

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: SHA 2619 A

Product name(s): KONARK

Chemical active substance:

Flufenacet, 60 g/L

Pendimethalin, 300 g/L

Central Zone

Zonal Rapporteur Member State: Czech Republic

CORE ASSESSMENT

(new authorization)

Applicant: Sharda Cropchem España S.L.

Submission date: March 2021

MS Finalisation date: January 2023; May 2023

Version history

When	What
01.2023	ZRMs evaluated dRR submitted by Applicant.
05.2023	zRMS revision after commenting phase – final version of the RR

Table of Contents

3	Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)	5
3.1	Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6).....	5
3.2	Efficacy data (KCP 6)	9
3.2.1	Preliminary tests (KCP 6.1)	19
3.2.1.1	Justification of the Mixture	19
3.2.1.2	Justification of Ratio of Active Ingredients in the Mixture	25
3.2.2	Minimum effective dose tests (KCP 6.2).....	26
3.2.3	Efficacy tests (KCP 6.2)	35
3.3	Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)	65
3.3.1	Summary and Conclusions	65
3.3.2	Mode of Action	65
3.3.3	Mechanism(s) of resistance.....	67
3.3.4	Evidence of resistance.....	67
3.3.5	Cross-resistance	68
3.3.6	Sensitivity data.....	68
3.3.7	Use pattern	69
3.3.8	Resistance Risk Assessment of unrestricted use patterns	69
3.3.9	Acceptability of the resistance risk	69
3.3.10	Management strategy for Flufenacet 6% + Pendimethalin 30% EC	69
3.3.11	Implementation of the management strategy	70
3.3.12	Monitoring, reporting and reaction to changes in performance.....	70
3.4	Adverse effects on treated crops (KCP 6.4).....	72
3.4.1	Phytotoxicity to host crop (KCP 6.4.1).....	75
3.4.1.1	Summary and evaluation of winter cereal trials treated pre-emergence.....	75
3.4.1.2	Summary and evaluation of winter cereal trials treated post-emergence	80
3.4.1.3	Overall conclusion	85
3.4.2	Effect on the yield of treated plants or plant product (KCP 6.4.2)	87
3.4.2.1	Summary and evaluation of crop yield from winter cereal field trials treated pre-emergence in the autumn	87
3.4.2.2	Summary and evaluation of crop yield from winter cereal field trials treated post-emergence in the autumn	89
3.4.2.3	Conclusion	91
3.4.2.4	Relationship between phytotoxicity and yield	91
3.4.3	Effects on the quality of plants or plant products (KCP 6.4.3).....	92
3.4.3.1	Conclusion	96
3.4.4	Effects on transformation processes (KCP 6.4.4).....	97
3.4.5	Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)	97
3.5	Observations on other undesirable or unintended side-effects (KCP 6.5)...	98
3.5.1	Impact on succeeding crops (KCP 6.5.1).....	98
3.5.2	Impact on other plants including adjacent crops (KCP 6.5.2)	103
3.5.3	Effects on beneficial and other non-target organisms (KCP 6.5.3)	107
3.5.4	Tank cleaning	107
3.6	Other/special studies	108

3.7	List of test facilities including the corresponding certificates	109
Appendix 1	Lists of data considered in support of the evaluation.....	110

3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

Comments of zRMS:	The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:
-------------------	---

Comments of zRMS:	Comments of zRMS are in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are in grey). Changes during commenting period were marked by yellow.
-------------------	---

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

This document summarises the information related to the efficacy data of the plant protection product **Flufenacet 6% + Pendimethalin 30% EC** containing the active substances flufenacet and pendimethalin, which are approved under Regulation 1107/2009.

The SANCO reports for pendimethalin (SANTE/11656/2016 rev 2 – 18.05.2017) and flufenacet (SANCO/7469/VI/98-Final – 03/07/2003) are considered to provide the relevant review information or a reference to where such information can be found.

Flufenacet 6% + Pendimethalin 30% EC is an Emulsifiable Concentrate (EC) containing 60 grams per Litre (g/L) flufenacet and 300 grams per Litre (g/L) pendimethalin for use in winter cereals.

This report demonstrates the broad efficacy spectrum of Flufenacet 6% + Pendimethalin 30% EC against a range of annual grasses and broadleaved weed species and demonstrates that the formulation is safe to the crop. To prove the herbicidal efficacy and crop safety of Flufenacet 6% + Pendimethalin 30% EC, trials have been set up in autumn- and winter-sown cereal field crops. The trials were conducted in 2015/16, 2016/2017 and 2018/19 seasons in a range of European countries in the Maritime (i.e. Germany, N-France, the Czech Republic and the UK), the North-east (i.e. Poland), the South-east (i.e. Hungary) and the Mediterranean (i.e. S-France, Spain and Italy) EPPO zones.

According to the GAP, the proposed application rate of Flufenacet 6% + Pendimethalin 30% EC is 4.0 L per hectare (L/ha), with a maximum of one application per season, for the pre- or early post-emergence control of annual grasses and broadleaved weeds in winter cereals (wheat, barley, rye and triticale). This will deliver 240 g flufenacet per hectare and 1200 g pendimethalin per hectare. In the treated crops, the test product was tested against registered rates of the reference products employed, currently marketed in the countries where the trials were conducted.

The data presented in this report fully support the label claim for Flufenacet 6% + Pendimethalin 30% EC for the control of grasses and broadleaved weeds in cereals.

Flufenacet 6% + Pendimethalin 30% EC gives excellent control of a number of key annual grasses and broadleaved weeds in winter cereals when applied pre-emergence or early post-emergence. Among the species that are controlled by Flufenacet 6% + Pendimethalin 30% EC are Annual bluegrass (*Poa annua*), Blackgrass (*Alopecurus myosuroides*), Loose silky-bent (*Apera spica-venti*), Annual meadow grass (*Poa annua*), Shepherd's purse (*Capsella bursa-pastoris*) and Scentless mayweed (*Matricaria inodorum*).

The claims of crop safety on cereals are supported with a total of 84 trials conducted in Germany, Czech Republic, England, Poland, Hungary, France, Spain and Italy in 2015/16, 2016/2017 and 2018/19 season.

In all trials, Flufenacet 6% + Pendimethalin 30% EC proved to be crop safe and in the vast majority of the trials did not significantly affect the crop adversely when applied at a range of growth stages within and occasionally beyond the label recommended range, at the maximum proposed label recommended rates of 4.0 L/ha in autumn- and winter-sown cereals. The same was observed in the treatments where Flufenacet 6% + Pendimethalin 30% EC was applied at twice the recommended rate, representative of sprayer overlap.

Overall, Flufenacet 6% + Pendimethalin 30% EC is an effective, selective broad-spectrum herbicide for weed control in winter cereals. The employment of a co-formulation containing actives with two different modes of action offers a solution for sustainable resistance strategies.

The Registration of Flufenacet 6% + Pendimethalin 30% EC in the GAP claimed crops is endorsed.

Comments of zRMS:	Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR.
-------------------	--

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expres- sion, dose range (min- max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val 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	CEU	Winter wheat	F	Broadleaved and grass weeds Annual dicotyledonous and annual monocotyledonous weeds	Foliar Spray	Pre- emergence BBCH 00-09	a) 1 b) 1	NA	a) 4.0 b) 4.0	a) 0.24 flufe- nacet + 1.2 pendimethalin b) 0.24 flufe- nacet + 1.2 pendimethalin	200- 400	-	Weeds at early stages	To be con- firmed by cMS Eff sec: in PL and DE not accepted
2	CEU	Winter wheat	F	Broadleaved and grass weeds Annual dicotyledonous and annual monocotyledonous weeds	Foliar Spray	Post- emergence BBCH 11-25	a) 1 b) 1	NA	a) 4.0 b) 4.0	a) 0.24 flufe- nacet + 1.2 pendimethalin b) 0.24 flufe- nacet + 1.2 pendimethalin	200- 400	-	Weeds at early stages	To be con- firmed by cMS In DE only soft winter wheat accept- ed.
3	CEU	Winter barley	F	Broadleaved and grass weeds Annual dicotyledonous and annual monocotyledonous weeds	Foliar Spray	Pre- emergence BBCH 00-09	a) 1 b) 1	NA	a) 4.0 b) 4.0	a) 0.24 flufe- nacet + 1.2 pendimethalin b) 0.24 flufe- nacet + 1.2 pendimethalin	200- 400	-	Weeds at early stages	To be con- firmed by cMS Eff sec: in PL and DE not accepted
4	CEU	Winter barley	F	Broadleaved and grass weeds Annual dicotyledonous and annual monocotyledonous weeds	Foliar Spray	Post- emergence BBCH 11-25	a) 1 b) 1	NA	a) 4.0 b) 4.0	a) 0.24 flufe- nacet + 1.2 pendimethalin b) 0.24 flufe- nacet + 1.2 pendimethalin	200- 400	-	Weeds at early stages	To be con- firmed by cMS
5	CEU	Winter rye	F	Broadleaved and grass weeds	Foliar Spray	Pre- emergence	a) 1	NA	a) 4.0	a) 0.24 flufe- nacet + 1.2	200- 400	-	Weeds at early stages	To be con-

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expres- sion, dose range (min- max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val 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			
				Annual dicotyledonous and annual monocotyledonous weeds		BBCH 00-09	b) 1		b) 4.0	pendimethalin b) 0.24 flufe- nacet + 1.2 pendimethalin				firmed by cMS Eff sec: in PL and DE not accepted
6	CEU	Winter rye	F	Broadleaved and grass weeds Annual dicotyledonous and annual monocotyledonous weeds	Foliar Spray	Post- emergence BBCH 11-25	a) 1 b) 1	NA	a) 4.0 b) 4.0	a) 0.24 flufe- nacet + 1.2 pendimethalin b) 0.24 flufe- nacet + 1.2 pendimethalin	200- 400	-	Weeds at early stages	To be con- firmed by cMS Eff sec: in PL and DE not accepted
7	CEU	Winter Triticale	F	Broadleaved and grass weeds Annual dicotyledonous and annual monocotyledonous weeds	Foliar Spray	Pre- emergence BBCH 00-09	a) 1 b) 1	NA	a) 4.0 b) 4.0	a) 0.24 flufe- nacet + 1.2 pendimethalin b) 0.24 flufe- nacet + 1.2 pendimethalin	200- 400	-	Weeds at early stages	To be con- firmed by cMS Eff sec: in PL and DE not accepted
8	CEU	Winter Triticale	F	Broadleaved and grass weeds Annual dicotyledonous and annual monocotyledonous weeds	Foliar Spray	Post- emergence BBCH 11-25	a) 1 b) 1	NA	a) 4.0 b) 4.0	a) 0.24 flufe- nacet + 1.2 pendimethalin b) 0.24 flufe- nacet + 1.2 pendimethalin	200- 400	-	Weeds at early stages	To be con- firmed by cMS

Column 15: zRMS conclusion.

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

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy data of the plant protection product **Flufenacet 6% + Pendimethalin 30% EC** containing the active substances flufenacet and pendimethalin, which are approved under Regulation 1107/2009.

The SANCO reports for pendimethalin (SANTE/11656/2016 rev 2 – 18.05.2017) and flufenacet (SANCO/7469/VI/98-Final – 03/07/2003) are considered to provide the relevant review information or a reference to where such information can be found.

The Annex I Inclusion Directive/Regulation for flufenacet (**Directive 2003/84/EC**) and pendimethalin (**Regulation 2017/1114**) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the active substances pendimethalin and flufenacet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 18/May/2017 for pendimethalin and 4/July/2003 for flufenacet shall be taken into account. Consideration of active substances for Annex 1 inclusion does not include an evaluation of efficacy. Therefore, there are no concerns to address arising from the inclusion directive of pendimethalin and flufenacet relating to efficacy.

These concerns have been addressed within the current submission.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

The detailed assessment of the individual trial and study data is located in the following report:

Report:	KCP 6.0/001 Biological Assessment Dossier Flufenacet 6% + Pendimethalin 30% EC, Central
----------------	--

Description of the plant protection product

Flufenacet 6% + Pendimethalin 30% EC is a Emulsifiable Concentrate (EC) containing 60 grams per Litre (g/L) flufenacet and 300 grams per Litre (g/L) pendimethalin for use in winter cereals.

To support the registration of Flufenacet 6% + Pendimethalin 30% EC in the GAP claimed crops, trials have been set up in autumn- and winter-sown cereal field crops. In all winter cereal trials, except five selectivity trials conducted in Italy, the pendimethalin + flufenacet EC formulation prepared by Sharda Cropchem España – Flufenacet 6% + Pendimethalin 30% EC – was compared against a reference flufenacet + pendimethalin co-formulation currently on the market in Central and South Europe (Aranda / Crystal / Malibu / Trooper; 60 g/L flufenacet + 300 g/L pendimethalin EC). In some efficacy trials, a flufenacet standard product was used as additional reference (Cadou / FOE50% SC / System 50; flufenacet 500 g/L SC), for comparison, as well as a flufenacet standard product was used as the only reference in Italian selectivity trials (FOE50% SC; flufenacet 500 g/L SC). Besides a flufenacet straight reference product, a pendimethalin straight reference product (Sharpen 330 EC; pendimethalin 330 g/L EC) was also included in four Hungarian efficacy trials as additional reference product, for comparison. Finally, in French and Spanish efficacy trials, a national standard reference product containing pendimethalin and picolinafen was used as 3rd reference product (Celtic / Picomax; Picolinafen 16 g/L + pendimethalin 320 g/L SC). The trials were conducted in 2015/16, 2016/17 and 2018/19 seasons in a range of European countries in the Maritime (i.e. Germany, N-France, the Czech Republic and the UK), the North-east (i.e. Poland), the South-east (i.e. Hungary) and the Mediterranean (i.e. S-France, Spain and Italy) EPPO zones.

According to the GAP, the proposed application rate of Flufenacet 6% + Pendimethalin 30% EC is 4.0 L per hectare (L/ha), with a maximum of one application per season, for the pre- or early post-emergence

control of annual grasses and broadleaved weeds in winter cereals (wheat, barley, rye and triticale). This will deliver 240 g flufenacet per hectare and 1200 g pendimethalin per hectare. In the treated crops, the test product was tested against registered rates of the reference products employed, currently marketed in the countries where the trials were conducted.

The data presented in this report fully support the label claim for Flufenacet 6% + Pendimethalin 30% EC for the control of grasses and broadleaved weeds in cereals.

Table 3.2-1: Simplified table of currently registered uses and requested uses for the product code.

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Winter wheat, Winter barley, Winter rye, Winter triticale	Grasses and broadleaved weeds	CEU	4.0 L/ha	Pre- or post-emergence application

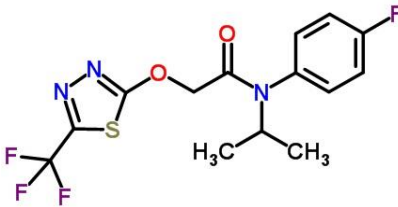
Further details are in the table “All intended uses” in Part B - Section 0.

Description of active substance flufenacet

Flufenacet is a selective contact and residual soil herbicide used in cereals and other crops for broad-spectrum control of important grasses and some broadleaved weeds across all climatic zones of Europe. The herbicidal properties of flufenacet were first described in 1998. It belongs to the chemical group of Oxyacetamides.

Today, flufenacet is registered and commercialised in several formulations around the world.

Table 3.2-2: Identity of flufenacet

Common name	Flufenacet
IUPAC name	4'-fluoro- <i>N</i> -isopropyl-2-[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yloxy]acetanilide
CA name	<i>N</i> -(4-fluorophenyl)- <i>N</i> -(1-methylethyl)-2-[[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl]oxy]acetamide
CIPAC No	588
CAS Registry No.	142459-58-3
EEC No	N.a.
Minimum purity	970 g/kg
Structural formula¹	
Empirical formula	C ₁₄ H ₁₃ F ₄ N ₃ O ₂ S
Molecular mass	363.33 g/mol

Mode of action

Flufenacet is absorbed by plant roots as well as foliage. When applied, flufenacet is taken up by the foliage and roots of the plant and moves through the plant to the meristematic regions by the xylem and phlo-

¹ Source: Royal Society of Chemistry (RSC). Internet, Monday June 18th, 2018. URL: <http://www.chemspider.com/Chemical-Structure.77944.html>

em. Once applied to the target species, growth is retarded within hours and visible symptoms will occur in several days.

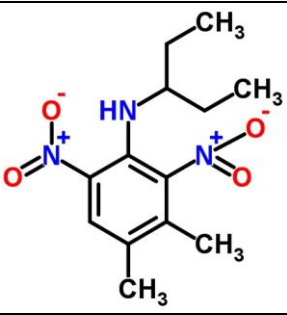
Flufenacet primarily acts by the inhibition of the thyroid hormone membrane and steroid receptor – co-regulator 2. The inhibition of mitosis and cell division results in retardation of plant growth processes leading to death of the plant. Due to the primary target site and the chemical subgroup, flufenacet is classified as a HRAC group 15 herbicide (Chloroacetamides and others). In the WSSA resistance classification system the Oxyacetamides are classified as group 15.

Description of active substance pendimethalin

The herbicidal properties of pendimethalin were first described in 1974. It belongs to the chemical group of dinitroanilines. It is absorbed by plant roots and shoots (seedlings). When applied post-emergence, it is taken up by shoots predominantly. Monocotyledonous weeds are predominantly sensitive to root and cotyledon uptake, while dicotyledonous weeds are also sensitive to leaf uptake. Susceptible weed seedlings die either shortly after germination or their growth is strongly inhibited for several days. The leaves may become red or purple in colour, may become necrotic and will finally die.

Today, pendimethalin is registered and commercialised in several formulations around the world.

Table 3.2-3: Identity of pendimethalin

Common name	Pendimethalin
IUPAC name	<i>N</i> -(1-ethylpropyl)-2,6-dinitro-3,4-xylidine
CA name	<i>N</i> -(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine
CIPAC No	357
CAS Registry No.	40487-42-1
EEC No	254-938-2
Minimum purity	900 g/kg
Structural formula²	
Empirical formula	C ₁₃ H ₁₉ N ₃ O ₄
Molecular mass	281.31 g/mol

Mode of action

Pendimethalin inhibits cell division by binding to β -tubuline and preventing assembly of tubuline heterodimers into microtubules (primary mode of action). In addition, Pendimethalin inhibits RNA, DNA and protein synthesis and at higher concentrations an uncoupling of the oxidative phosphorylation was observed. Due to the primary target site and the chemical subgroup, pendimethalin is classified as a HRAC group 3 herbicide (microtubule assembly inhibition). In the WSSA resistance classification system the dinitroanilines are classified as group 3.

For further physico-chemical properties, please refer to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

² Source: Royal Society of Chemistry (RSC). Internet, Monday June 18th, 2018. URL: <http://www.chemspider.com/Chemical-Structure.35265.html>

Information on similar formulations and current approvals

Data presented in this report is generated using this formulation in comparison with e.g. the BASF reference product containing flufenacet and pendimethalin. Flufenacet as well as pendimethalin are currently registered under a variety of trade names and formulations throughout Europe and a selection of these are described in table below.

Table 3.2-4: Current approvals of flufenacet and/or pendimethalin in the EU Central zone as well as connected EPPO zones where trials were conducted. Reference products used in trials are also included

Country	Product	Active ingredient	Approval number
Belgium	Malibu	Flufenacet 60 g/L + Pendimethalin 300 g/L EC	9316 P/B
Czech Republic	Malibu	Flufenacet 60 g/L + Pendimethalin 300 g/L EC	4959-0
	Cadou	Flufenacet 500 g/L SC	n.r.
	Fluent 500 SC	Flufenacet 500 g/L SC	5427-0
France	Trooper	Flufenacet 60 g/L + Pendimethalin 300 g/L EC	2090118
	Cadou	Flufenacet 500 g/L SC	2000339
	Celtic	Picolinafen 16 g/L + Pendimethalin 320 g/L SC	9900340
	Sharpen 330 EC	Pendimethalin 330 g/L EC	2150786
Germany	Malibu	Flufenacet 60 g/L + Pendimethalin 300 g/L EC	024834-00
	Cadou	Flufenacet 500 g/L SC	005908-00
Hungary	Malibu	Flufenacet 60 g/L + Pendimethalin 300 g/L EC	n.r.
	FOE50% SC	Flufenacet 500 g/L SC	n.r.
	Sharpen 330 EC	Pendimethalin 330 g/L EC	04.2/1213-1/2013
Italy	Malibu	Flufenacet 60 g/L + Pendimethalin 300 g/L EC	010328
	Trooper	Flufenacet 60 g/L + Pendimethalin 300 g/L EC	n.r.
	FOE50% SC	Flufenacet 500 g/L SC	n.r.
	Battle	Flufenacet 500 g/L SC	016586
	Sharpen 33% EC	Pendimethalin 330 g/L EC	015754
Netherlands	Malibu	Flufenacet 60 g/L + Pendimethalin 300 g/L EC	14123
Poland	Malibu	Flufenacet 60 g/L + Pendimethalin 300 g/L EC	R-1151/2015b
	Cadou	Flufenacet 500 g/L SC	R-1152/2015b
Spain	Malibu / Trooper	Flufenacet 60 g/L + Pendimethalin 300 g/L EC	n.r.
	FOE50% SC	Flufenacet 500 g/L SC	n.r.
	Fuga	Flufenacet 500 g/L SC	ES-00199
	Picomax	Picolinafen 16 g/L + Pendimethalin 320 g/L EC	25777
	Sharpen 33% EC	Pendimethalin 330 g/L EC	ES-00063
UK	Crystal	Flufenacet 60 g/L + Pendimethalin 300 g/L EC	13914
	System 50	Flufenacet 500 g/L SC	16612
	Penta	Pendimethalin 400 g/L SC	17680

Bold = Sharda formulations registered in the respective countries

Description of the target pests

The damaging economic effects of grass- and broadleaved weeds in cereals are well established, and justification for their control well documented. Flufenacet 6% + Pendimethalin 30% EC control a number of very important annual grass weeds and annual broadleaved weeds found in cereal crops. Among the species that are controlled by Flufenacet 6% + Pendimethalin 30% EC are Annual bluegrass (*Poa annua*), Blackgrass (*Alopecurus myosuroides*), Loose silky-bent (*Apera spica-venti*), Annual meadow grass (*Poa annua*), Shepherd's purse (*Capsella bursa-pastoris*) and Scentless mayweed (*Matricaria inodorum*).

All the listed weeds are present throughout or in parts of the Central zone and in relevant EPPO zones. These weed species compete with the crops for light, moisture and nutrients, reducing crop yields and may obstruct harvestability.

Table 3.2-5: Glossary of pests mentioned in the report.

EPPO code	Scientific name	Common name
Grass weeds		
AGRRE	<i>Elymus repens</i>	Couch grass
ALOMY	<i>Alopecurus myosuroides</i>	Blackgrass
APESV	<i>Apera spica-venti</i>	Silky Windgrass
AVEFA	<i>Avena fatua</i>	Wild oat
LOLMU	<i>Lolium multiflorum</i>	Italian ryegrass
LOLSS	<i>Lolium</i> spp.	Ryegrass
POAAN	<i>Poa annua</i>	Annual bluegrass
Broadleaved weeds		
AMABL	<i>Amaranthus blitoides</i>	Prostrate pigweed
ANGAR	<i>Anagallis arvensis</i>	Red chickweed
BRSNX	<i>Brassica napus</i>	Oilseed rape (volunteer)
CAPBP	<i>Capsella bursa-pastoris</i>	Shepherd's purse
CENCY	<i>Centaurea cyanus</i>	Cornflower
CHYCO	<i>Glebionis coronarium</i>	Crown daisy
CIRAR	<i>Cirsium arvensis</i>	Perennial thistle
DIPVG	<i>Diplotaxis virgata</i>	Sand mustard
FUMOF	<i>Fumaria officinalis</i>	Common fumitory
GALAP	<i>Galium aparine</i>	Cleavers
LAMAM	<i>Lamium amplexicaule</i>	Henbit dead-nettle
MATCH	<i>Matricaria chamomilla</i>	Scented mayweed
Broadleaved weeds (cont.)		
MATIN	<i>Tripleurospermum inodorum</i>	Scenless mayweed
MATMA	<i>Tripleurospermum maritimum</i>	False mayweed
MEDSA	<i>Medicago sativa</i>	Alfalfa
MERAN	<i>Mercurialis annua</i>	Annual mercury
PAPRH	<i>Papaver rhoeas</i>	Common poppy
PICHI	<i>Picris hieracioides</i>	Hawkweed

EPPO code	Scientific name	Common name
POLAV	<i>Polygonum aviculare</i>	Knotgrass
POLCO	<i>Fallopia convolvulus</i>	Black bindweed
SENAG	<i>Senecio angustifolius</i>	-
SENVU	<i>Senecio vulgaris</i>	Common groundsel
SINAR	<i>Sinapis arvensis</i>	Charlock
SLYMA	<i>Silybum marianum</i>	Milk thistle
SONAS	<i>Sonchus asper</i>	Prickly sow-thistle
STEME	<i>Stellaria media</i>	Common chickweed
THLAR	<i>Thlaspi arvense</i>	Field pennycress
TTTTT	-	All weeds
URTAN	<i>Urtica angustifolia</i>	-
VERHE	<i>Veronica hederifolia</i>	Ivy-leaved speedwell
VERPE	<i>Veronica persica</i>	Common field speedwell
VIOAR	<i>Viola arvensis</i>	Field violet

Table 3.2-6: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Winter wheat	CEU	-	Mono- and dicotyledon weeds	CEU	-
Winter barley	CEU	-	Mono- and dicotyledon weeds	CEU	-
Winter rye	CEU	-	Mono- and dicotyledon weeds	CEU	-
Winter triticales	CEU	-	Mono- and dicotyledon weeds	CEU	-

Compliance with the Uniform Principles

Comprehensive field trials were conducted in Germany, Czech Republic, France, England, Poland, Hungary, Spain and Italy in 2015/16, 2016/17 and 2018/19 season. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

Information on trials submitted (3.1 Efficacy data)

Trials in this report were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this report have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

In support of the current application for registration of Flufenacet 6% + Pendimethalin 30% EC, 47 efficacy trials and 37 selectivity trials were conducted in the Maritime (15 eff. and 12 sel.), the North-east (16 eff. and 12 sel.), the South-east (4 eff. and 1 sel.) and the Mediterranean (12 eff. and 12 sel.) EPPO zone.

Table 3.2-7: Presentation of efficacy trials (efficacy trials, preliminary trials...)

Use(s)	Target(s)	Country	Years	Type of trial	Number of trials (number of valid trials)				GEP, non- GEP, official	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
Winter cereals, pre-em.	Grasses and broadleaved weeds	Germany	2015/16	MED + E + S	2 (2)	-	-	-	GEP	
		Czech Rep.	2015/16	MED + E + S	2 (2)	-	-	-	GEP	
		UK	2015/16	MED + E + S	2 (2)	-	-	-	GEP	
		France	2015/16	MED + E + S	1 (1)	2 (2)	-	-	GEP	
		Poland	2015/16	MED + E + S	-	-	-	2 (2)	GEP	
		Hungary	2015/16	MED + E + S	-	-	2 (2)	-	GEP	
		Spain	2015/16	MED + E + S	-	2 (2)	-	-	GEP	
		Italy	2015/16	MED + E + S	-	2 (2)	-	-	GEP	
		France	2015/16	MED + E + S	-	1 (1)	-	-	GEP	
		Total, winter cereals (pre-em)				7 (7)	7 (7)	2 (2)	2 (2)	-
Winter cereals, post-em.	Grasses and broadleaved weeds	Germany	2015/16	MED + E + S	2 (2)	-	-	-	GEP	
		Czech Rep.	2015/16	MED + E + S	2 (2)	-	-	-	GEP	
		UK	2015/16	MED + E + S	2 (2)	-	-	-	GEP	
		France	2015/16	MED + E + S	2 (2)	2 (2)	-	-	GEP	
		Poland	2015/16	MED + E + S	-	-	-	2 (2)	GEP	
			2018/19	MED + E + S	-	-	-	12 (12)	GEP	
		Hungary	2015/16	MED + E + S	-	-	2 (2)	-	GEP	
		Spain	2015/16	MED + E + S	-	1 (1)	-	-	GEP	
		Italy	2015/16	MED + E + S	-	2 (2)	-	-	GEP	
		Total, winter wheat (post-em)				8 (8)	5 (5)	2 (2)	14 (14)	-
		Total, all crops			15 (15)	12 (12)	4 (4)	16 (16)		
		Hereof treated pre-emergence			7 (7)	7 (7)	2 (2)	2 (2)		
		and post-emergence			8 (8)	5 (5)	2 (2)	14 (14)		

In the 47 efficacy trials, the level of control obtained by Flufenacet 6% + Pendimethalin 30% EC was assessed on mono- and dicotyledonous weeds present in the trials. Data on each individual weed species is only included from trials in which a minimum of 5 plants per m² or 1% ground cover were seen at the timing of the assessment.

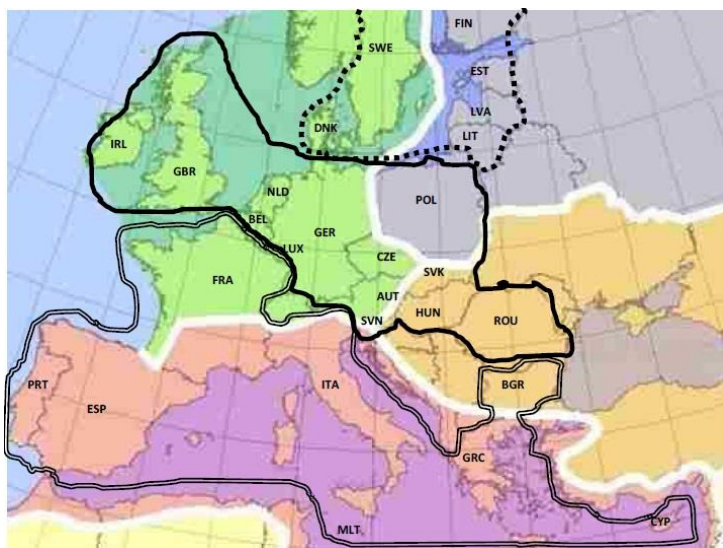
Climatic zones

Europe is divided into four climatic zones, according to EPPO standard PP 1/241 (1). Besides providing guidance in determining comparability of climatic conditions between geographical areas where efficacy evaluation trials are performed, the standard also supports the use of data generated in one country to support registration in another country³.

Germany, N-France, Czech Republic and United Kingdom are located in the Maritime EPPO zone; Poland is located in the North-east EPPO zone; Hungary is located in the South-east EPPO zone and Spain, Italy and the southern part of France are located in the Mediterranean EPPO zone (Figure 3.2-1).

³ Development of Comparable Agro-Climatic Zones for the International Exchange of Data on the Efficacy and Crop Safety of Plant Protection Products, E. Bouma, 2005 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 35, 233-238.

Figure 3.2-1: Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, Guidance on comparable climates) superimposed with the 3 European zones (EC Regulation 1107/2009) (Source: EPPO)



This Registration Report is prepared to support the submission of Flufenacet 6% + Pendimethalin 30% EC throughout the Central Registration zone, therefore data from the Maritime EPPO zone, the North-east EPPO zone and the South-east EPPO zone are included. Data obtained in the Mediterranean zone has also been added as supporting information, however, the data from each climatic zone is summarised separately.

Agronomic conditions

Cultural conditions of the different crops and agronomy (e.g. cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) do not differ significantly between UK, Germany, Czech Republic, France, Poland, Hungary, Spain and Italy. In winter cereals, the same flufenacet and/or pendimethalin containing herbicides are already registered and used in the countries where tested for the same uses, i.e. to control grasses and broadleaved weed species in winter cereals with pre- and post-emergence applications.

(i) Weed physiology

Grasses, like Blackgrass (*Alopecurus myosuroides*), Loose silky-bent (*Apera spica-venti*), Annual bluegrass (*Poa annua*), and broadleaved weeds, like Shepherd's-purse (*Capsella bursa-pastoris*), Common chickweed (*Stellaria media*), speedwells (*Veronica* spp.) and Mayweeds (*Matricaria* spp.) are all controlled by Flufenacet 6% + Pendimethalin 30% EC and are all key weeds throughout Central Europe. In each country these weeds are very common and can cause large reductions in yield.

According to Heap, 2018, one case of resistance to flufenacet has been reported from Europe on grass weeds, i.e. one case on *Alopecurus myosuroides* from Germany in 2007. Heap (2018) also reported that *Alopecurus myosuroides* was reported as being resistant to pendimethalin at three locations in Europe, i.e. UK in 1987, Belgium in 1996 and Denmark in 2001. Furthermore, *Echinochloa crus-galli* has also been reported as being resistant to pendimethalin at one location in Bulgaria in 1992. In the trials conducted, when treating the same weeds at the same application timing, no differences in level of control was observed between the countries and therefore the efficacy results from one country should be valid in another country.

(ii) Site selection

Although trials were performed throughout the EU, in each country the sites were carefully selected to ensure that for each weed species the level of control was assessed on a range of populations and application timings. To exert maximum control pressure and to exacerbate treatment differences in each country this included some trials which contained high weed densities. No differences in the level of control were apparent between the different countries or regions in which the trials were conducted. For each weed species equivalent levels of control were recorded in Germany, Czech Republic, England, France, Hungary, Spain and Italy.

(iii) *Agronomic practices*

Agronomic practices in cereal field crops are similar throughout the Central zone as well as in the countries in the connected EPPO zones where trials were conducted. The levels of inorganic fertilizers and other crop inputs are similar between the countries.

(iv) *Varieties*

Although crop varieties tend to differ between countries, the crop safety of Flufenacet 6% + Pendimethalin 30% EC has been tested on a wide range of varieties in both the selectivity- and efficacy trials. The results from these trials show that there are no particularly sensitive varieties. Crop tolerance and yield data generated in one country is therefore relevant in another Member state.

(v) *Trial methodology*

Similar trial methodology was used in all countries. All trials were conducted to GEP by officially recognised testing organisations and in accordance with relevant EPPO standards.

(vi) *Locations*

Trials were performed in the major crop growing areas in each respective country. These areas have been found to be particularly suitable for cereal production due to their innate similarity in terms of soil type and climate.

(vii) *Soil*

The active ingredients of Flufenacet 6% + Pendimethalin 30% EC have both soil- and foliar activity. Therefore, in each country, trials have been conducted on a range of soil types with no difference seen in the level of control.

On the basis that the above factors do not influence the overall performance of Flufenacet 6% + Pendimethalin 30% EC, it is the applicant's contention that data from Germany, the Czech Republic, the United Kingdom, Poland and Hungary is equally valid in demonstrating the products performance throughout the Central EU zone and the data from Spain, Italy and France is valid as supporting data.

In all winter cereal trials, except five selectivity trials conducted in Italy, the pendimethalin + flufenacet EC formulation prepared by Sharda Cropchem España – Flufenacet 6% + Pendimethalin 30% EC – was compared against a reference flufenacet + pendimethalin co-formulation currently on the market in Central and South Europe (Aranda / Crystal / Malibu / Trooper; 60 g/L flufenacet + 300 g/L pendimethalin EC). In all efficacy trials, a flufenacet standard product was used as additional reference (Cadou / FOE50% SC / System 50; flufenacet 500 g/L SC), for comparison, as well as a flufenacet standard product was used as the only reference in Italian selectivity trials (FOE50% SC; flufenacet 500 g/L SC). Besides a flufenacet straight reference product, a pendimethalin straight reference product (Sharpen 330 EC; pendimethalin 330 g/L EC) was also included in four Hungarian efficacy trials as additional reference product, for comparison. Finally, in French and Spanish efficacy trials, a national standard reference product containing pendimethalin and picolinafen was used as 3rd reference product (Celtic / Picomax; Picolinafen 16 g/L + pendimethalin 320 g/L SC). The trials were carried out on autumn- and winter-sown wheat and barley.

The reference products used in the efficacy trials are listed in Table 3.2-8.

Table 3.2-8: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Flufenacet + pendimethalin co-formulations					
Aranda	EC	60 g/L flufenacet + 300 g/L pendimethalin	2.5 4.0	FR	1
Crystal	EC	60 g/L flufenacet + 300 g/L pendimethalin	2.5 4.0	UK	4
Malibu	EC	60 g/L flufenacet + 300 g/L pendimethalin	2.5 4.0	CZ DE PL HU IT	4 4 16 4 4
Trooper	EC	60 g/L flufenacet + 300 g/L pendimethalin	2.5 4.0	ES FR	3 7
Flufenacet reference product					
Cadou	SC	500 g/L flufenacet	0.30 0.40 0.48	CZ DE FR PL	3 4 3 4
FOE50% SC	SC	500 g/L flufenacet	0.30 0.40 0.48	CZ ES FR HU IT	1 3 3 4 4
System 50	SC	500 g/L flufenacet	0.30 0.40	UK	4
Pendimethalin reference product					
Sharpen 330 EC	EC	330 g/L pendimethalin	4.0	HU	4
Picolinafen + pendimethalin co-formulations					
Celtic	SC	16 g/L picolinafen + 320 g/L pendimethalin	2.5	FR	8
Picomax	SC	16 g/L picolinafen + 320 g/L pendimethalin	2.5	ES	3

Comments of zRMS:	<p>This document was prepared by Applicant for registration of Konark (product code: SHA 2619A) containing 60 g/l flufenacet and 300 g/l pendimethalin. For now, flufenacet and pendimethalin are on the list of approved active substances. All needed information's were presented by Applicant.</p> <p>Pendimethalin inhibits RNA, DNA and protein synthesis and at higher concentrations an uncoupling of the oxidative phosphorylation was observed. Due to the primary target site and the chemical subgroup, pendimethalin is classified as a HRAC group 3 herbicide (microtubule assembly inhibition). In the WSSA resistance classification system the dinitroanilines are classified as group 3.</p> <p>Flufenacet primarily acts by the inhibition of the thyroid hormone membrane and steroid receptor – co-regulator 2. The inhibition of mitosis and cell division results in retardation of plant growth processes leading to death of the plant. Due to the primary target site and the chemical subgroup, flufenacet is classified as a HRAC group 15 herbicide (Chloroacetamides and others). In the WSSA resistance classification system the Oxyacetamides are classified as group 15.</p> <p>In Poland 41 herbicides with flufenacet and 24 with pendimethalin are registered and commonly used for protection crops against pests. No plant protection product with both, flufenacet and pendimethalin is registered in Poland. A few years ago,</p>
-------------------	--

	<p>products containing both substances were registered, for example: Malibu (R-1151/2015b) and Cadou (R-1152/2015b).</p> <p>The product – Konark (product code: SHA 2619A) by Sharda Cropchem España has not been previously evaluated in any country according to Uniform Principles. Poland is a ZRMs.</p>
--	--

3.2.1 Preliminary tests (KCP 6.1)

The activity of flufenacet and pendimethalin is well known, as both activities have been marketed since the end of the 1990's and the mid-seventies, respectively. Flufenacet is registered as straight product (e.g. Cadou) as well as in mixtures (mainly with diflufenican (e.g. Herold and Fosbury), but also isoxaflutole, pendimethalin, a.o.). Pendimethalin is also registered as straight products (e.g. Stomp) as well as in mixtures (mainly with flufenacet (e.g. Frozen, Crystal and Trooper), but also picolinafen, dimethenamid-P, bentazone, imazamox, a.o.).

Both active ingredients are well known. Flufenacet has a broad grass weed spectrum, whereas pendimethalin has effect on some important grass weeds as well as on a wide range of broadleaved weeds and provide also a residual effect. This mixture can be a useful tool in managing or preventing the establishment of resistant weeds.

Based on the knowledge about the active substances and the experiences in the label claimed crops, the necessary application rates to obtain sufficient control of the weeds are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

To demonstrate the benefits of the mixture and that the co-formulation does not compromise the effectiveness obtained with e.g. flufenacet applied alone, an EU approved flufenacet 50% SC straight formulation, i.e. Cadou (DE, CZ, PL and FR), System 50 (UK) or FOE50% SC (CZ, FR, HU, IT and ES) was included as treatment at comparable dose rates, for comparison. In four Hungarian trials, an EU approved pendimethalin 330 EC straight formulation, i.e. Sharpen 33 EC, was also included, to demonstrate the benefit of the mixture. The results obtained on grasses and broadleaved weeds in 35 efficacy trials, treated pre-emergence or post-emergence in wheat and barley are presented below, to justify the mixture.

Comments of zRMS:	<p>The active substances of SHA 2619A – flufenacet and pendimethalin are registered and have been commonly used in agricultural practice for many years. Large scale efficacy trials are available to evaluate the effectiveness of products containing flufenacet or pendimethalin as active compounds. Therefore, there was no need for preliminary range-finding tests in the opinion of Evaluator. However, for PL that justification is is advisable (no plant protection product with flufenacet and pendimethalin on market).</p>
-------------------	---

3.2.1.1 Justification of the Mixture

Flufenacet 6% + Pendimethalin 30% EC is composed of flufenacet and pendimethalin. These two active ingredients have different modes of action, i.e. flufenacet is an Oxyacetamide (HRAC 15, WSSA 15), whereas pendimethalin is a Dinitroaniline (HRAC 3, WSSA 3). Using a product which contains two modes of action will help to prevent resistance development. Flufenacet 6% + Pendimethalin 30% EC mixture is designed to complement the range of activity of the individual component active substances, to provide a complete product for the control of grasses and broadleaved weeds in cereals, with pre- or early post-emergence application in the autumn or late winter.

In the summary tables below, the mean control obtained on grasses and broadleaved weeds present in 35 cereal trials conducted in the Maritime (15), the North-east (4), the South-east (4) and the Mediterranean

(12) EPPO zones are presented, to demonstrate the benefits of the mixture and that the coformulation does not compromise the effectiveness expected by the single active substances.

Grass weeds

To compare the effectiveness of the mixture and the straight reference products at comparable dose rates when applied pre-emergence or early post-emergence in the autumn for the control of grass weeds in winter cereals, the assessment results of 28 efficacy trials performed in the Maritime (13), the North-east (4), the South-east (4) and the Mediterranean (7) EPPO zones in 2015/ 16 season are reported. In the trials, flufenacet straight was included at 0.30 L/ha and 0.40 L/ha or at 0.48 L/ha, which equals to 150, 200 and 240 g flufenacet per hectare. If 0.30 L/ha and 0.40 L/ha of flufenacet 500 g/L SC was tested, the results obtained with 0.30 L/ha (150 g ai/ha) was compared against Flufenacet 6% + Pendimethalin 30% EC at 2.5 L/ha (150 g flufenacet and 750 g pendimethalin per hectare) or if 0.48 L/ha of flufenacet 500 g/L SC was tested, the results obtained with 0.48 L/ha (240 g ai/ha) was compared against Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha (240 g flufenacet and 1200 g pendimethalin per hectare). Grass weeds were evaluated in 28 of the 35 efficacy trials included in the Preliminary range section and in these, Flufenacet 6% + Pendimethalin 30% EC was applied pre-emergence of the crop in 13 of the trials and post-emergence of the crop in the remaining 15 trials.

The control of frequently occurring monocotyledonous weeds in cereals was assessed at different timings throughout the trial period. However, as the most accurate representation of whole plot product performance, the data obtained from the assessment carried out after regrowth of the weeds had commenced in the spring is presented in the following summary tables. Table 3.2-9, Table 3.2-10, Table 3.2-11 and Table 3.2-12 therefore contains a summary of the assessment data obtained by visually estimating control obtained by the applied products at 98-210 days after pre-emergence application and 88-226 days after post-emergence application in the Maritime EPPO zone, the North-east EPPO zone, the South-east EPPO zone and the Mediterranean EPPO zone, respectively.

Table 3.2-9: Maritime zone: Preliminary range-finding results with Flufenacet 6% + Pendimethalin 30% EC and flufenacet straight applied against frequently occurring grass weeds in winter cereals. Spring assessment.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 900 g ai/ha is >, < or =, compared to the flufe- nacet reference product at 150 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet ref. prod. at	>	=	<	
				Mean (min-max)					
				2.5 L/ha (150 + 750 g ai/ha)	0.3 L/ha (150 g ai/ha)				
Pre-emergence application									
AGRRE	00	1	5	90	65	1			>
ALOMY	03	2	25-100	86.3 (-)	63.8 (55-72.5)	2			>
APESV	00	1	10	90	70	1			>
LOLMU	00-03	2	5-6.3	86.7 (75-98.3)	63.4 (40-86.7)	2			>
POAAN	03	1	22.5	100	94.8	1			>
Mean, all assessments		7		89.4 (75-100)	69.1 (40-94.8)	7			>
EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 900 g ai/ha is >, < or =, compared to the flufe- nacet + pendimethalin reference product at 900 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet ref. prod. at	>	=	<	
				Mean (min-max)					
				2.5-4.0 L/ha (150 + 750 or 240 + 1200 g ai/ha)	0.3-0.48 L/ha (150 or 240 g ai/ha)				
Post-emergence application									
ALOMY	03-15	5	6.5-21.3	81.6 (58.8-100)	69.8 (43.8-87.5)	3	1	1	>
APESV	11	2	8.8-16.5	90.0 (-)	70.0 (-)	2			>
AVEFA	n.r.	1	n.r.	0	0		1		=
LOLMU	03-11	2	5.5-10	90.5 (82.5-98.5)	68.8 (62.5-75)	2			>
POAAN	10-13	1	35	100	99.5	1			>

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 900 g ai/ha is >, < or =, compared to the flufe- nacet reference product at 150 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet ref. prod. at				
				Mean (min-max)					
				2.5 L/ha (150 + 750 g ai/ha)	0.3 L/ha (150 g ai/ha)	>	=	<	
Mean, all assessments		11		79.0 (0-100)	66.0 (0-99.5)	8	2	1	>

Table 3.2-10: North-east zone: Preliminary range-finding results with Flufenacet 6% + Pendimethalin 30% EC and straight reference products applied against frequently occurring grass weeds in winter cereals. Spring assessment.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 900 g ai/ha is >, < or =, compared to the flufe- nacet reference product at 150 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet ref. prod. at				
				Mean (min-max)					
				2.5 L/ha (150 + 750 g ai/ha)	0.3 L/ha (150 g ai/ha)	>	=	<	
Pre-emergence application									
APESV	00	2	3-6	100 (-)	100 (-)		2		=
Post-emergence application									
APESV	00	2	5	100 (-)	100 (-)		2		=

Table 3.2-11: South-east zone: Preliminary range-finding results with Flufenacet 6% + Pendimethalin 30% EC and straight reference products applied against frequently occurring grass weeds in winter cereals. Spring assessment.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 900 g ai/ha is >, < or =, compared to the flufe- nacet reference product at 150 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet ref. prod. at	>	=	<	
				Mean (min-max)					
				2.5 L/ha (150+750 gai/ha)	0.3 L/ha (150 g ai/ha)				
Pre-emergence application									
ALOMY	00-07	1	40	92.3	60	1			>
APESV	03-06	1	63.3	99.5	94.5		1		=
Mean, all assessments		2		95.9 (92.3-99.5)	77.3 (60-94.5)	1	1		>
Post-emergence application									
ALOMY	11	1	150	88.8	89.3		1		=
APESV	12	1	61.3	99	93.5	1			>
Mean, all assessments		2		93.9 (88.8-99)	91.4 (89.3-93.5)	1	1		=
EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the pendimethalin reference product at 1320 gai. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha (240 + 1200 g ai/ha)	4.0 L/ha (1320 g ai/ha)	>	=	<	
Pre-emergence application									
ALOMY	00-07	1	40	95	95.8		1		=
APESV	03-06	1	63.3	100	98.8		1		=
Mean, all assessments		2		97.5 (95-100)	97.3 (95.8-98.8)		2		=
Post-emergence application									
ALOMY	11	1	150	88.8	75	1			>
APESV	12	1	61.3	100	98.5		1		=
Mean, all assessments		2		94.4 (88.8-100)	86.8 (75-98.5)	1	1		>

Table 3.2-12: Mediterranean zone: Preliminary range-finding results with Flufenacet 6% + Pendimethalin 30% EC and flufenacet straight applied against frequently occurring grass weeds in winter cereals. Spring assessment.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 900 or 1440 g ai/ha is >, < or =, compared to the flufenacet reference product at 150 or 240 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet ref. prod. at				
				Mean (min-max)					
				2.5-4.0 L/ha (150 + 750 or 240 + 1200 g ai/ha)	0.3-0.48 L/ha (150 or 240 g ai/ha)	>	=	<	
Pre-emergence application									
ALOMY	00	2	99.5-	87.5 (78.8-96.3)	87.5 (76.3-98.8)		2		=
LOLSS	Pre-em.	1	n.r.	80	78.8		1		=
Mean, all assessments		3		85.0 (78.8-96.3)	84.6 (76.3-98.8)		3		=
Post-emergence application									
LOLMU	11-23	2	29-	53.3 (7.5-99)	49.3 (2.5-96)		2		=

The individual trial results show that Flufenacet 6% + Pendimethalin 30% EC gave good to excellent control of grass weed species present in the different trials, equivalent to superior to that achieved by the straight reference products. This conclusion was supported by the statistical evaluation which revealed that Flufenacet 6% + Pendimethalin 30% EC, at 14 of the 31 assessments, performed significantly better than the straight flufenacet at comparable dose rate. At the remaining seventeen assessments, no significant differences were observed between the two tested products, however, Flufenacet 6% + Pendimethalin 30% EC achieved consistently higher levels of control than obtained with the straight flufenacet reference product. When compared against the pendimethalin straight reference product, it was observed that Flufenacet 6% + Pendimethalin 30% EC performed significantly better than straight pendimethalin at one of the four assessments, whereas at the remaining three assessments, no significant differences were observed between the two tested products. However, at all assessments, Flufenacet 6% + Pendimethalin 30% EC achieved consistently higher levels of control than obtained with the straight pendimethalin reference product.

Broadleaved weeds

To compare the effectiveness of the mixture and the straight reference products at comparable dose rates when applied pre-emergence or early post-emergence in the autumn for the control of broadleaved weeds in winter cereals, the assessment results of 33 efficacy trials performed in the Maritime (15), the North-east (4), the South-east (2) and the Mediterranean (12) EPPO zones in 2015/16 season are reported. In the trials, flufenacet straight was included at 0.30 L/ha and 0.40 L/ha or at 0.48 L/ha, which equals to 150, 200 and 240 g flufenacet per hectare. If 0.30 L/ha and 0.40 L/ha of flufenacet 500 g/L SC was tested, the results obtained with 0.30 L/ha (150 g ai/ha) was compared against Flufenacet 6% + Pendimethalin 30% EC at 2.5 L/ha (150 g flufenacet and 750 g pendimethalin per hectare) or if 0.48 L/ha of flufenacet 500 g/L SC was tested, the results obtained with 0.48 L/ha (240 g ai/ha) was compared against Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha (240 g flufenacet and 1200 g pendimethalin per hectare). In two Hungarian trials, pendimethalin straight was included at 4.0 L/ha, which equals to 1320 g pendimethalin per hectare and these results were compared against Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha (240 g flufenacet and 1200 g pendimethalin per hectare). Broadleaved weeds were evaluated in 33 of the 35 efficacy trials included in the Preliminary range section and in these, Flufenacet 6% + Pendimethalin 30% EC was applied pre-emergence of the crop in 17 of the trials and post-emergence of the crop in the remaining 16 trials.

The control of frequently occurring dicotyledonous weeds in cereals was assessed at different timings throughout the trial period. However, as the most accurate representation of whole plot product performance, the data obtained from the assessment carried out after regrowth of the weeds had commenced in the spring is presented in the following summary tables. Table 3.2-13, Table 3.2-14, Table 3.2-15 and Table 3.2-16 therefore contains a summary of the assessment data obtained by visually estimating control

obtained by the applied products at 53-210 days after pre-emergence application and 28-226 days after post-emergence application in the Maritime EPPO zone, the North-east EPPO zone, the South-east EPPO zone and the Mediterranean EPPO zone, respectively.

Table 3.2-13: Maritime zone: Preliminary range-finding results with Flufenacet 6% + Pendimethalin 30% EC and flufenacet straight applied against frequently occurring broadleaved weeds in winter cereals. Spring assessment.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 900 or 1440 g ai/ha is >, < or =, compared to the flufenacet reference product at 150 or 240 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet ref. prod. at				
				Mean (min-max)					
				2.5-4.0 L/ha (150 + 750 or 240 + 1200 g ai/ha)	0.3-0.48 L/ha (150 or 240 g ai/ha)	>	=	<	
Pre-emergence application									
BRSNX	00	2	10-	94.9 (94.8-95)	62.5 (50-75)	2			>
CAPBP	00	1	4.3	100	0	1			>
FUMOF	03	2	6.8-	95 (-)	66.3 (65-67.5)	2			>
GALAP	00	1	5.3	100	75	1			>
MATCH	00-03	2	5.5-11.3	92.5 (85-100)	71.3 (42.5-100)	1	1		>
MATIN	00	1	5	100	40	1			>
PAPRH	00	1	5	90	80	1			>
POLAV	n.r.	1	n.r.	98.8	90	1			>
SENVU	03	1	8.8	75	30	1			>
SLYMA	00	1	5	27.5	20	1			>
STEME	00	1	5	100	50	1			>
Continued the following page...									
THLAR	00	1	5	90	50	1			>
VERHE	00-03	2	5-14	94.3 (90-98.5)	57.5 (52.5-62.5)	2			>
VERPE	03	1	36.3	100	53.8	1			>
VIOAR	00	3	4.8-6	92.1 (76.3-100)	54.2 (27.5-80)	3			>
TTTTT	n.r.	2	n.r.	88.4 (85-91.8)	74.7 (74.3-75)	2			>
Mean, all assessments		23		90.8 (27.5-100)	57.2 (0-100)	22	1		>
Post-emergence application									
BRSNX	12	2	4.3-10	97.5 (95-100)	50.0 (30-70)	2			>
CAPBP	00-07	2	4.0-5.5	100 (-)	62.5 (27.5-97.5)	1	1		>
FUMOF	03-13	2	6.5-	69.4 (40-98.8)	69.4 (50-88.8)	1		1	=
GALAP	00-12	2	5.5-10.3	90 (-)	35.0 (30-40)	2			>
MATCH	00-03	2	1.3-11.5	95.0 (90-100)	77.5 (55-100)	1	1		>
MATIN	10-12	2	5-10.3	85.0 (80-90)	42.5 (30-55)	2			>
MEDSA	15	1	n.r.	90.5	93.8		1		=
POLCO	n.r.	1	n.r.	98.3	0	1			>
SENVU	03	1	7.3	73.8	43.8	1			>
SINAR	10-13	1	15	60	0	1			>
STEME	12-14	3	8.3-12.5	90.0 (80-100)	56.7 (30-100)	2	1		>
THLAR	12-14	2	4.5-8	95.0 (90-100)	45.0 (30-60)	2			>
VERHE	10-13	2	15-23	90.0 (-)	48.8 (40-57.5)	2			>
VERPE	10-13	3	42.5-118.5	99.7 (99-100)	14.2 (0-32.5)	3			>
VERSS	10-13	1	14.3	98.3	15	1			>
VIOAR	00-11	3	5.5-38.8	98.3 (96.3-100)	10.0 (0-27.5)	3			>
TTTTT	n.r.	2	50-	73.2 (55-91.3)	72.5 (55-90)		2		=
Mean, all assessments		32		89.8 (40-100)	43.8 (0-100)	25	6	1	>

Table 3.2-14: North-east zone: Preliminary range-finding results with Flufenacet 6% + Pendimethalin 30% EC and straight reference products applied against frequently occurring broadleaved weeds in winter cereals. Spring assessment.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 900 g ai/ha is >, < or =, compared to the flufe- nacet reference product at 150 g ai/ha. = : ± 5% control			
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet ref. prod. at				Overall
				Mean (min-max)					
				2.5 L/ha (150 + 750 g ai/ha)	0.3 L/ha (150 g ai/ha)	>	=	<	

Weed Growth stage at application of [BBCH] No. of trials			Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 900 g ai/ha is >, < or =, compared to the flufenacet reference product at 150 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet ref. prod. at				
				Mean (min-max)		2.5 L/ha (150 + 750 g ai/ha)	0.3 L/ha (150 g ai/ha)	>	=
Pre-emergence application									
CENCY	00	2	13-36	80.5 (75-86)	41.5 (35-48)	2			>
GALAP	00	1	3	95	100		1		=
MATMA	00	2	6-33	95.0 (90-100)	82.5 (80-85)	1	1		>
VIOAR	00	2	17-51	91.5 (83-100)	15.0 (0-30)	2			>
Mean, all assessments		7		89.9 (75-100)	54.0 (0-100)	5	2		>
Post-emergence application									
CENCY	10-12	2	17-23	70.5 (63-78)	35.5 (33-38)	2			>
GALAP	00	1	5	38	30	1			>
MATMA	10-12	2	7-33	81.5 (73-90)	83.0 (70-96)		1	1	=
VIOAR	10	2	22-32	77.5 (70-85)	5.0 (0-10)	2			>
Mean, all assessments		7		70.0 (38-90)	39.6 (0-96)	5	1	1	>

The individual trial results show that Flufenacet 6% + Pendimethalin 30% EC gave good to excellent control of broadleaved weed species present in the different trials, equivalent to superior to that achieved by the straight reference products. This conclusion was supported by the statistical evaluation which revealed that Flufenacet 6% + Pendimethalin 30% EC, at 69 of the 105 assessments, performed significantly better than the straight flufenacet at comparable dose rate. At the remaining 36 assessments, no significant differences were observed between the two tested products, however, Flufenacet 6% + Pendimethalin 30% EC achieved consistently higher levels of control than obtained with the straight flufenacet reference product. When compared against the pendimethalin straight reference product, it was observed that Flufenacet 6% + Pendimethalin 30% EC performed statistically similar to the reference product at both assessments.

Table 3.2-15: South-east zone: Preliminary range-finding results with Flufenacet 6% + Pendimethalin 30% EC and straight reference products applied against frequently occurring broadleaved weeds in winter cereals. Spring assessment.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 900 g ai/ha is >, < or =, compared to the flufe- nacet reference product at 150 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet ref. prod. at	>	=	<	
				Mean (min-max)					
				2.5 L/ha (150 + 750 g ai/ha)	0.3 L/ha (150 g ai/ha)				
Pre-emergence application									
VERHE	00-07	1	10	95	50	1			>
Post-emergence application									
VERHE	10	1	10	94.5	81.3	1			>
EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the pendimethalin reference at 1320 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Pendimethalin ref. prod. at	>	=	<	
				Mean (min-max)					
				4.0 L/ha (240 + 1200 g ai/ha)	4.0 L/ha (1320 g ai/ha)				
Pre-emergence application									
VERHE	00-07	1	10	97.3	98		1		=
Post-emergence application									
VERHE	10	1	10	95	95.3		1		=

Table 3.2-16: Mediterranean zone: Preliminary range-finding results with Flufenacet 6% + Pendimethalin 30% EC and flufenacet straight applied against frequently occurring broadleaved weeds in winter cereals. Spring assessment.

Weed Growth stage at application No. of trials EPPO Code [BBCH]			Ground cover at assessm. (no/m²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 900 or 1440 g ai/ha is >, < or =, compared to the flufenacet reference product at 150 or 240 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet ref. prod. at				
				Mean (min-max)					
				2.5-4.0 L/ha (150 + 750 or 240 + 1200 gai)		0.3-0.48 L/ha (150 or 240 gai)		>	=
Pre-emergence application									
AMABL	Pre-em.	2	7-10.3	98.8 (97.6-100)	71.3 (57.1-85.4)	2			>
ANGAR	Pre-em.	3	6.3-18.5	89.3 (68-100)	74.6 (52-82.5)	3			>
CHYCO	Pre-em.	1	4.8	63.2	42.1	1			>
CIRAR	Pre-em.	1	n.r.	60	67.5			1	<
DIPVG	Pre-em.	1	5	95	80	1			>
GALAP	Pre-em.	1	8.8	85.7	71	1			>
MERAN	Pre-em.	1	n.r.	77.5	27.5	1			>
PICHI	Pre-em.	1	5.8	60.9	47.8	1			>
POLAV	Pre-em.	1	11	95.5	84.1	1			>
POLCO	Pre-em.	1	n.r.	63.8	20	1			>
SONAS	Pre-em.	2	5.5-6	91.7 (83.3-100)	70.0 (50-90)	2			>
STEME	00	1	9.8	100	77.5	1			>
VERPE	00	1	87.5	80	60	1			>
TTTTT	Pre-em.	2	n.r.	78.2 (75-81.3)	62.5 (47.5-77.5)	1	1		>
Mean, all assessments		19		83.5 (60-100)	63.6 (20-90)	17	1	1	>
Post-emergence application									
FUMOF	00	1	9	99.5	0	1			>
GALAP	16-21	2	8-	43.8 (5-82.5)	5.9 (2.5-9.3)	1	1		>
LAMAM	16	1	11.3	83.8	13.8	1			>
PAPRH	00-17	3	17-25	93.9 (88-99.8)	26.8 (0-70.5)	3			>
POLSS	00	1	105	94.5	0	1			>
SENAG	18	1	7.5	82.5	5	1			>
STEME	13-17	2	9.5-12.3	79.4 (78.8-80)	39.0 (8-70)	2			>
URTAN	14	1	12.8	88.8	20	1			>
VERHE	21	1	n.r.	100	100		1		=
VERPE	13-15	1	1	78.8	70	1			>
TTTTT	n.r.	1	n.r.	30	10	1			>
Mean, all assessments		15		79.0 (5-100)	25.9 (0-100)	13	2	0	>

Conclusion

When applied to the annual grasses and broadleaved weeds present in the trials, Flufenacet 6% + Pendimethalin 30% EC at comparable dose rates gave a more consistent and occasionally a higher level of weed control compared to that of flufenacet alone as well as pendimethalin alone. It is therefore considered demonstrated that the co-formulation of flufenacet with pendimethalin has its justification when controlling annual grasses and broadleaved weeds in winter cereals.

Combining two actives in Flufenacet 6% + Pendimethalin 30% EC, which are commonly tank-mixed, also has the benefit of reducing the number of products handled by the spray operator as well as an important tool in resistance management.

3.2.1.2 Justification of Ratio of Active Ingredients in the Mixture

Flufenacet 6% + Pendimethalin 30% EC is a EC formulation containing 60 g/L flufenacet and 300 g/L pendimethalin. The co-formulation of flufenacet with pendimethalin is not new and has been registered for several years with the same ratio of active substances in markets of Europe.

Comments of zRMS:	Applicant submitted justification for mixture tank of two active substances: flufenacet and pendimethalin which was accepted by Evaluator. Generally, it can be concluded that combining two actives in flufenacet 60 g/l and pendimethalin 300 g/l has the benefit of reducing the number of products handled by the spray operator as well as an important tool in resistance management.
-------------------	---

3.2.2 Minimum effective dose tests (KCP 6.2)

Flufenacet 6% + Pendimethalin 30% EC was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with Flufenacet 6% + Pendimethalin 30% EC applied at 1.5 L/ha, 2.0 L/ha, 2.5 L/ha, 3.3 L/ha and 4.0 L/ha was evaluated in 43 cereal trials for the control of the mono- and dicotyledonous weeds present in the trials. The dose rates tested reflects 37.5%, 50%, 62.5%, 82.5% and 100% of the recommended rate of Flufenacet 6% + Pendimethalin 30% EC, in accordance with the EPPO guideline PP 1/225(2) “Minimum effective dose”. The dose is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy was tested under a range of environmental conditions to fully challenge the product. Data are presented from trials conducted in the Maritime EPPO zone (i.e. N-France, Germany, Czech Republic and England), the North-east EPPO zone (i.e. Poland), the South-east EPPO zone (i.e. Hungary) and the Mediterranean EPPO zone (i.e. Spain, Italy and S-France).

Summary and evaluation of Minimum Effective Dose results for 4.0 L/ha Flufenacet 6% + Pendimethalin 30% EC target rate against grass weeds in winter cereals, autumn application

To prove and to support the requested dose rate of 4.0 L/ha Flufenacet 6% + Pendimethalin 30% EC [240 g flufenacet and 1200 g pendimethalin per hectare] applied pre-emergence or early post-emergence in the autumn for the control of grass weeds in winter cereals, the assessment results of 40 efficacy trials performed in the Maritime (13), the North-east (16), the South-east (4) and the Mediterranean (7) EPPO zones in 2015/16 and 2018/19 seasons are reported. Flufenacet 6% + Pendimethalin 30% EC was included in these trials at 4.0 L/ha to demonstrate the recommended dose rate as well as at lower than recommended dose rates (1.5 L/ha [90 g flufenacet and 450 g pendimethalin per hectare], 2.0 L/ha [120 g flufenacet and 600 g pendimethalin per hectare], 2.5 L/ha [120 g flufenacet and 600 g pendimethalin per hectare] and 3.3 L/ha [158 g flufenacet and 792 g pendimethalin per hectare]). Grass weeds were evaluated in 36 of the 43 efficacy trials included in the Minimum Effective Dose section and in these, Flufenacet 6% + Pendimethalin 30% EC was applied pre-emergence of the crop in 13 of the trials and post-emergence of the crop in the remaining 27 trials.

The control of frequently occurring monocotyledonous weeds in cereals was assessed at different timings throughout the trial period. However, as the most accurate representation of whole plot product performance, the data obtained from the assessment carried out after regrowth of the weeds had commenced in the spring is presented in the following summary tables. Table 3.2-17, Table 3.2-18, Table 3.2-19 and Table 3.2-20 therefore contains a summary of the assessment data obtained by visually estimating control obtained by the applied products at 98-210 days after pre-emergence application and 27-226 days after post-emergence application in the Maritime EPPO zone, the North-east EPPO zone, the South-east EPPO zone and the Mediterranean EPPO zone, respectively.

Maritime EPPO zone

In the Maritime EPPO zone, the average control of the assessed monocotyledonous weed species at the assessment after re-growth has commenced in the spring (162-208 days after application) was 50.4%, 78.1% and 89.4% following a pre-emergence application of Flufenacet 6% + Pendimethalin 30% EC at 1.5 L/ha, 2.0 L/ha and 2.5 L/ha, respectively, compared to 95.0% control achieved by the recommended rate, i.e. 4.0 L/ha. When applied post-emergence, Flufenacet 6% + Pendimethalin 30% EC achieved an average control of the assessed monocotyledonous weed species in the spring (146-226 days after application) of 66.5%, 72.3% and 79.2% when applied at 1.5 L/ha, 2.0 L/ha and 2.5 L/ha, respectively, compared to 86.3% control achieved by the recommended rate, i.e. 4.0 L/ha. The results indicate that the earlier the product is applied in comparison to growth stage of the weed to be controlled, the better the control. A satisfactory level of control may be achieved with lower than recommended dose rates when applied pre-emergence or early post-emergence, but if weeds have already emerged, or if less susceptible grass weed species are part of the flora in the field, Flufenacet 6% + Pendimethalin 30% EC should be applied at the maximum recommended dose rate to obtain a satisfactory control.

Table 3.2-17: Maritime zone: Minimum effective dose of Flufenacet 6% + Pendimethalin 30% EC applied against frequently occurring grass weeds in winter cereals.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with			
				Flufenacet 6% + Pendimethalin 30% EC at:			
				Mean (min-max)			
				1.5 L/ha (37.5%)	2.0 L/ha (50%)	2.5 L/ha (62.5%)	4.0 L/ha (100%)
Pre-emergence application							
AGRRE	00	1	5	50	55	90	100
ALOMY	03	2	25-100	50.0 (40-60)	71.3 (67.5-75)	86.3 (-)	91.3 (90-92.5)
APESV	00	1	10	70	80	90	100
LOLMU	00-03	2	5-6.3	17.5 (0-35)	85.0 (70-100)	86.7 (75-98.3)	91.3 (82.5-100)
POAAN	03	1	22.5	97.5	99.5	100	100
Mean of all assessments		7		50.4 (0-97.5)	78.1 (55-100)	89.4 (75-100)	95.0 (82.5-100)
Post-emergence application							
ALOMY	03-15	5	6.5-21.3	66.6 (26.3-100)	70.3 (40-100)	82.0 (58.8-100)	92.1 (82.5-100)
APESV	11	2	8.8-16.5	76.3 (75-77.5)	85.0 (-)	90.0 (-)	100 (-)
AVEFA	n.r.	1	n.r.	0	0	0	0
LOLMU	03-11	2	5.5-10	74.4 (61.3-87.5)	86.9 (75-98.8)	90.5 (82.5-98.5)	94.5 (90-99)
POAAN	10-13	1	35	97	100	100	100
Mean of all assessments		11		66.5 (0-100)	72.3 (0-100)	79.2 (0-100)	86.3 (0-100)

Statistical evaluation revealed that Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha performed significantly better than the 1.5 L/ha dose rate at 11 of the 18 assessments and at seven of the 18 assessments, Flufenacet 6% + Pendimethalin 30% EC at the recommended dose rate also performed significantly better than the 2.0 L/ha dose rate. Finally, at six of the 11 assessments, Flufenacet 6% + Pendimethalin 30% EC at recommended dose rate also performed significantly better than the 2.5 L/ha dose rate. At the remaining seven assessments, i.e. one assessment after pre-emergence application and six assessments after post-emergence application, no significant differences were observed between the tested Flufenacet 6% + Pendimethalin 30% EC dose rates when applied pre- or post-emergence, however, the proposed dose rate of 4.0 L/ha achieved consistently higher levels of control than obtained with the reduced dose rate.

North-east EPPO zone

In the North-east EPPO zone, the average control of the assessed monocotyledonous weed specie present in the 14 trials (APESV and ALOMY) at the assessment after re-growth has commenced in the spring (27-201 days after application) was complete control (100%) for all dose rates applied following a pre-emergence application of Flufenacet 6% + Pendimethalin 30% EC.

When applied post-emergence, Flufenacet 6% + Pendimethalin 30% EC achieved an average control of the assessed monocotyledonous weed species in the spring (32-195 days after application) of 100%, 100%, 73.0% and 78.0% when applied at 1.5 L/ha, 2.0 L/ha, 2.5 L/ha and 3.3 L/ha, respectively, compared to 85.2% control achieved by the recommended rate, i.e. 4.0 L/ha. The results indicate that the earlier the product is applied in comparison to growth stage of the weed to be controlled, the better the control. A satisfactory level of control may be achieved with lower than recommended dose rates when applied pre-emergence or early post-emergence, but if weeds have already emerged, or if less susceptible grass weed species are part of the flora in the field, Flufenacet 6% + Pendimethalin 30% EC should be applied at the maximum recommended dose rate to obtain a satisfactory control.

Statistical evaluation revealed that Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha performed significantly better than the lower doses. Data from 1.5 L/ha and 2.0 L/ha doses has to be considered a part of the rest due to a high performance of Flufenacet 6% + Pendimethalin 30% EC in those two trials. If weeds have already emerged, or if less susceptible grass weed species are part of the flora in the field, Flufenacet 6% + Pendimethalin 30% EC should be applied at the maximum recommended dose rate to obtain a satisfactory control.

Table 3.2-18: North-east zone: Minimum effective dose of Flufenacet 6% + Pendimethalin 30% EC applied against frequently occurring grass weeds in winter cereals.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with				
				Flufenacet 6% + Pendimethalin 30% EC at:				
				Mean (min-max)				
				1.5 L/ha (37.5%)	2.0 L/ha (50%)	2.5 L/ha (62.5%)	3.3 L/ha (82.5%)	4.0 L/ha (100%)
Pre-emergence application								
APESV	00	2	3-6	100 (-)	100 (-)	100 (-)		100 (-)
Post-emergence application								
APESV	00-12	14	8.9 (4.0-17.3)	100 (100-100)	100 (100-100)	76.7 (27.5-100)	81.0 (45.0-100)	90.3 (70.0-100)
ALOMY	10-11	3	15.0 (8.0-19.8)	-	-	69.2 (65.0-75.0)	75.0 (70.0-80.0)	80.0 (75.0-85.0)
Mean of all assessments		17	12.0 (4.0-19.8)	100 (100-100)	100 (100-100)	73.0 (27.5-100)	78.0 (45.0-100)	85.2 (70.0-100)

South-east EPPO zone

In the South-east EPPO zone, the average control of the assessed monocotyledonous weed species at the assessment after re-growth has commenced in the spring (132-143 days after application) was 85.3%, 94.0% and 95.9% following a pre-emergence application of Flufenacet 6% + Pendimethalin 30% EC at 1.5 L/ha, 2.0 L/ha and 2.5 L/ha, respectively, compared to 97.5% control achieved by the recommended rate, i.e. 4.0 L/ha. When applied post-emergence, Flufenacet 6% + Pendimethalin 30% EC achieved an average control of the assessed monocotyledonous weed species in the spring (126-143 days after application) of 81.9%, 89.8% and 93.9% when applied at 1.5 L/ha, 2.0 L/ha and 2.5 L/ha, respectively, compared to 94.4% control achieved by the recommended rate, i.e. 4.0 L/ha. A satisfactory level of control may be achieved with lower than recommended dose rates when applied pre-emergence or early post-emergence, but if weeds have already emerged, or if less susceptible grass weed species are part of the flora in the field, Flufenacet 6% + Pendimethalin 30% EC should be applied at the maximum recommended dose rate to obtain a satisfactory control.

Statistical evaluation revealed that Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha performed significantly better than the 1.5 L/ha dose rate at all four assessments, i.e. at two assessments when applied pre-emergence and at two assessments when applied post-emergence. At one of the four assessments, Flufenacet 6% + Pendimethalin 30% EC at recommended dose rate also performed significantly better than the 2.0 L/ha dose rate. At all assessments, the proposed dose rate of 4.0 L/ha achieved consistently higher levels of control than obtained with the reduced dose rate.

Table 3.2-19: South-east zone: Minimum effective dose of Flufenacet 6% + Pendimethalin 30% EC applied against frequently occurring grass weeds in winter cereals.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with			
				Flufenacet 6% + Pendimethalin 30% EC at:			
				Mean (min-max)			
				1.5 L/ha (37.5%)	2.0 L/ha (50%)	2.5 L/ha (62.5%)	4.0 L/ha (100%)
Pre-emergence application							
ALOMY	00-07	1	40	85	90.5	92.3	95
APESV	03-06	1	63.3	85.5	97.5	99.5	1
Mean of all assessments		2		85.3 (85-85.5)	94.0 (90.5-97.5)	95.9 (92.3-99.5)	97.5 (95-100)
Post-emergence application							
ALOMY	11	1	150	82.5	83.8	88.8	88.8
APESV	12	1	61.3	81.3	95.8	99	100
Mean of all assessments		2		81.9 (81.3-82.5)	89.8 (83.8-95.8)	93.9 (88.8-99)	94.4 (88.8-100)

Mediterranean EPPO zone

In the Mediterranean EPPO zone, the average control of the assessed monocotyledonous weed species at the assessment after re-growth has commenced in the spring (98-210 days after application) was 78.8%, 79.4% and 86.3% following a pre-emergence application of Flufenacet 6% + Pendimethalin 30% EC at 1.5 L/ha, 2.0 L/ha and 2.5 L/ha, respectively, compared to 86.7% control achieved by the recommended rate, i.e. 4.0 L/ha. When applied post-emergence, Flufenacet 6% + Pendimethalin 30% EC achieved an average control of the assessed monocotyledonous weed species in the spring (88-161 days after application) of 49.9%, 50.9% and 52.7% when applied at 1.5 L/ha, 2.0 L/ha and 2.5 L/ha, respectively, compared to 53.6% control achieved by the recommended rate, i.e. 4.0 L/ha. The results indicate that the earlier the product is applied in comparison to growth stage of the weed to be controlled, the better the control. A satisfactory level of control may be achieved with lower than recommended dose rates when applied pre-emergence or early post-emergence, but if weeds have already emerged, or if less susceptible grass weed species are part of the flora in the field, Flufenacet 6% + Pendimethalin 30% EC should be applied at the maximum recommended dose rate to obtain a satisfactory control.

Statistical evaluation revealed that Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha performed significantly better than the 1.5 L/ha dose rate at two of the 5 assessments, i.e. at one assessment when applied pre-emergence and at one assessment when applied post-emergence. At the remaining two and one assessments, respectively, no significant differences were observed between the tested Flufenacet 6% + Pendimethalin 30% EC dose rates when applied pre- or post-emergence, however, the proposed dose rate of 4.0 L/ha achieved consistently higher levels of control than obtained with the reduced dose rate.

Table 3.2-20: Mediterranean zone: Minimum effective dose of Flufenacet 6% + Pendimethalin 30% EC applied against frequently occurring grass weeds in winter cereals.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with			
				Flufenacet 6% + Pendimethalin 30% EC at:			
				Mean (min-max)			
				1.5 L/ha (37.5%)	2.0 L/ha (50%)	2.5 L/ha (62.5%)	4.0 L/ha (100%)
Pre-emergence application							
ALOMY	00	2	-99.5	86.9 (76.3-97.5)	77.9 (58.3-97.5)	88.1 (78.8-97.5)	90.0 (83.8-96.3)
LOLSS	n.r.	1	n.r.	62.5	82.5	82.5	80
Mean of all assessments		3		78.8 (62.5-97.5)	79.4 (58.3-97.5)	86.3 (78.8-97.5)	86.7 (80-96.3)
Post-emergence application							
LOLMU	11-23	2	29-	49.9 (3.8-96)	50.9 (3.8-98.0)	52.7 (6.3-99)	53.6 (7.5-99.8)

Conclusion

Based on results achieved on monocotyledonous weeds in 28 of the 35 winter cereal trials treated with pre-emergence application (13) or post-emergence application (15), it can be concluded that to consistently control frequently occurring grass weeds in winter cereals, Flufenacet 6% + Pendimethalin 30% EC should be applied pre- or early post-emergence at 4.0 L/ha.

Summary and evaluation of Minimum Effective Dose results for 4.0 L/ha Flufenacet 6% + Pendimethalin 30% EC target rate against broadleaved weeds in winter cereals, autumn application

To prove and to support the requested dose rate of 4.0 L/ha Flufenacet 6% + Pendimethalin 30% EC [240 g flufenacet and 1200 g pendimethalin per hectare] applied pre-emergence or early post-emergence in the autumn for the control of broadleaved weeds in winter cereals, the assessment results of 45 efficacy trials performed in the Maritime (15), the North-east (16), the South-east (2) and the Mediterranean (12) EPPO zones in 2015/16 and 2018/19 seasons are reported. Flufenacet 6% + Pendimethalin 30% EC was included in these trials at 4.0 L/ha to demonstrate the recommended dose rate as well as at lower than recom-

mended dose rates (1.5 L/ha [90 g flufenacet and 450 g pendimethalin per hectare], 2.0 L/ha [120 g flufenacet and 600 g pendimethalin per hectare] and 2.5 L/ha [120 g flufenacet and 600 g pendimethalin per hectare] and 3.3 L/ha [158 g flufenacet and 792 g pendimethalin per hectare]). Broadleaved weeds were evaluated in 43 of the 45 efficacy trials included in the Minimum Effective Dose section and in these, Flufenacet 6% + Pendimethalin 30% EC was applied pre-emergence of the crop in 17 of the trials and post-emergence of the crop in the remaining 28 trials.

The control of frequently occurring dicotyledonous weeds in cereals was assessed at different timings throughout the trial period. However, as the most accurate representation of whole plot product performance, the data obtained from the assessment carried out after regrowth of the weeds had commenced in the spring is presented in the following summary tables. Table 3.2-21, Table 3.2-22, Table 3.2-23 and Table 3.2-24 therefore contains a summary of the assessment data obtained by visually estimating control obtained by the applied products at 53-210 days after pre-emergence application and 27-226 days after post-emergence application in the Maritime EPPO zone, the North-east EPPO zone, the South-east EPPO zone and the Mediterranean EPPO zone, respectively.

Maritime EPPO zone

In the Maritime EPPO zone, the average control of the assessed dicotyledonous weed species at the assessment after re-growth has commenced in the spring (53-204 days after application) was 75.7%, 84.2% and 89.7% following a pre-emergence application of Flufenacet 6% + Pendimethalin 30% EC at 1.5 L/ha, 2.0 L/ha and 2.5 L/ha, respectively, compared to 93.3% control achieved by the recommended rate, i.e. 4.0 L/ha. When applied post-emergence, Flufenacet 6% + Pendimethalin 30% EC achieved an average control of the assessed dicotyledonous weed species in the spring (75-226 days after application) of 81.2%, 84.1% and 89.8% when applied at 1.5 L/ha, 2.0 L/ha and 2.5 L/ha, respectively, compared to 95.3% control achieved by the recommended rate, i.e. 4.0 L/ha. A satisfactory level of control may be achieved with lower than recommended dose rates when applied pre-emergence or early post-emergence, but if weeds have already emerged, or if less susceptible broadleaved weed species are part of the flora in the field, Flufenacet 6% + Pendimethalin 30% EC should be applied at the maximum recommended dose rate to obtain a satisfactory control.

Table 3.2-21: Maritime zone: Minimum effective dose of Flufenacet 6% + Pendimethalin 30% EC applied against frequently occurring broadleaved weeds in winter cereals.

Weed Growth stage at application No. of trials			Ground cover at assessm. (no/m ²)	Efficacy obtained with			
				Flufenacet 6% + Pendimethalin 30% EC at:			
				Mean (min-max)			
EPPO Code	application [BBCH]	No. of trials	assessm. (no/m ²)	1.5 L/ha (37.5%)	2.0 L/ha (50%)	2.5 L/ha (62.5%)	4.0 L/ha (100%)
Pre-emergence application							
BRSNX	00	2	10-	91.5 (90-93)	90.5 (90-91)	90.8 (86.5-95)	97.4 (94.8-100)
CAPBP	00	1	4.3	100	100	100	100
FUMOF	03	2	6.8-	65.9 (57.5-74.3)	89.7 (81.8-97.5)	90.3 (85.5-95)	97.5 (95-100)
GALAP	00	1	5.3	100	100	100	100
MATCH	00-03	2	5.5-11.3	71.3 (42.5-100)	86.3 (72.5-100)	92.5 (85-100)	93.8 (87.5-100)
MATIN	00	1	5	70	80	100	100
PAPRH	00	1	5	70	80	90	100
POLAV	n.r.	1	n.r.	93	100	100	98.8
SENVU	03	1	8.8	5	55	75	82.5
SLYMA	00	1	5	15	20	27.5	40
STEME	00	1	5	80	85	100	100
THLAR	00	1	5	65	80	90	100
VERHE	00-03	2	5-14	80.0 (70-90)	85.0 (80-90)	94.3 (90-98.5)	96.9 (93.8-100)
VERPE	03	1	36.3	100	100	100	100
VIOAR	00	3	4.8-41.5	87.5 (62.5-100)	91.3 (73.8-100)	92.5 (77.5-100)	92.1 (76.3-100)
TTTTT	n.r.	2	n.r.	81.3 (77.5-85)	80.3 (75-85.5)	83.7 (81.3-86)	88.4 (85-91.8)
Mean of all assessments		23	4.3-41.5	75.7 (5-100)	84.2 (20-100)	89.7 (27.5-100)	93.3 (40-100)
Post-emergence application							
BRSNX	12	2	7.1 (4.3-10)	90.0 (80-10)	92.5 (85-100)	97.5 (95-100)	100 (-)
CAPBP	00-07	2	4.8 (4.0-5.5)	100 (-)	100 (-)	100 (-)	100 (-)
FUMOF	03-13	2	6.5-	98.8 (97.5-100)	91.3 (82.5-100)	70.0 (40-100)	99.4 (98.8-100)

Weed Growth stage at application EPPO Code			Ground cover at assessm. (no/m ²)	Efficacy obtained with			
				Flufenacet 6% + Pendimethalin 30% EC at:			
				Mean (min-max)			
	No. of trials			1.5 L/ha (37.5%)	2.0 L/ha (50%)	2.5 L/ha (62.5%)	4.0 L/ha (100%)
[BBCH]							
GALAP	00-12	2	7.9 (5.5-10.3)	38.8 (37.5-40)	60.0 (-)	90.0 (-)	94.4 (93.8-95)
MATCH	00-03	2	6.4 (1.3-11.5)	87.5 (75-100)	72.5 (60-85)	95.0 (90-100)	95.0 (90-100)
MATIN	10-12	2	7.6 (5-10.3)	75 (-)	80 (-)	85.0 (80-90)	100 (-)
MEDSA	15	1	n.r.	95.5	96	91.8	90.5
POLCO	n.r.	1	n.r.	97.5	98	97.5	98.3
SENVU	03	1	7.3	38.8	36.3	73.8	87.5
SINAR	10-13	1	15	37.5	62.5	60	88.8
STEME	12-14	3	10.4 (8.3-12.5)	78.3 (67.5-100)	87.1 (78.8-100)	90.0 (80-100)	93.3 (85-100)
THLAR	12-14	2	6.3 (4.5-8)	83.8 (67.5-100)	90.0 (80-100)	95.0 (90-100)	98.8 (97.5-100)
VERHE	10-13	2	19.0 (15-23)	66.3 (55-77.5)	72.5 (65-80)	90.0 (-)	96.9 (95-98.8)
VERPE	10-13	3	67.8 (42.5-118.5)	97.9 (94.8-100)	97.1 (92.5-100)	99.6 (98.8-100)	99.7 (99-100)
VERS	10-13	1	14.3	87	95.3	98.3	97
VIOAR	00-11	3	17.8 (5.5-38.8)	97.5 (95-100)	97.9 (96.3-100)	98.0 (96.3-100)	97.9 (95-100)
TTTTT	n.r.	2	50-	69.7 (52.5-86.8)	70.0 (55-85)	71.6 (53.8-89.3)	73.2 (55-91.3)
Mean of all assessments		32	1.3-118.5	81.2 (37.5-100)	84.1 (36.3-100)	89.8 (40-100)	95.3 (55-100)

Statistical evaluation revealed that Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha performed significantly better than the 1.5 L/ha dose rate at twenty-four of the 55 assessments and at eighteen of the 55 assessments, Flufenacet 6% + Pendimethalin 30% EC at the recommended dose rate also performed significantly better than the 2.0 L/ha dose rate. Furthermore, at nine of the 55 assessments, Flufenacet 6% + Pendimethalin 30% EC at recommended dose rate also performed significantly better than the 2.5 L/ha dose rate. At the remaining 31 assessments, i.e. 12 assessments after pre-emergence application and 19 assessments after post-emergence application, no significant differences were observed between the tested Flufenacet 6% + Pendimethalin 30% EC dose rates when applied pre- or post-emergence, however, the proposed dose rate of 4.0 L/ha achieved consistently higher levels of control than obtained with the reduced dose rate.

North-east EPP0 zone

In the North-east EPPO zone, the average control of the assessed dicotyledonous weed species at the assessment after re-growth has commenced in the spring (166-201 days after application) was 78.1%, 84.7% and 89.9% following a pre-emergence application of Flufenacet 6% + Pendimethalin 30% EC at 1.5 L/ha, 2.0 L/ha and 2.5 L/ha, respectively, compared to 95.3% control achieved by the recommended rate, i.e. 4.0 L/ha. When applied post-emergence, Flufenacet 6% + Pendimethalin 30% EC achieved an average control of the assessed dicotyledonous weed species in the spring (27-195 days after application) of 53.0%, 61.3%, 55.4% and 62.4% when applied at 1.5 L/ha, 2.0 L/ha, 2.5 L/ha and 3.3 L/ha, respectively, compared to 74.5% control achieved by the recommended rate, i.e. 4.0 L/ha. The results indicate that the earlier the product is applied in comparison to growth stage of the weed to be controlled, the better the control. A satisfactory level of control may be achieved with lower than recommended dose rates when applied pre-emergence or early post-emergence, but if weeds have already emerged, or if less susceptible broadleaved weed species are part of the flora in the field, Flufenacet 6% + Pendimethalin 30% EC should be applied at the maximum recommended dose rate to obtain a satisfactory control.

Statistical evaluation revealed that Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha performed significantly better than the lower dose rates. The proposed dose rate of 4.0 L/ha achieved consistently higher levels of control than obtained with the reduced dose rate.

Table 3.2-22: North-east zone: Minimum effective dose of Flufenacet 6% + Pendimethalin 30% EC applied against frequently occurring broadleaved weeds in winter cereals.

EPPO Code	Weed Growth stage at application [BBCH]	No. of tri- als	Ground cover at assessm. (no/m ²)	Efficacy obtained with				
				Flufenacet 6% + Pendimethalin 30% EC at:				
				Mean (min-max)				
				1.5 L/ha (37.5%)	2.0 L/ha (50%)	2.5 L/ha (62.5%)	3.3 L/ha (82.5%)	4.0 L/ha (100%)
Pre-emergence application								

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with				
				Flufenacet 6% + Pendimethalin 30% EC at:				
				Mean (min-max)				
				1.5 L/ha (37.5%)	2.0 L/ha (50%)	2.5 L/ha (62.5%)	3.3 L/ha (82.5%)	4.0 L/ha (100%)
CENCY	00	2	13-36	57.0 (51-63)	68.0 (63-73)	80.5 (75-86)		88.0 (85-91)
GALAP	00	1	3	93	95	95		100
MATMA	00	2	6-33	92.5 (85-100)	93.5 (87-100)	95.0 (90-100)		98.0 (96-100)
VIOAR	00	2	17-51	77.5 (65-90)	87.5 (75-100)	91.5 (83-100)		97.5 (95-100)
Mean of all assessments		7	22.7 (3-51)	78.1 (51-100)	84.7 (63-100)	89.9 (75-100)		95.3 (85-100)
Post-emergence application								
CAPBP	8-12	9	12.0 (4.0-40.0)	-	-	61.6 (17.5-80.0)	74.2 (40.0-83.0)	83.6 (50.0-83.0)
CENCY	10-12	5	23.9 (4.0-59.8)	46.5 (33.0-60.0)	63.0 (61.0-65.0)	51.2 (30.0-78.0)	45.0 (40.0-55.0)	61.2 (50.0-80.0)
GALAP	0-13	4	12.5 (4.0-21.0)	30.0	33.0	32.0 (12.5-61.0)	49.1 (33.8-61.0)	63.3 (48.0-73.8)
MATMA	8-14	8	25.6 (7.0-62.5)	69.0 (63.0-75.0)	77.5 (68.0-87.0)	55.7 (18.8-90.0)	58.8 (41.3-96.5)	78.9 (52.5-100)
VERPE	11-12	5	16.0 (6.0-52.0)	-	-	77.8 (71.0-83.0)	86.2 (72.0-93.0)	90.0 (74.0-98.0)
VIOAR	8-12	12	25.5 (4.0-86.8)	66.5 (60.0-73.0)	71.5 (65.0-78.0)	53.8 (13.8-85.0)	61.1 (35.0-62.0)	69.9 (50.0-99.0)
Mean of all assessments		43	19.3 (4.0-86.8)	53.0 (30.0-69.0)	61.3 (33.0-77.5)	55.4 (12.5-90.0)	62.4 (33.8-96.5)	74.5 (48.0-99.0)

South-east EPPO zone

In the South-east EPPO zone, the average control of the assessed dicotyledonous weed species at the assessment after re-growth has commenced in the spring (143 days after application) was 86.3%, 88.8% and 95.0% following a pre-emergence application of Flufenacet 6% + Pendimethalin 30% EC at 1.5 L/ha, 2.0 L/ha and 2.5 L/ha, respectively, compared to 97.3% control achieved by the recommended rate, i.e. 4.0 L/ha. When applied post-emergence, Flufenacet 6% + Pendimethalin 30% EC achieved an average control of the assessed dicotyledonous weed species in the spring (143 days after application) of 91.3%, 93.0% and 94.5% when applied at 1.5 L/ha, 2.0 L/ha and 2.5 L/ha, respectively, compared to 95.0% control achieved by the recommended rate, i.e. 4.0 L/ha. A satisfactory level of control may be achieved with lower than recommended dose rates when applied pre-emergence or early post-emergence, but if weeds have already emerged, or if less susceptible broadleaved weed species are part of the flora in the field, Flufenacet 6% + Pendimethalin 30% EC should be applied at the maximum recommended dose rate to obtain a satisfactory control.

Statistical evaluation revealed that Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha performed significantly better than the 1.5 L/ha dose rate at one of the 2 assessments, i.e. when applied pre-emergence, Flufenacet 6% + Pendimethalin 30% EC at recommended dose rate performed significantly better than the 1.5 L/ha rate as well as the 2.0 L/ha dose rate. At the remaining assessment, i.e. one assessment after post-emergence application, no significant differences were observed between the tested Flufenacet 6% + Pendimethalin 30% EC dose rates, however, the proposed dose rate of 4.0 L/ha achieved consistently higher levels of control than obtained with the reduced dose rate.

Table 3.2-23: South-east zone: Minimum effective dose of Flufenacet 6% + Pendimethalin 30% EC applied against frequently occurring broadleaved weeds in winter cereals.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with			
				Flufenacet 6% + Pendimethalin 30% EC at:			
				Mean (min-max)			
				1.5 L/ha (37.5%)	2.0 L/ha (50%)	2.5 L/ha (62.5%)	4.0 L/ha (100%)
Pre-emergence application							
VERHE	00-07	1	10	86.3	88.8	95	97.3
Post-emergence application							
VERHE	10	1	10	91.3	93	94.5	95

Mediterranean EPPO zone

In the Mediterranean EPPO zone, the average control of the assessed dicotyledonous weed species at the assessment after re-growth has commenced in the spring (98-210 days after application) was 66.1%,

76.4% and 80.5% following a pre-emergence application of Flufenacet 6% + Pendimethalin 30% EC at 1.5 L/ha and 2.0 L/ha, respectively, compared to 83.6% control achieved by the recommended rate, i.e. 4.0 L/ha. When applied post-emergence, Flufenacet 6% + Pendimethalin 30% EC achieved an average control of the assessed monocotyledonous weed species in the spring (28-168 days after application) of 72.5%, 73.9% and 77.8% when applied at 1.5 L/ha, 2.0 L/ha and 2.5 L/ha, respectively, compared to 79.8% control achieved by the recommended rate, i.e. 4.0 L/ha. A satisfactory level of control may be achieved with lower than recommended dose rates when applied pre-emergence or early post-emergence, but if weeds have already emerged, or if less susceptible grass weed species are part of the flora in the field, Flufenacet 6% + Pendimethalin 30% EC should be applied at the maximum recommended dose rate to obtain a satisfactory control.

Statistical evaluation revealed that Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha performed significantly better than the 1.5 L/ha dose rate at thirteen of the 34 assessments and at eight of these, Flufenacet 6% + Pendimethalin 30% EC at the recommended dose rate also performed significantly better than the 2.0 L/ha dose rate. Furthermore, at three of the 34 assessments, Flufenacet 6% + Pendimethalin 30% EC at recommended dose rate also performed significantly better than the 2.5 L/ha dose rate. At the remaining 21 assessments, i.e. fifteen assessments after pre-emergence application and six assessments after post-emergence application, no significant differences were observed between the tested Flufenacet 6% + Pendimethalin 30% EC dose rates when applied pre- or post-emergence, however, the proposed dose rate of 4.0 L/ha achieved consistently higher levels of control than obtained with the reduced dose rate.

Table 3.2-24: Mediterranean zone: Minimum effective dose of Flufenacet 6% + Pendimethalin 30% EC applied against frequently occurring broadleaved weeds in winter cereals.

Weed Growth stage at application No. of trials			Ground cover at assessm. (no/m ²)	Efficacy obtained with			
				Flufenacet 6% + Pendimethalin 30% EC at:			
				Mean (min-max)			
EPPO Code	application [BBCH]	No. of trials	assessm. (no/m ²)	1.5 L/ha (37.5%)	2.0 L/ha (50%)	2.5 L/ha (62.5%)	4.0 L/ha (100%)
Pre-emergence application							
AMABL	Pre-em.	2	7-10.3	74.7 (71.4-78)	95.1 (90.2-100)	90.4 (85.7-95.1)	98.8 (97.6-100)
ANGAR	Pre-em.	3	6.3-18.5	87.5 (72-100)	82.2 (52-98.8)	88.0 (68-98.6)	89.3 (68-100)
CHYCO	Pre-em.	1	4.8	21.1	36.8	68.4	63.2
CIRAR	Pre-em.	1	n.r.	80.0	77.5	76.3	60
DIPVG	Pre-em.	1	5	85	90	90	95
GALAP	Pre-em.	1	8.8	80	80	85.7	85.7
MERAN	Pre-em.	1	n.r.	12.5	42.5	71.3	77.5
PICHI	Pre-em.	1	5.8	56.5	69.6	60.9	60.9
POLAV	Pre-em.	1	11	90.9	95.5	93.2	95.5
POLCO	Pre-em.	1	n.r.	15	50	47.5	63.8
SONAS	Pre-em.	2	5.5-6	72.8 (50-95.5)	83.4 (66.7-100)	83.4 (66.7-100)	91.7 (83.3-100)
STEME	00	1	9.8	100	100	100	100
VERPE	00	1	87.5	62.5	76.3	80	82.5
TTTTT	Pre-em.	2	n.r.	47.6 (8.8-86.3)	65.0 (45-85)	72.2 (60-84.3)	78.2 (75-81.3)
Mean of all assessments		19	4.8-87.5	66.1 (8.8-100)	76.4 (36.8-100)	80.5 (47.5-100)	83.6 (60-100)
Post-emergence application							
FUMOF	00	1	9	99	99.3	99.5	100
GALAP	16-21	2	8-	38.2 (5-71.3)	41.3 (3.8-78.8)	43.2 (5-81.3)	43.8 (5-82.5)
LAMAM	16	1	11.3	76.3	80	81.3	83.8
PAPRH	00-17	3	17-25	87.4 (77.5-99.3)	86.9 (76.3-99.5)	90.1 (82.5-99.8)	94.8 (90.5-100)
POLSS	00	1	105	71.3	78.8	94.5	96
SENAG	18	1	7.5	70	78.8	81.3	82.5
STEME	13-17	2	10.9 (9.5-12.3)	75.5 (70.5-80.5)	76.3 (71.3-81.3)	80.9 (80-81.8)	80.9 (78.8-83)
URTAN	14	1	12.8	77.5	80	86.3	30
VERHE	21	1	n.r.	100	100	100	88.8
VERPE	13-15	1	1	80	80	78.8	100
TTTTT	n.r.	1	n.r.	23.8	15	27.5	83
Mean of all assessments		15		72.5 (5-100)	73.9 (3.8-100)	77.8 (5-100)	79.8 (5-100)

Conclusion

Based on results achieved on dicotyledonous weeds in 41 of the 43 winter cereal trials treated with pre-emergence application (17) or post-emergence application (24), it can be concluded that to consistently control frequently occurring broadleaved weeds in winter cereals, Flufenacet 6% + Pendimethalin 30% EC should be applied pre- or early post-emergence at 4.0 L/ha.

Summary of all uses claimed on the label

Flufenacet 6% + Pendimethalin 30% EC applied pre-emergence or early post-emergence at 4.0 L/ha to control annual grasses and broadleaved weeds achieved moderate to excellent control of all target weeds. Reducing the application rate of Flufenacet 6% + Pendimethalin 30% EC from the proposed dose rate (4.0 L/ha) to 37.5%, 50%, 62.5% and 82.5% of that rate, results in lower levels of efficacy. To ensure that a satisfactory level of control is achieved with the proposed dose rate of 4.0 L/ha, it is recommended that Flufenacet 6% + Pendimethalin 30% EC is applied under optimal conditions, i.e. early growth stage of the weeds and optimal weather conditions.

As weeds often occur as a complex of several weeds with different susceptibility towards flufenacet and/or pendimethalin, one application of Flufenacet 6% + Pendimethalin 30% EC at the recommended rate should be used to efficiently control all weeds claimed on the label.

The same weeds are controlled by flufenacet and pendimethalin in the different winter cereals. When treating the weeds at similar growth stages, the same level of control would be expected, irrespective of applied in the early autumn or in the early spring, in all GAP claimed crops and this has been seen in the trials. Therefore, for any label claims not adequately supported for one crop type, Sharda requests that the Zonal Evaluators reads across to the data on the other crop types and application timings.

As will be demonstrated in the following sections, this document clearly demonstrates that the efficacy and crop safety of Flufenacet 6% + Pendimethalin 30% EC is equivalent to that of the standard flufenacet + pendimethalin co-formulated reference products (i.e. Aranda, Crystal, Malibu and Trooper) to which it was compared. The applicant therefore wishes to cite the original registrant's data on flufenacet and pendimethalin now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Comments of zRMS:	<p>Statement accepted. To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least one lower dose(s) (for example 60–80% of the recommended dose) to that which would be recommended. It is utilized to achieve the desired effect. During field tests Applicant used different doses of herbicide – SHA 2619A. So, in the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance with EPPO 1/225 (2). What is more, herbicides containing active ingredients – flufenacet and pendimethalin have been allowed to use for many years. Also, in the literature of crop protection vast amounts of information can be found on efficacy of the plant protection products containing those active compounds. However, the minimum effective dose was proposed by Applicant.</p> <p>For evaluate the minimum effective dose of SHA 2619 A for control of weeds following doses were studied:</p> <ul style="list-style-type: none"> • pre-emergence application: 1,5 l/ha (0,38N); 2,0 l/ha (0,5N); 2,5 l/ha (0,63N) and 4,0 l/ha (N dose) • post-emergence application: 1,5 l/ha (0,38N); 2,0 l/ha (0,5N); 2,5 l/ha (0,63N) and 4,0 l/ha (N dose)
-------------------	--

	<p>Following weeds during trials were studied:</p> <ul style="list-style-type: none"> pre-emergence application: MAR: AGREE, ALOMY, APESV, LOLMU, POAAN; N-E: APESV; S-E: ALOMY, APESV and MED: ALOMY, LOLSS post-emergence application: MAR: ALOMY, APESV, AVEFA, LOLMU, POAAN; N-E: APESV, ALOMY; S-E: ALOMY, APESV and MED: LOLMU. <p>Results of evaluated trials showed that irrespective to the EPPO zone where the trials were carried out, the dose rate 4,0 L product/ha is necessary for effective control of range of weed at pre- emergence and post-emetgence application.</p>
--	--

3.2.3 Efficacy tests (KCP 6.2)

Data from 47 efficacy trials conducted in the Maritime (15, i.e. Czech Republic (4), N-France (3), Germany (4) and UK (4)), the North-east (16, i.e. Poland), the South-east (4, i.e. Hungary) and the Mediterranean (12, i.e. Spain (3), Italy (4) and S-France (5)) EPPO zone have been included in this document to support the label claims and recommendations on efficacy and selectivity in the EU Central Registration zone.

The 47 efficacy trials were conducted in winter wheat (durum wheat (1) and soft wheat (23)), barley (winter barley (15) and spring barley (2)) and Triticale (winter triticale (6)). In the cereal trials, Flufenacet 6% + Pendimethalin 30% EC was applied either pre-emergence (18) or post-emergence (29) of the crop.

Table 3.2-25: Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/152(4), PP 1/181(4), PP 1/135(4)
	Specific guidelines	EPPO PP 1/93(3)
Experimental design	Plot design	RCBD (47)
	Plot size	12.2-30 m ²
	Number of replications	4 (47)
Crop	Trials per crop	Wheat (22), i.e. TRZAW (21) and TRZDU (1) Barley (19), i.e. HORVW (17) and HORVS (2) Triticale (6), i.e. TTLWI (6)
	Varieties per crop	<u>Winter (soft) wheat</u> : Adhoc, Armada, Calabro, Cellule, Don Ricardo, Genius, Hyfi, Julius, Palesio, Pionier, Sahara, Svitava, Trapez, Arkadia, Memory, Sailor, Linus (2), Smuga. <u>Winter durum wheat</u> : Cesare <u>Winter barley</u> : Arturio, California, Cassia, Chalap, Cometa, Jup, Ketos, KWS Meridian, Leibniz, Pewter, Tektoo <u>Spring barley</u> : Beatrix, Irina <u>Winter triticale</u> : Fredo (3), Trismart, Grenado, Meloman.
	Sowing period	September 23 rd to March 23 rd
Application	Crop stage (BBCH)* at application	Pre-emergence (18): BBCH 00-07 Post-emergence (29): BBCH 11-24 (range: BBCH 10-25)
	Timing Pest stage at appl. (1)	Pre-emergence to early post-emergence BBCH 00-59 – for details on the growth stage of the specific weed at application, please refer to summary tables in Appendix 5
	Number of appl. Intervals between appl.	1 (47) n.a.
	Spray volumes	200-300 L/ha

Assessment	Assessment types	- Visual estimation of biomass reduction per plot compared to 'untreated' ('untreated' = 0 % control); total control = 100 % control) or calculated, based on weed counts (COUPLA) or weed ground cover (GROUND) in a defined area, as compared to the untreated check. - Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was substituted or supplemented by assessments of individual symptoms.
	Assessment dates	6 to 230 DAT
Other relevant information	Soil type	Light to heavy soils
	Natural / artificial inoculation...	Natural
	Field / Greenhouse...	Field

For further information on the location of the trials, trialist and guidelines used in the trials from the Maritime, the North-east, the South-east and the Mediterranean EPPO zone, please refer to **Błąd! Nie można odnaleźć źródła odwołania.**, **Błąd! Nie można odnaleźć źródła odwołania.** and **Błąd! Nie można odnaleźć źródła odwołania.**, respectively. For further information on soils, trial design, crops and varieties in the trials from the Maritime, the North-east, the South-east and the Mediterranean EPPO zone, please refer to **Błąd! Nie można odnaleźć źródła odwołania.**, **Błąd! Nie można odnaleźć źródła odwołania.** and **Błąd! Nie można odnaleźć źródła odwołania.**, respectively. For further details on application in trials conducted in the Maritime, the North-east, the South-east and the Mediterranean EPPO zone, please refer to **Błąd! Nie można odnaleźć źródła odwołania.**, **Błąd! Nie można odnaleźć źródła odwołania.** and **Błąd! Nie można odnaleźć źródła odwołania.**, respectively. For further information on date of sowing, growth stage at application and reference products applied in the four EPPO zones, please refer to **Błąd! Nie można odnaleźć źródła odwołania.** to **Błąd! Nie można odnaleźć źródła odwołania.**.

In the 47 trials, the level of control obtained by Flufenacet 6% + Pendimethalin 30% EC was assessed on mono- and dicotyledonous weeds present in the trials. Data on each individual weed species is only included from trials in which a minimum of 5 plants per m² or 1% ground cover were seen at the timing of the assessment.

Use 001 and -003: Control of grasses and broadleaved weeds in winter cereals with a single application of 4.0 L/ha Flufenacet 6% + Pendimethalin 30% EC, applied pre-emergence to the crop in the autumn

The efficacy trials were conducted to prove the following label claims:

Description of Use 001 and Use 003

Crop, stage	Winter cereals, pre- or early post-emergence BBCH 00-09
Use rate Use frequency Application timing	4.0 L/ha Flufenacet 6% + Pendimethalin 30% EC 1x Pre-emergence to weeds and crop in the autumn
Target weeds	Annual grass weeds, e.g. <i>Alopecurus myosuroides</i> , <i>Apera spica-venti</i> , <i>Poa annua</i> Annual broadleaved weeds, e.g. <i>Capsella</i> , <i>Lamium</i> , <i>Matricaria</i> , <i>Stellaria media</i> , <i>Brassica napus</i>

The effectiveness of applying Flufenacet 6% + Pendimethalin 30% EC pre-emergence against mono- and dicotyledonous weeds in the autumn or late winter was evaluated in 18 efficacy trials conducted in winter cereals (16, i.e. winter wheat (8), winter durum wheat (1) and winter barley (7)) and spring cereals (2, i.e. spring barley). These trials were carried out in 2015/16 season in the Maritime EPPO zone (7, i.e. Germany (2), N-France (1), Czech Republic (2) and England (2)), the North-east (2, i.e. Poland), the South-east EPPO zone (2, i.e. Hungary) and the Mediterranean EPPO zone (7, i.e. Spain (2), Italy (2) and S-France

(3)). The objective was to confirm the performance of Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha (i.e. 240 g flufenacet and 1200 g pendimethalin per hectare) and compare this to national reference products registered for similar uses. In the trials, one application was applied in the autumn/winter (October-December) or early spring (March).

In all efficacy trials, Flufenacet 6% + Pendimethalin 30% EC was tested alongside an EU approved flufenacet + pendimethalin co-formulation, i.e. Aranda (FR), Crystal (UK), Malibu (DE, CZ, PL, HU and IT) and Trooper (ES and FR), as well as an EU approved flufenacet 50% SC straight formulation, i.e. Cadou (DE, CZ, PL and IT), FOE50% SC (CZ, HU, FR, ES and IT) and System 50 (UK). The benefits of applying the co-formulation of flufenacet and pendimethalin compared to flufenacet alone was already demonstrated in Section 3.2.1.1 and will therefore not be repeated here in this section. Furthermore, as also demonstrated in Section 3.2.1.1, an EU approved pendimethalin 33% EC straight formulation, i.e. Sharp-en 330 EC, was included in two Hungarian efficacy trials, to demonstrate the benefits of the mixture. Finally, in French and Spanish trials, Flufenacet 6% + Pendimethalin 30% EC was tested alongside the national reference product Celtic (FR) or Picomax (ES), a co-formulation containing picolinafen and pendimethalin.

Maritime zone

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following pre-emergence application in winter cereals in the autumn/late winter as well as compare it to the reference product included in the trials, results are presented from the last assessment in the autumn (Table 3.2-26) as well as one assessment carried out in the spring (Table 3.2-27), after regrowth of weeds and crops had commenced.

Table 3.2-26: Maritime zone, winter cereals – Annual grasses and broadleaved weed control results by Flufenacet 6% + Pendimethalin 30% EC applied at 4.0 L/ha pre-emergence in the early autumn to late winter and compared against control obtained with the flufenacet + pendimethalin reference product at comparable rate in the efficacy tests 2015/16. In the same table, the results obtained with the test product at 4.0 L/ha compared against the national reference product (Celtic) at 2.5 L/ha is also presented (Autumn assessment).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	4.0 L/ha	>	=	<	
Annual grass weeds, Visual control									
AGRRE	00	2	5-21.8	33.2 (23.8-42.5)	33.8 (27.5-40)		2		=
ALOMY	03	1	90	93.3	96.5		1		=
APESV	00	2	5-10	46.3 (40-52.5)	45.0 (40-50)		2		=
LOLMU	00	1	4.3	91.5	45	1			>
POAAN	03	1	16	100	70	1			>
Mean, all assessments		7	4.3-90	63.4 (23.8-100)	52.7 (27.5-96.5)	2	5		>
Annual broadleaved weeds, Visual control									
BRSNX	00	4	5-10	46.2 (0-100)	40.9 (0-100)	1	3		>
CAPBP	00	1	4.3	100	100		1		=
CHEAL	00	1	50	85	92.5			1	<
GALAP	00	1	1.5	100	100		1		=
MATCH	00	1	2.8	100	91.5	1			>
MATIN	00	2	5-10.8	70.0 (40-100)	70.0 (40-100)		2		=
PAPRH	00	1	5	40	40		1		=
SINAR	03	1	4.8	93.8	90		1		=
SLYMA	00	2	5	10.0 (0-20)	10.0 (0-20)		2		=
STEME	00-03	3	5-5.8	74.2 (50-95)	74.6 (50-93.8)		3		=
THLAR	00	2	5-7	71.3 (50-92.5)	71.3 (50-92.5)		2		=
VERHE	00-03	3	5-26	68.8 (42.5-85)	58.3 (35-85)	2	1		>
VERPE	03	1	173.5	98.5	81.3	1			>
VERSS	03	1	7.8	95	95		1		=
VIOAR	00	2	1-2.5	100 (-)	100 (-)		2		=

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall	
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at					
				Mean (min-max)						
				4.0 L/ha	4.0 L/ha	>	=	<		
Mean, all assessments			26	1.0-173.5	70.3 (0-100)	67.5 (0-100)	5	20	1	=
EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the national reference product at 2.5 L/ha. = : ± 5% control			Overall	
				Flufenacet 6% + Pendimethalin 30% EC at:	National ref. prod. at					
				Mean (min-max)						
				4.0 L/ha	2.5 L/ha	>	=	<		
Annual broadleaved weeds, Visual control										
BRSSNN		n.r.	1	7.8	34.8	37.3		1		=

When applied at 4.0 L/ha pre-emergence in the autumn in the Maritime zone, Flufenacet 6% + Pendimethalin 30% EC achieved good to excellent control of annual grasses and broadleaved weeds commonly found in winter cereals. In all species evaluated, the effect achieved with Flufenacet 6% + Pendimethalin 30% EC was similar to the effect obtained with the flufenacet + pendimethalin reference product applied in the trials. At the spring assessment, Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha performed significantly better than the flufenacet + pendimethalin reference product at three assessments whereas at the remaining 27 assessments, no significant differences were observed between the two tested products.

Table 3.2-27: Maritime zone, winter cereals – Annual grasses and broadleaved weed control results by Flufenacet 6% + Pendimethalin 30% EC applied at 4.0 L/ha pre-emergence in the early autumn to late winter and compared against control obtained with the flufenacet + pendimethalin reference product at comparable rate in the efficacy tests 2015/16. In the same table, the results obtained with the test product at 4.0 L/ha compared against the national reference product (Celtic) at 2.5 L/ha is also presented (Spring/summer assessment).

EPPO Code			Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
						Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
						Mean (min-max)					
						4.0 L/ha	4.0 L/ha	>	=	<	
Annual grass weeds, Visual control											
AGRRE	00	1	5	100	100		1			=	
ALOMY	03	2	25-100	91.3 (90-92.5)	82.6 (71.3-93.8)	1	1			>	
APESV	00	1	10	100	100		1			=	
LOLMU	00-03	2	5-6.3	91.3 (82.5-100)	55.8 (39-72.5)	2				>	
POAAN	03	1	22.5	100	95.5		1			=	
Mean, all assessments		7	5-100	95.0 (82.5-100)	81.7 (39-100)	3	4			>	
Annual broadleaved weeds, Visual control											
BRSNX	00	2	10-	97.4 (94.8-100)	95.0 (90-100)		2			=	
CAPBP	00	1	4.3	100	100		1			=	
FUMOF	03	2	6.8-	97.5 (95-100)	96.0 (93.8-98.2)		2			=	
GALAP	00	1	5.3	100	100		1			=	
MATCH	00-03	2	5.5-11.3	93.8 (87.5-100)	93.8 (87.5-100)		2			=	
MATIN	00	1	5	100	100		1			=	
PAPRH	00	1	5	100	100		1			=	
POLAV	n.r.	1	n.r.	98.8	98.8		1			=	
SENVU	03	1	8.8	82.5	65.4	1				>	
SLYMA	00	1	5	40	40		1			=	
STEME	00	1	5	100	100		1			=	
THLAR	00	1	5	100	100		1			=	
VERHE	00-03	2	5-14	96.9 (93.8-100)	84.4 (75-93.8)	1	1			>	
VERPE	03	1	36.3	100	91.5	1				>	
VIOAR	00	3	4.8-6	100 (-)	95.0 (85-100)	1	2			=	
TTTTT	n.r.	2	n.r.	88.4 (85-91.8)	85.8 (81.3-90.3)		2			=	
Mean, all assessments		23	4.3-36.3	94.3 (40-100)	90.9 (40-100)	4	19			=	

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the national reference product at 2.5 L/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	National ref. prod. at				
Mean (min-max)									
4.0 L/ha	2.5 L/ha	>	=	<					

Annual broadleaved weeds, Visual control									
BRSNX	n.r.	1	n.r.	94.8	89.5	1			>
FUMOF	n.r.	1	n.r.	95	71.8	1			>
POLAV	n.r.	1	n.r.	98.8	93.8		1		=
VIOAR	n.r.	1	n.r.	100	98.8		1		=
TTTTT	n.r.	2	n.r.	88.4 (85-91.8)	82.5 (80-85)	1	1		>
Mean, all assessments		6		94.2 (85-100)	86.5 (71.8-98.8)	3	3		>

In one of the seven efficacy trials, conducted in N-France, a national reference product containing pendimethalin and picolinafen (Celtic) was included, for comparison. In the species evaluated, the effect achieved with Flufenacet 6% + Pendimethalin 30% EC was similar to slightly superior to the effect obtained with the national reference product applied in the French trial. Statistical evaluation supports this statement: At the spring assessment, Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha performed significantly better than the national reference product at one assessment whereas at the remaining five assessments, no significant differences were observed between the two tested products.

In Table 3.2-28, the weed species are classified according to their average sensitivity at the spring assessment to 4.0 L/ha of Flufenacet 6% + Pendimethalin 30% EC in the Maritime EPPO zone. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4, based on the mean across the trial results. All weed species have been included in the table below, irrespective of the number of trials where the included weed species were evaluated. However, this does not replace individual MS systems for expressing control on national labels.

Based on the maximum level of control achieved on the individual weed species present in the trials, the combined proposed label claims of the grass- and broadleaved weed spectrum controlled after application of 4.0 L/ha Flufenacet 6% + Pendimethalin 30% EC pre- and post-emergence to weeds are listed in Table 3.2-50.

Table 3.2-28: Weed control spectrum of Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha in the Maritime zone

Scientific name	English common name	EPPO code
Highly Susceptible (≥95 %)		
<i>Elymus repens</i>	Couch grass	AGRRE
<i>Apera spica-venti</i>	Silky windgrass	APESV
<i>Poa annua</i>	Annual bluegrass	POAAN
<i>Brassica napus</i>	Oilseed rape (volunteer)	BRSNX
<i>Capsella bursa-pastoris</i>	Shepherd's purse	CAPBP
<i>Fumaria officinalis</i>	Common fumitory	FUMOF
<i>Galium aparine</i>	Cleavers	GALAP
<i>Tripleurospermum inodorum</i>	Scentless mayweed	MATIN
<i>Papaver rhoeas</i>	Common poppy	PAPRH
<i>Polygonum aviculare</i>	Knotgrass	POLAV
<i>Stellaria media</i>	Common chickweed	STEME
<i>Thlaspi arvense</i>	Field pennycress	THLAR
<i>Veronica hederifolia</i>	Ivy-leaved speedwell	VERHE
<i>Veronica persica</i>	Common field speedwell	VERPE
<i>Viola arvensis</i>	Field violet	VIOAR
Susceptible (85 – 94.9 %)		
<i>Alopecurus myosuroides</i>	Blackgrass	ALOMY
<i>Lolium multiflorum</i>	Italian ryegrass	LOLMU
<i>Matricaria chamomilla</i>	Scented mayweed	MATCH
Moderately Susceptible (70 – 84.9 %)		

Scientific name	English common name	EPPO code
<i>Senecio vulgaris</i>	Common groundsel	SENVU
Moderately tolerant (50 – 69.9 %)		
-	-	-
Tolerant (0 – 49.9 %)		
<i>Silybum marianum</i>	Milk thistle	SLYMA

North-east zone

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following pre-emergence application in winter cereals in the autumn/late winter as well as compare it to the reference product included in the trials, results are presented from the last assessment in the autumn (Table 3.2-29) as well as one assessment carried out in the spring (Table 3.2-30), after regrowth of weeds and crops had commenced. In one trial, the number of grass seed heads was also counted in the late spring.

When applied at 4.0 L/ha pre-emergence in the autumn in the North-east zone, Flufenacet 6% + Pendimethalin 30% EC achieved good to excellent control of annual grasses and broadleaved weeds commonly found in winter cereals. In all species evaluated, the effect achieved with Flufenacet 6% + Pendimethalin 30% EC was similar to the effect obtained with the flufenacet + pendimethalin reference product applied in the Polish trials. At the spring assessment, the flufenacet + pendimethalin reference product at 4.0 L/ha performed significantly better than Flufenacet 6% + Pendimethalin 30% EC at one assessment whereas at the remaining nine assessments, no significant differences were observed between the two tested products.

Table 3.2-29: North-east zone, winter cereals – Annual grasses and broadleaved weed control results by Flufenacet 6% + Pendimethalin 30% EC applied at 4.0 L/ha pre-emergence in the early autumn to late winter and compared against control obtained with the flufenacet + pendimethalin reference product at comparable rate in the efficacy tests 2015/16 (Autumn assessment).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	4.0 L/ha	>	=	<	
Annual grass weeds, Visual control									
APESV	n.r.	1	3	100	100		1		=
Annual broadleaved weeds, Visual control									
BRSNW	00	2	5-13	48.0 (43-53)	46.5 (43-50)		2		=
CENCY	00	2	17-52	56.5 (50-63)	46.5 (43-50)	2			>
MATMA	00	2	6-15	95.0 (90-100)	95.0 (90-100)		2		=
VIOAR	00	2	19-42	50.0 (-)	49.5 (46-53)		2		=
Mean, all assessments		8	5-52	62.4 (43-100)	59.4 (40-100)	2	6		=

Table 3.2-30: North-east zone, winter cereals – Annual grasses and broadleaved weed control results by Flufenacet 6% + Pendimethalin 30% EC applied at 4.0 L/ha pre-emergence in the early autumn to late winter and compared against control obtained with the flufenacet + pendimethalin reference product at comparable rate in the efficacy tests 2015/16 (Spring/summer assessment).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control	Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at		
				Mean (min-max)			

		4.0 L/ha	4.0 L/ha	>	=	<	
Annual grass weeds, Visual control							
APESV	n.r.	2	3-6	100 (-)	100 (-)	2	=
Annual broadleaved weeds, Visual control							
CENCY	00	2	13-36	88.0 (85-91)	91.0 (-)	1	=
GALAP	00	1	3	100	100	1	=
MATMA	00	2	6-33	98.0 (96-100)	100 (-)	2	=
VIOAR	00	2	17-51	97.5 (95-100)	97.0 (94-100)	2	=
Mean, all assessments		7	3-51	95.3 (85-100)	96.6 (91-100)	6	=
Annual grass weeds, Count of ears							
APESV	n.r.	1	10	100	100	1	=

In Table 3.2-31, the weed species are classified according to their average sensitivity at the spring assessment to 4.0 L/ha of Flufenacet 6% + Pendimethalin 30% EC in the North-east EPPO zone. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4, based on the mean across the trial results. All weed species have been included in the table below, irrespective of the number of trials where the included weed species were evaluated. However, this does not replace individual MS systems for expressing control on national labels.

Based on the maximum level of control achieved on the individual weed species present in the trials, the combined proposed label claims of the grass- and broadleaved weed spectrum controlled after application of 4.0 L/ha Flufenacet 6% + Pendimethalin 30% EC pre- and post-emergence to weeds are listed in Table 3.2-50.

Table 3.2-31: Weed control spectrum of Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha in the North-east zone

Scientific name	English common name	EPPO code
Highly Susceptible (≥ 95 %)		
<i>Apera spica-venti</i>	Silky windgrass	APESV
<i>Galium aparine</i>	Cleavers	GALAP
<i>Tripleurospermum maritimum</i>	False mayweed	MATMA
<i>Viola arvensis</i>	Field violet	VIOAR
Susceptible (85 – 94.9 %)		
<i>Centaurea cyanus</i>	Cornflower	CENCY
Moderately Susceptible (70 – 84.9 %)		
-	-	-
Moderately tolerant (50 – 69.9 %)		
-	-	-
Tolerant (0 – 49.9 %)		
-	-	-

South-east zone

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following pre-emergence application in winter cereals in the autumn/late winter as well as compare it to the reference product included in the trials, results are presented from the last assessment in the autumn (Table 3.2-32) as well as one assessment carried out in the spring (Table 3.2-33), after regrowth of weeds and crops had commenced. In one trial, the number of grass seed heads was also counted in the late spring.

Table 3.2-32: South-east zone, winter cereals – Annual grasses and broadleaved weed control results by Flufenacet 6% + Pendimethalin 30% EC applied at 4.0 L/ha pre-emergence in the early autumn to late winter and compared against control obtained with the flufenacet + pendimethalin reference product at comparable rate in the efficacy tests 2015/16 (Autumn assessment).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	4.0 L/ha	>	=	<	
Annual grass weeds, Visual control									
ALOMY	00-07	1	40	75	78.8		1		=
APESV	03-06	1	62.3	96.9	98.1		1		=
Mean, all assessments		2		86.0 (75-96.9)	88.4 (78.8-98.1)		2		=
Annual broadleaved weeds, Visual control									
VERHE	00-07	1	15	77.5	80		1		=

When applied at 4.0 L/ha pre-emergence in the autumn in the South-east zone, Flufenacet 6% + Pendimethalin 30% EC achieved good to excellent control of annual grasses and broadleaved weeds commonly found in winter cereals. In all species evaluated, the effect achieved with Flufenacet 6% + Pendimethalin 30% EC was similar to the effect obtained with the flufenacet + pendimethalin reference product applied in the Hungarian trials. Statistical evaluation supports this statement as no significant differences were observed between the two tested products.

Table 3.2-33: South-east zone, winter cereals – Annual grasses and broadleaved weed control results by Flufenacet 6% + Pendimethalin 30% EC applied at 4.0 L/ha pre-emergence in the early autumn to late winter and compared against control obtained with the flufenacet + pendimethalin reference product at comparable rate in the efficacy tests 2015/16 (Spring/summer assessment).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	4.0 L/ha	>	=	<	
Annual grass weeds, Visual control									
ALOMY	00-07	1	40	95	94.3		1		=
APESV	03-06	1	63.3	100	100		1		=
Mean, all assessments		2		97.5 (95-100)	97.1 (94.3-100)		2		=
Annual broadleaved weeds, Visual control									
VERHE	00-07	1	10	97.3	96.5		1		=
Annual grass weeds, Count of ears									
APESV	03-06	1	45.3	100	100		1		=

In Table 3.2-34, the weed species are classified according to their average sensitivity at the spring assessment to 4.0 L/ha of Flufenacet 6% + Pendimethalin 30% EC in the South-east EPPO zone. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4, based on the mean across the trial results. All weed species have been included in the table below, irrespective of the number of trials where the included weed species were evaluated. However, this does not replace individual MS systems for expressing control on national labels.

Based on the maximum level of control achieved on the individual weed species present in the trials, the combined proposed label claims of the grass- and broadleaved weed spectrum controlled after application of 4.0 L/ha Flufenacet 6% + Pendimethalin 30% EC pre- and post-emergence to weeds are listed in Table 3.2-50.

Table 3.2-34: Weed control spectrum of Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha in the South-east zone

Scientific name	English common name	EPPO code
Highly Susceptible (≥ 95 %)		
<i>Alopecurus myosuroides</i>	Blackgrass	ALOMY
<i>Apera spica-venti</i>	Silky windgrass	APESV
<i>Veronica hederifolia</i>	Ivy-leaved speedwell	VERHE
Susceptible (85 – 94.9 %)		
-	-	-
Moderately Susceptible (70 – 84.9 %)		
-	-	-
Moderately tolerant (50 – 69.9 %)		
-	-	-
Tolerant (0 – 49.9 %)		
-	-	-

Mediterranean zone

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following pre-emergence application in winter cereals in the autumn/late winter as well as compare it to the reference product included in the trials, results are presented from the last assessment in the autumn (Table 3.2-35) as well as one assessment carried out in the spring (Table 3.2-36), after regrowth of weeds and crops had commenced.

Table 3.2-35: Mediterranean zone, winter cereals – Annual grasses and broadleaved weed control results by Flufenacet 6% + Pendimethalin 30% EC applied at 4.0 L/ha pre-emergence in the early autumn to late winter and compared against control obtained with the flufenacet + pendimethalin reference product at comparable rate in the efficacy tests 2015/16. In the same table, the results obtained with the test product at 4.0 L/ha compared against the national reference product (Picomax / Celtic) at 2.5 L/ha is also presented (Autumn assessment).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	4.0 L/ha	>	=	<	
Annual grass weeds, Visual control									
ALOMY	00	1	14.5	90	90		1		=
LOLMU	Pre-em.	1	39.4	30	47.5			1	>
LOLSS	Pre-em.	1	1.5	82.5	73.8	1			>
TTTMM	Pre-em	1	2.3	100	66.7	1			>
Mean, all assessments		4		75.6 (30-100)	69.5 (47.5-90)	2	1	1	>
Annual broadleaved weeds, Visual control									
AMABL	Pre-em.	2	1.0-5.3	100 (-)	100 (-)		2		=
ANGAR	Pre-em.	2	3.3-6.5	100 (-)	100 (-)		2		=
CHYCO	Pre-em.	1	1.5	100	83.3	1			>
DIPVG	Pre-em.	1	4.3	100	100		1		=
GALAP	Pre-em.	2	1.4-4.5	46.1 (20-72.2)	67.5 (35-100)			2	<
PICHI	Pre-em.	1	1.8	100	100		1		=
POLAV	Pre-em.	1	3.8	100	100		1		=
RANSA	Pre-em.	1	22.6	47.5	65			1	<
SENVU	Pre-em.	1	30.5	65	28.8	1			>
SONAS	Pre-em.	2	2.8-4.3	100 (-)	100 (-)		2		=
VERHE	Pre-em.	1	19.4	47.5	62.5			1	<
VERPE	00	1	25.5	90	88.8		1		=

When applied at 4.0 L/ha pre-emergence in the autumn in the Mediterranean zone, Flufenacet 6% + Pendimethalin 30% EC achieved good to excellent control of annual grasses and broadleaved weeds commonly found in winter cereals. In all species evaluated, the effect achieved with Flufenacet 6% + Pendimethalin 30% EC was similar to the effect obtained with the flufenacet + pendimethalin reference product applied in the trials. At the spring assessment, Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha performed significantly better than the flufenacet + pendimethalin reference product at one assessment and another assessment, the reference product performed significantly better than Flufenacet 6% + Pendimethalin 30% EC. At the remaining 20 assessments, no significant differences were observed between the two tested products.

Table 3.2-36: Mediterranean zone, winter cereals – Annual grasses and broadleaved weed control results by Flufenacet 6% + Pendimethalin 30% EC applied at 4.0 L/ha pre-emergence in the early autumn to late winter and compared against control obtained with the flufenacet + pendimethalin reference product at comparable rate in the efficacy tests 2015/16. In the same table, the results obtained with the test product at 4.0 L/ha compared against the national reference product (Picomax / Celtic) at 2.5 L/ha is also presented (Spring/summer assessment).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	4.0 L/ha	>	=	<	
Annual grass weeds. Visual control									

Weed Growth stage No. of trials at application [BBCH]			Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall	
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at					
				Mean (min-max)						
				4.0 L/ha	4.0 L/ha	>	=	<		
ALOMY	00	2	99.5-	90.0 (83.8-96.3)	89.4 (82.5-96.3)		2		=	
LOLSS	Pre-em.	1	n.r.	80	77.5		1		=	
Mean, all assessments			3		86.7 (80-96.3)	85.4 (77.5-96.3)		3		=
Annual broadleaved weeds, Visual control										
AMABL	Pre-em.	2	7-10.3	98.8 (97.6-100)	96.4 (92.7-100)		2		=	
ANGAR	Pre-em.	3	6.3-18.5	89.3 (68-100)	86.8 (68-98.6)	1	2		=	
CHYCO	Pre-em.	1	4.8	63.2	57.9	1			>	
CIRAR	Pre-em.	1	n.r.	60	72.5			1	<	
DIPVG	Pre-em.	1	5	95	85	1			>	
GALAP	Pre-em.	1	8.8	85.7	97.1			1	<	
MERAN	Pre-em.	1	n.r.	77.5	47.5	1			>	
PICHI	Pre-em.	1	5.8	60.9	65.2		1		=	
POLAV	Pre-em.	1	11	95.5	95.5		1		=	
POLCO	Pre-em.	1	n.r.	63.8	47.5	1			>	
SONAS	Pre-em.	2	5.5-6	91.7 (83.3-100)	83.4 (66.7-100)	1	1		>	
STEME	00	1	9.8	100	100		1		=	
VERPE	00	1	87.5	82.5	86.3		1		=	
TTTTT	Pre-em.	2	n.r.	78.2 (75-81.3)	76.1 (71.3-80.8)	1		1	=	
Mean, all assessments			19	4.8-87.5	83.6 (60-100)	80.3 (47.5-100)	7	9	3	=
Weed Growth stage No. of trials at application [BBCH]			Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the national reference product at 2.5 L/ha. = : ± 5% control			Overall	
				Flufenacet 6% + Pendimethalin 30% EC at:	National ref. prod. at					
				Mean (min-max)						
				4.0 L/ha	2.5 L/ha	>	=	<		
Annual grass weeds, Visual control										
ALOMY	Pre-em.	1	n.r.	96.3	97.5		1		=	
LOLSS	Pre-em.	1	n.r.	80	65	1			>	
Mean, all assessments			2		88.2 (80-96.3)	81.3 (65-97.5)	1	1		>
Annual broadleaved weeds, Visual control										
AMABL	Pre-em.	2	7-10.3	98.8 (97.6-100)	100 (-)		2		=	
ANGAR	Pre-em.	3	6.3-18.5	89.3 (68-100)	93.3 (84-100)		2	1	=	
CHYCO	Pre-em.	1	4.8	63.2	57.9	1			>	
CIRAR	Pre-em.	1	n.r.	60	67.5			1	<	
DIPVG	Pre-em.	1	5	95	95		1		=	
GALAP	Pre-em.	1	8.8	85.7	91.4			1	<	
MERAN	Pre-em.	1	n.r.	77.5	47.5	1			>	
PICHI	Pre-em.	1	5.8	60.9	73.9			1	<	
POLAV	Pre-em.	1	11	95.5	95.5		1		=	
POLCO	Pre-em.	1	n.r.	63.8	45	1			>	
SONAS	Pre-em.	2	5.5-6	91.7 (83.3-100)	93.8 (87.5-100)		2		=	
TTTTT	Pre-em.	2	n.r.	78.2 (75-81.3)	68.8 (57.5-80)	1	1		>	
Mean, all assessments			17	4.8-18.5	82.8 (60-100)	81.1 (45-100)	4	9	4	=

In five of the seven efficacy trials, conducted in S-France (3) and Spain (2), a national reference product containing pendimethalin and picolinafen (Celtic (FR) or Picomax (ES)) was included, for comparison. In most species evaluated, the effect achieved with Flufenacet 6% + Pendimethalin 30% EC was similar to the effect obtained with the national reference product applied in the five trials. Statistical evaluation supports this statement. At the spring assessment, Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha performed significantly better than the national reference product at three assessments, whereas at the remaining 16 assessments, no significant differences were observed between the two tested products.

In Table 3.2-37, the weed species are classified according to their average sensitivity at the spring assessment to 4.0 L/ha of Flufenacet 6% + Pendimethalin 30% EC in the Mediterranean EPPO zone. The classification is made according to Appendix I of regulation SANCO/10055/ 2013 Rev. 4, based on the mean across the trial results. All weed species have been included in the table below, irrespective of the number of trials where the included weed species were evaluated. However, this does not replace individual MS systems for expressing control on national labels.

Based on the maximum level of control achieved on the individual weed species present in the trials, the

combined proposed label claims of the grass- and broadleaved weed spectrum controlled after application of 4.0 L/ha Flufenacet 6% + Pendimethalin 30% EC pre- and post-emergence to weeds are listed in Table 3.2-50.

Table 3.2-37: Weed control spectrum of Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha in the Mediterranean zone

Scientific name	English common name	EPPO code
Highly Susceptible (≥95 %)		
<i>Amaranthus blitoides</i>	Prostrate pigweed	AMABL
<i>Diplotaxis virgata</i>	Sand mustard	DIPVG
<i>Polygonum aviculare</i>	Knotgrass	POLAV
<i>Stellaria media</i>	Common chickweed	STEME
Susceptible (85 – 94.9 %)		
<i>Alopecurus myosuroides</i>	Blackgrass	ALOMY
<i>Anagallis arvensis</i>	Red chickweed	ANGAR
<i>Galium aparine</i>	Cleavers	GALAP
<i>Sonchus asper</i>	Prickly sow-thistle	SONAS
Moderately Susceptible (70 – 84.9 %)		
<i>Lolium spp.</i>	Ryegrass	LOLSS
<i>Mercurialis annua</i>	Annual mercury	MERAN
<i>Veronica persica</i>	Common field speedwell	VERPE
Moderately tolerant (50 – 69.9 %)		
<i>Glebionis coronarium</i>	Crown daisy	CHYCO
<i>Cirsium arvensis</i>	Perennial thistle	CIRAR
<i>Picris hieracioides</i>	Hawkweed	PICHI
<i>Fallopia convolvulus</i>	Black bindweed	POLCO
Tolerant (0 – 49.9 %)		
-	-	-

Use 002 and -004: Control of grasses and broadleaved weeds in winter cereals with a single application of 4.0 L/ha Flufenacet 6% + Pendimethalin 30% EC, applied post-emergence to the crop in the autumn

The efficacy trials were conducted to prove the following label claims:

Description of Use 002 and Use 004

Crop, stage	Winter cereals, pre- or early post-emergence BBCH 11-25
Use rate	4.0 L/ha Flufenacet 6% + Pendimethalin 30% EC
Use frequency	1x
Application timing	Post-emergence to weeds and crop in the autumn
Target weeds	Annual grass weeds, e.g. <i>Alopecurus myosuroides</i> , <i>Apera spica-venti</i> , <i>Poa annua</i> Annual broadleaved weeds, e.g. <i>Capsella</i> , <i>Lamium</i> , <i>Matricaria</i> and <i>Stellaria media</i>

The effectiveness of applying Flufenacet 6% + Pendimethalin 30% EC post-emergence against mono- and dicotyledonous weeds in the autumn or late winter was evaluated in 29 efficacy trials conducted in winter cereals (winter wheat (15), winter barley (8) and triticale (6)). These trials were carried out in 2015/16 and 2018/19 season in the Maritime EPPO zone (8, i.e. Germany (2), N-France (2), Czech Republic (2) and UK (2)), the North-east (14, i.e. Poland), the South-east EPPO zone (2, i.e. Hungary) and the Mediterranean EPPO zone (5; Italy (2), Spain (1) and S-France (2)). The objective was to confirm the performance of Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha (i.e. 240 g flufenacet and 1200 g

pendimethalin per hectare) and compare this to national reference products registered for similar uses. In the trials, one application was applied from early autumn to late winter (October-March).

In all efficacy trials, Flufenacet 6% + Pendimethalin 30% EC was tested alongside an EU approved flufenacet + pendimethalin co-formulation, i.e. Crystal (UK), Malibu (DE, CZ, PL, HU and IT) and Trooper (FR and ES), as well as an EU approved flufenacet 50% SC straight formulation, i.e. Cadou (DE, CZ, FR and PL), FOE50% SC (FR, HU, ES and IT) and System 50 (UK). The benefits of applying the co-formulation of flufenacet and pendimethalin compared to flufenacet alone was already demonstrated in Section 3.2.1.1 and will therefore not be repeated here in this section. Furthermore, as also demonstrated in Section 3.2.1.1, an EU approved pendimethalin 33% EC straight formulation, i.e. Sharpen 330 EC, was included in two Hungarian efficacy trials, to demonstrate the benefits of the mixture. Finally, in French and Spanish trials, Flufenacet 6% + Pendimethalin 30% EC was tested alongside the national reference product Picomax (ES) or Celtic (FR), a co-formulation containing picolinafen and pendimethalin.

Maritime zone

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following post-emergence application in winter cereals in the autumn/late winter as well as compare it to the reference product included in the trials, results are presented from the last assessment in the autumn (Table 3.2-38) as well as one assessment carried out in the spring (Table 3.2-39), after regrowth of weeds and crops had commenced.

When applied at 4.0 L/ha post-emergence in the autumn in the Maritime zone, Flufenacet 6% + Pendimethalin 30% EC achieved good to excellent control of annual grasses and broadleaved weeds commonly found in winter cereals. In all species evaluated, the effect achieved with Flufenacet 6% + Pendimethalin 30% EC was similar to the effect obtained with the flufenacet + pendimethalin reference product applied in the trials. At the spring assessment, Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha performed significantly better than the reference product at three assessments whereas at the remaining 40 assessments, no significant differences were observed between the two tested products.

Table 3.2-38: Maritime zone, winter cereals – Annual grasses and broadleaved weed control results by Flufenacet 6% + Pendimethalin 30% EC applied at 4.0 L/ha post-emergence in the autumn and compared against control obtained with the flufenacet + pendimethalin reference product at comparable rate in the efficacy tests 2015/16. In the same table, the results obtained with the test product at 4.0 L/ha compared against the national reference product (Celtic) at 2.5 L/ha is also presented (Autumn assessment).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	4.0 L/ha	>	=	<	
Annual grass weeds, Visual control									
ALOMY	10-15	4	5-7.5	40.3 (2.5-97.3)	40.6 (0-97.5)		4		=
APESV	11	2	8.8-20	47.5 (35-60)	50.0 (40-60)		2		=
LOLMU	11	1	5.5	10	10		1		=
POAAN	10-13	1	19.3	100	100		1		=
Mean, all assessments		8	5-20	45.8 (2.5-100)	46.6 (0-100)		8		=
Annual broadleaved weeds, Visual control									
BRSNX	11-12	3	5.5-55	42.5 (15-70)	41.7 (15-70)		3		=
CAPBP	00-07	2	4.5-5.0	7.5 (0-15)	7.5 (0-15)		2		=
FUMOF	13	1	31	98.5	99.5		1		=
GALAP	00-12	2	4-7	45.0 (40-50)	46.3 (42.5-50)		2		=
MATCH	00	1	4.8	10	10		1		=
MATIN	10-12	2	5-10	55.0 (40-70)	55.0 (40-70)		2		=
MEDSA	15	1	11	78.8	77.5		1		=

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	4.0 L/ha	>	=	<	
SINAR	10-13	1	5.3	36.3	16.3	1			>
STEME	12-14	3	6-12.5	69.1 (37.5-98.8)	70.4 (42.5-98.8)		3		=
THLAR	12-14	2	5.5-12	56.3 (42.5-70)	55.0 (40-70)		2		=
VERHE	10-13	2	8-30	45.0 (40-50)	27.5 (5-50)	1	1		>
VERPE	10-13	2	13.5-149.3	10.8 (4-17.5)	7.4 (4.8-10)	1	1		=
VERSS	10-13	1	21.3	25	18.8	1			>
VIOAR	00-11	3	2.3-15	27.5 (0-80)	27.5 (0-80)		3		=
TTTTT	n.r.	2	2.8-20	86.3 (80-92.5)	86.9 (80-93.8)		2		=
Mean, all assessments		28	2.3-149.3	45.6 (0-99.8)	43.3 (0-99.5)	4	24		=
EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the national reference product at 2.5 L/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	National ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	2.5 L/ha	>	=	<	
Annual grass weeds, Visual control									
ALOMY	15	1	7	97.3	93.8		1		=
Annual broadleaved weeds, Visual control									
FUMOF	13	1	31	98.5	93.5		1		=
MEDSA	15	1	11	78.8	83.8		1		=
STEME	14	1	6	99.8	100		1		=
VERPE	12	1	13.5	4	1		1		=
VIOAR	10	1	6	80	85		1		=
TTTTT	n.r.	2	2.8-20	86.3 (80-92.5)	93.2 (91.3-95)		1	1	<
Mean, all assessments		7	2.8-31	76.2 (4-99.8)	78.5 (1-100)		6	1	=

In two of the eight winter cereal trials, conducted in N-France, a national reference product containing pendimethalin and picolinafen (Celtic) was included, for comparison. In all species evaluated, the effect achieved with Flufenacet 6% + Pendimethalin 30% EC was similar to the effect obtained with the national reference product applied in the French trial. Statistical evaluation supports this statement as no significant differences were observed between the two tested products.

Table 3.2-39: Maritime zone, winter cereals – Annual grasses and broadleaved weed control results by Flufenacet 6% + Pendimethalin 30% EC applied at 4.0 L/ha post-emergence in the autumn and compared against control obtained with the flufenacet + pendimethalin reference product at comparable rate in the efficacy tests 2015/16. In the same table, the results obtained with the test product at 4.0 L/ha compared against the national reference product (Celtic) at 2.5 L/ha is also presented (Spring/summer assessment).

EPP0 Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	4.0 L/ha	>	=	<	
Annual grass weeds, Visual control									
ALOMY	03-15	5	6.5-21.3	92.1 (82.5-100)	88.4 (67.5-100)	2	3		=
APESV	11	2	8.8-16.5	100 (-)	100 (-)		2		=
AVEFA	n.r.	1	n.r.	0	0		1		=
LOLMU	03-11	2	5.5-10	94.5 (90-99)	88.2 (77.5-98.8)	1	1		>
POAAN	10-13	1	35	100	100		1		=
Mean, all assessments		11	5.5-35	86.3 (0-100)	83.5 (0-100)	3	8		=
Annual broadleaved weeds, Visual control									
BRSNX	12	2	4.3-10	100 (-)	100 (-)		2		=
CAPBP	00-07	2	4.0-5.5	100 (-)	90.0 (85-95)	1	1		>
FUMOF	03-13	2	6.5-	99.4 (98.8-100)	100 (-)		2		=
GALAP	00-12	2	5.5-10.3	94.4 (93.8-95)	95.0 (-)		2		=

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	4.0 L/ha	>	=	<	
MATCH	00-03	2	1.3-11.5	95.0 (90-100)	96.2 (92.3-100)		2	1	=
MATIN	10-12	2	5-10.3	100 (-)	97.5 (95-100)		2		=
MEDSA	15	1	n.r.	90.5	96				<
POLCO	n.r.	1	n.r.	98.3	98		1		=
SENVU	03	1	7.3	87.5	91.3		1		=
SINAR	10-13	1	15	88.8	90		1	=	
STEME	12-14	3	8.3-12.5	93.3 (85-100)	93.3 (85-100)		3	=	
THLAR	12-14	2	4.5-8	98.8 (97.5-100)	100 (-)		2	=	
VERHE	10-13	2	15-23	96.9 (95-98.8)	92.3 (89.5-95)	1	1	=	
VERPE	10-13	3	42.5-118.5	99.7 (99-100)	99.7 (99-100)		3	=	
VERSS	10-13	1	14.3	97	97		1	=	
VIOAR	00-11	3	5.5-38.8	97.9 (95-100)	92.9 (85-98.8)	1	2	=	
TTTTT	n.r.	2	50-	73.2 (55-91.3)	74.7 (55-94.3)		2	=	
Mean, all assessments		32	1.3-118.5	95.3 (55-100)	94.4 (55-100)	3	28	1	=
EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the national reference product at 2.5 L/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	National ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	2.5 L/ha	>	=	<	
Annual grass weeds, Visual control									
ALOMY	15	1	n.r.	90.5	76.3	1			>
AVEFA	n.r.	1	n.r.	0	0		1		=
Mean, all assessments		2	n.r.	45.3 (0-90.5)	38.2 (0-76.3)	1	1		>
Annual broadleaved weeds, Visual control									
FUMOF	13	1	n.r.	98.8	98.8		1		=
MEDSA	15	1	n.r.	90.5	94.3		1		=
POLCO	n.r.	1	n.r.	98.3	98.8		1		=
STEME	14	1	n.r.	100	100		1		=
VERPE	12	1	42.5	99	99		1		=
VIOAR	10	1	9	98.8	99		1		=
TTTTT	n.r.	2	50-	73.2 (55-91.3)	68.8 (55-82.5)	1	1		=
Mean, all assessments		8		91.5 (55-100)	90.9 (55-100)	1	7		=

In Table 3.2-40, the weed species are classified according to their average sensitivity at the spring assessment to 4.0 L/ha of Flufenacet 6% + Pendimethalin 30% EC in the Maritime EPPO zone. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4, based on the mean across the trial results. All weed species have been included in the table below, irrespective of the number of trials where the included weed species were evaluated. However, this does not replace individual MS systems for expressing control on national labels.

Table 3.2-40: Weed control spectrum of Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha in the Maritime zone

Scientific name	English common name	EPPO code
Highly Susceptible (≥95 %)		
<i>Apera spica-venti</i>	Silky windgrass	APESV
<i>Poa annua</i>	Annual bluegrass	POAAN
<i>Brassica napus</i>	Oilseed rape (volunteer)	BRSNW
<i>Capsella bursa-pastoris</i>	Shepherd's purse	CAPBP
<i>Fumaria officinalis</i>	Common fumitory	FUMOF
<i>Matricaria chamomilla</i>	Scented mayweed	MATCH
<i>Tripleurospermum inodorum</i>	Scentless mayweed	MATIN
<i>Fallopia convolvulus</i>	Black bindweed	POLCO
<i>Thlaspi arvensis</i>	Field pennycress	THLAR
<i>Veronica hederifolia</i>	Ivy-leaved speedwell	VERHE
<i>Veronica persica</i>	Common field speedwell	VERPE

Scientific name	English common name	EPPO code
<i>Viola arvensis</i>	Field violet	VIOAR
Susceptible (85 – 94.9 %)		
<i>Alopecurus myosuroides</i>	Blackgrass	ALOMY
<i>Lolium multiflorum</i>	Italian ryegrass	LOLMU
<i>Galium aparine</i>	Cleavers	GALAP
<i>Medicago sativa</i>	Alfalfa	MEDSA
<i>Senecio vulgaris</i>	Common groundsel	SENVU
<i>Sinapis arvensis</i>	Charlock	SINAR
<i>Stellaria media</i>	Common chickweed	STEME
Moderately Susceptible (70 – 84.9 %)		
-	-	-
Moderately tolerant (50 – 69.9 %)		
-	-	-
Tolerant (0 – 49.9 %)		
<i>Avena fatua</i>	Wild oat	AVEFA

Based on the maximum level of control achieved on the individual weed species present in the trials, the combined proposed label claims of the grass- and broadleaved weed spectrum controlled after application of 4.0 L/ha Flufenacet 6% + Pendimethalin 30% EC pre- and post-emergence to weeds are listed in Table 3.2-50.

North-east zone

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following post-emergence application in winter cereals in the autumn/late winter as well as compare it to the reference product included in the trials, results are presented from the last assessment in the autumn (Table 3.2-41) as well as one assessment carried out in the spring (Table 3.2-42), after regrowth of weeds and crops had commenced. In one trial, the number of grass seed heads was also counted in the late spring.

When applied at 4.0 L/ha post-emergence in the autumn in the North-east zone, Flufenacet 6% + Pendimethalin 30% EC achieved good to excellent control of annual grasses and broadleaved weeds commonly found in winter cereals. In all species evaluated, the effect achieved with Flufenacet 6% + Pendimethalin 30% EC was similar to the effect obtained with the flufenacet + pendimethalin reference product applied in the Polish trials. No significant differences were observed between the two tested products.

Table 3.2-41: North-east zone, winter cereals – Annual grasses and broadleaved weed control results by Flufenacet 6% + Pendimethalin 30% EC applied at 4.0 L/ha post-emergence in the autumn and compared against control obtained with the flufenacet + pendimethalin reference product at comparable rate in the efficacy tests 2015/16 and 2018/19 (Autumn assessment).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	4.0 L/ha	>	=	<	
Annual grass weeds, Visual control									
APESV	8-12	13	9.6 (4.0-19.0)	75.2 (53.8-100)	74.2 (48.0-100)	1	10	2	=
ALOMY	10-11	3	15.0 (8.0-19.8)	63.3 (50.0-85.0)	60.0 (50.0-75.0)	1	2		=
Mean, all assessments		16	12.3 (4.0-19.8)	69.3 (50.0-100)	67.1 (48.0-100)	2	12	2	=
Annual broadleaved weeds, Visual control									
BRSNW	10-12	3	9.3 (5.0-13.0)	48.7 (30.0-70.0)	40.0 (30.0-54.0)	1	2		=
CAPBP	11	4	7.5 (7.0-8.0)	82.5 (75.0-89.0)	83.8 (76.0-92.0)		4		=
CENCY	10-12	5	29.7 (4.0-55.0)	47.6 (35.0-53.0)	46.6 (33.0-50.0)		5		=
MATMA	10-15	8	22.7 (9.0-62.5)	48.7 (30.0-72.5)	53.5 (25.0-73.8)		5	3	=

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	4.0 L/ha	>	=	<	
VERPE	11	4	6.5 (5.0-8.0)	77.3 (70.0-83.0)	77.5 (70.0-84.0)		4		=
VIOAR	9-15	12	25.3 (4.0-84.5)	54.5 (30.0-75.0)	55.8 (26.0-65.0)	2	5	5	=, <
Mean, all assessments		36	23.3 (4.0-84.5)	48.3 (30.0-75.0)	47.4 (25.0-73.8)	3	25	8	=

Table 3.2-42: North-east zone, winter cereals – Annual grasses and broadleaved weed control results by Flufenacet 6% + Pendimethalin 30% EC applied at 4.0 L/ha post-emergence in the autumn and compared against control obtained with the flufenacet + pendimethalin reference product at comparable rate in the efficacy tests 2015/16 and 2018/19 (Spring/summer assessment).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
						Mean (min-max)			
				4.0 L/ha	4.0 L/ha	>	=	<	
Annual grass weeds, Visual control									
APESV	8-12	14	8.6 (2.0-16.0)	96.1 (75.0-100)	96.2 (91.0-100)	2	10	2	=
ALOMY	10/11	3	9.8 (4.0-16.0)	94.3 (75.0-98.0)	91.4 (91.0-95.0)	1	2		=
Mean, all assessments		13	9.2 (2.0-16.0)	95.2 (75.0-100)	93.8 (91.0-100)	1	10	2	=
Annual broadleaved weeds, Visual control									
CAPBP	10-12	9	12.8 (7.0-43.0)	92.9 (72.5-100)	93.1 (83.8-100)	1	7	1	=
CENCY	10-12	5	20.5 (4.0-42.0)	77.2 (65.0-90.0)	73.0 (62.5-81.3)	2	3		=
GALAP	00-13	4	12.5 (4.0-21.0)	72.0 (48.0-100)	67.0 (43.0-95.0)	1	3		=
MATMA	10-14	8	22.1 (7.0-49.5)	91.8 (67.5-100)	94.9 (83.8-100)	1	6	1	=
VERPE	11	4	6.3 (6.0-62.5)	94.3 (30.0-98.0)	92.0 (25.0-99.0)		4		=
VIOAR	9-15	12	12.3 (4.0-39.0)	91.3 (53.8-100)	87.3 (58.8-100)	1	11		=
Mean, all assessments		42	17.0 (4.0-49.5)	84.7 (48.0-100)	83.8 (43.0-100)	6	34	2	=
Annual grass weeds, Count of ears									
APESV	8-12	6	22.3 (4.0-73.0)	97.5 (85.0-100)	97.8 (93.8-100)		5	1	=

In Table 3.2-43, the weed species are classified according to their average sensitivity at the spring assessment to 4.0 L/ha of Flufenacet 6% + Pendimethalin 30% EC in the North-east EPPO zone. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4, based on the mean across the trial results. All weed species have been included in the table below, irrespective of the number of trials where the included weed species were evaluated. However, this does not replace individual MS systems for expressing control on national labels.

Based on the maximum level of control achieved on the individual weed species present in the trials, the combined proposed label claims of the grass- and broadleaved weed spectrum controlled after application of 4.0 L/ha Flufenacet 6% + Pendimethalin 30% EC pre- and post-emergence to weeds are listed in Table 3.2-50.

Table 3.2-43: Weed control spectrum of Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha in the North-east zone

Scientific name	English common name	EPPO code
Highly Susceptible (≥95 %)		
<i>Apera spica-venti</i>	Silky windgrass	APESV
Susceptible (85 – 94.9 %)		
<i>Alopecurus myosuroides</i>	Blackgrass	ALOMY
<i>Capsella bursa-pastoris</i>	Shepherd's purse	CAPBP
<i>Tripleurospermum maritimum</i>	False mayweed	MATMA
<i>Veronica persica</i>	Common field speedwell	VERPE

Scientific name	English common name	EPPO code
<i>Viola arvensis</i>	Field violet	VIOAR
Moderately Susceptible (70 – 84.9 %)		
<i>Centaurea cyanus</i>	Cornflower	CENCY
<i>Galium aparine</i>	Cleavers	GALAP
Moderately tolerant (50 – 69.9 %)		
-	-	-
Tolerant (0 – 49.9 %)		

South-east zone

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following post-emergence application in winter cereals in the autumn/late winter as well as compare it to the reference product included in the trials, results are presented from the last assessment in the autumn (Table 3.2-44) as well as one assessment carried out in the spring (Table 3.2-45), after regrowth of weeds and crops had commenced. In one trial, the number of grass seed heads was also counted in the late spring.

When applied at 4.0 L/ha post-emergence in the autumn/late winter in the South-east zone, Flufenacet 6% + Pendimethalin 30% EC achieved good to excellent control of annual grasses and broadleaved weeds commonly found in winter cereals. In all species evaluated, the effect achieved with Flufenacet 6% + Pendimethalin 30% EC was similar to the effect obtained with the flufenacet + pendimethalin reference product applied in the Hungarian trials. Statistical evaluation supports this statement as no significant differences were observed between the two tested products.

Table 3.2-44: South-east zone, winter cereals – Annual grasses and broadleaved weed control results by Flufenacet 6% + Pendimethalin 30% EC applied at 4.0 L/ha post-emergence in the autumn and compared against control obtained with the flufenacet + pendimethalin reference product at comparable rate in the efficacy tests 2015/16 (Autumn assessment).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	4.0 L/ha	>	=	<	
Annual grass weeds, Visual control									
ALOMY	11	1	150	77.5	75		1		=
APESV	12	1	58.5	2	2		1		=
Mean, all assessments		2		39.8 (2-77.5)	38.5 (2-75)		2		=
Annual broadleaved weeds, Visual control									
VERHE	10	1	10	90	90		1		=

Table 3.2-45: South-east zone, winter cereals – Annual grasses and broadleaved weed control results by Flufenacet 6% + Pendimethalin 30% EC applied at 4.0 L/ha post-emergence in the autumn and compared against control obtained with the flufenacet + pendimethalin reference product at comparable rate in the efficacy tests 2015/16 (Spring/summer assessment).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	4.0 L/ha	>	=	<	

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	4.0 L/ha	>	=	<	
Annual grass weeds, Visual control									
ALOMY	11	1	150	88.8	91.8		1		=
APESV	12	1	61.3	100	100		1		=
Mean, all assessments		2		94.4 (88.8-100)	95.9 (91.8-100)		2		=
Annual broadleaved weeds, Visual control									
VERHE	10	1	10	95	95		1		=
Annual grass weeds, Visual control									
APESV	12	1	61.3	100	100		1		=

In Table 3.2-46, the weed species are classified according to their average sensitivity at the spring assessment to 4.0 L/ha of Flufenacet 6% + Pendimethalin 30% EC in the South-east EPPO zone. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4, based on the mean across the trial results. All weed species have been included in the table below, irrespective of the number of trials where the included weed species were evaluated. However, this does not replace individual MS systems for expressing control on national labels.

Based on the maximum level of control achieved on the individual weed species present in the trials, the combined proposed label claims of the grass- and broadleaved weed spectrum controlled after application of 4.0 L/ha Flufenacet 6% + Pendimethalin 30% EC pre- and post-emergence to weeds are listed in Table 3.2-50.

Table 3.2-46: Weed control spectrum of Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha in the South-east zone

Scientific name	English common name	EPPO code
Highly Susceptible (≥95 %)		
<i>Apera spica-venti</i>	Silky windgrass	APESV
<i>Veronica hederifolia</i>	Ivy-leaved speedwell	VERHE
Susceptible (85 – 94.9 %)		
<i>Alopecurus myosuroides</i>	Blackgrass	ALOMY
Moderately Susceptible (70 – 84.9 %)		
-	-	-
Moderately tolerant (50 – 69.9 %)		
-	-	-
Tolerant (0 – 49.9 %)		
-	-	-

Mediterranean zone

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following post-emergence application in winter cereals in the autumn/late winter as well as compare it to the reference product included in the trials, results are presented from the last assessment in the autumn (Table 3.2-47) as well as one assessment carried out in the spring (Table 3.2-48), after regrowth of weeds and crops had commenced.

Table 3.2-47: Mediterranean zone, winter cereals – Annual grasses and broadleaved weed control results by Flufenacet 6% + Pendimethalin 30% EC applied at 4.0 L/ha post-emergence in autumn to late winter and compared against control obtained with the flufenacet + pendimethalin reference product at comparable rate in the efficacy tests 2015/16. In the same table, the results obtained with the test product at 4.0 L/ha compared against the national reference product (Picomax / Celtic) at 2.5 L/ha is also presented (Autumn assessment).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	4.0 L/ha	>	=	<	
Annual grass weeds, Visual control									
LOLMU	10-23	3	6.4-47	17.5 (5-37.5)	20.8 (5-42.5)		3		=
Annual broadleaved weeds, Visual control									
GALAP	16-21	2	3.8-5.3	2.5 (0-5)	3.8 (0-7.5)		2		=
LAMAM	16	1	7.5	0	0		1		=
PAPRH	16	1	13	83.8	92.5			1	<
RAPRA	10-12	1	0.5	10	7.5		1		=
SENAG	18	1	5	0	0		1		=
STEME	14	1	8.3	0	0		1		=
URTAN	14	1	4.5	0	0		1		=
VERHE	21	2	2.3-21.8	35.1 (13.8-56.3)	40.0 (20-60)		1	1	=
BBBBB	10	1	25	98.8	97.8		1		=
TTTTT	10-	2	2-12.3	36.3 (23.8-48.8)	48.8 (27.5-70)		1	1	<
Mean, all assessments		13	0.5-25.0	26.2 (0-98.8)	29.4 (0-97.8)		10	3	=
EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the national reference product at 2.5 L/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	National ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	2.5 L/ha	>	=	<	
Annual grass weeds, Visual control									
LOLMU	10-23	2	6.4-28.3	7.5 (5-10)	16.3 (15-17.5)		1	1	<
Annual broadleaved weeds, Visual control									
GALAP	16-21	2	3.8-5.3	2.5 (0-5)	61.9 (50-73.8)			2	<
LAMAM	16	1	7.5	0	65			1	<
PAPRH	16	1	13	83.8	96.5			1	<
RAPRA	10-12	1	0.5	10	20			1	<
SENAG	18	1	5	0	40			1	<
STEME	14	1	8.3	0	37.5			1	<
URTAN	14	1	4.5	0	80			1	<
VERHE	21	1	2.3-21.8	35.1 (13.8-56.3)	73.2 (70-76.3)			2	<
TTTTT	10-	2	2-12.3	35.7 (22.5-48.8)	56.9 (35-78.8)			2	<
Mean, all assessments		12	0.5-21.8	20.1 (0-83.8)	60.2 (20-96.5)			12	<

When applied at 4.0 L/ha post-emergence in the autumn/late winter in the Mediterranean zone, Flufenacet 6% + Pendimethalin 30% EC achieved poor to excellent control of annual grasses and broadleaved weeds commonly found in winter cereals. In all species evaluated, the effect achieved with Flufenacet 6% + Pendimethalin 30% EC was similar to the effect obtained with the flufenacet + pendimethalin reference product applied in the trials. At the spring assessment, Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha performed significantly better than the flufenacet + pendimethalin reference product at two assessments and at two assessments, the reference product performed significantly better than Flufenacet 6% + Pendimethalin 30% EC. At the remaining 11 assessments, no significant differences were observed between the two tested products.

In three of the five winter cereal trials, conducted in S-France (2) and Spain (1), a national reference product containing pendimethalin and picolinafen (Celtic (FR) or Picomax (ES)) was included, for comparison. In most species evaluated, the effect achieved with Flufenacet 6% + Pendimethalin 30% EC was similar to the effect obtained with the national reference product applied in the three trials. Statistical evaluation supports this statement. At the spring assessment, the national reference product performed

significantly better than Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha at three assessments, whereas at the remaining 6 assessments, no significant differences were observed between the two tested products.

Table 3.2-48: Mediterranean zone, winter cereals – Annual grasses and broadleaved weed control results by Flufenacet 6% + Pendimethalin 30% EC applied at 4.0 L/ha post-emergence in autumn to late winter and compared against control obtained with the flufenacet + pendimethalin reference product at comparable rate in the efficacy tests 2015/16. In the same table, the results obtained with the test product at 4.0 L/ha compared against the national reference product (Picomax / Celtic) at 2.5 L/ha is also presented (Spring/summer assessment).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the flufenacet + pendimethalin reference product at 1440 g ai/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	Flufenacet + pendimethalin ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	4.0 L/ha	>	=	<	
Annual grass weeds, Visual control									
LOLMU	11-23	2	29-	53.6 (7.5-99.8)	52.0 (5-99)		2		=
Annual broadleaved weeds, Visual control									
FUMOF	00	1	9	100	99.8		1		=
GALAP	16-21	2	8-	43.8 (5-82.5)	44.4 (6.3-82.5)		2		=
LAMAM	16	1	11.3	83.8	85		1		=
PAPRH	00-17	3	17-25	94.8 (90.5-100)	96.0 (93.3-99.8)		3		=
POLSS	00	1	105	96	95		1		=
Continued the following page...									
Annual broadleaved weeds, Visual control (cont.)									
SENAG	18	1	7.5	82.5	82		1		=
STEME	13-17	2	9.5-12.3	80.9 (78.8-83)	77.5 (75-80)	1	1		=
URTAN	14	1	12.8	88.8	90		1		=
VERHE	21	1	n.r.	100	100		1		=
VERPE	13-15	1	1	83	72.5	1			>
TTTTT	n.r.	1	n.r.	30	25		1		=
Mean, all assessments		15	1-105	79.8 (5-100)	78.7 (6.3-100)	2	13		=
EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m ²)	Efficacy obtained with		No. of trials where Flufenacet 6% + Pendimethalin 30% EC at 1440 g ai/ha is >, < or =, compared to the national reference product at 2.5 L/ha. = : ± 5% control			Overall
				Flufenacet 6% + Pendimethalin 30% EC at:	National ref. prod. at				
				Mean (min-max)					
				4.0 L/ha	2.5 L/ha	>	=	<	
Annual grass weeds, Visual control									
LOLMU	23	1	n.r.	7.5	8.8		1		=
Annual broadleaved weeds, Visual control									
GALAP	16-21	2	8-	43.8 (5-82.5)	66.3 (43.8-88.8)			2	<
LAMAM	16	1	11.3	83.8	88.8		1		=
PAPRH	16	1	n.r.	93.8	78.8	1			>
SENAG	18	1	7.5	82.5	86.3		1		=
STEME	14	1	12.3	78.8	85			1	<
URTAN	14	1	12.8	88.8	90		1		=
VERHE	21	1	n.r.	100	100		1		=
TTTTT	n.r.	1	n.r.	30	35		1		=
Mean, all assessments		9	7.5-12.8	71.7 (5-100)	77.4 (35-100)	1	5	3	<

In Table 3.2-49, the weed species are classified according to their average sensitivity at the spring assessment to 4.0 L/ha of Flufenacet 6% + Pendimethalin 30% EC in the Mediterranean EPPO zone. The classification is made according to Appendix I of regulation SANCO/10055/ 2013 Rev. 4, based on the mean across the trial results. All weed species have been included in the table below, irrespective of the number of trials where the included weed species were evaluated. However, this does not replace individual MS systems for expressing control on national labels.

Based on the maximum level of control achieved on the individual weed species present in the trials, the combined proposed label claims of the grass- and broadleaved weed spectrum controlled after application

of 4.0 L/ha Flufenacet 6% + Pendimethalin 30% EC pre- and post-emergence to weeds are listed in Table 3.2-50.

Table 3.2-49: Weed control spectrum of Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha in the Mediterranean zone

Scientific name	English common name	EPPO code
Highly Susceptible (≥95 %)		
<i>Fumaria officinalis</i>	Common fumitory	FUMOF
<i>Polygonum spp.</i>	Knotweeds	POLSS
<i>Veronica hederifolia</i>	Ivy-leaved speedwell	VERHE
Susceptible (85 – 94.9 %)		
<i>Papaver rhoeas</i>	Common poppy	PAPRH
<i>Urtica angustifolia</i>	-	URTAN
Moderately Susceptible (70 – 84.9 %)		
<i>Lamium amplexicaule</i>	Henbit dead-nettle	LAMAM
<i>Senecio angustifolius</i>	-	SENAG
<i>Stellaria media</i>	Common chickweed	STEME
<i>Veronica persica</i>	Common field speedwell	VERPE
Moderately tolerant (50 – 69.9 %)		
<i>Lolium multiflorum</i>	Italian ryegrass	LOLMU
Tolerant (0 – 49.9 %)		
<i>Galium aparine</i>	Cleavers	GALAP

Summary and conclusion

Based on the results of 47 field efficacy trials carried out in 2015/16 and 2018/19 season, the following can be concluded for the intended use ‘Control of annual grasses and broadleaved weeds’ with Flufenacet 6% + Pendimethalin 30% EC applied pre- or early post-emergence at the rate of 4.0 L/ha in winter cereals:

- Flufenacet 6% + Pendimethalin 30% EC applied pre- or early post-emergence at the proposed dose rate of 4.0 L/ha provides a high level of control of a range of annual grasses and broadleaved weeds commonly found in winter cereals. As weeds often occur as a complex of several weeds with different susceptibility towards flufenacet and/or pendimethalin, one application of Flufenacet 6% + Pendimethalin 30% EC at 4.0 L/ha in winter cereals should be used to efficiently control all weeds claimed on the label.
- Flufenacet 6% + Pendimethalin 30% EC controls mono- and dicotyledonous weeds when applied to the crop either pre-emergence or early post-emergence. Weeds will emerge after both application timings and very similar levels of control are seen from both the pre- and early post-emergence applications of Flufenacet 6% + Pendimethalin 30% EC. Therefore, the applicant request that the zonal evaluators reads across between the data on the two application timings.
- Compared to the flufenacet + pendimethalin co-formulated reference product, the efficacy obtained with Flufenacet 6% + Pendimethalin 30% EC is comparable against all weed species.
- Compared to the flufenacet straight reference product or the pendimethalin straight reference product, the efficacy obtained with Flufenacet 6% + Pendimethalin 30% EC is comparable to superior against all weed species.
- Compared to the national reference products containing pendimethalin and picolinafen, the efficacy obtained with Flufenacet 6% + Pendimethalin 30% EC was comparable against the weed species present in the trials at the majority of the assessments.
- The trial results are considered valid for all intended Central zone countries.

Flufenacet 6% + Pendimethalin 30% EC applied pre-emergence or early post-emergence is suitable for the control of annual grasses and broadleaved weeds in winter cereals.

The same weeds are controlled by flufenacet and pendimethalin in the different winter cereals. When treating the weeds at similar growth stages, the same level of control would be expected, irrespective of applied in the early autumn or in the early spring, in all GAP claimed crops and this has been seen in the trials. Therefore, for any label claims not adequately supported for one crop type, Sharda requests that the Zonal Evaluators reads across to the data on the other crop types and application timings.

This report also clearly demonstrates that the efficacy and cropsafety of Flufenacet 6% + Pendimethalin 30% EC is equivalent to the efficacy and cropsafety of the standard flufenacet + pendimethalin co-formulated reference products against which Flufenacet 6% + Pendimethalin 30% EC was compared. The applicant therefore wishes to cite the original registrant's data on flufenacet and pendimethalin now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

The proposed label claims across uses, based on control achieved with Flufenacet 6% + Pendimethalin 30% EC applied at 4.0 L/ha, has been summarized in Table 3.2-50. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4 (October 3rd, 2013), however this does not replace individual MS systems for expressing control on national labels:

Susceptibility	Abbreviation	Level of control
Highly Susceptible	HS	95-100 %
Susceptible	S	85 – 94.9 %
Moderately Susceptible	MS	70 – 84.9 %
Moderately tolerant	MT	50 – 69.9 %
Tolerant	T	0 – 49.9 %

Table 3.2-50: Annual grasses and broadleaved weed spectrum controlled by 4.0 L/ha Flufenacet 6% + Pendimethalin 30% EC after pre- and early post-emergence application to weeds, proven by testing results of the applicant in 2015/16 and 2018/19.

		Application timings	
EPPO code	Scientific name	Pre-emergence	Post-emergence
Grass weeds			
AGRRE	<i>Elymus repens</i>	HS	
ALOMY	<i>Alopecurus myosuroides</i>	HS	HS
ALOMY	<i>Alopecurus myosuroides</i>		S
APESV	<i>Apera spica-venti</i>	HS	HS
AVEFA	<i>Avena fatua</i>		T
LOLMU	<i>Lolium multiflorum</i>	HS	HS
LOLSS	<i>Lolium</i> spp.	MS	
POAAN	<i>Poa annua</i>	HS	HS
Broadleaved weeds			
AMABL	<i>Amaranthus blitoides</i>	HS	
ANGAR	<i>Anagallis arvensis</i>	HS	
BRSNX	<i>Brassica napus</i>	HS	HS
CAPBP	<i>Capsella bursa-pastoris</i>	HS	HS
CENCY	<i>Centaurea cyanus</i>	S	MS
CHYCO	<i>Glebionis coronarium</i>	MT	
CIRAR	<i>Cirsium arvensis</i>	MT	
DIPVG	<i>Diplotaxis virgata</i>	HS	
FUMOF	<i>Fumaria officinalis</i>	HS	HS
GALAP	<i>Galium aparine</i>	HS	HS
LAMAM	<i>Lamium amplexicaule</i>		MS
MATCH	<i>Matricaria chamomilla</i>	HS	HS
MATIN	<i>Matricaria inodorum</i>	HS	HS

EPPO code	Scientific name	Application timings	
		Pre-emergence	Post-emergence
MATMA	<i>Tripleurospermum maritimum</i>	HS	HS
MEDSA	<i>Medicago sativa</i>		S
MERAN	<i>Mercurialis annua</i>	MS	
PAPRH	<i>Papaver rhoeas</i>	HS	HS
PICHI	<i>Picris hieracioides</i>	MT	
POLAV	<i>Polygonum aviculare</i>	HS	
POLCO	<i>Fallopia convolvulus</i>	MT	HS
POLSS	<i>Polygonum spp.</i>		HS
SENAG	<i>Senecio angustifolius</i>		MS
SENVU	<i>Senecio vulgaris</i>	MS	S
SINAR	<i>Sinapis arvensis</i>		S
SLYMA	<i>Silybum marianum</i>	T	
SONAS	<i>Sonchus asper</i>	HS	
STEME	<i>Stellaria media</i>	HS	HS
THLAR	<i>Thlaspi arvense</i>	HS	HS
TTTTT	-	S	S
URTAN	<i>Urtica angustifolia</i>		S
VERHE	<i>Veronica hederifolia</i>	HS	HS
VERPE	<i>Veronica persica</i>	HS	HS
VERSS	<i>Veronica spp.</i>		HS
VIOAR	<i>Viola arvensis</i>	HS	HS

Comments of zRMS:	<p>We are dealing with the active substances used commonly for many years in many countries. According to the EPPO Standard PP1/226: Number of efficacy trials, a major target in a major crop must be supported by 10 trials (range 6-15 trials required depending on factors such as range of environmental and climatic conditions, levels of target pressure and consistency of results) and a minor use/target must be supported by 3 trials (range 2-6 trials).</p> <p>The field experiments of the herbicide – Konark (product code: SHA 2619 A) were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognized. The reports include a detailed data about conditions, agro-technological procedures, fore-crop as well as technical details etc. Submitted efficacy trials are correctly performed according to appropriate EPPO standards.</p> <p>cMS should use scale of efficacy in line with its national guidelines (ex. SANCO). Applicant presented scale of weed sensitivity according to SANCO scale. However, for Poland we should used different scale: S (susceptible) > 85%; MS (moderately susceptible) 70-85%; MT (moderately tolerant) 60-70%; T (tolerant) < 60%.</p> <p>We are dealing with the active substances used commonly for many years in many countries. However, in PL no product with both substances: pendimethalin and flufenacet are registered now. So, in the list of weeds controlled should include only those species that occurred (with appropriate intensity) a minimum of three localizations, and in the case of the species with the highest hazard of the plants at least in six locations. The level (>5%) of weed infestation in all studies was sufficient. Only trials with greater than 5 weeds/m² or over 2% ground cover have been included.</p> <p>Also, Concerned Member States will need to consider the relevance of the submitted formulation comparability data in relation to the current authorized uses for the reference product in their own Member State. The evaluation was conducted in accordance with Uniform Principles.</p> <p>cMS should decide which weed species can be accepted on the basis on presented</p>
-------------------	---

	<p>documentation and their national rules.</p> <p>Applicant submitted in total 47 efficacy trials: MAR – 15 trials (pre-emergence use – 7 trials: DE-2, CZ-2, UK-2, FR-1 and post-emergence use – 8 trials: DE-2, CZ-2, UK-2, FR-2), MED – 12 trials (pre-emergence use – 7 trials: FR-3, ES-2, IT-2 and post-emergence use – 5 trials: FR-2, ES-1, IT-2), S-E – 4 trials (pre-emergence use – 2 trials: HU and post-emergence use – 2 trials: HU), N-E – 16 trials (pre-emergence use – 2 trials: PL and post-emergence use: 14 trials – PL). In the opinion of Evaluator, Applicant submitted enough number of trials for pre-emergence use in MAR and MED and for post-emergence use in MAR and N-E. cMS from MED should decide if only 5 valid trials for post-emergence use can be accepted. Also, cMS from S-E should decide if only 2 trials for pre- and post-emergence use can be accepted. cMS from N-E should decide if only 2 trials for pre-emergence use can be accepted.</p> <p><u>Following cereals were studied during efficacy trials:</u></p> <p><i>Pre-emergence use:</i></p> <ul style="list-style-type: none"> • HORVW – MAR: 3 trials (DE, CZ, UK), N-E: 1 trial (PL), MED: 2 trials • TRZAW – MAR: 3 trials (DE, CZ, UK), N-E: 1 trial (PL), MED: 2 trials, S-E: 2 trials • HORVS – MAR: 1 trial (FR), MED: 1 trial • HORVX – MED: 1 trial • TRZDU – MED: 1 trial <p><i>Post-emergence use:</i></p> <ul style="list-style-type: none"> • HORVW – MAR: 4 trials (FR, UK, DE, CZ), N-E: 1 trial, MED: 2 trials • TRZAW – MAR: 4 trials (FR, UK, DE, CZ), N-E: 7 trials, S-E: 2 trials, MED: 2 trials • TTLWI – N-E: 6 trials • HORVX – MED: 1 trial <p>In the opinion of Evaluator, not enough studies have been presented for any of the cereals (in exception of winter triticale in N-E and winter wheat in N-E for post-emergence use). At least 6 valid trials for each EPPO zone should be presented for representative crop, to be able to extrapolate the results. However, final decision is left to each cMS. However, based on close comparability in agronomic practices, crop growing areas and conditions, application timing, crop growth habit and weed populations and spectrums between different cereal crops, extrapolation is permitted for efficacy against weeds between different winter cereals and the same can be applicable for spring cereals and between spring and winter cereals. Therefore, the submitted data can also be considered as supportive of demonstrating the efficacy of pre-emergence and post-emergence application of SHA 2619 A at a label rate of 4,0 L product/ha rate against broad-leaved weeds in winter cereals. In the opinion, of Evaluator each cMS should decide if this approach can be acceptable.</p> <p><u>Following weed species should be consider by each cMS if they can be acceptable on the basis on submitted documentation:</u></p> <p><i>Pre-emergence use:</i></p> <ul style="list-style-type: none"> • Maritime EPPO zone: <ul style="list-style-type: none"> ✓ 16-48 days after treatment: <p>AGREE (2 trials), APESV (2 trials), BRSNX (4 trials), MATIN (2 trials), SLY-MA (2 trials), STEME (3 trials), THLAR (2 trials), VERHE (3 trials), VIOAR (2</p>
--	---

	<p>trials).</p> <p>Following weed species should be excluded due to only 1 valid trial: ALOMY, LOLMU, POAAN, CAPBP, CHEAL, GALAP, MATCH, PAPRH, SINAR, VERPE, VERSS, BRSNN.</p> <p>✓ 53-204 days after treatment: ALOMY (2 trials), LOLMU (2 trials), BRSNX (2 trials), FUMOF (2 trials), MATCH (2 trials), VERHE (2 trials), VIOAR (3 trials), TTTTT (2 trials)</p> <p>Following weed species should be excluded due to only 1 valid trial: AGREE, APESV, POAAN, CAPBP, GALAP, MATIN, PAPRH, POLAV, SENVU, SLYMA, STEME, THLAR, VERPE.</p> <ul style="list-style-type: none"> • N-E EPPO zone: <p>✓ 50 days after treatment: BRSNW (2 trials), CENCY (2 trials), MATMA (2 trials), VIOAR (2 trials) APESV should be excluded due to only 1 valid trial.</p> <p>✓ 166-201 days after treatment: APESV (2 trials), CENCY (2 trials), MATMA (2 trials), VIOAR (2 trials) GALAP should be excluded due to only 1 valid trial.</p> • S-E EPPO zone: <p>✓ 6-34 days after treatment: No weed species was represented for at least 2 trials. In the opinion of Evaluator all weed species should be excluded due to only 1 valid trial: ALOMY, APESV, VERHE.</p> <p>✓ 132-143 days after treatment: No weed species was represented for at least 2 trials. In the opinion of Evaluator all weed species should be excluded due to only 1 valid trial: ALOMY, APESV, VERHE.</p> • MED EPPO zone: <p>✓ 12-82 days after treatment: AMABL (2 trials), ANGAR (2 trials), GALAP (2 trials), SONAS (2 trials), TTTTT (2 trials). Following weed species should be excluded due to only 1 valid trial: ALOMY, LOLMU, LOLSS, TTTMM, CHYCO, DIPVU, PICHI, POLAV, RANSA, SENVU, VERHE, VERPE, TTTDD.</p> <p>✓ 98-210 days after treatment: ALOMY (2 trials), AMABL (2 trials), ANGAR (3 trials), SONAS (2 trials), TTTTT (2 trials). Following weed species should be excluded due to only 1 valid trial: LOLSS, CHYCO, CIRA, DIPVG, GALAP, MERAN, PICHI, POLAV, POLCO, STEME, VERPE.</p> <p>Post-emergence use:</p> <ul style="list-style-type: none"> • Maritime EPPO zone: <p>✓ 7-78 days after treatment: ALOMY (4 trials), APESV (2 trials), BRSNW (3 trials), CAPBP (2 trials), GALAP (2 trials), MATIN (2 trials), STEME (3 trials), THLAR (2 trials), VERHE (2 trials), VERPE (2 trials), VIOAR (3 trials), TTTTT (2 trials). Following weed species should be excluded due to only 1 valid trial: LOLMU,</p>
--	---

	<p>POAAN, FUMOF, MATCH, MEDSA, SINAR.</p> <p>✓ 75-226 days after treatment:</p> <p>ALOMY (5 trials), APESV (2 trials), LOLMU (2 trials), BRSNW (2 trials), CAPBP (2 trials), FUMOF (2 trials), GALAP (2 trials), MATCH (2 trials), MAT-IN (2 trials), STEME (3 trials), THLAR (2 trials), TTTT (2 trials), VERHE (2 trials), VERPE (3 trials), VIOAR (3 trials).</p> <p>Following weed species should be excluded due to only 1 valid trial: AVEFA, POAAN, MEDSA, POLCO, SENVU, SINAR, VERSS.</p> <ul style="list-style-type: none"> • N-E EPPO zone: <p>✓ 22-31 days after treatment:</p> <p>APESV (13 trials), ALOMY (3 trials), BRSNW (3 trials), CAPBP (4 trials), CENCY (5 trials), MATMA (8 trials), VERPE (4 trials), VIOAR (12 trials).</p> <p>✓ 154-179 days after treatment:</p> <p>APESV (14 trials), ALOMY (3 trials), CAPBP (9 trials), CENCY (5 trials), GALAP (4 trials), MATMA (8 trials), VERPE (4 trials), VIOAR (12 trials).</p> • S-E EPPO zone: <p>✓ 14-16 days after treatment:</p> <p>No weed species was represented for at least 2 trials. In the opinion of Evaluator all weed species should be excluded due to only 1 valid trial: ALOMY, APESV, VERHE.</p> <p>✓ 126-143 days after treatment:</p> <p>No weed species was represented for at least 2 trials. In the opinion of Evaluator all weed species should be excluded due to only 1 valid trial: ALOMY, APESV, VERHE.</p> <p>✓ 233 days after treatment:</p> <p>No weed species was represented for at least 2 trials. In the opinion of Evaluator all weed species should be excluded due to only 1 valid trial: APESV.</p> • MED EPPO zone: <p>✓ 14-42 days after treatment:</p> <p>LOLMU (3 trials), GALAP (2 trials), VERHE (2 trials), TTTT (2 trials).</p> <p>Following weed species should be excluded due to only 1 valid trial: LAMAM, PAPRH, RAPRA, SENAG, STEME, URTAN, BBBB.</p> <p>✓ 28-168 days after treatment:</p> <p>LOLMU (2 trials), GALAP (2 trials), PAPRH (3 trials), STEME (2 trials).</p> <p>Following weed species should be excluded due to only 1 valid trial: LAMAM, SENAG, URTAN, VERHE, FUMOF, POLSS, TTTT, VERPE.</p> <p>Applicant submitted limited data for most studied weeds. In the opinion of Evaluator weeds studied only in 1 trial should be excluded from GAP table and label project. Applicant correctly presented results. Due to the limited number of results for particular weeds species, it is difficult to make a clear conclusion for the label, especially for weeds which are considered to be major. Perennial weeds are not sufficient documented. Therefore, the sufficiency of results should be considered on the national level based on importance of weed in their country.</p> <p>Extrapolations results from registered products containing flufenacet and pendimethalin should be considered by individual member states on a national level based on current registration, data protection and experience with similar active</p>
--	--

	<p>compounds products. The spectrum of weeds should be checked with label claims on these reference products.</p> <p>ASSESSMENT FOR POLAND (N-E EPPO ZONE):</p> <p><i>Pre-emergence use:</i></p> <p>Extrapolation of efficacy data is acceptable from other winter cereals crops based on close comparability in agronomic practices, crop growing areas and conditions, application timing, crop growth habit and weed populations and spectrums. This is endorsed in the EPPO extrapolation table for effectiveness of herbicide in winter cereals, where it is stated that extrapolation of efficacy is acceptable from any winter cereal to all winter cereals. However, for Poland extrapolation is possible only in case when full number of trials is presented for representative cereal (for ex. winter wheat) and at least 3-4 selectivity trials are presented for extrapolated cereal. However, in the opinion of ZRMs winter wheat and winter barley should be registered conditionally in Poland for pre-emergence use. In the pre-emergence applications for winter wheat and winter barley ZRMs and Applicant would like to indicate that the efficacy is independent of the crop present on the field. In these cases, when product is applied crops are not present on the field and have no impact in the efficacy that product can show to control weeds. Additionally, pre-emergence application to all winter cereals is applied on same moment and the target weeds are the same for all winter cereals, thus there is equivalence in terms of application independently of the winter cereal field treated.</p> <p>Winter wheat is a major crop in PL. Taking into account that the both active substances of KONARK are not currently registered in Poland in other products, the Applicant should submit at least 3 pre-emergence efficacy trials carried out on winter wheat in the N-E EPPO zone within 2 years of obtaining a positive certification.</p> <p><u>Classification of weeds (assessed together for winter cereals studied in CZ, DE, and PL).</u></p> <p>AGREE – 2 trials (CZ) – due to not enough number of trials, this weed should be excluded from Polish label.</p> <p>APESV – 4 trials (CZ-2, PL-2) – due to not enough number of trials, this weed should be excluded from Polish label.</p> <p>LOLMU (DE) - 1 trial - due to not enough number of trials, this weed should be excluded from Polish label.</p> <p>BRNSW – 5 trials (DE-1, CZ-2, PL-2) – it is a major weed in cereals. So, at least 6 trials are required. Due to not enough number of trials, this weed should be excluded from Polish label.</p> <p>CAPBP – 1 trial (DE) - due to not enough number of trials, this weed should be excluded from Polish label.</p> <p>CENCY – 2 trials (PL) - due to not enough number of trials, this weed should be excluded from Polish label.</p> <p>CHEAL – 1 trial (CZ) - due to not enough number of trials, this weed should be excluded from Polish label.</p> <p>GALAP – 1 trial (DE) - due to not enough number of trials, this weed should be excluded from Polish label.</p> <p>MATCH - 1 trial (DE) - due to not enough number of trials, this weed should be excluded from Polish label.</p>
--	---

	<p>MATIN – 2 trials (CZ) - due to not enough number of trials, this weed should be excluded from Polish label.</p> <p>MATMA – 2 trials (PL) - due to not enough number of trials, this weed should be excluded from Polish label.</p> <p>PAPRH - 1 trial (CZ) - due to not enough number of trials, this weed should be excluded from Polish label.</p> <p>SLYMA – 2 trials (CZ) - due to not enough number of trials, this weed should be excluded from Polish label.</p> <p>STEME – 2 trials (CZ) - due to not enough number of trials, this weed should be excluded from Polish label.</p> <p>THLAR - 2trials (CZ) - due to not enough number of trials, this weed should be excluded from Polish label.</p> <p>VERHE - 2 trials (CZ) - due to not enough number of trials, this weed should be excluded from Polish label.</p> <p>VIOAR – 4 trials (DE-2, PL-2) - due to not enough number of trials, this weed should be excluded from Polish label. At least 6 trials are required for a major weed.</p> <p>Since the required number of studies was not submitted for any weed, pre-emergence application will not be included in the Polish label. In the case of a new* active substance, a new active substance, a new mixture of active substances, the number should be increased by a minimum of ½ i.e. 3 and 6). It is also necessary to pay attention to the number of weeds per square meter. For now, no plant protection product with pendimethalin and flufenacet are registered in PL, so we cannot accept only 4 trials for major and 2 trials for minor weeds.</p> <p>Post-emergence use:</p> <p>Applicant submitted in total 16 valid trials for winter cereals: winter wheat-9 trials (DE-1, CZ-1, PL-7), winter triticale – 6 trials (PL) and winter barley- 3 trials (DE-1, CZ-1, PL-1). Winter barley can be accepted in Polish label on the basis on extrapolation results from winter wheat and winter triticale. Required number of selectivity trials was presented (winter barley – 5 trials, winter wheat-9 trials, winter triticale-4 trials), so that extrapolation of results is possible. Winter rye should be excluded due to lack of selectivity trials (extrapolation results is not possible).</p> <p><u>Classification of weeds (assessed together for winter cereals studied in CZ, DE, and PL).</u></p> <ul style="list-style-type: none"> - APESV – 14 trials (PL) – MS (75,2%) 22-31 days after treatment and S (96,1%) 154-179 days after treatment by recommended dose (4,0 L/ha). It can be concluded that APESV is a susceptibility weed against Konark use at recommended dose. 2 trials from Maritime (CZ) were characterized by very low efficiency after 7-78 days after treatment and excellent efficacy (100%) after treatment (75-226 days). - ALOMY – 3 trials (PL) – MT (63,3%) 22-31 days after treatment and S (94,3%) 154-179 days after treatment by recommended dose (4,0 L/ha). 2 trials from Maritime (CZ and DE) were characterized by very low efficiency after 7-78 days after treatment and excellent efficacy (96,3%) after treatment (75-226 days). In total 5 trials are not sufficient for including ALOMY in Polish label as susceptible weed. At least 6 trials for major weed is required. - BRSNW – 3 trials (PL) – T (48,7%) 22-31 days after treatment. 3 trials
--	---

	<p>from CZ and DE – T (41,7%) 7-78 days after treatment and 2 trials from CZ – S (100%) 75-226 days after treatment. In total number of trials is not sufficient. BRSNW is a major weed in PL, so at least 6 trials are required.</p> <ul style="list-style-type: none"> - CAPBP – 4 trials (PL) – MS (82,5%) 22-31 days after treatment and 9 trials (PL) – S (92,9%) 154-179 days after treatment. 2 trials from Maritime (DE) were characterized by very low efficiency after 7-78 days after treatment and excellent efficacy (100%) after treatment (75-226 days). CAPBP can be including in Polish label as susceptible weed against Konark use at recommended dose. - CENCY – 5 trials (PL) – T (47,6%) 22-31 days after treatments and MS (77,2%) 154-179 days after treatment. In total number of trials is not sufficient. CENCY is a major weed in PL, so at least 6 trials are required - MATMA – 8 trials (PL) – T (48,7%) 22-31 days after treatment and S (91,8%) 154-179 days after treatment. In total number of trials is sufficient. MATMA can be including in Polish label as susceptible weed against Konark use at recommended dose. - VERPE – 4 trials (PL) – MS (77,3%) 22-31 days after treatment and S (94,3%) 154-179 days after treatment. In total number of trials is sufficient. VERPE can be including in Polish label as susceptible weed against Konark use at recommended dose. - VIOAR – 12 trials (PL) – T (54,5%) 22-31 days after treatment and S (91,3%) 154-179 days after treatment. 2 trials from Maritime (DE) were characterized by very low efficiency after 7-78 days after treatment and excellent efficacy (97,5%) after treatment (75-226 days). Number of trials is sufficient for including VIOAR in Polish label as susceptible weed. - GALAP – 4 trials (PL) – MS (72,0%) 154-179 days after treatment and 2 trials from CZ – S (94,4%) 75-226 days after treatment. Number of trials is sufficient for including GALAP in Polish label as moderately susceptible weed. - MATIN – 2 trials (CZ) – S (100%) 75-226 days after treatment. MATIN is a major weed in winter cereals, so number of trials is not sufficient. In the opinion of Evaluator, MATIN should be excluded from Polish label. - STEME – 2 trials (CZ) – S (90%) 75-226 days after treatment. STEME is a minor weed in winter cereals, so number of trials is not sufficient for including STEME in Polish label as susceptible weed (at least 3 are required). - THLAR – 2 trials (CZ) – S (98,8%) 75-226 days after treatment. THLAR is a minor weed in winter cereals, so number of trials is not sufficient for including THLAR in Polish label as susceptible weed (at least 3 are required). <p><u>In the Polish label following weeds can be accepted:</u></p> <ul style="list-style-type: none"> - Susceptible weeds: APESV, CAPBP, MATMA, VERPE, VIOAR - Moderately susceptible weeds: GALAP. <p>Due to not enough trials following weed species should be excluded from Polish label: MATIN, STEME, THLAR, ALOMY, BRSNW, CENCY.</p> <p>Post-emergence use in Poland can be accepted on winter wheat, winter barley and winter triticale. Winter rye should be excluded from label due to lack of trials.</p>
--	---

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

3.3.1 Summary and Conclusions

Resistance is a natural phenomenon embodied in the process of the evolution of biological systems and has been experienced over and over again in the past. According to Heap (2018⁴) resistance is the naturally occurring inheritable ability of some weed biotypes within a population to survive an herbicide treatment that would, under normal conditions of use, effectively control that weed population. Selection of resistant biotypes may eventually result in control failures.

The risk of resistance was analysed following the EPPO-Standard (2015⁵), the classification of the Herbicide Resistance Action Committee (HRAC)⁶ and the international Survey of Herbicide Resistant Weeds (Heap 2018).

Flufenacet: So far, two cases of resistance with flufenacet in Blackgrass and Italian Ryegrass have been reported worldwide. Of these, one has been reported from Europe. The active substance is therefore classified as having a low inherent risk.

Pendimethalin: So far, ten cases of resistance with pendimethalin in grasses have been reported worldwide. Of these, four has been reported from Europe, i.e. 3 x ALOMY and 1 x ECHCG. The active substance is therefore classified as having a low inherent risk.

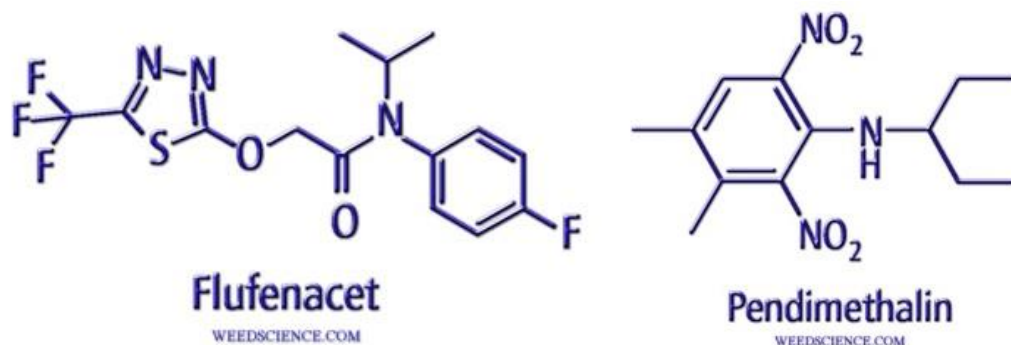
The evaluation of the agronomic risk concludes, that Flufenacet 6% + Pendimethalin 30% EC bears a low risk of resistance.

The Registration of Flufenacet 6% + Pendimethalin 30% EC is endorsed.

3.3.2 Mode of Action

Flufenacet 6% + Pendimethalin 30% EC is a mixture of 2 active ingredients with different modes of action. The chemical structure of the two active ingredients is shown in Figure 3.3-1.

Figure 3.3-1: Structure of flufenacet (left) and pendimethalin (right) (Source: Heap, I.; The International Survey of Herbicide Resistant Weeds. Online. Internet. Monday, July 16th, 2018. Available at www.weedscience.com)



⁴ Heap, I. M., 2018: The International Survey of Herbicide Resistant Weeds. Web site visited January 2018. <http://www.weedscience.com>

⁵ EPPO 2015: Standard PP 1/213 (4): Resistance risk analysis.

⁶ HRAC: <http://www.HRACglobal.com>. Web site visited January 2020.

Mode of action, flufenacet

Flufenacet, with the chemical name 4'-fluoro-*N*-isopropyl-2-[5-(trifluoromethyl)-1,3,4-thiadiazol-2-yl-oxy]acetanilide (IUPAC), belongs to the chemical group of oxyacetamides. It is a selective contact and residual soil herbicide used in cereals and other crops for broad-spectrum control of important grasses and some broadleaved weeds across all climatic zones of Europe.

Flufenacet acts by the inhibition of the Long Chain Fatty Acid synthesis. Long Chain Fatty Acid Inhibitors are preemergent herbicides that are used to control annual grasses and some small-seeded broadleaf weeds in a variety of crops. They do not control or seriously damage emerged plants. The primary site of absorption and action of these herbicides on broadleaf species is the roots, while the primary site of absorption and action on grass species is the emerging shoot. Long Chain Fatty Acid Inhibitors are not readily translocated in the plant. Long Chain Fatty Acid Inhibitors include acetamide, chloroacetamide, oxyacetamide, and tetrazolinone herbicides that are currently thought to inhibit very long chain fatty acid (VLCFA) synthesis. These compounds typically affect susceptible weeds before emergence but do not inhibit seed germination.

Injury symptoms: Symptoms on grass plants include failure of the shoot to emerge from the coleoptile or whorl of the plant, giving the plant a buggy-whip appearance. Susceptible grass seedlings often fail to emerge from the soil. Injury symptoms on broadleaf plants include enlarged cotyledons, restricted growth of the true leaves, dark green colour and stunting. Other symptoms on broadleaf plants include leaf crinkling, leaf red colouring, chlorosis, necrosis, and leaf distortion.

Due to the primary target site and the chemical subgroup, flufenacet is classified as a HRAC group 15 herbicide (Long Chain Fatty Acid Inhibitors). In the WSSA resistance classification system, the Oxyacetamides are classified as group 15. The other chemical groups in HRAC group 15 are: Acetamides, Chloroacetamides, others, Oxyacetamide and Tetrazolinones.

Chemical families	Examples of Herbicides/active ingredient
Acetamides	e.g. napropamide
Chloroacetamides	e.g. alachlor, pethoxamide
Others	e.g. cafenstrole
Oxyacetamides	Flufenacet , mefenacet
Tetrazolinones	Fentrazamide

Mode of action, pendimethalin

Pendimethalin, with the chemical name *N*-(1-ethylpropyl)-2,6-dinitro-3,4-xylidine (IUPAC), belongs to the chemical group of the dinitroanilines. Applied pre-emergence, pendimethalin is effective on some important grass weeds as well as on a wide range of broadleaved weeds. In the post-emergence application, pendimethalin is predominantly effective on broad-leaved weeds.

Pendimethalin inhibits cell division by binding to β -tubuline and preventing assembly of tubuline heterodimers into microtubules (primary mode of action). In addition, pendimethalin inhibits RNA, DNA and protein synthesis and at higher concentrations an uncoupling of the oxidative phosphorylation was observed.

Due to the primary target site and the chemical subgroup, pendimethalin is classified as a HRAC group 3 herbicide (microtubule assembly inhibition). In the WSSA resistance classification system the dinitroanilines are classified as group 3. The other chemical groups in HRAC group 3 are: phosphoramidates, pyridines, benzamides and benzoic acids.

Chemical families	Herbicides/active ingredient
Phosphoramidates	Amiprofos-methyl, butamiphos
Pyridines	Dithiopyr, thiazopyr
Benzamides	Propyzamide, tebutam
Benzoic acids	Chlorthal-dimethyl
Dinitroanilines	e.g. pendimethalin, trifluralin, butralin

3.3.3 Mechanism(s) of resistance

Flufenacet

The mechanism for resistance of Blackgrass (*Alopecurus myosuroides*) and Italian ryegrass (*Lolium multiflorum*) to flufenacet is suggested to be due to enhanced metabolism.

Pendimethalin

The reason for the reduced sensitivity of resistant weed biotypes against HRAC group 3 herbicides can be metabolic resistance due to enhanced metabolism (e.g. *Alopecurus myosuroides*) as well as an altered site of action (e.g. *Eleusine indica*; *Setaria viridis*).

3.3.4 Evidence of resistance

Flufenacet

To date, five different monocotyledonous weed species has been reported in eight cases to have evolved resistance towards one HRAC group 15 herbicide (Heap, 2018). The first report of 15 herbicide resistance was from Australia in 1982 where *Lolium rigidum* (Rigid Ryegrass) showed multiple resistance towards a range of herbicides with different modes of action, including 15 herbicides (metolachlor). Since then a few new weeds has been added to the list.

The next cases were reported from Asia (China (1993), Thailand (1998) and Philippines (2005)), where resistance had evolved in Barnyard grass (*Echinochloa crus-galli*) on rice fields treated with 15 herbicides (butachlor). In 1998 and 2005, the Barnyardgrass was also reported to having evolved resistance to propanil, which is a PSII Inhibitor (C2/7).

The first of the two cases of flufenacet resistance came from the United States, in 2005, where a population of Italian ryegrass (*Lolium multiflorum*) had evolved multiple resistance towards flufenacet, ALS inhibitors (B/2) and ACCase inhibitors (A/1). The second case was reported from Germany, in 2007, where a population of Blackgrass (*Alopecurus myosuroides*) was reported to be resistant specifically to flufenacet (15) as well as herbicides with other sites of action (A/1, B/2 and C2/7) (Heap, 2018). The crop in which the resistant weed was identified was wheat.

The latest case of 15 resistance was reported from Canada in 2015, where Wild Oat (*Avena fatua*) had evolved resistance to 15 (pyroxasulfone) as well as other herbicides with different sites of action (A/1, B/2, E/14 and N/8).

Further information and updates regarding resistance and weed populations can be found on www.weedscience.org.

Pendimethalin

To date, ten different monocotyledonous weed species and two dicotyledonous weed species has been reported in a total of 39 cases to have evolved resistance towards one HRAC group 3 herbicide (Heap, 2018). The first report of 3 herbicide resistance was reported from USA in 1973 where *Eleusine indica* (Goosegrass) showed resistance towards trifluralin in cotton fields. Since then, a number of cases of 3 resistance has been reported, whereof the majority are from outside Europe, i.e. USA, Australia and Canada.

Out of the ten cases of pendimethalin resistance, six cases were from the US and the remaining four cases were from within Europe. The first of the four European cases of pendimethalin resistance came from the UK, in 1987, where a population of Blackgrass (*Alopecurus myosuroides*) had evolved resistance specifically towards pendimethalin. The second case was reported from Bulgaria, in 1992, where a population of Barnyardgrass (*Echinochloa crus-galli*) was reported to be resistant to pendimethalin. The third case was reported in 1996 from Belgium where Blackgrass (*Alopecurus myosuroides*) had evolved multiple resistance towards pendimethalin as well as herbicides with other sites of action (A/1, B/2, C1/5 and C2/7).

Finally, in 2001, a population of Blackgrass (*Alopecurus myosuroides*) in Denmark had evolved multiple resistance towards pendimethalin, ALS inhibitors (B/2) and ACCase inhibitors (A/1). The ten cases of pendimethalin resistance reported are presented in the table below.

Year	Species	Country	MoA
1987	<i>Alopecurus myosuroides</i>	United Kingdom	K1/3
1988	<i>Eleusine indica</i>	USA (Tennessee)	K1/3
1992	<i>Sorghum halepense</i>	USA (Mississippi)	K1/3
1992	<i>Echinochloa crus-galli</i>	Bulgaria	K1/3
1994	<i>Eleusine indica</i>	USA (Mississippi)	K1/3
1996	<i>Alopecurus myosuroides</i>	Belgium	A/1, B/2, K1/3, C1/5, C2/7
1997	<i>Poa annua</i>	USA (North Carolina)	K1/3
2001	<i>Alopecurus myosuroides</i>	Denmark	A/1, B/2, K1/3
2007	<i>Poa annua</i>	USA (Tennessee)	K1/3
2012	<i>Poa annua</i>	USA (Alabama)	K1/3

MoA: A=ACCase inhibitors, B=ALS inhibitors; C1=Photosystem II inhibitors, C2=PSII inhibitors (Ureas and amides), E=PPO inhibitors, K1=Microtubule inhibitors, N=Lipid inhibitors, F4=DOXP inhibitors

The latest case of 3 resistance was reported from various places in Australia in 2017, where Annual bluegrass (*Poa annua*) had evolved resistance to 3 (propyzamide). In one of the four latest cases, the Annual bluegrass had also developed multiple resistance towards other herbicides with different sites of action (B/2, C1/5, G/9 and Z/27).

Further information and updates regarding resistance and weed populations can be found on www.weedscience.org.

3.3.5 Cross-resistance

“When a plant expressing resistance to an herbicide also demonstrates resistance to other herbicides that target the same plant process even though the plant has not been exposed to the other herbicides, the resistance is termed cross-resistance” (Prather et al. 2000).

HRAC 15 herbicides: All five weed species mentioned in section 3.3.4 were reported to be cross resistant between 15 herbicides (3 x Chloroacetamides and 2 x Oxyacetamides) and others Sites of Action, including ALS inhibitors (HRAC group B/2), ACCase inhibitors (A/1), Ureas and amides (C2/7), Triazoles, ureas, isoxazolidiones (F3/11), Dinitroanilines and others (K1/3), Mitosis inhibitors (K2/23) and/or Thiocarbamates and others (N/8). The reported cases in Blackgrass and Italian ryegrass were specifically cross-resistant to flufenacet and a number of herbicide groups (A/1, B/2 and/or C2/7). However, to date, still no cases of cross-resistance within the 15 group of herbicides has been reported.

HRAC 3 herbicides: Based on the HRAC classification, cross resistance could be expected to be likely between pendimethalin and other HRAC group 3 herbicides, as was observed in e.g. 1988 where *Eleusine indica* was cross-resistant to pendimethalin, proflumicarb and trifluralin, which all are 3 herbicides. Cases of multiple resistance including HRAC group 3 herbicides are reported for biotypes of *Alopecurus myosuroides* (ALOMY), *Lolium rigidum* (LOLRI) and *Setaria viridis* (SETVI).

3.3.6 Sensitivity data

Weeds vary in their sensitivity towards herbicides both between and within populations, and this natural variation should be understood before shifts in sensitivity can be assessed. Long chain fatty acid inhibitors and Microtubule inhibitors have been tested and used worldwide for almost 60 years, it is therefore difficult to find unexposed weed populations. No true base line sensitivity data can therefore be established.

3.3.7 Use pattern

Flufenacet 6% + Pendimethalin 30% EC is composed of flufenacet and pendimethalin which both are selective herbicides applied pre-emergence or early post-emergence. In the EU Central zone, the formulation is proposed for use against annual grasses and some broadleaved weeds in winter cereals during the growing season (BBCH 00-25). The recommended dose rate is 4.0 L/ha, which will deliver 240 g flufenacet and 1200 g pendimethalin per hectare. The maximum number of applications is one application per growing season.

Flufenacet as well as pendimethalin have been used as straight products as well as in mixtures for many years.

3.3.8 Resistance Risk Assessment of unrestricted use patterns

To avoid resistance, it is important to have a reasonable crop rotation and respect the label recommended application rates and doses. Resistance has often developed where mono-cropping, reduced tillage and subsequent use of LCFA inhibitors as well as microtubule inhibitors has been practiced. There is a risk of developing resistance towards flufenacet and/or pendimethalin if the recommended application interval is exceeded as well as if lower than recommended dose rates are applied.

The inherited resistance towards flufenacet should be considered as high due to the mode of action, the short life cycle of many of the target weeds etc. Furthermore, the genes involved in resistance are transmitted both by pollen and seeds and many of the annual grasses and broadleaved weeds produce large amounts of seeds which are dispersed over large areas. By using flufenacet in mixture with pendimethalin as it is the case with the mixture Flufenacet 6% + Pendimethalin 30% EC, this trait is broken and a built up of resistance is put on hold.

The degradation time of flufenacet is slower in certain soils compared to others, which might have an influence on the inherited risk in these. Pendimethalin has residual effect and therefore high soil activity.

3.3.9 Acceptability of the resistance risk

Without any precautions, the resistance risk is unacceptable. However; taking the right precautions and following Good Agricultural Practise, the risk is acceptable. Should resistant populations arise, control could be achieved through use of alternative products.

3.3.10 Management strategy for Flufenacet 6% + Pendimethalin 30% EC

Good Agricultural Practices and Good Plant Protection Practices (EPPO Standard 2/1 (2)) should be the followed in the weed management strategy.

Flufenacet 6% + Pendimethalin 30% EC should be used in alternation with herbicides comprising different modes of action to avoid the build-up of resistant biotypes and cross resistance.

Uses of mixtures with herbicides with different modes of action and weed spectrum is recommended, in order to obtain a high degree of weed control and get rid of eventually resistant weeds in the field and prevent resistance build up.

Follow the label recommendations regarding application rate (max. 1 application per year), growth stage, doses etc.

Apply Flufenacet 6% + Pendimethalin 30% EC:

- Preferably shortly before emergence of the weeds and not later than the BBCH 14 stage of the weeds.
- Apply the dose rate as recommended

- Late applications – when the weeds are too developed.
- Use of reduced rates particularly where late applications are made.

- Apply to weeds where target site resistance to any of the herbicide classes included in Flufenacet 6% + Pendimethalin 30% EC has been confirmed.

Cultural practices:

Since cross resistance between different modes of action cannot be excluded, application limitations and the alternation of herbicides should be supported by additional agricultural measures. To minimize the weed pressure, deep soil cultivation (plough) and late sowing are recommended.

The basic recommendations for resistance risk management (maximum 1 application for weed control) will be clearly recommended on the label. Additional recommendations for product alternations and cultural practices will be given on the label.

Allegations of weeds control failures in Europe and around the world are monitored.

Sharda will inform the regulatory authorities of any new confirmed occurrence of resistance regarding the use of Flufenacet 6% + Pendimethalin 30% EC.

Comments of zRMS: **Flufenacet:** HRAC group ~~K3~~ 15 herbicides are used for weeding control in agricultural crops for about 50 years. Some naturally occurring weed biotypes resistant to F1 herbicides may exist through normal genetic variability in any weed population. The resistant biotypes are unusual. ~~A PDS mutation leading to resistance has been identified.~~ Also, non-target-site resistance has been suggested. Based on the HRAC resistance classification, cross resistance is very reduced but can be expected to be likely between flufenacet (oxyacetamides) and the other HRAC group herbicides. Based on the HRAC database only one case of cross resistance to herbicides belonging to different HRAC groups are reported for European countries. i.e., Germany in *Alopecurus myosuroides* being resistant to multiple actives (A/1, B/2, C2/7, and ~~K3~~ 15).

Reported cases of resistance to flufenacet:

#	Year	Species	Country	MOAs	Actives	Situations
1	2018	<i>Lolium perenne ssp. multiflorum</i>	France	Very Long-Chain Fatty Acid Synthesis inhibitors HRAC Group 15 (Legacy K3 N)	flufenacet	Wheat
2	2007	<i>Alopecurus myosuroides</i>	Germany	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Acetyl CoA Carboxylase HRAC Group 1 (Legacy	fenoxaprop-ethyl, isoproturon, chloroto-	Wheat

				A), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2), Very Long-Chain Fatty Acid Synthesis inhibitors HRAC Group 15 (Legacy K3 N)	luron, flufenacet, mesosulfuron-methyl, pinoxaden	
3	2018	Lolium perenne ssp. multiflorum	United Kingdom	Very Long-Chain Fatty Acid Synthesis inhibitors HRAC Group 15 (Legacy K3 N)	flufenacet	Wheat
4	2005	Lolium perenne ssp. multiflorum	United States (Idaho)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Acetyl CoA Carboxylase HRAC Group 1 (Legacy A), Very Long-Chain Fatty Acid Synthesis inhibitors HRAC Group 15 (Legacy K3 N)	clodinafop-propargyl, diclofop-methyl, quizalofop-ethyl, clethodim, triasulfuron, flufenacet	Lentils, Wheat, Canola, Peas, Chick-pea
5	2018	Lolium perenne ssp. multiflorum	United States (Oregon)	Very Long-Chain Fatty Acid Synthesis inhibitors HRAC Group 15 (Legacy K3 N)	flufenacet	Wheat
6	2018	Lolium perenne ssp. multiflorum	United States (Washington)	Very Long-Chain Fatty Acid Synthesis inhibitors HRAC Group 15 (Legacy K3 N)	flufenacet	Wheat

Pendimethalin: predominantly effective on broad-leaved weeds. Konark is a pre and post-emergence herbicide for the control of weeds in many different crops. Due to the primary target site and the chemical subgroup, Pendimethalin is classified as a HRAC group ~~K4~~ 3 herbicide (microtubule assembly inhibition). In the WSSA resistance classification system the dinitroanilines are classified as group 3. The other chemical groups in HRAC group ~~K4~~ 3 are: phosphoramidates, pyridines, benzamides and benzoic acids.

The following table shows the current worldwide resistance weeds specifically to the herbicide pendimethalin (according to <http://www.weedscience.org>):

#	Year	Species	Country	MOAs	Actives	Situations
1	1996	Alopecurus myosuroides	Belgium	ACCase inhibitors (A/1), ALS inhibitors (B/2), Microtubule Assembly inhibitors (K1/3), Photosystem II- Serine 264 Binders (C1/5), PSII inhibitors - Serine 264 Binders (C2/7)	clodinafop-propargyl, propaquizafop, fenoxa-prop-P-ethyl, flupyr-sulfuron-methyl-sodium, atrazine, chlorotoluron, pendimethalin	Winter wheat
2	1992	Echinochloa crus-galli var. crus-galli	Bulgaria	Microtubule Assembly inhibitors (K1/3)	pendimethalin	Orchards
3	2001	Alopecurus myosuroides	Denmark	ACCase inhibitors (A/1), ALS inhibitors (B/2), Microtubule Assembly inhibitors (K1/3)	clodinafop-propargyl, fenoxaprop-P-ethyl, cycloxydim, flupyr-sulfuron-methyl-sodium, pendimethalin, florasulam, iodosulfuron-methyl-sodium, mesosulfuron-methyl, pyroxsulam	Winter wheat
4	1987	Alopecurus myosuroides	United Kingdom	Microtubule Assembly inhibitors (K1/3)	pendimethalin	Wheat
5	2012	Poa annua	United States (Alabama)	Microtubule Assembly inhibitors (K1/3)	prodiamine, pendimethalin, dithiopyr	Turf
6	2016	Amaranthus palmeri	United States (Arkansas)	ALS inhibitors (B/2), EPSP synthase inhibitors (G/9), Microtubule Assembly inhibitors (K1/3), PPO inhibitors (E/14), Very Long-Chain Fatty Acid Synthesis inhibitors (K3/15)	imazethapyr, pyri-thiobac-sodium, flumetsulam, fomesafen, lactofen, acifluorfen-sodium, fluthi-acet-methyl, carfentrazone-ethyl, glyphosate, pendimethalin, pyraflufen-ethyl.	Cotton, Soybean

					trifloxysulfuron-sodium, S-metolachlor	
7	1992	Sorghum halepense	United States (Mississippi)	Microtubule Assembly inhibitors (K1/3)	pendimethalin	Cotton
8	1994	Eleusine indica	United States (Mississippi)	Microtubule Assembly inhibitors (K1/3)	pendimethalin, trifluralin	Cotton
9	1997	Poa annua	United States (North Carolina)	Microtubule Assembly inhibitors (K1/3)	proflaminate, pendimethalin	Golf courses, Turf
10	1988	Eleusine indica	United States (Tennessee)	Microtubule Assembly inhibitors (K1/3)	proflaminate, pendimethalin, trifluralin	Cotton, Golf courses, Turf
11	2007	Poa annua	United States (Tennessee)	Microtubule Assembly inhibitors (K1/3)	proflaminate, pendimethalin, dithiopyr	Golf courses, Turf
<p>Applicant submitted detailed information's about possibilities of development the resistance or cross-resistance. Evaluator accepted the strategy management about possible development of resistance or cross-resistance proposed by Applicant.</p> <p>Final assessment of the resistance risk has to be carried out on member state level since the agronomic factors influencing the risk of resistance development tend to vary between the Member Without any precautions the resistance risk is unacceptable. The abundance of the requirements within the good agricultural practice is necessary. The resistance management is coordinated by HRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restriction should be put on the label.</p> <p>The overall resistance risk for KONARK (product code: SHA 2619 A) is moderate.</p> <p>The herbicide KONARK is intended to control annual mono- and dicotyledonous weed species pre- and early post-emergence in winter cereals and triticale. In Europe, short cereal-based crop rotations are common. Therefore, consecutive uses of KONARK are possible. This enhances the selection pressure. Yet, other herbicide modes of action can be used to control weeds post-emergence. Therefore, the agronomic risk is rated moderate.</p> <p>The herbicide KONARK is intended to control annual mono- and dicotyledonous weed species such as <i>Apera spica-venti</i>, <i>Digitaria sanguinalis</i>, <i>Echinochloa crus-galli</i>, <i>Amaranthus retroflexus</i>, <i>Capsella bursa-pastoris</i>, <i>Chenopodium album</i>, <i>Stellaria media</i> and <i>Tripleurospermum perforatum</i>. These weeds have already evolved resistance towards one or more herbicide modes of action. Therefore, the inherent risk of these target species is high.</p>						

3.4 Adverse effects on treated crops (KCP 6.4)

Data from 37 selectivity trials conducted in the Maritime EPPO zone (12, i.e. N-France (4), Germany (4), Czech Republic (2) and England (2)), the North-east EPPO zone (12, i.e. Poland), the South-east EPPO zone (1, i.e. Hungary) and the Mediterranean EPPO zone (12, i.e. Spain (4), Italy (6) and S-France (2)) have been included in this biological assessment dossier to support the label claims and recommendations on selectivity in the EU Central Registration zone.

The 37 selectivity trials were conducted in winter wheat (14, i.e. “soft” wheat (17) and durum wheat (1)), winter barley (15) and triticale (4).

Information on trials submitted (6.4 Adverse effects on treated crops)

Trials in this report were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The GEP-requirement and the Uniform Principles are therefore taken care of.

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this report have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

Table 3.4-1: Presentation of selectivity trials

Crop*	Country	Type of trial**	Number of trials				Years	GEP, non-GEP, official***	Comments (any other relevant information)
			EPPO zone						
			MAR	MED	S-E	N-E			
HORVW	Germany	Q + Y + S	2	-	-	-	2015/16	GEP	Pre- and post-emergence
	Czech Rep.	Q + Y + S	1	-	-	-	2015/16	GEP	Pre- and post-emergence
	France	Q + Y + S	2	1	-	-	2015/16	GEP	Pre- and post-emergence
	UK	Q + Y + S	1	-	-	-	2015/16	GEP	Pre- and post-emergence
	Poland	S	-	-	-	2	2015/16	GEP	Pre- and post-emergence
	Spain	Q + Y + S	-	2	-	-	2015/16	GEP	Pre- and post-emergence
	Italy	Q + Y + S	-	4	-	-	2015/16	GEP	Pre- and post-emergence
	Total, Winter barley (Sel.)		6	7	-	2			
TRZAW	Germany	Q + Y + S	2	-	-	-	2015/16	GEP	Pre- and post-emergence
	Czech Rep.	Q + Y + S	1	-	-	-	2015/16	GEP	Pre- and post-emergence
	France	Q + Y + S	2	-	-	-	2016/17	GEP	Pre- and post-emergence
	UK	Q + Y + S	1	-	-	-	2015/16	GEP	Pre- and post-emergence
	Poland	Q + Y + S	-	-	-	2	2015/16	GEP	Pre- and post-emergence
			-	-	-	4	2018/19	GEP	Pre- and post-emergence
	Hungary	Q + Y + S	-	-	1	-	2015/16	GEP	Pre- and post-emergence
	Spain	Q + Y + S	-	2	-	-	2015/16	GEP	Pre- and post-emergence
	Italy	Q + Y + S	-	2	-	-	2015/16	GEP	Pre- and post-emergence
	Total, Winter wheat (Sel.)		6	4	1	6			
TRZDU	France	Q + Y + S	-	1	-	-	2015/16	GEP	Pre- and post-emergence
	Total, Durum wheat (Sel.)		-	1	-	-			
TTLWI	Poland	Q + Y + S	-	-	-	4	2018/19	GEP	Pre- and post-emergence
	Total, Triticale (Sel.)		-	-	-	4			
	Total		12	12	1	12			

Table 3.4-2: Details on selectivity trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(4)
	Specific guidelines	EPPO PP 1/93(3)

Experimental design	Plot design	RCBD (37)
	Plot size	17.5-30 m ²
	Number of replications	4 (37)
Crop	Trials per crop	Winter wheat (17), durum wheat (1), winter barley (15), triticale (4).
	Varieties per crop	Winter wheat: Asano, Bologna, Csillag, Don Ricardo, Dorondon, Gallant, Hywin, Julius, Matheo, Rebelde, Seilor (2), Svitava, Patras, KWS Ozon, Kilimanjaro. Durum wheat: Babylone Winter barley: Caribic, Cassia, Chalap, Esterel, Etincell, Irina, Jup, Lomerit, Marjorie, Matesca, Odyssey, Pewter R2, Tonic, Varenne, Volano Triticale: Trapero (2), Borwo, Panteon.
	Sowing period	Winter wheat: September 24 th to December 18 th Winter barley: September 30 th to January 29 th Triticale: September 28 th to October 2 nd
Application	Application period	Winter cereals, pre-emergence (29): October 9 th to March 14 th Winter cereals, post-emergence (37): October 26 th to April 1 st
	Crop stage (BBCH)* at application	Winter cereals, pre-emergence (29): BBCH 00-09 Winter cereals, post-emergence (37): BBCH 10-25
	Number of appl.	Two distinct appl. timings, where one part of the trials was treated pre-emergence and the other part was treated post-emergence (37 trials)
	Intervals between appl.	10-86 days (mean = 34 days, n=37)
	Spray volumes	200-300 L/ha
Assessment	Assessment types	<ul style="list-style-type: none"> - Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was substituted or supplemented by assessments of individual symptoms. - crop vigour
	Assessment dates	As a rule 3 crop injury ratings
Other relevant information	Soil type	Calcareous clay (2), Clay loam (9), Loam (4), Loamy clay (1), Loamy clay sand (1), Loamy sand (2), Sandy clay (8), Sandy loam (5), Sandy silt loam (1), Silt (1), Silt loam (2), Silty clay loam (1)
	Organic matter content	<1.5%(17), 1.5 to 2.49%(9); 2.5 to 3.5%(2), >3.5%(5); not indicated(4)
	pH	5.1-8.4 (mean = 7.10, n = 35; not indicated (2))
	Natural / artificial inoculation...	Preferably weed-free conditions
	Field / Greenhouse...	Field

Reference products

In 32 of 37 selectivity trials, the performance of Flufenacet 6% + Pendimethalin 30% EC was measured against a commercial standard flufenacet + pendimethalin co-formulation currently on the market in Central and South Europe (Aranda / Crystal / Malibu / Trooper; 60 g/L flufenacet + 300 g/L pendimethalin EC). In the remaining five selectivity trials, conducted in Italy, a flufenacet standard product was used as the only reference (FOE50% SC; flufenacet 500 g/L SC). The trials were carried out on autumn- and winter-sown wheat and barley.

The reference products used in the trials are listed in Table 3.4-3.

Table 3.4-3: Presentation of reference standards used in trials (selectivity trials, transformation trials...)

Trade name	Formulation	Composition	Rates	Country	N° of Trials / Appl. timings
Flufenacet + pendimethalin co-formulations					
Crystal	EC	60 g/L flufenacet + 300 g/L pendimethalin	4.0 8.0	UK	2 / 4
Malibu	EC	60 g/L flufenacet + 300 g/L pendimethalin	4.0 8.0	CZ DE ES FR HU PL	2 / 4 4 / 8 4 / 8 1 / 2 1 / 2 12 / 16
Trooper	EC	60 g/L flufenacet + 300 g/L pendimethalin	4.0 8.0	FR	6 / 12
Flufenacet reference product					
FOE50% SC	SC	500 g/L flufenacet	0.48 0.96	IT	5 / 10

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

The crop safety of Flufenacet 6% + Pendimethalin 30% EC was assessed in winter cereals in 47 efficacy trials (15 MAR, 16 N-E, 4 S-E and 12 MED) where Flufenacet 6% + Pendimethalin 30% EC was applied at 1.5 L/ha, 2.0 L/ha, 2.5 L/ha and 4.0 L/ha, and in 37 crop safety trials (12 MAR, 12 N-E, 1 S-E and 12 MED) where Flufenacet 6% + Pendimethalin 30% EC was applied at 4.0 L/ha to 8.0 L/ha. In the efficacy- and selectivity trials conducted in winter cereals, Flufenacet 6% + Pendimethalin 30% EC was applied at 2 distinct application timings, i.e. pre-emergence and post-emergence, respectively, and as results from both application timings are included in the summary, a total of 109 applications were assessed in 84 winter cereal trials.

The trials were conducted in the Maritime zone (27; i.e. Germany (8), N-France (7), the Czech Republic (6) and the United Kingdom (6)), the North-east zone (28; i.e. Poland), the South-east zone (5; i.e. Hungary) and the Mediterranean zone (24, i.e. Spain (7), Italy (10) and S-France (7)) in 2015/16 season, 2016/17 season and 2018/19 season, to evaluate the crop safety of Flufenacet 6% + Pendimethalin 30% EC in cereals.

3.4.1.1 Summary and evaluation of winter cereal trials treated pre-emergence

The crop safety of applying Flufenacet 6% + Pendimethalin 30% EC pre-emergence of the crop in winter cereals was evaluated in 18 efficacy trials (7 MAR, 2 N-E, 2 S-E and 7 MED) and 29 crop safety trials (12 MAR, 4 N-E, 1 S-E and 12 MED). The results obtained in two spring-sown barley trials (efficacy) has been included in this section to give additional support to the claims of safe use in wheat and barley.

Winter barley, pre-emergence

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Flufenacet 6% + Pendimethalin 30% EC was applied pre-emergence, at growth stages ranging from BBCH 00 to BBCH 09, at the rate of 1.5 to 8.0 L/ha in barley. 8.0 L/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals, from application and up to harvest (BBCH 89).

Phytotoxicity in barley trials, Maritime EPPO zone

Four efficacy trials and six selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Flufenacet 6% + Pendimethalin 30% EC when applied as recommended in winter barley, i.e. pre-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in three of the four efficacy trials as well as no adverse effects were observed in four of the six selectivity trials conducted in the Maritime EPPO zone.

Adverse effects of the pre-emergence application of Flufenacet 6% + Pendimethalin 30% EC was observed in one French efficacy trial, conducted on the spring-sown variety Irina, as well as two French selectivity trials conducted on the varieties Etincell and Esterel. In all three trials, similar levels of adverse effects were observed for test- as well as reference product. At later assessments, in all trials, the crop had outgrown all symptoms. The national reference product (Celtic) caused similar levels of adverse effects (PHYGEN = 5.0) in 15E HCESHA FR166 at 53 DAA.

The phytotoxicity observed in the Maritime efficacy- and selectivity trials is presented in Table 3.4-4. In the Czech efficacy trial as well as in the Czech selectivity trial, the number of emerged plants was assessed after emergence in the autumn. In the Czech selectivity trial, no significant differences were observed in the number of emerged plants. In the efficacy trial, significantly increased number of emerged plants was observed in plots treated with Flufenacet 6% + Pendimethalin 30% EC at the recommended dose rate. Only where significant differences in emerged plants were observed is included in Table 3.4-4.

Table 3.4-4: Visual assessment of crop phytotoxicity in barley treated with Flufenacet 6% + Pendimethalin 30% EC and reference products in efficacy- and selectivity trials (maximum crop phytotoxicity observed) as well as relationship to yield (t/ha in untreated and % relative to untreated in treated columns (Untreated = 100%).

Trial number	Variety	Ass. date DAA	UTC	Max. phytotoxicity [%]				Type of phytotoxicity
				Flufenacet 6% + Pendimethalin 30% EC		Flufenacet + pendimethalin Ref. Prod.		
				2.5 L/ha	4.0 L/ha	2.5 L/ha	4.0 L/ha	Symptom
Efficacy trials								
15E HCESHA FR166	Irina	53	0.0	4.8	10.0	8.0	6.8	PHYGEN (%)
SWEPL-CZ...-KUJ10	Jup	29	90.6	95.7	96.0	96.2	93.2	EMERG (no.)
Trial number	Variety	Ass. date DAA	UTC	Max. phytotoxicity [%]				Type of phytotoxicity
				Flufenacet 6% + Pendimethalin 30% EC		Flufenacet + pendimethalin Ref. Prod.		
				4.0 L/ha	8.0 L/ha	4.0 L/ha	8.0 L/ha	Symptom
Selectivity trials								
15E HCESHA FR178	Etincell	28	10.0	10.0	9.8	10.0	9.9	VIGOR (0-10)
		234	9.3	102	94	97	93	Yield (% rel.)
15E HCESHA FR177	Esterel	172	0.0	0.5	5.5	1.0	2.3	PHYGEN (%)
		172	10.0	10.0	9.0	10.0	10.0	VIGOR (%)
		251	8.1	105	88	86	94	Yield (% rel.)

Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Phytotoxicity in barley trials, North-east EPPO zone

One efficacy trial and two selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Flufenacet 6% + Pendimethalin 30% EC when applied as recommended in winter barley, i.e. pre-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the Polish efficacy trials as well as no adverse effects were observed in either of the two selectivity trials conducted in the North-east EPPO zone.

The Polish selectivity trials conducted in winter barley were not harvested.

Phytotoxicity in winter barley trials, Mediterranean EPPO zone

Four efficacy trials and seven selectivity trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Flufenacet 6% + Pendimethalin 30% EC when applied as recommended in winter barley, i.e. pre-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in three of the four efficacy trials as well as no adverse effects were observed in six of the seven selectivity trials conducted in the Mediterranean EPPO zone.

Adverse effects of the pre-emergence application of Flufenacet 6% + Pendimethalin 30% EC were observed in one French efficacy trial, conducted on the spring-sown variety Beatrix, as well as one French selectivity trial conducted on the variety Irina. In both trials, similar levels of adverse effects were observed for test- as well as reference product. At later assessments, in all trials, the crop had outgrown all symptoms. In the French efficacy trial, the national reference product (Celtic) caused similar levels of adverse effects (PHYGEN = 8.8 and PHYTHI = 17.5) in 15E HCESHA FR165 at 54 DAA. In the Spanish efficacy trial, the national reference product Picomax caused chlorosis (PHYGEN = 15%, with chlorosis on 90% of leaf surface) at the first assessment (36 DAA). As mentioned above, Flufenacet 6% + Pendimethalin 30% EC did not cause any adverse effects in this trial.

The phytotoxicity observed in the French efficacy trial as well as the French selectivity trial is presented in Table 3.4-5. In neither of the 11 trials conducted in the Mediterranean EPPO zone with Flufenacet 6% + Pendimethalin 30% EC, the number of emerged plants were counted.

Table 3.4-5: Visual assessment of crop phytotoxicity in barley treated with Flufenacet 6% + Pendimethalin 30% EC and reference products in efficacy- and selectivity trials (maximum crop phytotoxicity observed) as well as relationship to yield (t/ha in untreated and % relative to untreated in treated columns (Untreated = 100%).

Trial number	Variety	Ass. date DAA	UTC	Max. phytotoxicity [%]				Type of phytotoxicity
				Flufenacet 6% + Pendimethalin 30% EC		Flufenacet + pendimethalin Ref. Prod.		
				2.5 L/ha	4.0 L/ha	2.5 L/ha	4.0 L/ha	Symptom
Efficacy trials								
15E HCESHA FR165	Beatrix	54	0.0	7.5	12.5	13.8	16.3	PHYGEN (%)
		54	0.0	25.0	27.5	21.3	25.0	PHYTHI (%)
Trial number	Variety	Ass. date DAA	UTC	Max. phytotoxicity [%]				Type of phytotoxicity
				Flufenacet 6% + Pendimethalin 30% EC		Flufenacet + pendimethalin Ref. Prod.		
				4.0 L/ha	8.0 L/ha	4.0 L/ha	8.0 L/ha	Symptom
Selectivity trials								
15E HCESHA FR179	Irina	42	0.0	5.0	7.5	3.8	11.3	PHYGEN (%)
		42	8.5	7.5	6.8	7.3	6.5	VIGOR (%)
		146	6.8	119	115	108	115	Yield (% rel.)

Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Winter wheat, pre-emergence

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Flufenacet 6% + Pendimethalin 30% EC was applied pre-emergence, at growth stages ranging from BBCH 00 to BBCH 09, at the rate of 1.5 to 8.0 L/ha in winter wheat. 8.0 L/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals, from application and up to harvest (BBCH 89).

Phytotoxicity in winter wheat trials, Maritime EPPO zone

Three efficacy trials and six selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Flufenacet 6% + Pendimethalin 30% EC when applied as recommended in winter wheat, i.e. pre-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the three efficacy trials as well as no adverse effects were observed in four of the six selectivity trials conducted in the Maritime EPPO zone.

Adverse effects of the pre-emergence application of Flufenacet 6% + Pendimethalin 30% EC was observed in two French selectivity trials conducted on the varieties Hywin and Matheo. In both trials, similar levels of adverse effects were observed for test- as well as reference product. At later assessments, in all trials, the crop had outgrown all symptoms.

The phytotoxicity observed in the Maritime selectivity trials is presented in Table 3.4-6. In the Czech efficacy trial, the number of emerged plants was assessed after emergence in the autumn. No significant differences were observed in the number of emerged plants. Only where significant differences in emerged plants were observed is included in Table 3.4-6.

Table 3.4-6: Visual assessment of crop phytotoxicity in winter wheat treated with Flufenacet 6% + Pendimethalin 30% EC and reference products in selectivity trials (maximum crop phytotoxicity observed) as well as relationship to yield (t/ha in untreated and % relative to untreated in treated columns (Untreated = 100%).

Trial number	Variety	Ass. date DAA	UTC -	Max. phytotoxicity [%]				Type of phyto- toxicity
				Flufenacet 6% + Pendimethalin 30% EC		Flufenacet + pendimethalin Ref. Prod.		
				4.0 L/ha	8.0 L/ha	4.0 L/ha	8.0 L/ha	Symptom
Selectivity trials								
15E HCESHA FR173	Hywin	172	0.0	0.5	2.3	1.0	3.5	PHYGEN (%)
		273	7.3	99	99	100	98	Yield (% rel.)
15E HCESHA FR174	Matheo	34	0.0	4.5	10.0	4.5	9.3	PHYGEN (%)
		27	8.0	7.0	6.5	7.0	6.8	VIGOR (%)
		276	8.1	96	88	97	91	Yield (% rel.)

Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Phytotoxicity in winter wheat trials, North-east EPPO zone

A total of one efficacy trial and two selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Flufenacet 6% + Pendimethalin 30% EC when applied as recommended in winter wheat, i.e. pre-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the Polish efficacy trial as well as no adverse effects were observed in either of the two selectivity trials conducted in the North-east EPPO zone. Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Phytotoxicity in winter wheat trials, South-east EPPO zone

A total of two efficacy trials and one selectivity trial were conducted in the South-east EPPO zone to assess the crop safety of Flufenacet 6% + Pendimethalin 30% EC when applied as recommended in winter wheat, i.e. pre-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in either of the two efficacy trials as well as no adverse effects were observed in the Hungarian selectivity trial. Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Phytotoxicity in winter wheat trials, Mediterranean EPPO zone

Three efficacy trials and five selectivity trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Flufenacet 6% + Pendimethalin 30% EC when applied as recommended in winter wheat, i.e. pre-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in one of the three efficacy trials as well as no adverse effects were observed in three of the five selectivity trials conducted in the Mediterranean EPPO zone.

Adverse effects following the pre-emergence application of Flufenacet 6% + Pendimethalin 30% EC was observed in one Italian efficacy trial, conducted on the durum wheat variety Cesare. Furthermore, adverse effects were also observed in a French trial conducted on the “soft” winter wheat variety Rebelde, as well as one Italian selectivity trial conducted on the durum wheat variety Babylone. In all three trials, similar levels of adverse effects were observed for test- as well as reference product. At later assessments, in all three trials, the crop had outgrown all symptoms.

The phytotoxicity observed in the Italian efficacy trial as well as the French and Italian selectivity trials is presented in Table 3.4-7. In neither of the eight trials conducted in the Mediterranean EPPO zone with Flufenacet 6% + Pendimethalin 30% EC, the number of emerged plants were counted.

Table 3.4-7: Visual assessment of crop phytotoxicity in winter wheat treated with Flufenacet 6% + Pendimethalin 30% EC and reference products in efficacy- and selectivity trials (maximum crop phytotoxicity observed) as well as relationship to yield (t/ha in untreated and % relative to untreated in treated columns (Untreated = 100%).

Trial number	Variety	Ass. date DAA	UTC	Max. phytotoxicity [%]				Type of phytotoxicity
				Flufenacet 6% + Pendimethalin 30% EC		Flufenacet + pendimethalin Ref. Prod.		
				2.5 L/ha	4.0 L/ha	2.5 L/ha	4.0 L/ha	Symptom
Efficacy trials								
952.H.SAG15/e	Cesare (TRZDU)	146	0.0	4.3	4.8	3.5	4.8	PHYDIS (%)
		146	0.0	8.0	9.8	6.8	9.8	PHYGEN (%)
		146	0.0	4.5	4.8	3.8	4.8	PHYSTU (%)
		146	100.0	91.0	90.0	92.0	90.0	VIGOR (%)
Trial number	Variety	Ass. date DAA	UTC	Max. phytotoxicity [%]				Type of phytotoxicity
				Flufenacet 6% + Pendimethalin 30% EC		Flufenacet + pendimethalin Ref. Prod.		
				4.0 L/ha	8.0 L/ha	4.0 L/ha	8.0 L/ha	Symptom
Selectivity trials								
15E HCESHA FR171	Babylone (TRZDU)	110	0.0	25.0	75.0	26.3	77.5	PHYGEN (%)
		110	0.0	28.8	85.0	32.5	77.5	PHYDEL (%)
		110	0.0	21.3	27.5	20.0	32.5	PHYTHI (%)
		110	10.0	7.8	1.3	8.3	1.5	VIGOR (0-10)
		247	6.3	97	83	93	84	Yield (% rel.)
			UTC			Flufenacet Ref. Prod.		
			-	4.0 L/ha	8.0 L/ha	0.48 L/ha	0.96 L/ha	Symptom
956.S.SAG15/e	Rebelde (TRZAW)	128	0.0	0.0	1.0	0.0	1.0	PHYGEN (0-10)
		128	0.0	0.0	1.3	0.0	1.0	PHYSTU (0-10)
		128	10.0	10.0	9.0	10.0	9.0	VIGOR (0-10)
		227	4.7	94	89	96	85	Yield (% rel.)

Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

3.4.1.2 Summary and evaluation of winter cereal trials treated post-emergence

The crop safety of applying Flufenacet 6% + Pendimethalin 30% EC post-emergence of the crop in winter cereals was evaluated in 29 efficacy trials (8 MAR, 14 N-E, 2 S-E and 5 MED) and 37 crop safety trials (12 MAR, 12 N-E, 1 S-E and 12 MED).

Winter barley, post-emergence

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Flufenacet 6% + Pendimethalin 30% EC was applied post-emergence, at growth stages ranging from BBCH 10 to BBCH 23, at the rate of 1.5 to 8.0 L/ha in barley. 8.0 L/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals, from application and up to harvest (BBCH 89).

Phytotoxicity in winter barley trials, Maritime EPPO zone

Four efficacy trials and six selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Flufenacet 6% + Pendimethalin 30% EC when applied as recommended in winter barley, i.e. early post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the four efficacy trials as well as no adverse effects were observed in three of the six selectivity trials conducted in the Maritime EPPO zone.

Adverse effects of the post-emergence application of Flufenacet 6% + Pendimethalin 30% EC was observed in three selectivity trials conducted on the varieties Tonic, Etincell and Esterel in Germany and 2 x France, respectively. In all three trials, similar levels of adverse effects were observed for test- as well as reference product. At later assessments, in all trials, the crop had outgrown all symptoms.

The phytotoxicity observed in the Maritime selectivity trials is presented in Table 3.4-8. In neither of the 10 trials conducted in the Maritime EPPO zone with Flufenacet 6% + Pendimethalin 30% EC, the number of emerged plants were counted.

Table 3.4-8: Visual assessment of crop phytotoxicity in winter barley treated with Flufenacet 6% + Pendimethalin 30% EC and reference products in selectivity trials (maximum crop phytotoxicity observed) as well as relationship to yield in selectivity trials (t/ha in untreated and % relative to untreated in treated columns (Untreated = 100%).

Trial number	Variety	Ass. date DAA	UTC -	Max. phytotoxicity [%]				Type of phyto- toxicity
				Flufenacet 6% + Pendimethalin 30% EC		Flufenacet + pendimethalin Ref. Prod.		
				4.0 L/ha	8.0 L/ha	4.0 L/ha	8.0 L/ha	Symptom
Selectivity trials								
Sharda16-023	Tonic	15	-	0.0	10.3	0.0	10.0	PHYCHL (%)
		15	-	0.0	20.8	0.0	20.0	PHYDEP (%)
		15	100.0	100.0	90.0	100.0	90.0	VIGOR (0-10)
		259	9.2	99	89	93	92	Yield (% rel.)
15E HCESHA FR178	Etincell	15	0.0	0.0	2.3	0.0	3.0	PHYCHL (%)
		15	0.0	0.0	3.8	0.0	5.0	PHYGEN (%)
		15	10.0	10.0	10.0	10.0	10.0	VIGOR (0-10)
		214	9.3	95	97	98	95	Yield (% rel.)
15E HCESHA FR177	Esterel	153	0.0	1.0	9.8	1.3	7.3	PHYGEN (%)
		153	10.0	10.0	8.8	10.0	9.3	VIGOR (%)
		232	8.1	87	92	99	93	Yield (% rel.)

Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Phytotoxicity in barley trials, North-east EPPO zone

One efficacy trial and two selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Flufenacet 6% + Pendimethalin 30% EC when applied as recommended in winter barley, i.e. early post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the Polish efficacy trials as well as no adverse effects were observed in either of the two selectivity trials conducted in the North-east EPPO zone. Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Phytotoxicity in winter barley trials, Mediterranean EPPO zone

Three efficacy trials and seven selectivity trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Flufenacet 6% + Pendimethalin 30% EC when applied as recommended in winter barley, i.e. early post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in two of the three efficacy trials as well as no adverse effects were observed in five of the seven selectivity trials conducted in the Mediterranean EPPO zone.

Adverse effects of the post-emergence application of Flufenacet 6% + Pendimethalin 30% EC was observed in one Italian efficacy trial, conducted on the variety Cometa, as well as two selectivity trials conducted on the varieties Volano and Irina in Italy and France, respectively. In all three trials, similar levels of adverse effects were observed for test- as well as reference product. At later assessments, in all trials, the crop had outgrown all symptoms. In a Spanish efficacy trial, the national reference product Picomax caused chlorosis (PHYGEN = 15%, with chlorosis on 90% of leaf surface) at the first assessment (14 DAA). As mentioned above, Flufenacet 6% + Pendimethalin 30% EC did not cause any adverse effects in this trial.

The phytotoxicity observed in the Italian efficacy trial as well as the Italian and French selectivity trials is presented in Table 3.4-9. In neither of the 10 trials conducted in the Mediterranean EPPO zone with Flufenacet 6% + Pendimethalin 30% EC, the number of emerged plants were counted.

Table 3.4-9: Visual assessment of crop phytotoxicity in winter barley treated with Flufenacet 6% + Pendimethalin 30% EC and reference products in efficacy- and selectivity trials (maximum crop phytotoxicity observed) as well as relationship to yield in selectivity trials (t/ha in untreated and % relative to untreated in treated columns (Untreated = 100%).

Trial number	Variety	Ass. date DAA	UTC	Max. phytotoxicity [%]				Type of phytotoxicity
				Flufenacet 6% + Pendimethalin 30% EC		Flufenacet + pendimethalin Ref. Prod.		
				2.5 L/ha	4.0 L/ha	2.5 L/ha	4.0 L/ha	Symptom
Efficacy trials								
955.H.SAG15/e	Cometa	14	0.0	0.0	1.3	0.0	0.0	YELLOW (%)
		14	100.0	100.0	97.8	100.0	100.0	VIGOR (%)
		88	0.0	1.8	4.8	0.0	2.0	PHYTHI (%)
Trial number	Variety	Ass. date DAA	UTC	Max. phytotoxicity [%]				Type of phytotoxicity
				Flufenacet 6% + Pendimethalin 30% EC		Flufenacet + pendimethalin Ref. Prod.		
				4.0 L/ha	8.0 L/ha	4.0 L/ha	8.0 L/ha	Symptom
Selectivity trials								
15E HCESHA FR179	Irina	14	0.0	1.3	2.5	0.0	2.5	PHYGEN (%)
		27	8.5	8.3	8.0	8.3	7.8	VIGOR (0-10)
		131	6.8	104	106	108	97	Yield (%) rel.)
			UTC			Flufenacet Ref. Prod.		Symptom
			-	4.0 L/ha	8.0 L/ha	0.48 L/ha	0.96 L/ha	
960.S.SAG15/e	Volano	29	0.0	0.0	5.0	0.0	0.0	PHYGEN (%)
		140	6.3	99	99	99	102	Yield (%) rel.)

Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Winter wheat, post-emergence

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Flufenacet 6% + Pendimethalin 30% EC was applied post-emergence, at growth stages ranging from BBCH 10 to BBCH 25, at the rate of 1.5 to 8.0 L/ha in winter wheat. 8.0 L/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals, from application and up to harvest (BBCH 89).

Phytotoxicity in winter wheat trials, Maritime EPPO zone

Four efficacy trials and six selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Flufenacet 6% + Pendimethalin 30% EC when applied as recommended in winter wheat, i.e. early post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the four efficacy trials as well as no adverse effects were observed in four of the six selectivity trials conducted in the Maritime EPPO zone.

Adverse effects of the post-emergence application of Flufenacet 6% + Pendimethalin 30% EC was observed in two French selectivity trials conducted on the varieties Hywin and Matheo. In both trials, similar levels of adverse effects were observed for test- as well as reference product. In both trials, the highest level of adverse effects was observed at the last assessment timing reported, in the spring. In the Matheo trial, test- as well as reference product caused significantly reduced yield in the overlapping dose rate whereas in the Hywin trial, no statistical differences were observed between treated and untreated plots in regards to harvest.

The phytotoxicity observed in the French selectivity trials is presented in Table 3.4-10. In neither of the 10 trials conducted in the Maritime EPPO zone with Flufenacet 6% + Pendimethalin 30% EC, the number of emerged plants were counted.

Table 3.4-10: Visual assessment of crop phytotoxicity in winter wheat treated with Flufenacet 6% + Pendimethalin 30% EC and reference products in selectivity trials (maximum crop phytotoxicity observed) as well as relationship to yield in selectivity trials (t/ha in untreated and % relative to untreated in treated columns (Untreated = 100%).

Trial number	Variety	Ass. date DAA	UTC	Max. phytotoxicity [%]				Type of phytotoxicity
				Flufenacet 6% + Pendimethalin 30% EC		Flufenacet + pendimethalin Ref. Prod.		
				4.0 L/ha	8.0 L/ha	4.0 L/ha	8.0 L/ha	Symptom
Selectivity trials								
15E HCESHA FR173	Hywin	133	0.0	0.0	0.5	0.0	0.5	PHYGEN (%)
		234	7.3	101	100	101	100	Yield (% rel.)
15E HCESHA FR174	Matheo	162	0.0	0.0	7.8	0.0	6.5	PHYGEN (%)
		162	7.0	7.0	6.3	7.0	6.0	VIGOR (%)
		256	8.1	97	92	101	93	Yield (% rel.)

In the remaining trials, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Phytotoxicity in winter wheat trials, North-east EPPO zone

A total of 7 efficacy trial and 6 selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Flufenacet 6% + Pendimethalin 30% EC when applied as recommended in winter wheat, i.e. early post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the Polish efficacy trials as well as no adverse effects were observed in either of the 6 selectivity trials conducted in the North-east EPPO zone. Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Phytotoxicity in winter wheat trials, South-east EPPO zone

A total of two efficacy trials and one selectivity trial were conducted in the South-east EPPO zone to assess the crop safety of Flufenacet 6% + Pendimethalin 30% EC when applied as recommended in winter wheat, i.e. early post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in either of the two efficacy trials treated with Flufenacet 6% + Pendimethalin 30% EC in the South-east EPPO zone.

Adverse effects of the post-emergence application of Flufenacet 6% + Pendimethalin 30% EC was observed in the Hungarian selectivity trial conducted on the variety GK Csillag. In this trial, only the test product caused adverse effects at the first assessment timing after application in the autumn. At later assessments, in the spring, the crop had outgrown all symptoms.

The phytotoxicity observed in the Hungarian selectivity trial is presented in Table 3.4-11. In neither of the three trials conducted in the South-east EPPO zone with Flufenacet 6% + Pendimethalin 30% EC, the number of emerged plants were counted.

Table 3.4-11: Visual assessment of crop phytotoxicity in winter wheat treated with Flufenacet 6% + Pendimethalin 30% EC and reference products in selectivity trials (maximum crop phytotoxicity observed) as well as relationship to yield in selectivity trials (t/ha in untreated and % relative to untreated in treated columns (Untreated = 100%).

Trial number	Variety	Ass. date DAA	UTC	Max. phytotoxicity [%]				Type of phytotoxicity
				Flufenacet 6% + Pendimethalin 30% EC		Flufenacet + pendimethalin Ref. Prod.		
				4.0 L/ha	8.0 L/ha	4.0 L/ha	8.0 L/ha	Symptom
Selectivity trials								
SRHU15-558-034HE	GK Csillag	14	0.0	4.5	6.0	0.0	0.0	PHYCHL (%)
		14	0.0	1.5	2.5	0.0	0.0	PHYGEN (%)
		14	100.0	100.0	100.0	100.0	100.0	VIGOR (%)
		213	5.0	101	101	100	101	Yield (% rel.)

Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Phytotoxicity in winter wheat trials, Mediterranean EPPO zone

Two efficacy trials and five selectivity trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Flufenacet 6% + Pendimethalin 30% EC when applied as recommended in winter wheat, i.e. early post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in either of the two efficacy trials as well as no adverse effects were observed in two of the five selectivity trials conducted in the Mediterranean EPPO zone.

Adverse effects following the post-emergence application of Flufenacet 6% + Pendimethalin 30% EC at overlapping dose rate only was observed in three selectivity trials, i.e. one French trial conducted on the durum wheat variety Babylone, as well as two Italian selectivity trials conducted on the “soft” winter wheat varieties Rebelde and Bologna. In the French durum wheat trial, similar levels of adverse effects were observed for the test product as well as the flufenacet + pendimethalin reference product (Malibu). Significantly reduced yield was obtained from Flufenacet 6% + Pendimethalin 30% EC applied at the 4.0 L/ha rate and at the overlapping dose rate (8.0 L/ha), the reduction in yield was higher. In one of the Ital-

ian trials, Flufenacet 6% + Pendimethalin 30% EC caused slight adverse effects (PHYGEN) in the 8.0 L/ha treatment whereas none were observed in the plots treated with the flufenacet reference product (FOE50% SC). In this trial, increased yield (non-significant) was obtained from treated crops, compared to untreated. In the other Italian trial, the flufenacet straight reference product caused more severe adverse effects (PHYGEN, as PHYSTU, PHYCHL and reduced vigour) than was observed in the plots treated with the test product at the 8.0 L/ha rate. In the Rebelde trial, test- as well as reference product caused significantly reduced yield in the overlapping dose rate. In the two French trials, the crop had outgrown all symptoms at last assessment, whereas in the French durum wheat trial, the highest level of adverse effects was observed at the last assessment timing reported, in the spring (98 DAA (March 15th)).

The phytotoxicity observed in the Mediterranean selectivity trials is presented in Table 3.4-12. In neither of the seven trials conducted in the Mediterranean EPPO zone with Flufenacet 6% + Pendimethalin 30% EC, the number of emerged plants were counted.

Table 3.4-12: Visual assessment of crop phytotoxicity in winter wheat treated with Flufenacet 6% + Pendimethalin 30% EC and reference products in selectivity trials (maximum crop phytotoxicity observed) as well as relationship to yield in selectivity trials (t/ha in untreated and % relative to untreated in treated columns (Untreated = 100%).

Trial number	Variety	Ass. date DAA	UTC	Max. phytotoxicity [%]				Type of phytotoxicity
				Flufenacet 6% + Pendimethalin 30% EC		Flufenacet + pendimethalin Ref. Prod.		
				4.0 L/ha	8.0 L/ha	4.0 L/ha	8.0 L/ha	Symptom
Selectivity trials								
15E HCESHA FR171	Babylone (TRZDU)	98	0.0	42.5	80.0	50.0	77.5	PHYGEN (%)
		98	0.0	47.5	87.5	45.0	77.5	PHYDEL (%)
		98	0.0	22.5	35.0	27.5	22.5	PHYTHI (%)
		98	10.0	5.0	1.0	3.0	1.3	VIGOR (0-10)
		247	6.3	91	89	95	83	Yield (% rel.)
			UTC			Flufenacet Ref. Prod.		
			-	4.0 L/ha	8.0 L/ha	0.48 L/ha	0.96 L/ha	Symptom
957.S.SAG15/e	Bologna (TRZAW)	31	0.0	0.0	5.0	0.0	0.0	PHYGEN (%)
		221	4.0	117	101	111	118	Yield (% rel.)
956.S.SAG15/e	Rebelde (TRZAW)	65	0.0	0.0	1.0	0.0	0.0	PHYGEN (0-10)
		65	0.0	0.0	1.0	0.0	2.8	PHYSTU (0-10)
		65	0.0	0.0	1.0	0.0	3.5	PHYCHL (0-10)
		65	10.0	10.0	9.0	10.0	7.5	VIGOR (0-10)
		164	4.7	96	81	96	81	Yield (% rel.)

In the remaining two (Spanish) trials harvested, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Triticale, post-emergence

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Flufenacet 6% + Pendimethalin 30% EC was applied post-emergence, at growth stages ranging from BBCH 10 to BBCH 25, at the rate of 1.5 to 8.0 L/ha in winter triticale. 8.0 L/ha corresponds to 200% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals, from application and up to harvest (BBCH 89).

Phytotoxicity in winter triticale trials, North-east EPPO zone

A total of 6 efficacy trial and 4 selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Flufenacet 6% + Pendimethalin 30% EC when applied as recommended in winter triticale, i.e. early post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the Polish efficacy trials as well as no adverse effects were observed in either of the 4 selectivity trials conducted in the North-east EPPO zone.

Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

3.4.1.3 Overall conclusion

Winter cereals are claimed on the label. The claims of crop safety on cereals are supported with a total of 84 trials conducted in Germany, Czech Republic, England, France, Poland, Hungary, Spain and Italy in 2015/16 to 2018/19 season. In all trials, Flufenacet 6% + Pendimethalin 30% EC proved to be crop safe and in the vast majority of the trials did not significantly affect the crop adversely when applied at a range of growth stages within and occasionally beyond the label recommended range, at the maximum proposed label recommended rates of 4.0 L/ha in autumn- and winter-sown cereals. The same was observed in the treatments where Flufenacet 6% + Pendimethalin 30% EC was applied at twice the recommended rate, representative of sprayer overlap.

Pre- and post-emergence application in winter cereals are claimed on the label. For crops and recommendation claimed on the label not supported with trials, the applicant wishes to bridge to the trials conducted in autumn to early spring sown cereals where pre- and post-emergence applications were tested. This BAD also clearly demonstrates that the efficacy and crop safety of Flufenacet 6% + Pendimethalin 30% EC is equivalent to the standard flufenacet + pendimethalin co-formulation to which it was compared in 79 of the 84 trials. The applicant therefore wishes to cite the original registrant's data on flufenacet and pendimethalin now out of protection in additional support of any recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal evaluator extrapolate from those data.

Table 3.4-13: Phytotoxicity of product, efficacy trials

Number of trials with...		Efficacy trials (43 trials)			
		Test product		Standard	
		2.5 L/ha	4.0 L/ha	1N	1.6N
Maximum of phytotoxicity recorded during the trials	0% to 5%	26 / 27	25 / 28	25 / 28	13 / 15
	>5% to 10%	2 / 0	2 / 0	2 / 0	2 / 0
	>10% to 15%	0 / 0	1 / 0	1 / 0	0 / 0
	>15 %	0 / 0	0 / 0	0 / 0	1 / 0
Level of symptoms at the last assessments	0% to 5%	27 / 27	27 / 27	27 / 27	23 / 23
	>5% to 10%	0 / 0	1 / 0	1 / 0	1 / 0
	>10% to 15%	0 / 0	0 / 0	0 / 0	0 / 0
	>15 %	0 / 0	0 / 0	0 / 0	0 / 0

Pre-emergence / Post-emergence

Table 3.4-14: Phytotoxicity of product, selectivity trials

Number of trials with...		Selectivity trials (33 trials)			
		Test product		Standard	
		4.0 L/ha	8.0 L/ha	1.6N	3.2N
Maximum of phytotoxicity recorded during the trials	0% to 5%	32 / 32	28 / 28	32 / 32	21 / 20
	>5% to 10%	0 / 0	4 / 3	0 / 0	2 / 2
	>10% to 15%	0 / 0	0 / 0	0 / 0	1 / 0
	>15 %	1 / 1	1 / 2	1 / 1	1 / 3

Number of trials with...		Selectivity trials (33 trials)			
		Test product		Standard	
		4.0 L/ha	8.0 L/ha	1.6N	3.2N
Level of symptoms at the last assessments	0% to 5%	32 / 32	30 / 30	32 / 32	23 / 22
	>5% to 10%	0 / 0	2 / 2	0 / 0	1 / 2
	>10% to 15%	0 / 0	0 / 0	0 / 0	0 / 0
	>15 %	1 / 1	1 / 1	1 / 1	1 / 1

Pre-emergence / Post-emergence

Comments of zRMS:	<p>The selectivity tests about herbicide Konark (product code: SHA 2619 A) have been carried out in accordance with appropriate EPPO Guidelines. The conduct of the field work is principally compliant with “Good Agricultural Practice “and in accordance with EPPO-Guidelines PP 1/135 (4).</p> <p>Selectivity studies on herbicide were performed by companies authorized to conduct studies on efficacy of plant protection products. The trials were performed with the use of different agricultural practice. The trials were performed with the use of cultivars, differing in growth strength as well as soil and water requirements. The appropriate experimental design was applied. The herbicide has been used in two doses: N and 2N. In all trials studied product was compared to the standard reference products.</p> <p>Applicant in total submitted 37 selectivity trials: MAR – 12 trials (FR-4, DE-4, CZ-2, UK-2), N-E – 12 trials (PL), S-E – 1 trial (HU) and MED – 12 trials (ES-4, IT-6, FR-2). Trials were performed on winter wheat (17 trials), durum wheat (1 trial), winter barley (15 trials) and winter triticale (4 trials).</p> <ul style="list-style-type: none"> • HORVW: MAR-6 trials (DE-2, CZ-1, FR-2, UK-1); MED-7 trials (FR-1, ES-2, IT-4) and N-E-2 trials (PL). Lack of trials from S-E. • TRZAW: MAR-6 trials (DE-2, CZ-1, FR-2, UK-1); MED-4 trials (ES-2, IT-2); S-E-1 trial (HU) and N-E-6 trials (PL) • TRZDU: MED-1 trial (FR). Lack of trials from N-E, S-E and MAR. • TTLWI: N-E-4 trials (PL). Lack of triald from MED, MAR and S-E. <p>For pre-emergence use Applicant submitted in total 29 selectivity trials carried out on winter barley (MAR: 6 trials, N-E: 2 trials, MED: 7 trials) and winter wheat (MAR: 6 trials, N-E: 2 trials, S-E: 1 trial, MED: 5 trials).</p> <p>For post-emergence use Applicant submitted in total 37 selelctivity trials carried out on winter barley (MAR: 6 trials, N-E: 2 trials, MED: 7 trials), winter wheat (MAR: 6 trials, N-E: 6 trials, S-E: 1 trial, MED: 5 trials) and winter triticale (N-E: 4 trials).</p> <p>For Poland (N-E), Applicant submitted enough number of selectivity trials for post-emergence use on winter triticale, winter wheat and winter barley. Lack of trials for winter rye. Extrapolating of phytotoxicity results in Poland between ce-reals is not allowed.</p> <p>Pre-emergence use in Poland: only for winter wheat and winter barley Applicant submitted acceptable number of selectivity trials for Poland. Lack of trials for winter triticale and winter rye (at least 4-5 selectivity trials should be submitted).</p> <p>The decisions whether each of proposed crop is supported by enough trials considering their importance and possibilities of data extrapolation between</p>
-------------------	---

	<p>EPPO zones is left to each of cMS.</p> <p>Based on the results, it is reasonable to conclude that a single application of Konark at the proposed label rate of 4,0 L product/ha, and applied according to label recommendations, is crop safe on studied crops. However, in the label should be put an entry about sensitivity of some varieties of cereals (some phytotoxicity effect was observed in few trials. In the opinion of Evaluator, sensitivity varieties can be for example: durum wheat variety Cesare and Babylone, “soft” winter wheat varieties Rebelde, Bologna, Hywin and Matheo winter wheat variety GK Csillag, winter barley variety Beatrix, Etincell and Esterel, Cometa, Volano and Irina.</p>
--	---

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

35 selectivity trials were conducted between autumn 2015 to summer 2019 to evaluate the effect of Flufenacet 6% + Pendimethalin 30% EC on yield of winter cereals. Two Polish selectivity trials were not harvested due to the poor condition of the crop. In selectivity trials conducted in winter cereals, Flufenacet 6% + Pendimethalin 30% EC was applied at 2 distinct application timings, i.e. pre-emergence and post-emergence, respectively, and as results from both application timings are included in the summary, a total of 62 applications were assessed in 35 selectivity trials.

Flufenacet 6% + Pendimethalin 30% EC was applied on winter cereals in the autumn or early spring (35, i.e. winter wheat (17), winter durum wheat (1), winter barley (13) and triticale (4)) at pre-emergence (i.e. BBCH 00-09) or early post-emergence (i.e. BBCH 10-25). All trials conducted on cereals presented in this Biological Assessment Dossier were located within the Maritime zone (12), the North-east zone (10), the South-East zone (1) and the Mediterranean zone (12), as defined by EPPO Standard PP1/241(1).

3.4.2.1 Summary and evaluation of crop yield from winter cereal field trials treated pre-emergence in the autumn

A summary of the mean yield assessments expressed as %-relative of the untreated, from winter cereal trials treated with pre-emergence applications in the autumn to late winter in the Maritime, the North-east, the South-east and the Mediterranean EPPO zone, are presented in Table 3.4-15.

Winter barley (HORVW)

Thirteen selectivity trials conducted in winter barley were harvested. The trials were conducted in Germany (2), Czech Republic (1), United Kingdom (1), N-France (2), S-France (1), Spain (2) and Italy (4) in 2015/16 and 2016/17. In these trials, Flufenacet 6% + Pendimethalin 30% EC was applied pre-emergence at 4.0 L/ha (i.e. 240 g flufenacet and 1200 g pendimethalin per hectare) and 8.0 L/ha (i.e. 480 g flufenacet and 2400 g pendimethalin per hectare). The trials were sprayed when the majority of the crop was at growth stages ranging between BBCH 00 and BBCH 07 (range: BBCH 00-09).

The harvest results obtained in the thirteen trials demonstrate that Flufenacet 6% + Pendimethalin 30% EC did not significantly affected the yield of winter barley (Table 3.4-15) when applied at the recommended dose rate (4.0 L/ha) or the overlapping dose rate (8.0 L/ha), in the vast majority of the thirteen trials. In one Italian trial, two hailstorms in May and June affected the crop and the results should therefore be used with caution. In the report, it was concluded that the statistical difference observed in the trial could not be linked to treatments. In the trials, Flufenacet 6% + Pendimethalin 30% EC performed like the reference products. The results obtained in these trials supports the label claim that Flufenacet 6% + Pendimethalin 30% EC is safe to be applied pre-emergence at the recommended dose rate in winter barley at the recommended application interval.

Winter wheat (TRZAW)

Thirteen selectivity trials conducted in winter wheat were harvested. The trials were conducted in Germany (2), N-France (2), United Kingdom (1), Czech Republic (1), Poland (2), Hungary (1), Spain (2) and Italy (2) in 2015/16 and 2016/17. In these trials, Flufenacet 6% + Pendimethalin 30% EC was applied pre-emergence at 4.0 L/ha (i.e. 240 g flufenacet and 1200 g pendimethalin per hectare) and 8.0 L/ha (i.e. 480 g flufenacet and 2400 g pendimethalin per hectare). The trials were sprayed when the majority of the crop was at growth stages ranging between BBCH 00 and BBCH 07.

The harvest results obtained in the thirteen trials demonstrate that Flufenacet 6% + Pendimethalin 30% EC did not significantly affected the yield of winter wheat (Table 3.4-15) when applied at the recommended dose rate (4.0 L/ha) or the overlapping dose rate (8.0 L/ha) in the vast majority of the thirteen trials. In one French trial, where PHYGEN of up to 10% as well as some minor reductions of vigour was observed in the 8.0 L/ha dose rate, a significant reduction in yield in 2n dose rate was observed. The same was observed in the plots treated with the flufenacet + pendimethalin reference product at 8.0 L/ha. In an Italian trial, the flufenacet reference product applied at 0.96 L/ha caused a significant reduction in yield. In the remaining 11 trials, Flufenacet 6% + Pendimethalin 30% EC performed like the reference products. The results obtained in these trials supports the label claim that Flufenacet 6% + Pendimethalin 30% EC is safe to be applied pre-emergence at the recommended dose rate in winter wheat at the recommended application interval.

Table 3.4-15: Maritime, North-east, South-east and Mediterranean zone – Crop yield (t/ha) of winter barley, winter wheat and winter durum wheat treated with Flufenacet 6% + Pendimethalin 30% EC, single application pre- or post-emergence in autumn or late winter, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Flufenacet 6% + Pendimethalin 30% EC at:		National Ref. prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	4.0 L/ha [240+1200 g ai/ha]	8.0 L/ha [480+2400 g ai/ha]	1N	2N
Maritime zone, selectivity trials, pre-emergence						
Winter barley (t/ha)	6	8.1 (4.8-9.3)	99 (94-105)	95 (88-103)	93 (86-100)	96 (93-100)
Winter wheat (t/ha)	6	7.4 (6.4-8.2)	101 (96-105)	99 (88-103)	100 (97-106)	98 (91-102)
North-east zone, selectivity trials, pre-emergence						
Winter wheat (t/ha)	2	2.6 (2.3-3.0)	195 (190-200)	193 (189-196)	196 (177-216)	188 (180-196)
South-east zone, selectivity trials, pre-emergence						
Winter wheat (t/ha)	1	5.0	101	102	103	102
Mediterranean zone, selectivity trials, pre-emergence						
Winter barley (t/ha)	7	4.3 (1.7-6.8)	99 (64-119)	98 (75-115)	98 (74-108)	98 (72-115)
Winter wheat (t/ha)	4	4.3 (4.0-4.7)	100 (94-109)	100 (89-109)	102 (96-116)	100 (85-116)
Winter durum wheat (t/ha)	1	6.3	97	83	93	84
Maritime zone, selectivity trials, post-emergence						
Winter barley (t/ha)	6	8.1 (4.8-9.3)	94 (87-99)	95 (89-100)	97 (88-103)	96 (92-99)
Winter wheat (t/ha)	6	7.4 (6.4-8.2)	101 (97-105)	99 (92-104)	99 (95-101)	98 (93-103)
North-east zone, selectivity trials, post-emergence						
Winter wheat (t/ha)	2	2.6 (2.3-3.0)	146 (139-153)	131 (119-143)	151 (148-154)	130 (122-138)
South-east zone, selectivity trials, post-emergence						
Winter wheat (t/ha)	1	5.0	101	101	100	101
Mediterranean zone, selectivity trials, post-emergence						
Winter barley (t/ha)	7	4.3 (1.7-6.8)	98 (91-104)	100 (80-107)	104 (99-117)	100 (88-116)
Winter wheat (t/ha)	4	4.3 (4.0-4.7)	103 (96-117)	96 (81-102)	101 (96-111)	99 (81-118)
Winter durum wheat (t/ha)	1	6.3	91	89	95	83
Crop, trial type	No. of trials	Untreated	Flufenacet 6% + Pendimethalin 30% EC at:		Flufenacet + pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	4.0 L/ha [240+1200 g ai/ha]	8.0 L/ha [480+2400 g ai/ha]	4.0 L/ha [240+1200 g ai/ha]	8.0 L/ha [480+2400 g ai/ha]
Maritime zone, selectivity trials, pre-emergence						
Winter barley (t/ha)	6	8.1 (4.8-9.3)	99 (94-105)	95 (88-103)	93 (86-100)	96 (93-100)
Winter wheat (t/ha)	6	7.4 (6.4-8.2)	101 (96-105)	99 (88-103)	100 (97-106)	98 (91-102)
North-east zone, selectivity trials, pre-emergence						
Winter wheat (t/ha)	2	2.6 (2.3-3.0)	195 (190-200)	193 (189-196)	196 (177-216)	188 (180-196)
South-east zone, selectivity trials, pre-emergence						
Winter wheat (t/ha)	1	5.0	101	102	103	102

Crop, trial type	No. of trials	Untreated	Flufenacet 6% + Pendimethalin 30% EC at:		National Ref. prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	4.0 L/ha [240+1200 g ai/ha]	8.0 L/ha [480+2400 g ai/ha]	1N	2N
Mediterranean zone, selectivity trials, pre-emergence						
Winter barley (t/ha)	4	3.8 (1.7-6.8)	95 (64-119)	97 (75-115)	95 (74-108)	97 (72-115)
Winter wheat (t/ha)	2	4.2 (4.1-4.4)	99 (99-100)	101 (101-101)	99 (99-99)	99 (98-100)
Winter durum wheat (t/ha)	1	6.3	97	83	93	84
Maritime zone, selectivity trials, post-emergence						
Winter barley (t/ha)	6	8.1 (4.8-9.3)	94 (87-99)	95 (89-100)	97 (88-103)	96 (92-99)
Winter wheat (t/ha)	6	7.4 (6.4-8.2)	101 (97-105)	99 (92-104)	99 (95-101)	98 (93-103)
North-east zone, selectivity trials, post-emergence						
Winter wheat (t/ha)	2	2.6 (2.3-3.0)	146 (139-153)	131 (119-143)	151 (148-154)	130 (122-138)
South-east zone, selectivity trials, post-emergence						
Winter wheat (t/ha)	1	5.0	101	101	100	101
Mediterranean zone, selectivity trials, post-emergence						
Winter barley (t/ha)	4	3.8 (1.7-6.8)	100 (94-104)	96 (80-106)	102 (100-108)	96 (88-100)
Winter wheat (t/ha)	2	4.2 (4.1-4.4)	100 (100-100)	101 (101-102)	100 (99-100)	99 (98-100)
Winter durum wheat (t/ha)	1	6.3	91	89	95	83
Mediterranean zone, selectivity trials, pre-emergence						
Winter barley (t/ha)	3	5.0 (4.3-6.3)	105 (101-107)	100 (94-103)	102 (102-102)	100 (96-105)
Winter wheat (t/ha)	2	4.4 (4.0-4.7)	101 (94-109)	99 (89-109)	106 (96-116)	100 (85-116)
Mediterranean zone, selectivity trials, post-emergence						
Winter barley (t/ha)	3	5.0 (4.3-6.3)	97 (91-100)	104 (99-107)	106 (99-117)	107 (102-116)
Winter wheat (t/ha)	2	4.4 (4.0-4.7)	106 (96-117)	91 (81-101)	103 (96-111)	100 (81-118)

Winter durum wheat (TRZDU)

One selectivity trial conducted in winter durum wheat was harvested. The trial was conducted in S-France in 2015/16. In this trial, Flufenacet 6% + Pendimethalin 30% EC was applied pre-emergence at 4.0 L/ha (i.e. 240 g flufenacet and 1200 g pendimethalin per hectare) and 8.0 L/ha (i.e. 480 g flufenacet and 2400 g pendimethalin per hectare). The trial was sprayed when the majority of the crop was at growth stage BBCH 09 (range: BBCH 07-09).

The harvest results obtained in this trial demonstrate that Flufenacet 6% + Pendimethalin 30% EC did not significantly affected the yield of winter durum wheat (Table 3.4-15) when applied at the recommended dose rate (4.0 L/ha). When applied at the overlapping dose rate (8.0 L/ha), a significant reduction in yield was observed for both test- as well as reference product. The results obtained in this trial supports the label claim that Flufenacet 6% + Pendimethalin 30% EC is safe to be applied pre-emergence at the recommended dose rate in winter durum wheat at the recommended application interval.

3.4.2.2 Summary and evaluation of crop yield from winter cereal field trials treated post-emergence in the autumn

A summary of the mean yield assessments expressed as %-relative of the untreated, from winter cereal trials treated with post-emergence applications in the autumn to late winter in the Maritime, the North-east, the South-east and the Mediterranean EPPO zone, are presented in Table 3.4-15.

Winter barley (HORVW)

Thirteen selectivity trials conducted in winter barley were harvested. The trials were conducted in Germany (2), Czech Republic (1), United Kingdom (1), N-France (2), S-France (1), Spain (2) and Italy (4) in 2015/16 and 2016/17. In these trials, Flufenacet 6% + Pendimethalin 30% EC was applied post-emergence at 4.0 L/ha (i.e. 240 g flufenacet and 1200 g pendimethalin per hectare) and 8.0 L/ha (i.e. 480 g flufenacet and 2400 g pendimethalin per hectare). The trials were sprayed when the majority of the crop was at growth stages ranging between BBCH 11 and BBCH 21 (range: BBCH 10-23).

The harvest results obtained in the thirteen trials demonstrate that Flufenacet 6% + Pendimethalin 30% EC did not significantly affected the yield of winter barley (Table 3.4-15) when applied at the recommended dose rate (4.0 L/ha) or the overlapping dose rate (8.0 L/ha), in any of the thirteen trials. In the trials, Flufenacet 6% + Pendimethalin 30% EC performed like the reference products. The results obtained in these trials supports the label claim that Flufenacet 6% + Pendimethalin 30% EC is safe to be applied post-emergence at the recommended dose rate in winter barley at the recommended application interval.

Winter wheat (TRZAW)

17 selectivity trials conducted in winter wheat were harvested. The trials were conducted in Germany (2), N-France (2), United Kingdom (1), Czech Republic (1), Poland (6), Hungary (1), Spain (2) and Italy (2) in 2015/16 to 2018/19. In these trials, Flufenacet 6% + Pendimethalin 30% EC was applied post-emergence at 4.0 L/ha (i.e. 240 g flufenacet and 1200 g pendimethalin per hectare) and 8.0 L/ha (i.e. 480 g flufenacet and 2400 g pendimethalin per hectare). The trials were sprayed when the majority of the crop was at growth stages ranging between BBCH 11 and BBCH 25 (range: BBCH 10-25).

The harvest results obtained in the 17 trials demonstrate that Flufenacet 6% + Pendimethalin 30% EC did not significantly affected the yield of winter wheat (Table 3.4-15) when applied at the recommended dose rate (4.0 L/ha) or the overlapping dose rate (8.0 L/ha) in the vast majority of the thirteen trials. In one French trial, where PHYGEN of up to 10% as well as some minor reductions of vigour was observed in the 8.0 L/ha dose rate, a significant reduction in yield in 2n dose rate was observed. The same was observed in the plots treated with the flufenacet + pendimethalin reference product at 8.0 L/ha. In an Italian trial, where adverse effects as chlorosis and stunting of up to 10% as well as some minor reductions of vigour was observed in the 2n treatments, the test product at 8.0 L/ha as well as the flufenacet reference product applied at 0.96 L/ha caused a significant reduction in yield. In the remaining trials, Flufenacet 6% + Pendimethalin 30% EC performed like the reference products. The results obtained in these trials supports the label claim that Flufenacet 6% + Pendimethalin 30% EC is safe to be applied post-emergence at the recommended dose rate in winter wheat at the recommended application interval.

Winter durum wheat (TRZDU)

One selectivity trial conducted in winter durum wheat was harvested. The trial was conducted in S-France in 2015/16. In this trial, Flufenacet 6% + Pendimethalin 30% EC was applied post-emergence at 4.0 L/ha (i.e. 240 g flufenacet and 1200 g pendimethalin per hectare) and 8.0 L/ha (i.e. 480 g flufenacet and 2400 g pendimethalin per hectare). The trial was sprayed when the crop was at growth stage BBCH 11.

The harvest results obtained in this trial demonstrate that Flufenacet 6% + Pendimethalin 30% EC did have a significant effect on the yield of winter durum wheat (Table 3.4-15) when applied at the recommended dose rate (4.0 L/ha). A slightly more severe reduction in yield was observed in the plots treated with the overlapping dose rate (8.0 L/ha). The same level of reductions in yield as caused with Flufenacet 6% + Pendimethalin 30% EC was observed in the plots treated with the reference products.

Winter triticale (TTLWI)

4 selectivity trials conducted in winter triticale was harvested. The trial was conducted in Poland in 2018/19. In this trial, Flufenacet 6% + Pendimethalin 30% EC was applied post-emergence at 4.0 L/ha (i.e. 240 g flufenacet and 1200 g pendimethalin per hectare) and 8.0 L/ha (i.e. 480 g flufenacet and 2400 g pendimethalin per hectare). The trial was sprayed when the crop was at growth stage BBCH 11.

The harvest results obtained in this trial demonstrate that Flufenacet 6% + Pendimethalin 30% EC did have a significant effect on the yield of winter triticale (Table 3.4-15) Table 3.4-15 when applied at the recommended dose rate (4.0 L/ha). A slightly more severe reduction in yield was observed in the plots treated with the overlapping dose rate (8.0 L/ha). The same level of reductions in yield as caused with Flufenacet 6% + Pendimethalin 30% EC was observed in the plots treated with the reference products.

3.4.2.3 Conclusion

Flufenacet 6% + Pendimethalin 30% EC applied at the recommended dose rate (4.0 L/ha) did not affect crop yield significantly in 61 of the 62 application timings evaluated in 35 selectivity trials taken to harvest. In the vast majority of the trials, Flufenacet 6% + Pendimethalin 30% EC applied at dose rates higher than the recommended rate – representative for sprayer overlap – did not significantly affect the crop yield.

Pre- and post-emergence application in winter cereals is claimed on the label. For crops and recommendation claimed on the label not supported with trials, the applicant wishes to bridge to the trials conducted in autumn- and winter-sown cereals where pre- and post-emergence applications were tested. This BAD also clearly demonstrates that the efficacy and crop safety of Flufenacet 6% + Pendimethalin 30% EC is equivalent to the standard flufenacet + pendimethalin co-formulation to which it was compared in 30 of the 35 selectivity trials harvested (52 of 62 applications). The applicant therefore wishes to cite the original registrant's data on flufenacet and pendimethalin now out of protection in additional support of any recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal evaluator extrapolate from those data.

Comments of zRMS:	<p>Selectivity trials were carried out to evaluate the yield level of pre- and post-emergence use on winter cereals. All trials were conducted to GEP and followed the appropriate EPPO standards by officially recognised testing organisations. No negative effect on the yield was observed.</p> <p>Based on the absence of significant effects across trials, it is reasonable to conclude that a single spring application of Konark at the proposed label rate of 4,0 L product/ha, and applied according to label recommendations, has no adverse impact on crop yield on studied cereals.</p> <p>The decisions whether each of proposed crop is supported by enough trials taking into account their importance and possibilities of data extrapolation between EPPO zones is left to each of CMS. For Poland (zRMS) submitted results are acceptable for post-emergence use on winter wheat, winter barley and winter triticale and for pre-emergence use on winter wheat and winter barley.</p> <p>Overall, the zRMS concluded that Konark should not cause any negative effects on the yield amount of winter cereals when it is applied as recommended on the label.</p>
-------------------	--

3.4.2.4 Relationship between phytotoxicity and yield

Minor adverse effects were observed after 16 of 62 applications in selectivity trials in which crop yields were assessed. The adverse effects were observed in winter barley (3 pre- and 5 post-em.), winter wheat (3 pre- and 4 post-em.) and winter durum wheat (1 pre- and 1 post-em.).

In the tables presented in section 3.4.1.1 and section 3.4.1.2, the maximum level of phytotoxic symptoms, recorded as reduced crop vigour and/or reduction in general crop health (PHYGEN), are presented as well as the grain yield achieved from untreated and treated plots in the affected trials.

No significant reductions in crop yield were recorded in the vast majority of the plots treated with Flufenacet 6% + Pendimethalin 30% EC at dose rates representative of the recommended dose rate or the 2N rate in the trials in which adverse effects were observed.

Comments of zRMS:	<p>Konark (product code: SHA 2619A) can be consider as safe for winter cereals crops on the basis on the submitted documentation by Applicant. No significant reductions in crop yield were recorded in most of the plots treated with Flufenacet 6% + Pendimethalin 30% EC at dose rates representative of the recommended</p>
-------------------	---

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

The materials and methods of these trials are described in Section 3.4.

The results obtained from assessments on the quality of the harvested winter barley grains are presented in Table 3.4-16.

In the majority of the trials evaluated, Flufenacet 6% + Pendimethalin 30% EC had no detrimental effect on the quality parameters assessed on the harvested winter barley grains. In two trials, Moisture content was recorded as being significantly lower in plots treated with 4.0 L/ha and 8.0 L/ha. Furthermore, in three trials, significantly higher TGW was recorded in three trials when treated with Flufenacet 6% + Pendimethalin 30% EC at 8.0 L/ha – in one of these three trials, the 4.0 L/ha dose rate also achieved an increased TGW, when compared to the untreated control plots. When comparing the results obtained with Flufenacet 6% + Pendimethalin 30% EC against the results obtained with the national reference products, hereunder the flufenacet + pendimethalin co-formulation as included in the majority of the trials, or the flufenacet reference product included in Italian trials, at registered dose rates, all three products performed statistically similar on all quality parameters assessed.

Table 3.4-16: Mediterranean and Maritime zone – Quality of harvested winter barley grains – crop treated with Flufenacet 6% + Pendimethalin 30% EC, single application pre- or post-emergence in autumn, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Flufenacet 6% + Pendimethalin 30% EC at:		National reference prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	4.0 L/ha [240+1200 g ai/ha]	8.0 L/ha [480+2400 g ai/ha]	1N	2N
Selectivity trials – Maritime zone, pre-emergence						
Moisture content (%)	6	13.5 (10.8-18.2)	99 (92-103)	100 (93-103)	97 (79-103)	99 (92-105)
HectoLitre Weight (kg/hL)	4	66.2 (60.5-70.0)	101 (99-103)	100 (99-102)	100 (98-102)	101 (99-103)
Thousand Grain Weight (g)	5	47.0 (38.3-52.8)	102 (97-106)	103 (97-109)	101 (99-103)	102 (99-107)
Selectivity trials – Mediterranean zone, pre-emergence						
Moisture content (%)	7	11.8 (11.0-14.9)	102 (90-115)	100 (86-106)	100 (91-111)	100 (90-111)
HectoLitre Weight (kg/hL)	4	62.9 (53.4-68.5)	99 (96-101)	100 (96-102)	100 (99-101)	100 (97-102)
Thousand Grain Weight (g)	3	45.1 (38.7-48.6)	99 (97-100)	102 (100-105)	100 (99-100)	101 (100-102)
Selectivity trials – Maritime zone, post-emergence						
Moisture content (%)	6	13.5 (10.8-18.2)	95 (75-104)	100 (97-102)	99 (92-105)	98 (92-102)
HectoLitre Weight (kg/hL)	4	66.2 (60.5-70.0)	101 (99-103)	100 (99-102)	101 (100-103)	101 (100-103)
Thousand Grain Weight (g)	5	47.0 (38.3-52.8)	102 (97-105)	105 (100-109)	101 (99-104)	104 (100-108)
Selectivity trials – Mediterranean zone, post-emergence						
Moisture content (%)	7	11.8 (11.0-14.9)	100 (84-115)	99 (89-104)	101 (89-112)	99 (87-106)
HectoLitre Weight (kg/hL)	4	62.9 (53.4-68.5)	100 (98-101)	100 (98-102)	100 (100-101)	100 (97-101)
Thousand Grain Weight (g)	3	45.1 (38.7-48.6)	99 (97-100)	100 (100-102)	99 (97-100)	99 (98-100)
Crop, trial type	No. of trials	Untreated	Flufenacet 6% + Pendimethalin 30% EC at:		Flufenacet + pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	4.0 L/ha [240+1200 g ai/ha]	8.0 L/ha [480+2400 g ai/ha]	4.0 L/ha [240+1200 g ai/ha]	8.0 L/ha [480+2400 g ai/ha]
Selectivity trials – Maritime zone, pre-emergence						

Moisture content (%)	6	13.5 (10.8-18.2)	99 (92-103)	100 (93-103)	97 (79-103)	99 (92-105)
HectoLitre Weight (kg/hL)	4	66.2 (60.5-70.0)	101 (99-103)	100 (99-102)	100 (98-102)	101 (99-103)
Thousand Grain Weight (g)	5	47.0 (38.3-52.8)	102 (97-106)	103 (97-109)	101 (99-103)	102 (99-107)
Selectivity trials – Mediterranean zone, pre-emergence						
Moisture content (%)	4	12.3 (11.0-14.9)	101 (90-115)	97 (86-105)	99 (91-106)	100 (90-111)
HectoLitre Weight (kg/hL)	3	63.3 (53.4-68.5)	100 (100-101)	101 (100-102)	101 (100-101)	101 (101-102)
Thousand Grain Weight (g)	3	45.1 (38.7-48.6)	99 (97-100)	102 (100-105)	100 (99-100)	101 (100-102)
Selectivity trials – Maritime zone, post-emergence						
Moisture content (%)	6	13.5 (10.8-18.2)	95 (75-104)	100 (97-102)	99 (92-105)	98 (92-102)
HectoLitre Weight (kg/hL)	4	66.2 (60.5-70.0)	101 (99-103)	100 (99-102)	101 (100-103)	101 (100-103)
Thousand Grain Weight (g)	5	47.0 (38.3-52.8)	102 (97-105)	105 (100-109)	101 (99-104)	104 (100-108)
Selectivity trials – Mediterranean zone, post-emergence						
Moisture content (%)	4	12.3 (11.0-14.9)	96 (84-103)	98 (89-104)	100 (89-112)	98 (87-106)
HectoLitre Weight (kg/hL)	3	63.3 (53.4-68.5)	100 (100-101)	101 (100-102)	101 (100-101)	100 (100-101)
Thousand Grain Weight (g)	3	45.1 (38.7-48.6)	99 (97-100)	100 (100-102)	99 (97-100)	99 (98-100)
Crop, trial type	No. of trials	Untreated	Flufenacet 6% + Pendimethalin 30% EC at:		Flufenacet Ref. prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	4.0 L/ha [240+1200 g ai/ha]	8.0 L/ha [480+2400 g ai/ha]	0.48 L/ha [240 g ai/ha]	0.96 L/ha [480 g ai/ha]
		Selectivity trials – Mediterranean zone, pre-emergence				
Moisture content (%)	3	11.2 (11.1-11.4)	103 (98-107)	103 (98-106)	102 (96-111)	101 (100-102)
HectoLitre Weight (kg/hL)	1	61.9	96	96	99	97
Selectivity trials – Mediterranean zone, post-emergence						
Moisture content (%)	3	11.2 (11.1-11.4)	104 (98-115)	99 (97-101)	102 (98-105)	100 (98-101)
HectoLitre Weight (kg/hL)	1	61.9	98	98	100	97

Winter wheat (TRZAW)

The results obtained from assessments on the quality of the harvested winter wheat grains are presented in Table 3.4-17.

In all trials evaluated, except one, Flufenacet 6% + Pendimethalin 30% EC had no detrimental effect on the quality parameters assessed on the harvested winter wheat grains. In one Czech trial, significantly lower thousand grain weight was recorded in plots treated with Flufenacet 6% + Pendimethalin 30% EC post-emergence with 8.0 L/ha. When comparing the results obtained with Flufenacet 6% + Pendimethalin 30% EC against the results obtained with the national reference products, hereunder the flufenacet + pendimethalin co-formulation as included in the majority of the trials, or the flufenacet reference product included in Italian trials, at registered dose rates, all three products performed statistically similar on all quality parameters assessed.

Table 3.4-17: Maritime, North-east, South-east and Mediterranean zone – Quality of harvested winter wheat grains – crop treated with Flufenacet 6% + Pendimethalin 30% EC, single application pre- or post-emergence in autumn, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Flufenacet 6% + Pendimethalin 30% EC at:		National reference prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	4.0 L/ha [240+1200 g ai/ha]	8.0 L/ha [480+2400 g ai/ha]	1N	2N
Selectivity trials – Maritime zone, pre-emergence						
Moisture content (%)	5	14.4 (13.9-14.7)	99 (97-101)	98 (95-101)	100 (99-102)	99 (94-101)
HectoLitre Weight (kg/hL)	4	73.1 (69.3-75.3)	100 (99-102)	99 (95-101)	101 (100-101)	99 (94-101)
Thousand Grain Weight (g)	5	42.5 (34.2-52.4)	99 (96-101)	99 (96-101)	99 (98-102)	98 (94-100)
Selectivity trials – North-east zone, pre-emergence						
Ergosterol content (%)	2	13.9 (13.5-14.3)	83 (80-85)	82 (78-86)	85 (84-87)	81 (77-84)
Gluten content (%)	2	27.0 (25.2-28.9)	102 (96-107)	106 (102-109)	97 (97-97)	101 (97-105)
HectoLitre Weight (kg/hL)	2	71.3 (68.7-74.0)	108 (105-111)	108 (105-111)	107 (104-111)	107 (105-110)
Protein content (%)	2	13.7 (12.6-14.8)	96 (89-103)	98 (91-104)	92 (88-96)	96 (91-102)
Starch content (%)	2	67.5 (65.4-69.5)	102 (100-104)	101 (100-103)	103 (102-104)	102 (101-103)
Thousand Grain Weight (g)	2	40.6 (39.1-42.0)	113 (111-116)	114 (113-114)	112 (110-114)	111 (111-112)
Selenium content (cm ³)	2	45.2 (40.1-50.3)	98 (86-111)	101 (90-113)	89 (84-95)	97 (88-106)
Selectivity trials – South-east zone, pre-emergence						
Moisture content (%)	1	10.3	97	98	100	99

HectoLitre Weight (kg/hL)	1	78.2	100	100	100	100
Protein content (%)	1	12.2	101	101	100	101
Thousand Grain Weight (g)	1	39.7	100	101	101	101
Selectivity trials – Mediterranean zone, pre-emergence						
Moisture content (%)	4	11.9 (11.5-12.6)	100 (98-102)	100 (99-102)	100 (99-102)	100 (99-100)
HectoLitre Weight (kg/hL)	3	75.4 (67.6-79.3)	100 (100-101)	100 (100-101)	100 (99-101)	100 (99-101)
Thousand Grain Weight (g)	2	44.1 (41.8-46.4)	100 (98-101)	101 (99-103)	100 (98-101)	100 (98-101)
Selectivity trials – Maritime zone, post-emergence						
Moisture content (%)	5	14.4 (13.9-14.7)	100 (99-101)	100 (94-105)	99 (96-101)	99 (94-101)
HectoLitre Weight (kg/hL)	4	73.1 (69.3-75.3)	102 (100-108)	100 (98-101)	99 (98-101)	99 (95-101)
Thousand Grain Weight (g)	5	42.5 (34.2-52.4)	101 (99-103)	99 (93-102)	100 (99-102)	100 (98-102)
Selectivity trials – North-east zone, post-emergence						
Ergosterol content (%)	4	14.0 (12.4-15.8)	95.0 (91.0-95.6)	91.9 (87.0-94.0)	96.1 (89.0-100)	94.1 (88.0-96.8)
Gluten content (%)	6	25.7 (24.7-28.9)	99.5 (97.0-101.6)	100.4 (96.0-101.6)	99.2 (95.1-103.6)	102.1 (100-102.4)
HectoLitre Weight (kg/hL)	6	74.5 (68.7-78.2)	101.3 (99.7-107.0)	101.2 (98.7-106.0)	101.7 (99.7-107.0)	100.9 (99.1-104.0)
Protein content (%)	6	12.8 (12.0-14.8)	98.3 (91.0-101.7)	99.4 (91.0-102.0)	98.3 (91.0-101.6)	99.9 (94.0-101.6)
Starch content (%)	6	69.0 (65.4-70.5)	100.5 (99.6-102.0)	100 (98.4-102.0)	100.6 (99.3-103.0)	100.1 (99.1-102.0)
Thousand Grain Weight (g)	6	42.0 (39.1-44.9)	102.4 (97.6-106.0)	101.7 (92.2-106.0)	103.4 (99.3-106.5)	103.2 (93.8-111.3)
Selenium content (cm³)	6	41.8 (36.6-50.3)	97.0 (87.0-103.3)	99.4 (86.0-104.3)	97.7 (88.0-100.9)	100.8 (93.0-102.2)
Selectivity trials – South-east zone, post-emergence						
Moisture content (%)	1	10.3	99	98	98	98
HectoLitre Weight (kg/hL)	1	78.2	100	100	100	100
Protein content (%)	1	12.2	101	99	100	100
Thousand Grain Weight (g)	1	39.7	102	101	100	101
Selectivity trials – Mediterranean zone, post-emergence						
Moisture content (%)	4	11.9 (11.5-12.6)	99 (98-101)	100 (98-102)	99 (98-101)	100 (99-102)
HectoLitre Weight (kg/hL)	3	75.4 (67.6-79.3)	100 (99-101)	100 (99-101)	100 (99-101)	100 (100-100)
Thousand Grain Weight (g)	2	44.1 (41.8-46.4)	100 (99-102)	101 (99-102)	100 (97-102)	101 (99-102)
Crop, trial type	No. of trials	Untreated	Flufenacet 6% + Pendimethalin 30% EC at:		Flufenacet + pendimethalin Ref. prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	4.0 L/ha	8.0 L/ha	4.0 L/ha	8.0 L/ha
			[240+1200 g ai/ha]	[480+2400 g ai/ha]	[240+1200 g ai/ha]	[480+2400 g ai/ha]
Selectivity trials – Maritime zone, pre-emergence						
Moisture content (%)	5	14.4 (13.9-14.7)	99 (97-101)	98 (95-101)	100 (99-102)	99 (94-101)
HectoLitre Weight (kg/hL)	4	73.1 (69.3-75.3)	100 (99-102)	99 (95-101)	101 (100-101)	99 (94-101)
Thousand Grain Weight (g)	5	42.5 (34.2-52.4)	99 (96-101)	99 (96-101)	99 (98-102)	98 (94-100)
Selectivity trials – North-east zone, pre-emergence						
Ergosterol content (%)	2	13.9 (13.5-14.3)	83 (80-85)	82 (78-86)	85 (84-87)	81 (77-84)
Gluten content (%)	2	27.0 (25.2-28.9)	102 (96-107)	106 (102-109)	97 (97-97)	101 (97-105)
HectoLitre Weight (kg/hL)	2	71.3 (68.7-74.0)	108 (105-111)	108 (105-111)	107 (104-111)	107 (105-110)
Protein content (%)	2	13.7 (12.6-14.8)	96 (89-103)	98 (91-104)	92 (88-96)	96 (91-102)
Starch content (%)	2	67.5 (65.4-69.5)	102 (100-104)	101 (100-103)	103 (102-104)	102 (101-103)
Thousand Grain Weight (g)	2	40.6 (39.1-42.0)	113 (111-116)	114 (113-114)	112 (110-114)	111 (111-112)
Selenium content (cm³)	2	45.2 (40.1-50.3)	98 (86-111)	101 (90-113)	89 (84-95)	97 (88-106)
Selectivity trials – South-east zone, pre-emergence						
Moisture content (%)	1	10.3	97	98	100	99
HectoLitre Weight (kg/hL)	1	78.2	100	100	100	100
Protein content (%)	1	12.2	101	101	100	101
Thousand Grain Weight (g)	1	39.7	100	101	101	101
Selectivity trials – Mediterranean zone, pre-emergence						
Moisture content (%)	2	12.0 (11.5-12.6)	99 (99-99)	100 (99-101)	100 (99-100)	99 (99-99)
HectoLitre Weight (kg/hL)	2	73.4 (67.6-79.3)	100 (100-101)	100 (100-101)	101 (100-101)	101 (101-101)
Thousand Grain Weight (g)	2	44.1 (41.8-46.4)	100 (98-101)	101 (99-103)	100 (98-101)	100 (98-101)
Selectivity trials – Maritime zone, post-emergence						
Moisture content (%)	5	14.4 (13.9-14.7)	100 (99-101)	100 (94-105)	99 (96-101)	99 (94-101)
HectoLitre Weight (kg/hL)	4	73.1 (69.3-75.3)	102 (100-108)	100 (98-101)	99 (98-101)	99 (95-101)
Thousand Grain Weight (g)	5	42.5 (34.2-52.4)	101 (99-103)	99 (93-102)	100 (99-102)	100 (98-102)
Selectivity trials – North-east zone, post-emergence						
Ergosterol content (%)	4	14.0 (12.4-15.8)	95.0 (91.0-95.6)	91.9 (87.0-94.0)	96.1 (89.0-100)	94.1 (88.0-96.8)
Gluten content (%)	6	25.7 (24.7-28.9)	99.5 (97.0-101.6)	100.4 (96.0-101.6)	99.2 (95.1-103.6)	102.1 (100-102.4)
HectoLitre Weight (kg/hL)	6	74.5 (68.7-78.2)	101.3 (99.7-107.0)	101.2 (98.7-106.0)	101.7 (99.7-107.0)	100.9 (99.1-104.0)
Protein content (%)	6	12.8 (12.0-14.8)	98.3 (91.0-101.7)	99.4 (91.0-102.0)	98.3 (91.0-101.6)	99.9 (94.0-101.6)
Starch content (%)	6	69.0 (65.4-70.5)	100.5 (99.6-102.0)	100 (98.4-102.0)	100.6 (99.3-103.0)	100.1 (99.1-102.0)
Thousand Grain Weight (g)	6	42.0 (39.1-44.9)	102.4 (97.6-106.0)	101.7 (92.2-106.0)	103.4 (99.3-106.5)	103.2 (93.8-111.3)
Selenium content (cm³)	6	41.8 (36.6-50.3)	97.0 (87.0-103.3)	99.4 (86.0-104.3)	97.7 (88.0-100.9)	100.8 (93.0-102.2)
Selectivity trials – South-east zone, post-emergence						
Moisture content (%)	1	10.3	99	98	98	98
HectoLitre Weight (kg/hL)	1	78.2	100	100	100	100
Protein content (%)	1	12.2	101	99	100	100

Thousand Grain Weight (g)	1	39.7	102	101	100	101
Selectivity trials – Mediterranean zone, post-emergence						
Moisture content (%)	2	12.0 (11.5-12.6)	99 (98-99)	99 (98-100)	99 (98-99)	99 (99-100)
HectoLitre Weight (kg/hL)	2	73.4 (67.6-79.3)	100 (99-101)	100 (100-101)	100 (99-101)	100 (100-100)
Thousand Grain Weight (g)	2	44.1 (41.8-46.4)	100 (99-102)	101 (99-102)	100 (97-102)	101 (99-102)
Crop, trial type	No. of trials	Untreated	Flufenacet 6% + Pendimethalin 30% EC at:		Flufenacet Ref. prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	4.0 L/ha [240+1200 g ai/ha]	8.0 L/ha [480+2400 g ai/ha]	0.48 L/ha [240 g ai/ha]	0.96 L/ha [480 g ai/ha]
		Selectivity trials – Mediterranean zone, pre-emergence				
Moisture content (%)	2	11.7 (11.7-11.8)	100 (98-102)	101 (100-102)	101 (100-102)	100 (100-100)
HectoLitre Weight (kg/hL)	1	79.2	100	100	99	99
Selectivity trials – Mediterranean zone, post-emergence						
Moisture content (%)	2	11.7 (11.7-11.8)	100 (99-101)	102 (101-102)	99 (98-101)	101 (101-102)
HectoLitre Weight (kg/hL)	1	79.2	100	99	99	100

Winter durum wheat (TRZDU)

The results obtained from assessments on the quality of the harvested winter durum wheat grains are presented in Table 3.4-18.

In the trial evaluated, Flufenacet 6% + Pendimethalin 30% EC had no detrimental effect on the quality parameters assessed on the harvested durum wheat grains. When comparing the results obtained with Flufenacet 6% + Pendimethalin 30% EC against the results obtained with the flufenacet + pendimethalin reference product at the same dose rates, both products performed statistically similar on all quality parameters assessed.

Table 3.4-18: Mediterranean zone – Quality of harvested winter durum wheat grains – crop treated with Flufenacet 6% + Pendimethalin 30% EC, single application pre- or post-emergence in autumn, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Flufenacet 6% + Pendimethalin 30% EC at:		National reference prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	4.0 L/ha [240+1200 g ai/ha]	8.0 L/ha [480+2400 g ai/ha]	1N	2N
Selectivity trials – Mediterranean zone, pre-emergence						
Moisture content (%)	1	14.3	99	99	99	100
HectoLitre Weight (kg/hL)	1	80.3	101	99	100	100
Thousand Grain Weight (g)	1	62.9	100	99	100	99
Selectivity trials – Mediterranean zone, post-emergence						
Moisture content (%)	1	14.3	99	99	99	99
HectoLitre Weight (kg/hL)	1	80.3	100	100	100	100
Thousand Grain Weight (g)	1	62.9	99	98	99	98

Winter triticale (TTLWI)

The results obtained from assessments on the quality of the harvested winter triticale grains are presented in Table 3.4-18.

Table 3.4-19: North-east zone – Quality of harvested winter triticale grains – crop treated with Flufenacet 6% + Pendimethalin 30% EC, single application post-emergence in autumn, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Flufenacet 6% + Pendimethalin 30% EC at:		National reference prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	4.0 L/ha [240+1200 g ai/ha]	8.0 L/ha [480+2400 g ai/ha]	1N	2N
Selectivity trials – Mediterranean zone, post-emergence						
Gluten content (%)	2	27.7 (27.3-28.1)	101.1 (100-102.2)	104.7 (102.6-106.8)	101.1 (99.3-102.8)	106.4 (104.3-108.4)

HectoLitre Weight (kg/hL)	4	69.0 (67.7-70.9)	99.9 (99.0-100.3)	99.8 (98.8-100.3)	99.8 (99.3-100)	99.8 (99.4-100)
Protein content (%)	4	11.8 (11.0-12.9)	100.2 (99.1-101.8)	101.9 (98.3-103.6)	100.2 (99.1-102.6)	101.1 (97.5-105.3)
Starch content (%)	4	64.1 (59.7-68.9)	100.1 (99.8-100.3)	99.2 (98.8-100)	99.7 (99.5-100)	99.6 (99.2-100)
Thousand Grain Weight (g)	4	43.1 (42.5-43.7)	103.2 (101.9-104.3)	104.2 (99.1-107.6)	101.8 (98.6-103.0)	102.1 (97.6-106.7)
Selenium content (cm ³)	2	32.9 (29.5-36.2)	100 (95.6-104.4)	99.8 (92.9-106.6)	99.7 (98.6-100.8)	97.5 (90.8-104.1)

In the trials evaluated, Flufenacet 6% + Pendimethalin 30% EC had no detrimental effect on the quality parameters assessed on the harvested winter triticale grains. When comparing the results obtained with Flufenacet 6% + Pendimethalin 30% EC against the results obtained with the flufenacet + pendimethalin reference product at the same dose rates, both products performed statistically similar on all quality parameters assessed.

3.4.3.1 Conclusion

Flufenacet 6% + Pendimethalin 30% EC applied at the recommended dose rate (4.0 L/ha) did not affect the quality of the harvested grains significantly in the vast majority of the 35 trials taken to harvest, when considering ergosterol content, gluten content, protein content, starch content, selenium content, hectolitre weight and thousand grain weight. When evaluating Moisture content, it was observed that the treated grains occasionally had a significantly lower moisture content than grains from untreated plots. In the vast majority of the trials, Flufenacet 6% + Pendimethalin 30% EC applied at dose rates higher than the recommended rate – representative for sprayer overlap – did not significantly affect the quality of the harvested crop either.

Pre- and post-emergence application in winter cereals is claimed on the label. For crops and recommendation claimed on the label not supported with trials, the applicant wishes to bridge to the trials conducted in autumn- and winter-sown cereals where pre- and post-emergence applications were tested. This BAD also clearly demonstrates that the efficacy and crop safety of Flufenacet 6% + Pendimethalin 30% EC is equivalent to the standard flufenacet + pendimethalin co-formulation to which it was compared in 30 of the 35 selectivity trials harvested (52 of 62 applications). The applicant therefore wishes to cite the original registrant's data on flufenacet and pendimethalin now out of protection in additional support of any recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal evaluator extrapolate from those data.

Comments of zRMS:	<p>Selectivity trials were carried out to evaluate the quality of yield of pre- and post-emergence use on winter cereals. All trials were conducted to GEP and followed the appropriate EPPO standards by officially recognised testing organisations. No negative effect on the quality of yield was observed.</p> <p>Flufenacet 6% + Pendimethalin 30% EC applied at the recommended dose rate (4.0 L/ha) did not affect the quality of the harvested grains significantly in the vast majority of the 35 trials taken to harvest, when considering ergosterol content, gluten content, protein content, starch content, selenium content, hectolitre weight and thousand grain weight. When evaluating Moisture content, it was observed that the treated grains occasionally had a significantly lower moisture content than grains from untreated plots. In most of the trials, Flufenacet 6% + Pendimethalin 30% EC applied at dose rates higher than the recommended rate – representative for sprayer overlap – did not significantly affect the quality of the harvested crop either.</p> <p>The decisions whether each of proposed crop is supported by enough trials considering their importance and possibilities of data extrapolation between EPPO zones is left to each of cMS. For Poland (zRMS) submitted results are acceptable for post-emergence use for winter barley, winter wheat and winter triticale and for</p>
-------------------	--

	<p>pre-emergence use on winter barley and winter wheat.</p> <p>Overall, the zRMS concluded that Konark should not cause any negative effects on the quality of yield of winter cereals when it is applied as recommended on the label.</p>
--	--

3.4.4 Effects on transformation processes (KCP 6.4.4)

Flufenacet 6% + Pendimethalin 30% SC is composed of flufenacet and pendimethalin which both have widely used for several years on winter wheat and winter barley without identifying any quality problems on the treated crops. According to the Technical circular 471 (December 2015) from the British Beer & Pub association, flufenacet as well as pendimethalin are included in the UK recommended brewing and bread making list.

Flufenacet 6% + Pendimethalin 30% SC is applied early in the season (up to BBCH 25), before inflorescence emergence and heading, and as the active ingredients are not systemic, it is therefore not expected that the active ingredient is transferred to the grains.

According EPPO PP 1/243(1) Effects of plant protection products on transformation processes, “ *If the applicant can demonstrate that residues are undetectable, or that any residues will not affect yeasts, a reasoned case may be sufficient to address these requirements*”. As can be observed on residues section, Part B, Section 7: Metabolism and residues, residues are below MRL so there is no further testing of transformation processes.

Comments of zRMS:	<p>Any significant differences between the test and reference product were not observed and SHA 2619A can considered to be selective when applied in winter brewing barley and wheat. Any negative impact on transformation processes as malting and brewing of barley and wheat is therefore not expected.</p> <p>Besides the results in the opinion of Evaluator, in terms of processing procedures the applicant also can provided a reasoned case based on the absence of negative effects on the amount and quality of harvested grain at proposed and increased dose rates. This is not in line with EPPO PP1/243 (1). However, in the same standard it is indicated that no information on processing data is required when residues are not detectable.</p> <p>Assuming a long history of safe use of a.s.: pendimethalin and flufenacet no special trials dedicated to evaluation of effects of Konark (product code: SHA 2619A) on transformation process were undertaken.</p> <p>In the opinion of Evaluator, since applications of Konark are made at an early stage (up to BBCH 25) in the crop's development there is no risk that the actives would be translocated to the grain. The germination of seeds (ex. cereals) will be not negatively affected by the application of Konark (product code: 2619A), in the opinion of Evaluator.</p>
-------------------	--

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Flufenacet 6% + Pendimethalin 30% EC is composed of flufenacet and pendimethalin, which both have been widely used for several years on the GAP claimed crops, without identifying any issues in regards to ability of grains of treated plants to germinate.

Flufenacet 6% + Pendimethalin 30% EC is applied early in the season (pre-emergence to early post-emergence), before inflorescence emergence and heading, and as the active ingredient is not systemic, it is

therefore not expected that the active ingredient is transferred to seeds and grains. Thus, no influence on the ability of plant parts from treated crops to germinate is expected.

The product complies with the Uniform Principles.

Comments of zRMS:	<p>EPPO PP1/135 (3) indicates that data are needed for foliar applied herbicides where application is made at or after seed initiation e.g., for cereals when the first node is detectable or where detectable residues occur in harvested seed. The proposed latest time of application is before BBCH 25, which for cereals is before inflorescence emergence and heading. No further data are necessary in the opinion of Evaluator.</p> <p>The active substances: pendimethalin and flufenacet, are commonly used for many years in many countries. No adverse effects on parts of plant used for propagating purposes were reported.</p> <p>No adverse effect on the yield and quality and no phytotoxicity symptoms were recorded in the field trials. Also, no information is available pointing to presence of any limitations to using of pendimethalin and flufenacet in seed crops of winter cereals. In the opinion of Evaluator, the product – Konark (product code: SHA 2619A) has no negative impact on parts of plants used for propagating purposes.</p>
-------------------	--

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

The applicant conducted a study on seedling emergence to study the impact of the formulation Flufenacet 6% + Pendimethalin 30% EC in succeeding crops.

Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test

Study Code: G-71-17

Materials and methods:	Flufenacet 6% + Pendimethalin 30% EC
Test item:	batch number: SCL - 78154 active substance – flufenacet – 60 g/L pendimethaline – 300 g/L (Appendix No. 1)
Test species:	sunflower (<i>Helianthus annuus</i>), cabbage (<i>Brassica oleracea</i> var. <i>capitata</i>), pea (<i>Pisum sativum</i>), carrot (<i>Daucus carota</i>), perennial ryegrass (<i>Lolium perenne</i>), oats (<i>Avena sativa</i>).
Soil:	Sandy loam
Study design:	number of rates: 10 + control; number of replicates/rate: 4 (carrot, perennial ryegrass, oats) or 7 (sunflower, cabbage, pea). the total number of seeds per application rate – 20 (carrot, perennial ryegrass, oats) or 21 (sunflower, cabbage, pea). test termination: 14 days after the emergence of 50% of the control seedlings
Application rates:	control, 0.20, 0.61, 1.83, 5.49, 16.46, 49.38, 148.15, 444.44, 1333.33, and 4000.00 mL of test item/ha, volume of deionized water used to prepare the highest rate corre-

sponded 300 L water/ha

Test conditions: temperature: 20.7 – 27.8°C, humidity: 48.1 – 86.7%,
 lighting: 16 h light: 8 h dark; light intensity: 88.8 – 144.7
 µE/m²/s; carbon dioxide concentration: 351 – 397 ppm

Statistical analysis: ER10, ER25, ER50 – probit or logit analysis using linear max.
 likelihood regression,
 NOER:
 In order to determine the NOER values for the emergence statistical tests were used:
 Fisher's Exact Binomial Test with Bonferroni Correction
 Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Williams Multiple Sequential t-test Procedure.
 In order to determine the NOER values for the shoot length and the plant weight at the end of the experiment (shoots cut down above the ground), the following statistical tests were used:
 Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals) or Bartlett's Test Procedure on Variance Homogeneity, Williams Multiple Sequential t-test Procedure.

Endpoints: ER10, ER25, ER50, NOER

Results and conclusions

The ER50 and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as mL of the test item/ha for all test species are given below.

	Sunflower <i>Helianthus annuus</i>	Cabbage <i>Brassica oleracea var. capitata</i>	Pea <i>Pisum sativum</i>	Carrot <i>Daucus carota</i>	Perennial ryegrass <i>Lolium perenne</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER₅₀	> 4000.00	> 4000.00	> 4000.00	> 4000.00	545.46 (394.30 – 760.48)	> 4000.00
NOER	≥ 4000.00	≥ 4000.00	≥ 4000.00	≥ 4000.00	148.15	≥ 4000.00
Shoot length (plants without roots)						
ER₅₀	> 4000.00	> 4000.00	> 4000.00	> 4000.00	725.79 (375.53 – 2464.93)	2302.52 (2085.49 – 2548.59)
NOER	≥ 4000.00	444.44	≥ 4000.00	≥ 4000.00	49.38	444.44
Plant dry weight (plants without roots)						
ER₅₀	> 4000.00	3063.21	> 4000.00	> 4000.00	545.57 (396.45 – 758.40)	1750.87 (1417.06 – 2192.74)
NOER	≥ 4000.00	444.44	≥ 4000.00	≥ 4000.00	148.15	444.44

The ER50 and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of flufenacet/ha for all test species are given below.

	Sunflower <i>Helianthus annuus</i>	Cabbage <i>Brassica oleracea var. capitata</i>	Pea <i>Pisum sativum</i>	Carrot <i>Daucus carota</i>	Perennial ryegrass <i>Lolium perenne</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER₅₀	> 240.00	> 240.00	> 240.00	> 240.00	32.73 (23.66 – 45.63)	> 240.00
NOER	≥ 240.00	≥ 240.00	≥ 240.00	≥ 240.00	8.89	≥ 240.00
Shoot length (plants without roots)						
ER₅₀	> 240.00	> 240.00	> 240.00	> 240.00	43.55 (22.53 – 147.90)	138.15 (125.13 – 152.92)
NOER	≥ 240.00	26.67	≥ 240.00	≥ 240.00	2.96	26.67
Plant dry weight (plants without roots)						
ER₅₀	> 240.00	183.79	> 240.00	> 240.00	32.73 (23.79 – 45.50)	105.05 (85.02 -131.56)
NOER	≥ 240.00	26.67	≥ 240.00	≥ 240.00	8.89	26.67

The ER50 and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of pendimethaline/ha for all test species are given below.

	Sunflower <i>Helianthus annuus</i>	Cabbage <i>Brassica oleracea var. capitata</i>	Pea <i>Pisum sativum</i>	Carrot <i>Daucus carota</i>	Perennial ryegrass <i>Lolium perenne</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER₅₀	> 1200.00	> 1200.00	> 1200.00	> 1200.00	163.64 (118.29 – 228.14)	> 1200.00
NOER	≥ 1200.00	≥ 1200.00	≥ 1200.00	≥ 1200.00	44.45	≥ 1200.00
Shoot length (plants without roots)						
ER₅₀	> 1200.00	> 1200.00	> 1200.00	> 1200.00	217.74 (112.66 – 739.48)	690.76 (625.65 – 764.58)
NOER	≥ 1200.00	133.33	≥ 1200.00	≥ 1200.00	14.81	133.33
Plant dry weight (plants without roots)						
ER₅₀	> 1200.00	918.96	> 1200.00	> 1200.00	163.67 (118.93 – 227.52)	525.26 (425.12 - 657.82)
NOER	≥ 1200.00	133.33	≥ 1200.00	≥ 1200.00	44.45	133.33

Conclusions

The test item i.e. **Flufenacet 6% + Pendimethaline 30% EC** had significant impact on the growth and seedling emergence of the perennial ryegrass, oats and cabbage.

Seedling emergence of all tested species was not delayed in comparison to the control group. In case of perennial ryegrass, at the rate equal to 4000.00 mL/ha plants did not emerged.

On the basis of ER10, ER25, ER50 and NOER values determined from final number of plants it was proved that the test item did not inhibit the seedling emergence of sunflower, cabbage, pea, carrot and oats. The test item inhibited the seedling emergence of perennial ryegrass.

On the basis of NOER and ER10, ER25, ER50 values determined from the shoot length and dry shoot weight it was proved that the test item had impact on the process of growth of perennial ryegrass, cabbage and oats.

During the experiment the plant damages as stunted growth and deformations were observed.

The following order of the test plant sensitivity was noticed:

perennial ryegrass > cabbage, oats > sunflower, pea, carrot.

Risk assessment

As can be observed in results below conclusions presented above are correct and can be used for recommendation of succeeding crops after the application of **pendimethalin**.

Succeeding crop ⁽¹⁾	Days after application ⁽²⁾	EC10 g/ha ⁽³⁾	EC10 mg/kg soil ⁽³⁾	PEC ⁽⁴⁾		TER ⁽⁵⁾	
				mg/kg soil e.g. 5 cm	mg/kg soil e.g. 25 cm	EC10/PEC e.g. 5 cm	EC10/PEC e.g. 25 cm
Pea (<i>Pisum sativum</i>)	0	1200	1.6	>1	>1	>1	>1
Cabbage (<i>Brassica oleracea</i>)	0	140.43	0.187	1.6	0.32	0.117	0.585
	21			1.3611	0.2722	0.138	0.688
	50			10.886	0.2177	0.172	0.86
	250			0.2333	0.0467	0.803	>1
Carrot (<i>Daucus carota</i>)	0	1200	1.6	1.6	0.32	>1	>1
	50			10.886	0.2177		
	250			0.2333	0.0467		
Sunflower (<i>Helianthus annuus</i>)	0	1200	1.6	1.6	0.32	>1	>1
	50			10.886	0.2177		
	200			0.3429	0.0686		
Perennial grass (<i>Lolium perenne</i>)	0	27.92	0.037	1.6	0.32	0.0223	0.116
	250			0.2333	0.0467	0.160	0.798
	365			0.0962	0.0192	0.387	>1
	423			0.0616	0.0123	0.605	
Oats (<i>Avena sativa</i>)	0	162.87	0.217	1.6	0.32	0.136	0.679
	14			1.4365	0.2873	0.151	0.756
	50			10.886	0.2177	0.199	0.997
	250			0.2333	0.0467	0.931	>1

As can be observed in results below conclusions presented above are correct and can be used for recommendation of succeeding crops after the application of **flufenacet**.

Succeeding crop ⁽¹⁾	Days after application ⁽²⁾	EC10 g/ha ⁽³⁾	EC10 mg/kg soil ⁽³⁾	PEC ⁽⁴⁾		TER ⁽⁵⁾	
				mg/kg soil e.g. 5 cm	mg/kg soil e.g. 25 cm	EC10/PEC e.g. 5 cm	EC10/PEC e.g. 25 cm
Pea (<i>Pisum sativum</i>)	0	240	0.32	>1	>1	>1	>1
Cabbage (<i>Brassica oleracea</i>)	0	28.09	0.037	0.32	0.064	0.117	0.585
	21			0.2722	0.544	0.138	0.688
	50			0.2177	0.0435	0.172	0.860
	250			0.0467	0.0093	0.803	>1
Carrot (<i>Daucus carota</i>)	0	240	0.32	0.32	0.064	>1	>1
	50			0.2177	0.0435		
	250			0.0467	0.0093		
Sunflower (<i>Helianthus annuus</i>)	0	240	0.32	0.32	0.064	>1	>1
	50			0.2177	0.0435		
	200			0.0686	0.0137		
Perennial grass (<i>Lolium perenne</i>)	0	5.58	0.007	0.32	0.064	0.023	0.116
	250			0.0467	0.0093	0.159	0.797
	365			0.0192	0.0038	0.387	>1
	423			0.0123	0.0025	0.604	
Oats (<i>Avena sativa</i>)	0	32.57	0.043	0.32	0.064	0.136	0.679
	14			0.2873	0.0575	0.151	0.756
	50			0.2177	0.0435	0.199	0.997
	250			0.0467	0.0093	0.931	>1

- (1) possible following crops in a regular crop rotation
(2) adequate value for following crop in a regular crop rotation
(3) NOEC-values of succeeding crops.
(4) PEC (soil depth e.g. 5,20 cm)
(5) TER (soil depth e.g. 5,20 cm)

Following crops after normal harvest

There are no restrictions on following crops when Flufenacet 6% + Pendimethalin 30% EC is used alone. Plough to at least 15 cm before planting all the following crops except for potatoes, peas, wheat and barley.

In the event of crop failure

Plough to at least 15 cm. The following crops may then be sown: potatoes, peas, wheat and barley.

Comments of zRMS:	<p>The evaluation of any possible effects on rotational (succeeding) or replacement crops was carried out according to the step-wise approach in EPPO PP 1/207 Effects on succeeding crops. To examine whether the active substances (flufenacet and pendimethalin) of SHA 2619A can cause negative effects on crops grown after cereals treated with the product a bioassay on representative crops was conducted.</p> <p>IMPACT ON SUCCEEDING CROPS</p>
-------------------	---

	<p>Based on ER₁₀, ER₂₅, ER₅₀ and NOER values determined from final number of plants it was proved that the test item did not inhibit the seedling emergence of sunflower, cabbage, pea, carrot, and oats. The test item inhibited the seedling emergence of perennial ryegrass.</p> <p>Based on NOER and ER₁₀, ER₂₅, ER₅₀ values determined from the shoot length and dry shoot weight it was proved that the test item had impact on the process of growth of perennial ryegrass, cabbage, and oats.</p> <p>The half-life (DT₅₀) for pendimethalin is 64-86 days and for flufenacet remains active in the soil for many weeks after treatment.</p> <p>ZRMs agree with Applicant: <i>“There are no restrictions on following crops when Flufenacet 6% + Pendimethalin 30% EC is used alone. Plough to at least 15 cm before planting all the following crops except for potatoes, peas, wheat and barley”.</i></p> <p>In the event of crop failure: <i>“Plough to at least 15 cm. The following crops may then be sown potatoes, peas, wheat and barley”.</i></p>
--	--

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

During the conduct of efficacy trials and selectivity trials, no observations about negative or positive effects on other plants or neighbouring crops were reported.

EPPO guidelines PP1/256(1) is intended to examine whether the active substance of a plant protection product can cause negative effects on crop which would be in contact with that product. Based on the actual drift value calculated with the Ganzelmeier model and on the EC₅₀ value obtained from herbicidal screening studies presented in the DAR, TER values are obtained.

- If the active substance has no activity against plants at the highest doses tested in the bioassays. Then field trials are unnecessary.
- If the TER values are > 5. Then no further testing is necessary.
- If the TER values are ≤ 5. Damage to the relevant succeeding crop is possible and further field testing is necessary as described in the EPPO guideline.

The maximum proposed rate of Flufenacet 6% + Pendimethalin 30% EC is 4.0 L/ha (equivalent to 240 g flufenacet/ha and 1200 g pendimethalin/ha).

Materials and methods:

The applicant conducted a study on test vigour to study the impact of the formulation Flufenacet 6% + Pendimethalin 30% EC in succeeding crops.

Test item:	Flufenacet 6% + Pendimethaline 30% EC batch number: SCL-78154 active substances: flufenacet – 60 g/L pendimethaline – 300 g/L
Test species:	pea (<i>Pisum sativum</i>), cabbage (<i>Brassica oleracea</i> var. capitata), carrot (<i>Daucus carota</i>), sunflower (<i>Helianthus annuus</i>), perennial ryegrass (<i>Lolium perenne</i>), oats (<i>Avena sativa</i>).
Soil:	Sandy loam
Study design:	number of rates: 10 + control; number of replicates/rate: 4 (carrot, perennial ryegrass, oats) or 7 (sunflower, cabbage, pea). The total number of plants per application rate – 20 (carrot, perennial ryegrass, oats) or 21 (cabbage, pea, sunflower)

test termination: 21 days after the spraying

Application rates: a control, 0.20, 0.61, 1.83, 5.49, 16.46, 49.38, 148.15, 444.44, 1333.33, and 4000.00 mL/ha. Volume of deionized water used to prepare the highest rate corresponded to 300 L water/ha

Test conditions: temperature: 17.4 – 24.2°C, humidity: 49.2 – 90.5%, lighting: 16 h light : 8 h dark; light intensity: 59.9 – 144.0 µE/m²/s; carbon dioxide concentration: 322 – 364 ppm

Statistical analysis: ER10, ER25, ER50 – probit analysis using linear max. likelihood regression or logit analysis using linear max. likelihood regression or the nonlinear regression using the 4-parameter logistic.

NOER:
In order to determine the NOER value for the plant number at the end of the experiment any computations had been performed because of no change in mortality of plants.
In order to determine the NOER values for the shoot length at the end of the experiment (shoots cut down above the ground) and for the plant weight at the end of the experiment (shoots cut down above the ground), the following statistical tests were used:
Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals) or Bartlett's Test Procedure on Variance Homogeneity, Williams Multiple Sequential t-test Procedure or Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment.

Endpoints: ER10, ER25, ER50, NOER

Results and conclusions

The ER50 and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as mL of the test item/ha for all test species are given below.

	Sunflower <i>Helianthus annuus</i>	Cabbage <i>Brassica oleracea var. capitata</i>	Pea <i>Pisum sativum</i>	Carrot <i>Daucus carota</i>	Perennial ryegrass <i>Lolium perenne</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER ₅₀	> 4000.00	> 4000.00	> 4000.00	> 4000.00	> 4000.00	> 4000.00
NOER	≥ 4000.00	≥ 4000.00	≥ 4000.00	≥ 4000.00	≥ 4000.00	≥ 4000.00
Shoot length (plants without roots)						
ER ₅₀	> 4000.00	> 4000.00	> 4000.00 (3302.34 - > 4000.00)	> 4000.00	965.99	> 4000.00
NOER	≥ 4000.00	444.44	148.15	1333.33	444.44	444.44
Plant dry weight (plants without roots)						
ER ₅₀	> 4000.00	> 4000.00	> 4000.00	> 4000.00	515.16	> 4000.00
NOER	≥ 4000.00	148.15	148.15	1333.33	444.44	444.44

The ER50 and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of flufenacet/ha for all test species are given below.

	Sunflower <i>Helianthus annuus</i>	Cabbage <i>Brassica oleracea var. capitata</i>	Pea <i>Pisum sativum</i>	Carrot <i>Daucus carota</i>	Perennial ryegrass <i>Lolium perenne</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER₅₀	> 240.00	> 240.00	> 240.00	> 240.00	> 240.00	> 240.00
NOER	≥ 240.00	≥ 240.00	≥ 240.00	≥ 240.00	≥ 240.00	≥ 240.00
Shoot length (plants without roots)						
ER₅₀	> 240.00	> 240.00	> 240.00 (198.14 - > 240.00)	> 240.00	57.96	> 240.00
NOER	≥ 240.00	26.67	8.89	80.00	26.67	26.67
Plant dry weight (plants without roots)						
ER₅₀	> 240.00	> 240.00	> 240.00	> 240.00	30.91	> 240.00
NOER	≥ 200.00	8.89	8.89	80.00	26.67	26.67

The ER₅₀ and NOER values determined on the basis of plants number at the end of the experiment, shoot length and shoot dry weight measurements expressed as g of pendimethaline /ha for all test species are given below.

	Sunflower <i>Helianthus annuus</i>	Cabbage <i>Brassica oleracea var. capitata</i>	Pea <i>Pisum sativum</i>	Carrot <i>Daucus carota</i>	Perennial ryegrass <i>Lolium perenne</i>	Oats <i>Avena sativa</i>
Plant number at the end of the experiment						
ER₅₀	> 1200.00	> 1200.00	> 1200.00	> 1200.00	> 1200.00	> 1200.00
NOER	≥1200.00	≥1200.00	≥1200.00	≥1200.00	≥1200.00	≥1200.00
Shoot length (plants without roots)						
ER₅₀	> 1200.00	> 1200.00	> 1200.00 (990.70 - > 1200.00)	> 1200.00	289.80	> 1200.00
NOER	≥1200.00	133.33	44.45	400.00	133.33	133.33
Plant dry weight (plants without roots)						
ER₅₀	> 1200.00	> 1200.00	> 1200.00	> 1200.00	154.55	> 1200.00
NOER	≥1200.00	44.45	44.45	400.00	133.33	133.33

On the basis of the obtained results it was proved that the test item i.e. Flufenacet 6% + Pendimethaline 30% EC had no influence on the plant number.

On the basis of the obtained results it was proved that the test item i.e. Flufenacet 6% + Pendimethaline 30% EC had influence on shoot length and shoot dry weight of cultivation of cabbage, pea, carrot, perennial ryegrass and oats at the end of the experiment. The impact depended on the rate and species.

During the experiment the plant damages were observed: stunted growth, wilting, chlorosis, spots, deformations, necrosis.

The following order of the test plant sensitivity was noticed:

pea > cabbage > perennial ryegrass > oats > carrot > sunflower

In the vegetative vigour study representative species (sunflower (*Helianthus annuus*), cabbage (*Brassica oleracea* var. *capitata*), pea (*Pisum sativum*), carrot (*Daucus carota*), perennial ryegrass (*Lolium perenne*), oats (*Avena sativa*)) were tested. The results are presented in the tables below.

Table 3.5-1: Results of Shoot length test in plant species [Flufenacet 6% + Pendimethalin 30% EC]

Application rate [mL/ha]	Pea (<i>Pisum sativum</i>)	Cabbage (<i>Brassica oleracea</i>)	Carrot (<i>Daucus carota</i>)	Sunflower (<i>Helianthus annuus</i>)	Perennial grass (<i>Lolium perenne</i>)	Oats (<i>Avena sativa</i>)
Shoot length in comparison to the control [%]						
Control	-	-	-	-	-	-
0.2	90.5	108.8	109.7	107.6	105.2	101.3
0.61	95.7	113.4	111.8	115.0	106.7	103.2
1.83	93.6	112.3	122.2	115.0	103.9	107.1
5.49	94.0	108.9	120.2	107.3	103.5	117.8
16.46	94.3	111.8	113.5	102.3	101.5	108.8
49.38	92.9	115.7	105.6	99.9	102.4	110.4
148.15	119.0	110.9	116.5	101.8	90.2	105.1
444.44	79.9	102.1	128.2	112.3	99.4	105.4
1333.33	74.0	89.1	98.3	126.1	40.0	88.5
4000	57.8	88.8	85.1	120.3	37.7	72.4

Table 3.5-2: Results of Plant weight test in plant species [Flufenacet 6% + Pendimethalin 30% EC]

Application rate [mL/ha]	Pea (<i>Pisum sativum</i>)	Cabbage (<i>Brassica oleracea</i>)	Carrot (<i>Daucus carota</i>)	Sunflower (<i>Helianthus annuus</i>)	Perennial grass (<i>Lolium perenne</i>)	Oats (<i>Avena sativa</i>)
Plant weight in comparison to the control [%]						
Control	-	-	-	-	-	-
0.2	93.1	97.5	92.7	110.2	125.8	104.9
0.61	109.7	93.6	101.7	104.8	113.4	103.1
1.83	95.0	94.4	101.8	92.6	94.9	98.8
5.49	101.0	102.4	100.4	120.9	116.7	109.9
16.46	108.7	111.5	100.4	95.2	114.2	103.5
49.38	103.5	108.9	99.3	106.5	96.0	100.5
148.15	109.5	99.4	98.6	110.8	108.3	105.1
444.44	76.5	86.2	99.9	105.4	91.8	105.7
1333.33	74.6	83.0	91.5	102.8	19.2	85.7
4000	67.2	77.8	71.2	86.6	25.4	82.6

Conclusion

On the basis of the obtained results it was proved that the test item i.e. Flufenacet 6% + Pendimethaline 30% EC had no influence on the plant number.

On the basis of the obtained results it was proved that the test item i.e. Flufenacet 6% + Pendimethaline 30% EC had influence on shoot length and shoot dry weight of cultivation of cabbage, pea, carrot, perennial ryegrass and oats at the end of the experiment. The impact depended on the rate and species.

During the experiment the plant damages were observed: stunted growth, wilting, chlorosis, spots, deformations, necrosis.

The following order of the test plant sensitivity was noticed:

pea > cabbage > perennial ryegrass > oats > carrot > sunflower.

Comments of zRMS:	<p>The applicant conducted a study on test vigour to study the impact of the formulation Flufenacet 6% + Pendimethalin 30% EC in succeeding crops. In the vegetative vigour study representative species (sunflower, pea, cabbage, carrot, perennial ryegrass, and oats) were tested. Based on the obtained results, it was proved that the test item i.e., Flufenacet 6% + Pendimethalin 30% EC had no influence on the plant number. Based on the obtained results, it was proved that the test item i.e., Flufenacet 6% + Pendimethalin 30% EC had influence on shoot length and shoot dry weight of cultivation of cabbage, pea, carrot, perennial ryegrass, and oats at the end of the experiment. The impact depended on the rate and species. During the experiment the plant damages were observed: stunted growth, wilting, chlorosis, spots, deformations, necrosis. The following order of the test plant sensitivity was noticed: pea > cabbage > perennial ryegrass > oats > carrot > sunflower.</p> <p>The negative effect on adjacent crops is expected. The restriction should be put on the label. E.g., <i>Avoid spray drift outside the target plot</i>. The risk mitigation measures will correspond to the long-term experience with the use of this active substance within the good agricultural practice. It generally corresponds with the herbicidal use.</p> <p>As every plant protection product – including Konark (product code: SHA 2619 A) should not be used during wind that may cause drift spray solution on adjacent plants. Such recommendation will be contained on the label - instruction of use.</p> <p>In conclusion, considering both TER calculated (based on ED₅₀ and HC5), the risk for adjacent crops in the worst-case scenario was demonstrated to be acceptable with a buffer zone of 5 m or with 75% drift reduction nozzles are used.</p>
-------------------	--

3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

From the experimentation carried out with Flufenacet 6% + Pendimethalin 30% EC in 2015/16, 2016/17 and 2018/19, no problems regarding adverse effects on beneficial organisms were reported.

Special tests to investigate this purpose are not required.

For more information, see the results of the standard ecotoxicological tests being presented in dRR Part B section 6.

Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Directive 91/414/EEC.

Comments of zRMS:	No study results were submitted. The applicant's reference is acceptable, and no further data are required under this evaluation. The product was evaluated in accordance with Uniform principles. However, detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 6 (Ecotoxicology).
-------------------	---

3.5.4 Tank cleaning

Report:	KCP 6.5.4-01, B. Rajasekhar, 2020
Title:	Washing efficiency of Flufenacet 6% + Pendimethalin 30% EC after application.
Document No:	7712/2020
Guidelines:	EEC No 1107/2009

	(EU) No 284/2013 SANCO 3029/99 rev. 5 OECD-204/2014
GLP	Yes

Effectiveness of Cleaning

Test item

Flufenacet 6% + Pendimethalin 30% EC

Batch No. SCL-39855

Date of manufacture: 29th August 2019

Date of expiry 28th August 2021

An appropriate quantity of 20 mL/L of the test substance was taken into 400 mL beaker and mixed with 300 mL of Standard Water D, stirred well with a glass rod. After 2 minutes an aliquot of 100 mL (A, B and C) of test solution was transferred into a separate 150 mL polyethylene bottles, stoppered and placed at room temperature 25.1°C overnight.

The next day each polyethylene bottle was inverted twice for 2 seconds and shaken to resuspend any settled material and the content was discharged from each bottle. An aliquot of 10 mL tap water was added and inverted twice and then rinsed with water and discarded.

The empty polyethylene bottle was again rinsed with acetonitrile and the rinsed solution was analysed under Gas Chromatography. An amount of 0.00294 mg and 0.014841 mg was detected and the total was content of Flufenacet 6% + Pendimethalin 30% EC was determined to be 100% and 100% respectively.

Determination of Active ingredient content

Preparation of Sample solution

An amount of 100 mg and 100.10 mg of test substance were accurately weighed into a clean and dry separate two different 100 mL volumetric flask dissolved in Acetonitrile and made up to the mark with the Acetonitrile. These concentrations of prepared stock solutions were equivalent to 1000 mg/L and 1001 mg/L respectively. An aliquot of 0.480 mL sample stock solutions were taken into two different 100 mL volumetric flasks respectively and diluted with Acetonitrile. The prepared solutions were equivalent to 4.80 and 4.81 mg/L respectively. The duplicate injection of the standard and triplicate injection of the sample of two different concentrations were analyzed by validated GC method.

For validation of method details please refer to Section B5.

Conclusion

From the determined results the percentage of the test substance (Flufenacet 6% + Pendimethalin 30% EC) removed by water washing was 100%. Hence the washing procedure is considered effective.

Comments of zRMS:	ZRMs accepted tank cleaning procedure. From the determined results the percentage of the test substance (Flufenacet 6% + Pendimethalin 30% EC) removed by water washing was 100%.
-------------------	---

3.6 Other/special studies

No other studies were conducted

Comments of zRMS:	ZRMs agree,
-------------------	-------------

3.7 List of test facilities including the corresponding certificates

The following table gives information about the testing facilities where trials mentioned in this document were conducted. All facilities are certified, and the trials were conducted according to GEP guidelines.

Table 3.7-1: List of test facilities

Testing facility	Zone	Country	Year and trial type								
			2015/16			2016/17			2018/19		
			Winter cereals Autumn application			Winter cereals Autumn application			Winter cereals Autumn application		
			Efficacy		Selectivity	Efficacy		Selectivity	Efficacy		Selectivity
			Pre-em.	Post - em.	Pre- & Post-em.	Pre-em.	Post - em.	Pre- & Post-em.	Pre-em.	Post-em.	Pre- & Post-em.
Barley											
Hetterich	MAR	DE	1	1	2			2			
Z.z.s. Kujavy	MAR	CZ	1	1	1						
SGS Group	MAR	UK	1	1	1						
Promovert	MAR	FR	1	1							
IOR-PIB Poznan	N-E	PL	1	1	2						
Promovert	MED	FR	2	1	1						
Promovert	MED	ES	1	1	3						
SAGEA	MED	IT	1	1	3						
Total, Barley			9	8	13			2			
Wheat											
Hetterich	MAR	DE	1	1	2			2			
Z.z.s. Kujavy	MAR	CZ	1	1	1						
SGS Group	MAR	UK	1	1	1						
Promovert	MAR	FR		1							
IOR-PIB Poznan	N-E	PL	1	1	2						
Institute of soil science and plant cultivation national research intitute	N-E	PL								3	
Institute of Plant Protection	N-E	PL							3	4	
SynTech Research	S-E	HU	2	2	1						
Promovert	MED	FR	1	1	2						
Promovert	MED	ES	1		1						
SAGEA	MED	IT	1	1	2						
Total, Wheat			9	9	12			2		6	4
Institute of soil science and plant cultivation national research intitute	N-E	PL								3	
Institute of Plant Protection	N-E	PL								3	4
Total, Triticale										6	4
Total, All crops			18	17	25			4		12	8

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.0-001	Anonymous	2021	Biological Assessment Dossier: Flufenacet 6% + Pendimethalin 30% EC (60 g/L flufenacet + 300 g/L pendimethalin EC) – EU Central zone Sharda Cropchem España -, - Unpublished	N	Sharda