 1.09 µg a.s./L	Fenoxaprop-P-acid RAC = 1260 µg/L	Chlorobenzoxazolone RAC = 66 µg/L	HOPP-acid RAC = 868 µg/L	Phenol RAC = 17.5 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 99.8 µg/L
Step 1	**2.27**	0.03	0.037	0.016	0.18	0.048

Step 2	N-EU	0.69	0.0068	0.011	0.00012	0.017	0.0013
	S-EU	0.71	0.006	0.0086	0.00012	0.014	0.0013

Bold: PEC_{SW}/RAC ratios > 1

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS		**Aquatic invertebrates, acute**					
		Fenoxaprop-P-ethyl RAC = 1.09 µg a.s./L	Fenoxaprop-P-acid RAC = 1260 µg/L	Chlorobenzoxazolone RAC = 66 µg/L	HOPP-acid RAC = 868 µg/L	Phenol RAC = 17.5 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 99.8 µg/L
Step 1		**2.27**	0.03	0.037	0.016	0.18	0.048
Step 2	N-EU	0.69	0.003	0.0045	0.00012	0.0091	0.0013
	S-EU	0.69	0.006	0.0086	0.00012	0.014	0.0013

Bold: PEC_{SW}/RAC ratios > 1

Based on a Tier 1 risk assessment considering FOCUS Step 1 and 2 PEC_{sw} values a low acute risk to aquatic invertebrates from exposure to the active substance Fenoxaprop-P-ethyl and the metabolites Fenoxaprop-P-acid, Chlorobenzoxazolone, HOPP-acid, Phenol and Fenoxaprop-deschloro was identified.

Fish chronic:

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS		**Fish, chronic**		
		Fenoxaprop-P-ethyl RAC = 2.832 µg a.s./L	Chlorobenzoxazolone RAC = 2.832 µg/L	Phenol RAC = 2.832 µg/L
Step 1		0.88	0.87	**1.11**
Step 2	N-EU	0.27	0.25	0.10
	S-EU	0.27	0.20	0.088

Bold: PEC_{SW}/RAC ratios > 1

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS		**Fish, chronic**		
		Fenoxaprop-P-ethyl RAC = 2.832µg a.s./L	Chlorobenzoxazolone RAC = 2.832 µg/L	Phenol RAC = 2.832 µg/L
Step 1		0.88	0.87	**1.11**
Step 2	N-EU	0.27	0.11	0.056
	S-EU	0.27	0.20	0.088

Bold: PEC_{SW}/RAC ratios > 1

Based on a Tier 1 risk assessment considering FOCUS Step 1 and 2 PEC_{sw} values a low chronic risk to fish from exposure to the active substance Fenoxaprop-P-ethyl and respective metabolites was identified.

Aquatic invertebrates chronic:

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS	**Aquatic invertebrates, chronic**

		Fenoxaprop-P-ethyl RAC = 1.1 µg a.s./L	Fenoxaprop-P-acid RAC = 49 µg/L	Chlorobenzoxazolone RAC = 1.1 µg/L	HOPP-acid RAC = 300 µg/L	Phenol RAC = 1.1 µg/L
Step 1		**2.25**	0.81	**2.23**	0.047	**2.85**
Step 2	N-EU	0.69	0.017	0.65	0.00033	0.26
	S-EU	0.69	0.014	0.52	0.00033	0.23

Bold: PEC_{SW}/RAC ratios > 1

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS			**Aquatic invertebrates, chronic**			
		Fenoxaprop-P-ethyl RAC = 1.1 µg a.s./L	Fenoxaprop-P-acid RAC = 49 µg/L	Chlorobenzoxazolone RAC = 1.1 µg/L	HOPP-acid RAC = 300 µg/L	Phenol RAC = 1.1 µg/L
Step 1		**2.25**	0.81	**2.23**	0.047	**2.85**
Step 2	N-EU	0.69	0.076	0.27	0.00033	0.15
	S-EU	0.69	0.14	0.52	0.00033	0.23

Bold: PEC_{SW}/RAC ratios > 1

Based on a Tier 1 risk assessment considering FOCUS Step 1 and 2 PEC_{sw} values a low chronic risk to aquatic invertebrates from exposure to the active substance Fenoxaprop-P-ethyl and respective metabolites was identified.

Sediment dwelling organisms:

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PEC_{SW} Step 1 and Step 2

FOCUS		**Sediment dwelling organisms, chronic, RAC = 20 µg a.s./L (Tier 1)**	
		Winter cereals, 1 x 83 g a.s./ha	Spring cereals, 1 x 83 g a.s./ha
Step 1		0.124	0.124
Step 2	N-EU	0.038	0.038
	S-EU	0.038	0.038

Bold: PEC_{SW}/RAC ratios > 1

The risk to sediment dwelling organisms is considered acceptable based on FOCUS Step 1 PECsw values.

Algae:

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS		**Algae**					
		Fenoxaprop-P-ethyl RAC = 41.8 µg a.s./L[a]	Fenoxaprop-P-acid RAC = 6990 µg/L	Chlorobenzoxazolone RAC = 878 µg/L	HOPP-acid RAC = 5340 µg/L	Phenol RAC = 333 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 873 µg/L
Step 1		0.059	0.0057	0.0028	0.0026	0.0094	0.0055
Step 2	N-EU	0.018	0.0012	0.00081	0.000019	0.00087	0.00015

	S-EU	0.018	0.001	0.00065	0.000019	0.00075	0.00015

Bold: PEC_{SW}/RAC ratios > 1
[a] The most sensitive endpoint is based on a study with the representative formulation.

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS		**Algae**					
		Fenoxaprop-P-ethyl RAC = 41.8 µg a.s./L[a]	Fenoxaprop-P-acid RAC = 6990 µg/L	Chlorobenzoxazolone RAC = 878 µg/L	HOPP-acid RAC = 5340 µg/L	Phenol RAC = 333 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 873 µg/L
Step 1		0.059	0.0057	0.0028	0.0026	0.0094	0.0055
Step 2	N-EU	0.018	0.00053	0.00034	0.000019	0.00048	0.00015
	S-EU	0.018	0.00099	0.00065	0.000019	0.00075	0.00015

Bold: PEC_{SW}/RAC ratios > 1
[a] The most sensitive endpoint is based on a study with the representative formulation.

Based on a Tier 1 risk assessment considering FOCUS Step 1 and 2 PEC_{sw} values a low risk to algae from exposure to the active substance Fenoxaprop-P-ethyl and respective metabolites was identified.

<u>Aquatic macrophytes:</u>

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS		**Aquatic macrophytes**					
		Fenoxaprop-P-ethyl RAC = 3.36 µg a.s./L	Fenoxaprop-P-acid RAC = 10000 µg/L	Chlorobenzoxazolone RAC = 0.336 µg/L	HOPP-acid RAC = 0.336 µg/L	Phenol RAC = 270 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 2940 µg/L
Step 1		0.74	0.0040	**7.29**	**41.96**	0.012	0.0016
Step 2	N-EU	0.23	0.00085	**2.11**	0.30	0.0011	0.000044
	S-EU	0.23	0.00069	**1.70**	0.30	0.0009	0.000044

Bold: PEC_{SW}/RAC ratios > 1

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS		**Aquatic macrophytes**					
		Fenoxaprop-P-ethyl RAC = 3.36 µg a.s./L	Fenoxaprop-P-acid RAC = 10000 µg/L	Chlorobenzoxazolone RAC = 0.336 µg/L	HOPP-acid RAC = 0.336 µg/L	Phenol RAC = 270 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 2940 µg/L
Step 1		0.74	0.0040	**7.29**	**41.96**	0.012	0.0016
Step 2	N-EU	0.23	0.00037	0.89	0.30	0.00059	0.000044
	S-EU	0.23	0.00069	**1.70**	0.30	0.00093	0.000044

Bold: PEC_{SW}/RAC ratios > 1

Based on the risk assessment a low risk to aquatic plants was identified for Fenoxaprop-P-ethyl and respective metabolites except for Chlorobenzoxazolone and HOPP-acid. However, the risk is considered acceptable as a 10 times higher toxicity was assumed for the metabolites.

CHA 4960

Fish acute:

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS		**Fish, acute**					
		Fenoxaprop-P-ethyl RAC = 1.7 µg a.s./L[a]	Fenoxaprop-P-acid RAC = 688.2 µg/L	Chlorobenzoxazolone RAC = 100 µg/L	HOPP-acid RAC = 3530 µg/L	Phenol RAC = 5.9 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 7.34 µg/L
Step 1		**1.46**	0.06	0.025	0.004	0.53	0.65
Step 2	N-EU	0.45	0.012	0.0071	0.000028	0.049	0.018
	S-EU	0.45	0.01	0.0057	0.000028	0.042	0.018

Bold: PEC_{SW}/RAC ratios > 1

[a] The most sensitive endpoint is based on a study with the representative formulation.

Tier 1 risk assessment – PEC/RAC ratios, Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS		**Fish, acute**					
		Fenoxaprop-P-ethyl RAC = 1.7 µg a.s./L[a]	Fenoxaprop-P-acid RAC = 688.2 µg/L	Chlorobenzoxazolone RAC = 100 µg/L	HOPP-acid RAC = 3530 µg/L	Phenol RAC = 5.9 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 7.34 µg/L
Step 1		**1.46**	0.06	0.025	0.004	0.53	0.65
Step 2	N-EU	0.45	0.0054	0.003	0.000028	0.027	0.018
	S-EU	0.45	0.01	0.0057	0.000028	0.042	0.018

Bold: PEC_{SW}/RAC ratios > 1

[a] The most sensitive endpoint is based on a study with the representative formulation.

Under consideration of FOCUS Step 2 PECsw values an acceptable acute risk to fish was identified for Fenoxaprop-P-ethyl and the respective metabolites.

Aquatic invertebrates acute:

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS	**Aquatic invertebrates, acute**					
	Fenoxaprop-P-ethyl RAC = 1.09 µg a.s./L	Fenoxaprop-P-acid RAC = 1260 µg/L	Chlorobenzoxazolone RAC = 66 µg/L	HOPP-acid RAC = 868 µg/L	Phenol RAC = 17.5 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 99.8

							µg/L
Step 1		**2.27**	0.03	0.037	0.016	0.18	0.048
Step 2	N-EU	0.69	0.0068	0.011	0.00012	0.017	0.0013
	S-EU	0.69	0.006	0.0086	0.00012	0.014	0.0013

Bold: PEC_{SW}/RAC ratios > 1

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS		**Aquatic invertebrates, acute**					
		Fenoxaprop-P-ethyl RAC = 1.09 µg a.s./L	Fenoxaprop-P-acid RAC = 1260 µg/L	Chlorobenzoxazolone RAC = 66 µg/L	HOPP-acid RAC = 868 µg/L	Phenol RAC = 17.5 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 99.8 µg/L
Step 1		**2.27**	0.03	0.037	0.016	0.18	0.048
Step 2	N-EU	0.69	0.003	0.0045	0.00012	0.0091	0.0013
	S-EU	0.69	0.006	0.0086	0.00012	0.014	0.0013

Bold: PEC_{SW}/RAC ratios > 1

Based on a Tier 1 risk assessment considering FOCUS Step 1 and 2 PEC_{sw} values a low acute risk to aquatic invertebrates from exposure to the active substance Fenoxaprop-P-ethyl and the metabolites Fenoxaprop-P-acid, Chlorobenzoxazolone, HOPP-acid, Phenol and Fenoxaprop-dechloro was identified

Fish chronic:

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS		**Fish, chronic**		
		Fenoxaprop-P-ethyl RAC = 2.832 µg a.s./L	Chlorobenzoxazolone RAC = 2.832 µg/L	Phenol RAC = 2.832 µg/L
Step 1		0.88	0.87	**1.11**
Step 2	N-EU	0.27	0.25	0.10
	S-EU	0.27	0.20	0.088

Bold: PEC_{SW}/RAC ratios > 1

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS		**Fish, chronic**		
		Fenoxaprop-P-ethyl RAC = 2.832µg a.s./L	Chlorobenzoxazolone RAC = 2.832 µg/L	Phenol RAC = 2.832 µg/L
Step 1		0.88	0.87	**1.11**
Step 2	N-EU	0.27	0.11	0.056
	S-EU	0.27	0.20	0.088

Bold: PEC_{SW}/RAC ratios > 1

Based on a Tier 1 risk assessment considering FOCUS Step 1 and 2 PEC_{sw} values a low chronic risk to fish from exposure to the active substance Fenoxaprop-P-ethyl and respective metabolites was identified.

Aquatic invertebrates chronic:

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS		Aquatic invertebrates, chronic				
		Fenoxaprop-P-ethyl RAC = 1.1 µg a.s./L	Fenoxaprop-P-acid RAC = 49 µg/L	Chlorobenzoxazolone RAC = 1.1 µg/L	HOPP-acid RAC = 300 µg/L	Phenol RAC = 1.1 µg/L
Step 1		**2.25**	0.81	**2.23**	0.047	**2.85**
Step 2	N-EU	0.69	0.017	0.65	0.00033	0.26
	S-EU	0.69	0.014	0.52	0.00033	0.23

Bold: PEC_{SW}/RAC ratios > 1

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS			Aquatic invertebrates, chronic			
		Fenoxaprop-P-ethyl RAC = 1.1 µg a.s./L	Fenoxaprop-P-acid RAC = 49 µg/L	Chlorobenzoxazolone RAC = 1.1 µg/L	HOPP-acid RAC = 300 µg/L	Phenol RAC = 1.1 µg/L
Step 1		**2.25**	0.81	**2.23**	0.047	**2.85**
Step 2	N-EU	0.69	0.076	0.27	0.00033	0.15
	S-EU	0.69	0.14	0.52	0.00033	0.23

Bold: PEC_{SW}/RAC ratios > 1

Based on a Tier 1 risk assessment considering FOCUS Step 1 and 2 PEC_{sw} values a low chronic risk to aquatic invertebrates from exposure to the active substance Fenoxaprop-P-ethyl and respective metabolites was identified.

Sediment dwelling organisms:

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PEC_{SW} Step 1 and Step 2

FOCUS		Sediment dwelling organisms, chronic, RAC = 20 µg a.s./L (Tier 1)	
		Winter cereals, 1 x 83 g a.s./ha	Spring cereals, 1 x 83 g a.s./ha
Step 1		0.124	0.124
Step 2	N-EU	0.038	0.038
	S-EU	0.038	0.038

Bold: PEC_{SW}/RAC ratios > 1

The risk to sediment dwelling organisms is considered acceptable based on FOCUS Step 1 PECsw values.

Algae:

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS	Algae					
	Fenoxaprop-P-ethyl RAC = 12 µg a.s./L[a]	Fenoxaprop-P-acid RAC = 6990 µg/L	Chlorobenzoxazolone RAC = 878 µg/L	HOPP-acid RAC = 5340 µg/L	Phenol RAC = 333 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 873 µg/L
Step 1	0.21	0.0057	0.0028	0.0026	0.0094	0.0055

Step 2	N-EU	0.063	0.0012	0.00081	0.000019	0.00087	0.00015
	S-EU	0.063	0.001	0.00065	0.000019	0.00075	0.00015

Bold: PEC_{SW}/RAC ratios > 1
[a] The most sensitive endpoint is based on a study with the representative formulation.

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS		Algae					
		Fenoxaprop-P-ethyl RAC = 12 µg a.s./L[a]	Fenoxaprop-P-acid RAC = 6990 µg/L	Chlorobenzoxazolone RAC = 878 µg/L	HOPP-acid RAC = 5340 µg/L	Phenol RAC = 333 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 873 µg/L
Step 1		0.21	0.0057	0.0028	0.0026	0.0094	0.0055
Step 2	N-EU	0.063	0.00053	0.00034	0.000019	0.00048	0.00015
	S-EU	0.063	0.00099	0.00065	0.000019	0.00075	0.00015

Bold: PEC_{SW}/RAC ratios > 1
[a] The most sensitive endpoint is based on a study with the representative formulation.

Based on a Tier 1 risk assessment considering FOCUS Step 1 and 2 PEC_{sw} values a low risk to algae from exposure to the active substance Fenoxaprop-P-ethyl and respective metabolites was identified.

Aquatic macrophytes:

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – winter cereals, 1 x 83 g a.s./ha

FOCUS		Aquatic macrophytes					
		Fenoxaprop-P-ethyl RAC = 3.36 µg a.s./L	Fenoxaprop-P-acid RAC = 10000 µg/L	Chlorobenzoxazolone RAC = 0.336 µg/L	HOPP-acid RAC = 0.336 µg/L	Phenol RAC = 270 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 2940 µg/L
Step 1		0.74	0.0040	**7.29**	**41.96**	0.012	0.0016
Step 2	N-EU	0.23	0.00085	**2.11**	0.30	0.0011	0.000044
	S-EU	0.23	0.00069	**1.70**	0.30	0.0009	0.000044

Bold: PEC_{SW}/RAC ratios > 1

Tier 1 risk assessment – PEC/RAC ratios, FOCUS PECsw Step 1 and Step 2 – spring cereals, 1 x 83 g a.s./ha

FOCUS		Aquatic macrophytes					
		Fenoxaprop-P-ethyl RAC = 3.36 µg a.s./L	Fenoxaprop-P-acid RAC = 10000 µg/L	Chlorobenzoxazolone RAC = 0.336 µg/L	HOPP-acid RAC = 0.336 µg/L	Phenol RAC = 270 µg/L	Fenoxaprop-P-ethyl-dechloro-hydroxy RAC = 2940 µg/L
Step 1		0.74	0.0040	**7.29**	**41.96**	0.012	0.0016
Step 2	N-EU	0.23	0.00037	0.89	0.30	0.00059	0.000044
	S-EU	0.23	0.00069	**1.70**	0.30	0.00093	0.000044

Bold: PEC_{SW}/RAC ratios > 1

Based on the risk assessment a low risk to aquatic plants was identified for Fenoxaprop-P-ethyl and respective metabolites except for Chlorobenzoxazolone and HOPP-acid. However, the risk is considered acceptable as a 10 times higher toxicity was assumed for the metabolites.

2.9.9.4. *Risk assessment for bees*

Fenoxaprop-P-ethyl EW 69 (69 g/L)

Risk assessment for use of Fenoxaprop-P-ethyl EW 69 (69 g/L) at 1.2 L product/ha [1 application in cereals]

Species	Test substance	Risk quotient	HQ/ETR	Trigger
Apis mellifera	a.s.	HQ_{oral}	< 0.06	0.2
Apis mellifera	CHA 4960	HQ_{oral}	< 0.03	0.2
Bombus terrestris	a.s.	HQ_{oral}	< 0.01	7
Apis mellifera	a.s.	$HQ_{contact}$	< 0.8	42
Apis mellifera	CHA 4960	$HQ_{contact}$	< 2.1	42
Bombus terrestris	a.s.	$HQ_{contact}$	< 0.8	7
Apis mellifera	CHA 4960	$ETR_{acute\ adult\ oral}$	< 0.03	> 0.2
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	$ETR_{chronic\ adult\ oral}$	**0.062**	>0.03
Apis mellifera	a.s., preparation	ETR_{larvae}	-	-
Apis mellifera	a.s., preparation	ETR_{hpg}	-	-

Tier 1 level assessment for use of Fenoxaprop-P-ethyl EW 69 (69 g/L) at 1.2 L product/ha [1 application in cereals]

Species	Test substance	Scenario	Risk quotient	HQ/ETR	Trigger
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Treated crop BBCH 10-29	$ETR_{chronic\ adult\ oral}$	0.005	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Treated crop BBCH 30-39	$ETR_{chronic\ adult\ oral}$	0.005	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Weeds BBCH 10-29	$ETR_{chronic\ adult\ oral}$	0.017	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Weeds BBCH 30-39	$ETR_{chronic\ adult\ oral}$	0.009	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Field margin BBCH 10-29	$ETR_{chronic\ adult\ oral}$	0	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Field margin BBCH 30-39	$ETR_{chronic\ adult\ oral}$	0	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Adjacent crop BBCH 10-29	$ETR_{chronic\ adult\ oral}$	0	> 0.03

Species	Test substance	Scenario	Risk quotient	HQ/ETR	Trigger
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Adjacent crop BBCH 30-39	ETR $_{\text{chronic adult oral}}$	0	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Adjacent crop BBCH 40-69	ETR $_{\text{chronic adult oral}}$	0	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	next crop BBCH 10-29	ETR $_{\text{chronic adult oral}}$	0.003	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	next crop BBCH 30-39	ETR $_{\text{chronic adult oral}}$	0.003	> 0.03

FPP + MPR EW 144

Risk assessment for use of FPP + MPR EW 144 at 1.2 L product/ha [1 application in cereals]

Species	Test substance	Risk quotient	HQ/ETR	Trigger
Apis mellifera	a.s.	$ETR_{\text{acute adult oral}}$	< 0.06	0.2
Apis mellifera	CHA 4960	$ETR_{\text{acute adult oral}}$	< 0.05	0.2
Bombus terrestris	a.s.	$ETR_{\text{acute adult oral}}$	< 0.01	7
Apis mellifera	a.s.	$ETR_{\text{acute adult contact}}$	< 0.8	42
Apis mellifera	CHA 4960	$ETR_{\text{acute adult contact}}$	< 6.3	42
Bombus terrestris	a.s.	$ETR_{\text{acute adult contact}}$	< 0.8	7
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	ETR $_{\text{chronic adult oral}}$	**0.062**	>0.03
Apis mellifera	a.s., preparation	ETR_{larvae}	-	-
Apis mellifera	a.s., preparation	ETR_{hpg}	-	-

Tier 1 level assessment for use of FPP + MPR EW 144 at 1.2 L product/ha [1 application in cereals]

Species	Test substance	Scenario	Risk quotient	HQ/ETR	Trigger
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Treated crop BBCH 10-29	ETR $_{\text{chronic adult oral}}$	0.005	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Treated crop BBCH 30-39	ETR $_{\text{chronic adult oral}}$	0.005	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Weeds BBCH 10-29	ETR $_{\text{chronic adult oral}}$	0.017	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Weeds BBCH 30-39	ETR $_{\text{chronic adult oral}}$	0.009	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Field margin BBCH 10-29	ETR $_{\text{chronic adult oral}}$	0	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Field margin BBCH 30-39	ETR $_{\text{chronic adult oral}}$	0	> 0.03

Species	Test substance	Scenario	Risk quotient	HQ/ETR	Trigger
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Adjacent crop BBCH 10-29	ETR $_{\text{chronic adult oral}}$	0	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Adjacent crop BBCH 30-39	ETR $_{\text{chronic adult oral}}$	0	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	Adjacent crop BBCH 40-69	ETR $_{\text{chronic adult oral}}$	0	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	next crop BBCH 10-29	ETR $_{\text{chronic adult oral}}$	0.003	> 0.03
Apis mellifera	Fenoxaprop-P-ethyl EW 69 (69 g/L)	next crop BBCH 30-39	ETR $_{\text{chronic adult oral}}$	0.003	> 0.03

Risk to honey-bee brood:

Test substance	Exposure route	Results	Risk acceptable?
FPP + MPR EW 144 (69+75) "Ralon Super"	Honey bee brood feeding (Oomen *et al.*, 1992)	Slightly increased termination rate of eggs and old larvae and decreased termination rate of young larvae. No effects on honey bee pupae and larvae were observed. In both, in the test item treatment group and in the control group, post-application adult mortality was on the same level as the corresponding pre-application adult mortality, with the post-application adult mortality in the test item treatment group being only slightly higher. Overall, it can be concluded according to the results of this study that the administration of FPP + MPR EW 144 (69+75 g/L) fortified sugar syrup 0.21 g/L fenoxaprop-P-ethyl to honey bee colonies does neither adversely affect honey bee colonies nor bee brood development.	Yes
FPP + MPR EW 144 "Ralon Super"	Honeybee brood development	Slightly increased termination rate of eggs and young larvae, not significant compared to the control and decreased termination rate of old larvae. No effects on honey bee pupae and larvae were observed. Adult bee mortality in the test item treatment group was slightly lower compared to control. In both, in the test item treatment group and in the control group, post-application adult mortality was on the same level as the corresponding pre-application adult mortality in the test item treatment and control group being only slightly higher. Overall it can be concluded according to the results of this study that the administration of fenoxaprop 69 g/L EW fortified sugar syrup 0.21 g/L fenoxaprop-P-ethyl to honey bee colonies did not adversely affect honey bee colonies or bee brood development.	Yes

2.9.9.5. *Risk assessment for non-target arthropods*

FPP+MPR EW 144 (69+75 g/L)

Species	Application rate [mL prod./ha]	MAF	Drift [%]	LR_{50} [mL prod./ha]	$HQ_{in\text{-}field}$	$HQ_{off\text{-}field}$
Aphidius rhopalosiphi	1200	1	2.77	678	1.8	0.05
Typhlodromus pyri		1		> 1200	< 1	< 0.03

CHA 4960

Species	Application rate [g prod./ha]	MAF	Drift [%]	LR_{50} [g prod./ha]	$HQ_{in\text{-}field}$	$HQ_{off\text{-}field}$
Aphidius rhopalosiphi	1236*	1	2.77	578	**2.1**	0.06
Typhlodromus pyri				478	**2.6**	0.07

*based on a product density of 1.03 g/mL

2.9.9.6. *Risk assessment for earthworms and other soil meso- and macro-organisms*

FPP+MPR EW 144 (69+75 g/L)

GAP use	Test substance	NOEC [mg/kg soil dw]	max PEC_{soil} [mg/kg soil dw]	TER_{LT}	Trigger
Eisenia fetida					
Cereals 1 x 1.2 L form./ha	Fenoxaprop-P-ethyl (technical)	NOEC ≥ 28*	0.111	≥ 252	5
	FPP+MPR EW 144 (69+75 g/L)	EC_{10} = 85 *	1.688	50	5
	Fenxoaprop-P-acid	NOEC = 100	0.097	1030	5
	Chlorobenzoxazolone	NOEC = 89	0.01	8900	5
	HOPP acid	NOEC = 158	0.041	3853	5
Folsomia candida					
Cereals 1 x 1.2 L form./ha	FPP+MPR EW 144 (69+75 g/L)	EC_{10} = 28 *	1.688	16	5
	Fenxoaprop-P-ethyl	NOEC ≥ 500 *	0.111	≥ 4504	5
	HOPP acid	NOEC ≥ 50 *	0.041	≥ 1219	5
	Chlorobenzoxazolone	NOEC ≥ 100	0.01	≥ 5000	5

GAP use	Test substance	NOEC [mg/kg soil dw]	max PEC_{soil} [mg/kg soil dw]	TER_{LT}	Trigger
	Fenoxaprop-P-acid	NOEC ≥ 111.6	0.097	≥ 1150	5
Hypoaspis aculeifer					
Cereals 1 x 1.2 L form./ha	FPP+MPR EW 144 (69+75 g/L)	NOEC = 28	1.688	16	5
	Fenxoaprop-P-ethyl	NOEC ≥ 500 *	0.111	≥ 4504	5
	HOPP acid	NOEC ≥ 50 *[1]	0.041	≥ 1219	5
	Chlorobenzoxazolone	NOEC ≥ 100	0.01	≥ 5000	5
	Fenoxaprop-P-acid	NOEC ≥ 111.6	0.097	≥ 1150	5

* corrected by a factor of 2 due to the log P_{OW} of Fenxoaprop-P-ethyl > 2
[1] parent/10

CHA 4960

GAP use	Test substance	NOEC [mg/kg soil dw]	max PEC_{soil} [mg/kg soil dw]	TER_{LT}	Trigger
Earthworms					
Cereals 1 x 1.2 L form./ha	CHA 4960	NOEC = 26.9 *	1.648	> 16	5
	Fenxoaprop-P-ethyl	NOEC ≥ 28 *	0.111	≥ 252	5
	Fenxoaprop-P-acid	NOEC = 100	0.097	1030	5
	Chlorobenzoxazolone	NOEC = 89	0.01	8900	5
	HOPP acid	NOEC = 158	0.041	3853	5
Folsomia candida					
Cereals 1 x 1.2 L form./ha	CHA 4960	NOEC = 95.5 mg *	1.648	58	5
	Fenxoaprop-P-ethyl	NOEC ≥ 500 *	0.111	≥ 4504	5
	Fenoxaprop-P-acid	NOEC ≥ 111.6	0.097	≥ 1150	5
	HOPP acid	NOEC ≥ 50 *	0.041	≥ 1219	5
	Chlorobenzoxazolone	NOEC ≥ 100	0.01	≥ 5000	5
Hypoaspis aculeifer					
Cereals 1 x 1.2 L form./ha	CHA 4960	NOEC = 95.5 *	1.648	58	5
	Fenxoaprop-P-ethyl	NOEC ≥ 500 *	0.111	≥ 4504	5
	HOPP acid	NOEC ≥ 50 *[1]	0.041	≥ 1219	5

GAP use	Test substance	NOEC [mg/kg soil dw]	max PEC_{soil} [mg/kg soil dw]	TER_{LT}	Trigger
	Chlorobenzoxazolone	NOEC ≥ 100	0.01	≥ 5000	5
	Fenoxaprop-P-acid	NOEC ≥ 111.6	0.097	≥ 1150	5

* corrected by a factor of 2 due to the log P_{OW} of Fenxoaprop-P-ethyl > 2

[1] parent/10

2.9.9.7. *Risk assessment for soil micro-organisms*

FPP+MPR EW 144 (69+75 g/L)

Test substance	Effects < 25% at test concentration	$PEC_{soil, accumulation}$	Risk acceptable?
FPP+MPR EW 144 (69+75 g/L)	8.44 m/kg soil dw	1.688 mg/kg soil dw	Yes
Fenoxaprop-P-ethyl	0.67 mg/kg soil dw	0.111 mg ai/kg soil dw	Yes
Fenoxaprop-P-acid	0.5244 mg/kg soil dw	0.097 mg ai/kg soil dw	Yes
Chlorobenzoxazolone	0.263 mg/kg soil dw	0.01 mg ai/kg soil dw	Yes
HOPP acid	0.3 mg/kg soil dw	0.041 mg ai/kg soil dw	Yes

CHA 4960

Test substance	Effects < 25% at test concentration	$PEC_{soil, max}$	Risk acceptable?
CHA 4960	13.73 mg from./kg dry soil	1.648 mg form./kg soil dw	Yes
Fenoxaprop-P-ethyl	0.67 mg/kg soil dw	0.111 mg ai/kg soil dw	Yes
Fenoxaprop-P-acid	0.5244 mg/kg soil dw	0.097 mg ai/kg soil dw	Yes
Chlorobenzoxazolone	0.263 mg/kg soil dw	0.01 mg ai/kg soil dw	Yes
HOPP acid	0.3 mg/kg soil dw	0.041 mg ai/kg soil dw	Yes

2.9.9.8. *Risk assessment for non-target plants*

FPP+MPR EW 144 (69+75 g/L)

Distance	Drift rate	Drift reducing nozzles	$PER_{off-field}$ [mL prod./ha]	Toxicity [mL prod./ha]	TER
1 m	2.77%	-	33.24	ER_{50} = 108.7	**3.3**
		50%	16.62		6.5
		75%	8.31		13
		90%	3.324		33
5 m	0.57%	-	6.84		16

CHA 4960

Distance	Drift rate	Drift reducing nozzles	$PER_{off-field}$ [mL prod./ha]	Toxicity [mL prod./ha]	TER
1 m	2.77%	-	33.24	ER_{50} = 84.85	**2.6**
		50%	16.62		5.1
		75%	8.31		10

		90%	3.3		26
5 m	0.57%	-	6.84		12

2.10. CLASSIFICATION AND LABELLING

Proposed classification according to Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification [1)]	Reason for no classification [2)]
2.1.	Explosives	-	-	-	Conclusive but not sufficient for classification
2.2.	Flammable gases	-	-	-	Conclusive but not sufficient for classification
2.3.	Flammable aerosols	-	-	-	Conclusive but not sufficient for classification
2.4.	Oxidising gases	-	-	-	Conclusive but not sufficient for classification
2.5.	Gases under pressure	-	-	-	Conclusive but not sufficient for classification
2.6.	Flammable liquids	-	-	-	Conclusive but not sufficient for classification
2.7.	Flammable solids	-	-	-	Conclusive but not sufficient for classification
2.8.	Self-reactive substances and mixtures	-	-	-	Conclusive but not sufficient for classification
2.9.	Pyrophoric liquids	-	-	-	Conclusive but not sufficient for classification
2.10.	Pyrophoric solids	-	-	-	Conclusive but not sufficient for classification
2.11.	Self-heating substances and mixtures	-	-	-	Conclusive but not sufficient for classification
2.12.	Substances and mixtures which in contact with water emit flammable gases	-	-	-	Conclusive but not sufficient for classification
2.13.	Oxidising liquids	-	-	-	Conclusive but not sufficient for classification
2.14.	Oxidising solids	-	-	-	Conclusive but not sufficient for classification
2.15.	Organic peroxides	-	-	-	Conclusive but not sufficient for

					classification
2.16.	Substance and mixtures corrosive to metals	-	-	-	Conclusive but not sufficient for classification
3.1.	Acute toxicity - oral	Acute Tox. 4 H302	-	-	
	Acute toxicity - dermal	-	-	-	Conclusive but not sufficient for classification
	Acute toxicity - inhalation	-	-	-	Conclusive but not sufficient for classification
3.2.	Skin corrosion / irritation	-	-	-	Conclusive but not sufficient for classification
3.3.	Serious eye damage / eye irritation	-	-	-	Conclusive but not sufficient for classification
3.4.	Respiratory sensitisation	-	-	-	
3.4.	Skin sensitisation	Skin Sens. 1 H317	-	Skin Sens. 1 H317	
3.5.	Germ cell mutagenicity	-	-	-	Conclusive but not sufficient for classification
3.6.	Carcinogenicity	-	-	-	Conclusive but not sufficient for classification
3.7.	Reproductive toxicity	-	-	-	Conclusive but not sufficient for classification
3.8.	Specific target organ toxicity –single exposure	-	-	-	Conclusive but not sufficient for classification
3.9.	Specific target organ toxicity – repeated exposure	STOT-RE Cat. 2 H373 (kidneys)	-	STOT-RE Cat. 2 H373 (kidneys)	
3.10.	Aspiration hazard	-	-	-	Conclusive but not sufficient for classification
4.1.	Hazardous to the aquatic environment	Aquatic acute Cat.1 H400 Aquatic chronic Cat. 1 H410		Aquatic acute Cat.1 H400 Aquatic chronic Cat. 1 H410	
5.1.	Hazardous to the ozone layer				

[1)] Including specific concentration limits (SCLs) and M-factors
[2)] Data lacking, inconclusive, or conclusive but not sufficient for classification

Labelling: Signal word: Warning
Hazard statements: H400, H410, H317, H373, EUH066

Precautionary statements: P260, P261, P272, P280, P391, P314 P302 + P352, P333 + P313, P321, P362+P364, P501

Proposed notes assigned to an entry:
Notes in accordance with CLP Regulation, Annex VI, Section 1.1.3

Proposed classification according to Dangerous Substances Directive (Directive 67/548/EEC)

Hazardous property	Proposed classification	Proposed SCLs	Current classification [1)]	Reason for no classification [2)]
Explosiveness				
Oxidising properties				
Flammability				
Other physico-chemical properties *[Add rows when relevant]*				
Thermal stability				
Acute toxicity				
Acute toxicity – irreversible damage after single exposure				
Repeated dose toxicity				
Irritation / Corrosion				
Sensitisation				
Carcinogenicity				
Mutagenicity – Genetic toxicity				
Toxicity to reproduction – fertility				
Toxicity to reproduction – development				
Toxicity to reproduction – breastfed babies. Effects on or via lactation				
Environment				

[1)] Including SCLs
[2)] Data lacking, inconclusive, or conclusive but not sufficient for classification

Labelling: Indication of danger:
R-phrases:
S-phrases:

2.11. RELEVANCE OF METABOLITES IN GROUNDWATER

The 80th percentile annual average PECgw concentrations at 1 m depth were predicted as < 0.01 µg/l for fenoxaprop-P-acid (AE F088406), chlorobenzoxazolone (AE F054014) and HOPP-acid (AE F096918) in all cases.

2.11.1. STEP 1: Exclusion of degradation products of no concern

According to *Guidance document on the assessment of the relevance of the metabolites in groundwater of substances regulated under Council Directive 91/414/EEC* (Sanco/221/2000 – rev.10 - final, 25 February 2003**)** no degradation products of no concern were detected.

2.11.2. STEP 2: Quantification of potential groundwater contamination

The 80th percentile annual average PECgw concentrations at 1 m depth were predicted as < 0.01 µg/l for fenoxaprop-P-acid (AE F088406), chlorobenzoxazolone (AE F054014) and HOPP-acid (AE F096918) in all cases applying FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and FOCUS MACRO 5.5.4. The risk for groundwater leaching is considered low.

2.11.3. STEP 3: Hazard assessment – identification of relevant metabolites

2.11.3.1 STEP 3, Stage 1: screening for biological activity
Not necessary since no metabolite predicted > 0.1 µg/l in groundwater.

2.11.3.2 STEP 3, Stage 2: screening for genotoxicity
Not necessary since no metabolite predicted > 0.1 µg/l in groundwater.

2.11.3.3 STEP 3, Stage 3: screening for toxicity
Not necessary since no metabolite predicted > 0.1 µg/l in groundwater.

2.11.4. STEP 4: Exposure assessment – threshold of concern approach

Not necessary since no metabolite predicted > 0.1 µg/l in groundwater.

2.11.5. STEP 5: Refined risk assessment

Not necessary since no metabolite predicted > 0.1 µg/l in groundwater.

2.11.6. Overall conclusion

Not necessary since no metabolite predicted > 0.1 µg/l in groundwater.

2.12. CONSIDERATION OF ISOMERIC COMPOSITION IN THE RISK ASSESSMENT

2.12.1. Identity and physical chemical properties

Fenoxaprop-P-ethyl is the optical active *R*-enantiomer of fenoxaprop-ethyl which is a racemic mixture.

2.12.2. Methods of analysis

The ratio of the stereoisomers Fenoxaprop-P-ethyl (R-enantiomer) and Fenoxaprop-M-ethyl (inactive S-enantiomer) was determined by a gradient, chiral HPLC-method. Methods for risk assessment and methods for post-approval control and monitoring purposes are not enantio-selective.

2.12.3. Mammalian toxicity

Nearly all studies were conducted with the active isomer (fenoxaprop-P-ethyl). Only the chronic toxicity data package as well as the multi-generation rat study were performed with the racemic mixture (fenoxaprop-ethyl), and in the interests of animal welfare were not repeated with the pure active isomer. Instead the results of those were bridged to the active isomer on the basis of the comparison of the results from acute, short-term and sub-chronic toxicity studies with both the racemic mixture and the pure active enantiomer. The bridging approach was evaluated and accepted as part of the original Annex I inclusion.

2.12.4. Operator, Worker, Bystander and Resident exposure

All exposure estimations were conducted with products containing fenoxaprop-P-ethyl. As the toxicological profile of the racemic mixture (fenoxaprop-ethyl) has been considered to be very similar to that of the active isomer (fenoxaprop-P-ethyl) and bridging has been accepted as part of the original Annex I inclusion, no further estimation is deemed necessary.

2.12.5. Residues and Consumer risk assessment

Fenoxaprop-P-ethyl is the herbicidal effective R-enantiomer of the racemic substance fenoxaprop-ethyl. A metabolism study on soya beans and wheat showed that no racemisation either of the parent compound or the free acid occurs.

2.12.6. Environmental fate

Studies on the environmental fate and behaviour were conducted with pure active enantiomer fenoxaprop-P-ethyl (R-enantiomer) with the exception of soil photolysis, where the racemic mixture fenoxaprop-ethyl (R/S) was applied. Literature data from dedicated soil degradation experiments with both enantiomers of fenoxaprop-P-ethyl (R or S enantiomer) indicate that there is no transformation from the R- to the S-enantiomer in soil. The pure R-enantimer is considered to degradate more slowly than the S-enantiomer.

2.12.7. Ecotoxciology

Studies on effects to non-target organisms were conducted with pure active isomer Fenoxaprop-P-ethyl. As an exemption from the above the chronic toxicity data package was not repeated with the pure active isomer in the interests of animal welfare. Instead the results of the studies with the racemic mixture were bridged to the active isomer on the basis of the comparison of the results from acute, short-term and sub-chronic studies with both the racemic mixture and the pure active enantiomer. The bridging approach was evaluated and accepted as part of the original Annex I inclusion.

2.13. RESIDUE DEFINITIONS

2.13.1. Definition of residues for exposure/risk assessment

Food of plant origin: 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.

Food of animal origin: 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

Soil: Fenoxaprop-P-ethyl, fenoxaprop-P-acid, chlorobenzoxazolone, HOPP-acid

Groundwater: Fenoxaprop-P-ethyl, fenoxaprop-P-acid, chlorobenzoxazolone, HOPP-acid

Surface water: Fenoxaprop-P-ethyl, fenoxaprop-P-acid, chlorobenzoxazolone, HOPP-acid, phenol metabolite, fenoxaprop-P-ethyl-dechloro-hydroxy

Sediment: Fenoxaprop-P-ethyl, fenoxaprop-P-acid, chlorobenzoxazolone, HOPP-acid, phenol metabolite, fenoxaprop-P-ethyl-dechloro-hydroxy

Air: Fenoxaprop-P-ethyl, fenoxaprop-P-acid

2.13.2. Definition of residues for monitoring

Food of plant origin: Sum of fenoxaprop-ethyl and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-ethyl.

Food of animal origin: Sum of fenoxaprop-ethyl and all metabolites which may be converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-ethyl.

Soil: Fenoxaprop-P-ethyl, fenoxaprop-P-acid

Groundwater: Fenoxaprop-P-ethyl, fenoxaprop-P-acid

Surface water: Fenoxaprop-P-ethyl, fenoxaprop-P-acid

Sediment: Fenoxaprop-P-ethyl, fenoxaprop-P-acid

Air: Fenoxaprop-P-ethyl, fenoxaprop-P-acid

Level 3

Fenoxaprop-P-ethyl

3. PROPOSED DECISION WITH RESPECT TO THE APPLICATION

3.1. BACKGROUND TO THE PROPOSED DECISION

3.1.1. Proposal on acceptability against the decision making criteria – Article 4 and annex II of regulation (EC) No 1107/2009

3.1.1.1. *Article 4*				
		Yes	No	
i)	It is considered that Article 4 of Regulation (EC) No 1107/2009 is complied with. Specifically the RMS considers that authorisation in at least one Member State is expected to be possible for at least one plant protection product containing the active substance for at least one of the representative uses.	x		It is considered that Article 4 of Regulation(EC) No 1107/2009 is complied with Fenoxaprop-P-ethyl for the representative uses (please refer to Section 1.5.1 Level 1 for details of representative uses)
3.1.1.2. *Submission of further information*				
		Yes	No	
i)	It is considered that a complete dossier has been submitted	x		With regards to the submission made, a complete dossier is considered to have been submitted, which enables a regulatory decision of Fenoxaprop-P-ethyl to be made. Regarding the data gaps identified in the separate dossiers of the notifiers please refer to point 3.1.4.
ii)	It is considered that in the absence of a full dossier the active substance may be approved even though certain information is still to be submitted because: (a) the data requirements have been amended or refined after the submission of the dossier; or (b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision.			Not applicable.
3.1.1.3. *Restrictions on approval*				
		Yes	No	
	It is considered that in line with Article 6 of Regulation (EC) No 1107/2009 approval should be subject to conditions and restrictions.			*(a) the minimum degree of purity of the active substance:* *920 g/kg (Reference specification for first Annex I inclusion)* *(b) the nature and maximum content of certain impurities*

				N/A *(c) restrictions arising from the evaluation of the information referred to in Article 8 of 1107/2009 taking account of the agricultural, plant health and environmental, including climatic, conditions in question;* *N/A* *(d) type of preparation;* *N/A* *(e) manner and conditions of application;* *N/A* *(f) submission of further confirmatory information to Member States, the Commission and the European Food Safety Authority, (the Authority), where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge;* *N/A* *(g) designation of categories of users, such as professional and non-professional;* *N/A* *(h) designation of areas where the use of plant protection products, including soil treatment products, containing the active substance may not be authorised or where the use may be authorised under specific conditions;* *N/A* *(i) the need to impose risk mitigation measures and monitoring after use;* *N/A* *(j) any other particular conditions that result from the evaluation of information made available in the context of Regulation 1107/2009.* *N/A*

	3.1.1.4. *Criteria for the approval of an active substance*			
Dossier				
		Yes	No	
	It is considered the dossier contains the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and Acute Reference Dose (ARfD).	x		The data submitted are sufficient to establish an Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and an Acute Reference Dose (ARfD).
	It is considered that the dossier contains the information necessary to carry out a risk assessment and for enforcement purposes (relevant for substances for which one or more representative uses includes use on feed or food crops or leads indirectly to residues in food or feed). In particular it is considered that the dossier: (a) permits any residue of concern to be defined; (b) reliably predicts the residues in food and feed, including succeeding crops (c) reliably predicts, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing; (d) permits a maximum residue level to be defined and to be determined by appropriate methods in general use for the commodity and, where appropriate, for products of animal origin where the commodity or parts of it is fed to animals; (e) permits, where relevant, concentration or dilution factors due to processing and/or mixing to be defined.	X		The data necessary to establish adequate MRLs and consumer risk assessment were submitted and are considered as sufficient for the current approval process. Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. No risk for consumers could be identified with respect to the representative uses.
	It is considered that the dossier submitted is sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.	x		See detailed evaluation in sections 8 and 9.
Efficacy				
		Yes	No	
	It is considered that it has been established for one or more representative uses that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective.		X	The representative uses for the renewal of Fenoxaprop-p-ethyl are intended to be applied post-emergence in soft wheat, durum wheat, rye, triticale (BBCH 11-39) and barley (BBCH 12-32) for the control of grass weeds (1x1.2 l PPP/ha). A summary of achieved control (%control, number of trials) and a summary of crop safety, as required according to SANCO/10054/2013-rev.3, 11 July 2013 (Appendix I) are not available.

				It is concluded that effectiveness and crop safety cannot be assessed conclusively.
Relevance of metabolites				
		Yes	No	
	It is considered that the documentation submitted is sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.	X		The toxicological, ecotoxicological or environmental relevance of metabolites can be established.
Composition				
		Yes	No	
	It is considered that the specification defines the minimum degree of purity, the identity and maximum content of impurities and, where relevant, of isomers/diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.	X		Sufficient information has been presented by all notifiers to support the declared technical specification of Fenoxaprop-P-ethyl with respect to the identity and content of impurities in the respective technical specifications.
	It is considered that the specification is in compliance with the relevant Food and Agriculture Organisation specification, where such specification exists.			No FAO specification exists
	It is considered for reasons of protection of human or animal health or the environment, stricter specifications than that provided for by the FAO specification should be adopted			No FAO specification exists
Methods of analysis				
		Yes	No	
	It is considered that the methods of analysis of the active substance, safener or synergist as manufactured and of determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities greater than 1 g/kg in the active substance, safener or synergist as manufactured, have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.	X		Adequate analytical methods are available for the determination of fenoxaprop-P-ethyl and all significant impurities in the technical material.
	It is considered that the methods of residue analysis for the active substance and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.	X		Adequate methods are available and sufficiently sensitive to monitor the respective current residue definition in plant material, soil, drinking water, surface water and air.
	It is confirmed that the evaluation has been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.	X		Please refer to Level 2 Section 2.2 for further details The information submitted with regards to methods of analysis is sufficient to support approval. Refer also to Level 2, Section 2.5.

Impact on human health				
Impact on human health - ADI, AOEL, ARfD				
		Yes	No	
	It is confirmed that (where relevant) an ADI, AOEL and ARfD can be established with an appropriate safety margin of at least 100 taking into account the type and severity of effects and the vulnerability of specific groups of the population.	X		The new data submitted for the renewal of fenoxaprop-P-ethyl do not change derivation of ADI, AOEL and ARfD. Therefore, all reference values established by the European Commission (SANCO/3777/08-rev.1, 2007) during the original EU review of fenoxaprop-P-ethyl are still valid. The ADI of 0.01 mg/kg bw/d based on the lowest NOAEL derived from the 2-year repeated oral study in the dog (supported by the 2-year and multigeneration rat studies) by applying a safety factor of 100. The lowest NOAEL in this study was 1.1mg/kg bw/d (2-year, dog). The AOEL of 0.014 mg/kg bw/d was based on the lowest relevant NOAEL derived from the rat multi-generation study in the rat (supported by the 2-year dog study) by applying a safety factor of 100. The lowest NOAEL is 1.42 mg/kg bw/d and a correction factor for oral absorption is not needed. The ARfD of 0.1 mg/kg bw/d is based on the foetal NOAEL of approximately 10 mg/kg bw/d from the developmental study in rats (see Volume 3CA B6, section 6.6.2.1). A safety factor of 100 is applied to the endpoint.
Impact on human health – proposed genotoxicity classification				
		Yes	Yes	No
	It is considered that, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as mutagen category 1A or 1B.**		X	All *in vitro* genotoxicity tests as well as an *in vivo* micronucleus test conducted with fenoxaprop-P-ethyl demonstrated negative results. Also for the racemate, all *in vitro* genotoxicity tests as well as an *in vivo* micronucleus test demonstrated negative results. It is concluded that based on the complete genotoxicity data package, fenoxaprop-P-ethyl is considered to be non-genotoxic. Classification for mutagenicity is not warranted.
Impact on human health – proposed carcinogenicity classification				
		Yes	Yes	No
i)	It is considered that, on the basis of assessment of the carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as carcinogen category 1A or 1B.**		X	In the carcinogenicity study in mice, hepatocellular hypertrophy, liver adenomas and carcinomas were observed. These findings are considered to be rodent-specific (mouse-specific activation of peroxisomal enzymes) and not relevant to humans. Classification for carcinogenicity is not warranted.

ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			*Not applicable*
Impact on human health – proposed reproductive toxicity classification				
		Yes	Yes	No
i)	It is considered that, on the basis of assessment of the reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, **the substance SHOULD BE classified or proposed for classification**, in accordance with the provisions of Regulation (EC) No 1272/2008, **as toxic for reproduction category 1A or 1B.**		X	The reproductive toxicity of fenoxaprop-P-ethyl has been adequately addressed in a rat 2-generation study and in rat and rabbit developmental toxicity studies. These studies demonstrated that fenoxaprop-P-ethyl does not possess hazardous properties in relation to reproduction or development. Classification for reproductive toxicity is not warranted.
ii)	Linked to above classification proposal. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			*Not applicable*
Impact on human health – proposed endocrine disrupting properties classification				
		Yes	Yes	No
i)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **carcinogenic category 2 and toxic for reproduction category 2 and on that basis shall be considered to have endocrine disrupting properties**		X	No evidence of carcinogenicity relevant to humans or reproductive toxicity was seen in the standard carcinogenicity and reproductive toxicity studies.
ii)	It is considered that **the substance SHOULD BE classified or proposed for classification** in accordance with the provisions of Regulation (EC) No 1272/2008, as **toxic for reproduction category 2**		X	No evidence of reproductive toxicity was seen in the reproductive toxicity data package. The findings of increased hepatocellular hypertrophy, liver adenomas and

	and in addition the RMS considers the substance **has toxic effects on the endocrine organs and on that basis shall be considered to have endocrine disrupting properties**			carcinomas are considered to be rodent-specific (mouse-specific activation of peroxisomal enzymes) and not relevant to humans.
iii)	Linked to either i) or ii) immediately above. It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			*Not applicable*
Fate and behaviour in the environment				
Persistent organic pollutant (POP)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent organic pollutant (POP) as laid out in Regulation 1107/2009 Annex II Section 3.7.1.		x	Persistence: The criterion for persistence (P) is not fulfilled (DT_{50} in water < 60 days; DT_{50} in soil < 120 days; DT_{50} in sediment < 120 days). There is no indication for long range transport. Bioaccumulation: The bioconcentration factor (BCFfish = 338) and the partition co-efficient (logPow = 4.58) are below the trigger of 5000 and > 5 respectivly.
Persistent, bioaccumulative and toxic substance (PBT)				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a persistent, bioaccumulative and toxic (PBT) substance as laid out in Regulation 1107/2009 Annex II Section 3.7.2.		x	Persistence: The criterion for persistence (P) is not fulfilled (DT_{50} in fresh surface water < 40 days; DT_{50} in marine surface water most probably < 60 days (hydrolysis), DT_{50} in soil or fresh water sediment < 120 days, no data for marine or estuarine environments). Bioaccumulation: The bioconcentration factor (BCF_{fish} = 338) is below the trigger of 2000. Toxicity: The NOEC values for marine and freshwater species are above the trigger of > 0.01 mg a.s./L Fenoxaprop-P-ethyl is not classified as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B

				or 2) pursuant to Regulation (EC) No 1272/2008. However, classification as STOT RE 1 is proposed.
Very persistent and very bioaccumulative substance (vPvB).				
		Yes	No	
	It is considered that the active substance **FULFILS** the criteria of a very persistent and very bioaccumulative substance (vPvB) as laid out in Regulation 1107/2009 Annex II Section 3.7.3.		x	Persistence: The criterion for very persistent (vP) is not fulfilled (DT_{50} in fresh surface water < 60 days; DT_{50} in soil or fresh water sediment < 180 days; no data for marine or estuarine environments) Bioaccumulation: The bioconcentration factor is below the trigger of 5000 (BCF_{fish} = 338).
Ecotoxicology				
		Yes	No	
	It is considered that the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) under realistic proposed conditions of use of a plant protection product containing the active substance, safener or synergist. The RMS is content that the assessment takes into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance, safener or synergist is expected to affect adversely by the intended use.	x		The intended use is a spray application in cereals (Spring and winter wheat, durum wheat, rye, winter rye, triticale, spring and winter barley) at a BBCH of 11-39. Based on the available studies no adverse effects on non-target organisms were identified.
	It is considered that, on the basis of the assessment of Community or internationally agreed test guidelines, the substance **HAS** endocrine disrupting properties that may cause adverse effects on non-target organisms.		x	There are currently no defined criteria for identifying endocrine disruptors under Regulation (EC) 1107/2009. From the toxicological point of view no evidence of carcinogenicity or reproductive toxicity was seen in the reproductive toxicity studies. No evidence of adverse effects on endocrine organs was observed. There is currently no concern regarding endocrine disruption.
	Linked to the consideration of the endocrine properties immediately above. It is considered that the exposure of non-target organisms to the active substance in a plant protection product under realistic proposed conditions of use is negligible.		x	An exposure of non-target organisms based on the proposed GAP uses cannot be excluded.
	It is considered that it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist:			Laboratory studies on acute oral and contact toxicity an on chronic toxicity to adult honey-bees were conducted by both notifiers. Based on the available data and the outcome of the risk assessment considering all GAP uses (pre- and post-emergence) no risks to honey-bees

	— will result in a negligible exposure of honeybees, or — has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.			considering adult and larvae mortality, effects on honey-bee populations and chronic effects were identified.
Residue definition				
		Yes	No	
	It is considered that, where relevant, a residue definition can be established for the purposes of risk assessment and for enforcement purposes.	X		<u>Residue definition for riskassessment (plant and animals):</u> Sum of fenoxaprop-P-ethyl and all metabolites converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-P-ethyl. <u>Residue definition for enforcement (plant and animals):</u> Sum of fenoxaprop-ethyl and all metabolites converted to 6-chloro-2,3-dihydrobenzoxazol-2-one, expressed as fenoxaprop-ethyl. There is no obvious difference in the metabolic behaviour of the racemic compound fenoxaprop-ethyl and the P-enantiomer. Since the parent compound and its free acid form cannot be considered as valid indicator of the residue situation at harvest, the requirement of an enantio-selective method of analysis is not reasonable. The analytical target is the non enantioselective compound 6-chloro-2,3- dihydrobenzoxazol-2-one.
Fate and behaviour concerning groundwater				
		Yes	No	
	It is considered that it has been established for one or more representative uses, that consequently after application of the plant protection product consistent with realistic conditions on use, the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater complies with the respective criteria of the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.			Neither fenoxaprop-P-ethyl (AE F046360) nor its metabolites fenoxaprop-P-acid (AE F088406), chlorobenzoxazolone (AE F054014) or HOPP-acid (AE F096918) are considered to leach into shallow groundwater at concentrations > 0.1 µg/L for all uses.

3.1.2. Proposal – Candidate for substitution

Candidate for substitution				
		Yes	No	
	It is considered that the active substance shall be approved as a candidate for substitution			Fenoxaprop-p does not meet the criteria to be considered as a candidate for substitution (as bellow): *- its ADI, ARfD or AOEL is significantly lower than those of the majority of the approved active substances within groups of substances/use categories -* ***NO*** *— it meets two of the criteria to be considered as a PBT substance –**NO*** *— there are reasons for concern linked to the nature of the critical effects (such as developmental neurotoxic or immunotoxic effects) which, in combination with the use/exposure patterns, amount to situations of use that could still cause concern, for example, high potential of risk to groundwater; even with very restrictive risk management measures (such as extensive personal protective equipment or very large buffer zones) – **NO*** *— it contains a significant proportion of non-active isomers – **NO*** *— it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, if the substance has not been excluded in accordance with the criteria laid down in point 3.6.3 -* ***NO*** *— it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B if the substance has not been excluded in accordance with the criteria laid down in point 3.6.4- **NO*** *— if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, reviewed by the Authority, it is considered to have endocrine disrupting properties that may*

				*cause adverse effects in humans if the substance has not been excluded in accordance with the criteria laid down in point 3.6.5.]- **NO***

3.1.3. Proposal – Low risk active substance

Low-risk active substances				
		Yes	No	
	It is considered that the active substance **shall be considered of low risk.** In particular it is considered that the substance **should NOT be classified or proposed for classification** in accordance with Regulation (EC) No 1272/2008 as at least one of the following: — carcinogenic, — mutagenic, — toxic to reproduction, — sensitising chemicals, — very toxic or toxic, — explosive, — corrosive. In addition it is considered that **the substance is NOT**: — persistent (half-life in soil more than 60 days), — has a bioconcentration factor higher than 100, — is deemed to be an endocrine disrupter, or — has neurotoxic or immunotoxic effects.		x	… The substance is not considered persistent (half-life in soil less than 60 days) … Fenoxaprop-p cannot be considered a low risk substance because it should be classified in accordance with Regulation (EC) No 1272/2008 as "Very toxic to aquatic life with long lasting effects" (H400; H410) - classified or to be classified as carcinogenic – **NO** - classified or to be classified as mutagenic – **NO** - classified or to be classified as toxic to reproduction – **NO** - classified or to be classified as sensitising – **YES** - classified or to be classified as very toxic or toxic – **YES (H400; H410)** - classified or to be classified as explosive – **NO** - classified or to be classified as corrosive – **NO** - persistent – **NO** - bioconcentration factor higher than 100 – **YES** - endocrine disruptor – **NO** (based on current knowledge) - neurotoxic or immunotoxic effects - **NO**

3.1.4. List of studies to be generated, still ongoing or available but not peer reviewed

Data gap	Relevance in relation to representative use(s)	Study status		
		No confirmation that study available or on-going.	Study on-going and anticipated date of completion	Study available but not peer-reviewed
3.1.4.1. ***Identity of the active substance or formulation***				
None				
3.1.4.2. ***Physical and chemical properties of the active substance and physical, chemical and technical properties of the formulation***				
None				
3.1.4.3. ***Data on uses and efficacy***				
Applicant to provide a summary of achieved control (% control, number of trials) and a summary of crop safety (x specific crop safety trials with N, NN, max. % phytotoxicity) according to the guidance document SANCO/10054/2013-rev.3, 11 July 2013 (Appendix I). Chapter B.3.9., B.3.10, B.3.11. of SANCO/10054/2013-rev.3, 11 July 2013 should be addressed in Volume 3, CP B3.	All uses	No confirmation that study/summary available or on-going		

3.1.4.4. *Data on handling, storage, transport, packaging and labelling*				
None				
3.1.4.5. *Methods of analysis*				
None				
3.1.4.6. *Toxicology and metabolism*				
None.				
3.1.4.7. *Residue data*				
None				
3.1.4.8. *Environmental fate and behaviour*				
Applicant to address an unknown metabolite fraction ('M8') exceeded 5 % AR at two consecutive sampling points (max. 6.2 % at 120 DAT, declining thereafter) in one anaerobic soil degradation study (Voelkel, 2001a), thus triggering identification and an exposure assessment according to Regulation (EU) No 283/2013.	All uses	No confirmation that study available or on-going		
Applicant to provide public monitoring data (ground water and surface water) available in the EU as far as this feasible.	All uses	No confirmation that study available or on-going		

3.1.4.9. *Ecotoxicology*				
Bayer Crop Science: The risk assessment for aquatic plants could not be finalised based on the available studies with the representative formulation. The active substance fenoxaprop-P-ethyl is an herbicide; hence, one aquatic macrophyte has to be tested with the formulation.	All uses.	No confirmation that study available or on-going		

3.1.5. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) No 546/2011, and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

Area of the risk assessment that could not be finalised on the basis of the available data	**Relevance in relation to representative use(s)**
1. The risk assessment for the active substance Fenoxaprop-P-ethyl could not be finalised considering the risk to aquatic plants (Bayer Crop Science., all uses).	Application to creals (FPP+MPR EW 144 (69+75 g/L), representative formulation)

3.1.6. Critical areas of concern

An issue is listed as a critical area of concern:
(a) where the substance does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II of Regulation (EC) No 1107/2009 and the applicant has not provided detailed evidence that the active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, taking into account risk mitigation measures to ensure that exposure of humans and the environment is minimised, or
(b) where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) 546/2011, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

Critical area of concern identified	**Relevance in relation to representative use(s)**
None identified in the renewal assessment	Not applicable

3.1.7. Overview table of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in 3.3.1, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)
All columns are grey as the material tested in the toxicological studies has not been demonstrated to be representative of the technical specification.

Representative use		Use " wheat (s+w) durum wheat rye, w.-rye triticale" (X^1)	Use " barley (s+w)" (X^1)
Operator risk	Risk identified		
	Assessment not finalised		
Worker risk	Risk identified		
	Assessment not finalised		
Bystander risk	Risk identified		
	Assessment not finalised		
Consumer risk	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial vertebrates	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified		
	Assessment not finalised		
Risk to aquatic organisms	Risk identified		
	Assessment not finalised	x^1	x^1
Groundwater exposure	Legal parametric value breached	-	-

active substance	Assessment not finalised	-	-
Groundwater exposure metabolites	Legal parametric value breached	-	-
	Parametric value of 10µg/L[(a)] breached	-	-
	Assessment not finalised	-	-
Comments/Remarks			

The superscript numbers in this table relate to the numbered points indicated within chapter 3.1.5 and 3.1.6. Where there is no superscript number, see level 2 for more explanation.
(a): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

3.1.8. Area(s) where expert consultation is considered necessary

It is recommended to organise a consultation of experts on the following parts of the assessment report:

Area(s) where expert consultation is considered necessary	**Justification**
None	

3.1.9. Critical issues on which the Co RMS did not agree with the assessment by the RMS

Points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur member state. Only the points relevant for the decision making process should be listed.

Co-RMS Finland decided to participate in the first bilateral peer review but to provide the comments for the official peer review. Therefore, currently no critical issues on which the Co RMS did not agree with the assessment by the RMS could be identified.

Issue on which Co-RMS disagrees with RMS	**Opinion of Co-RMS**	**Opinion of RMS**

-	-	-

3.2. PROPOSED DECISION

[redacted]

3.3. RATIONAL FOR THE CONDITIONS AND RESTRICTIONS TO BE ASSOCIATED WITH THE APPORVAL OR AUTHORISATION(S), AS APPROPRIATE

3.3.1. Particular conditions proposed to be taken into account to manage the risks identified

Proposed condition/risk mitigation measure	Relevance in relation to representative use(s)

[redacted]	

3.4. APPENDICES

GUIDANCE DOCUMENTS USED IN THIS ASSESSEMENT

Volume 3 – B1: Identity

None

Volume 3 - B2: Physicochemical properties

None

Volume 3 - B5: Analytical methods

Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414 (SANCO/3029/99 rev. 4)

Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414 (SANCO/3030/99 rev. 4)

Guidance document on pesticide residue analytical methods (SANCO/825/00 rev. 8.1)

Volume 3 - B6: Toxicology and metabolism of the active substance

Draft Guidance for the setting and application of acceptable operator exposure levels (AOELs), European Commission SANCO 7531- rev. 10, 2006

EFSA (2011). Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092

EFSA Panel on Plant Protection Products and their Residues (PPR); Guidance on Dermal Absorption. EFSA Journal 2012;10(4):2665. [30 pp.] doi:10.2903/j.efsa.2012.2665

EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products, EFSA Journal 2014; 12(10):3874

Guidance on the Application of the CLP Criteria, ECHA, Version 5 (July 2017)

Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) 283/2013 and Regulation (EU) No 284/2013 (SANCO/10181/2013– rev. 2, May 2013)

Guidance Document 8064/VI/97 rev. 4 on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated Under Council Directive 91/414/EEC (SANCO/221/2000 rev. 10 25 February 2003)

Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data, EFSA Journal 2012;10(3):2579

Guidance for the setting of an Acute Reference Dose (ARfD), European Commission 7199/VI/99 rev. 5

Guidance document on standardised test guidelines for evaluating chemicals for endocrine disruption, OECD No. 150, 2012

Outcome of the pesticides peer review meeting on general recurring issues in mammalian toxicology, EFSA Technical Report, July 2016 (Question number: EFSA-Q-2016-00355)

Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment [EFSA Journal 2011;9(9):2379]

Volume 3 - B7: Residues

Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) 283/2013 and Regulation (EU) No 284/2013 (SANCO/10181/2013– rev. 2, May 2013)

OECD, 2009, Guidance document on the definition of residue, (ENV/JM/MONO(2009)30), Series on testing and assessment No. 63 and Series on pesticides No. 31

Residues trials and MRL calculations, Proposals for a harmonised approach for the selection of the trials and data used for the estimation of MRL, STMR and HR, EFSA, September 2015

Estimation of animal intakes and HR, STMR and MRL calculations for products of animal origin, EFSA, September 2015

EC (European Commission), 2010. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, finalized in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010.

EC (European Commission), 2016. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.10.2.

FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.

EFSA (2011). Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092

OECD (Organisation for Economic Co-operation and Development), 2011; OECD MRL Calculator: User Guide. In: Series on Pesticides No 56. ENV/JM/MONO(2011)2, 01 March 2011.

Volume 3 - B8: Environmental fate and behaviour and environmental exposure assessment

EFSA (2011). Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092.

EFSA (2014). EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active subsrances in soil. EFSA Journal 2014; 12(5):3662, 37pp.

EC (2014) Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, version: 1.1, 18 December 2014

EC (2014) Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. Sanco/13144/2010, version 3, 10 October 2014

EC (2015) Generic guidance for FOCUS surface water Scenarios. Version: 1.4, May 2015

FOCUS (2007). Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.

FOCUS (2008) Pesticides in air: Considerations for exposure assessment. SANCO/10553/2006, Rev 2, June 2008

Volume 3 - B9: Ecotoxicology

Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters, EFSA Journal 2013;11(7):3290

Risk Assessment for Birds and Mammals, EFSA Journal 2009;7(12):1438

Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/141/EEC, SANCO/10329/2002, 17 October 2002 rev. 2 final

Candolfi et al., 2000, Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products with Non-Target Arthropods, ESCORT 2 SETAC Workshop

EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus spp*. and solitary bees), EFSA Journal 2013;11(7):3295

EFSA (2011). Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092

Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) 283/2013 and Regulation (EU) No 284/2013 (SANCO/10181/2013– rev. 2, May 2013)

Volume 4 Annex C:

Guidance document on the assessment of the equivalence of technical materials of substances regulated under regulation (EC) No 1107/2009 (SANCO/10597/2003 –rev. 10)

3.5. REFERENCE LIST

No references specifically cited in Volume 1