

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product name: KAGURA/GENKI

Product code: SAE053H/01

Chemical active substances:

mesotrione, 80 g/L

nicosulfuron, 30 g/ L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Document number - SAEDoc-00015a CEU
(authorization)

Applicant: Sumi Agro Europe Limited

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Version history

When	What
November 2019	dRR submitted by applicant
August 2020	Dossier sent for evaluation to Merit Mark (PL)
October 2021	zRMS finalised evaluation
January 2022	Final version prepared by zRMS after Commenting period
February 2022	Final version prepared by zRMS after Commenting period

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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:	Conclusions from the assessment were prepared using grey commenting boxes placed at the end of each chapter. The parts of the text amended or added by the zRMS evaluator are highlighted in grey and the parts struck off are visibly marked with the grey front.
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3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

zRMS

The submitted efficacy data (reports from field trials) fulfil requirements and conditions determined in the EPPO guidelines, the Commission Regulation (EU) No 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products. The reports and data were submitted to support the evaluation for the authorization of SAE053H/01 in AT, BE, CZ, DE, IE, NL, UK, HU, RO, SI, SK and PL.

SAE053H/01 The product contains 80 g/l of mesotrion and 30 g/l of nicosulfuron and is formulated an oil dispersion (OD). It is used as herbicide in maize for the control of a wide range of weeds at dose rates of 1,0 l/ha and 1,2 l/ha (spray volume applied on the crop 200 – 300 l/ha) as post – emergence one application in season.

The applicant submitted 60 reports showing the results in research into product efficacy carried out in the Maritime, North-East and South-East EPPO climatic from 2014 to 2018 in different cultivars of *Zea mays* against grass and broad-leaved weeds to supports the registration of SAE053H/01 in AT, BE, CZ, DE, IE, NL, UK, HU, RO, SI, SK and PL.

Control of weeds in the North-east EPPO climatic zone (Poland)

The following target weed species were categorized as:

- susceptible (S)

for dose rate 1,0 l/ha: CAPBP, CHEAL, GASPA, MATIN, SINAR, THLAR,

for dose rate 1,2 l/ha: CAPBP, CHEAL, GASPA, MATIN, SINAR, STEME, THLAR, VERHE, VIOAR, ECHCG, AGGRE

- moderately susceptible (MS)

for dose rate 1,0 l/ha: VIOAR, ECHCG, AGGRE

for dose rate 1,2 l/ha: POLCO

- moderately tolerant (MT)

for dose rate 1,0 l/ha: POLCO

for dose rate 1,2 l/ha: GERPU

SAE053H/01 caused insufficient (tolerant) susceptibility for GERPU at dose rate 1,0 l/ha. On the dose rate 1,2 l/ha the weed appeared only moderately tolerant.

It might be concluded that the application of SAE053H/01 at 1,0 l/ha and 1,2l/ha dose rates (spray volume 200 - 300 l/ha), post-emergence provides benefit against weeds in maize comparable or better with standard products: Elumis, Calisto 100 SC. The dose rate 1,2 l/ha gave better and more consistent control of AGREE, ECHCG and POLCO.

Control of weeds in the Maritime EPPO climatic zone

The following target weed species were categorized as:

- very susceptible (VS)

for dose rate 1,0 l/ha: AMARE, BRSNW, CHEAL, CHEHY, LAMPU, MATCH, MERAN, SOLNI, STEME

for dose rate 1,2 l/ha: AMARE, BRSNW, CHEAL, CHEHY, CHEPO, LAMPU, MATCH, MATMA, MERAN, SOLNI, STEME

- susceptible (S)

for dose rate 1,0 l/ha: DATST, FUMOF, GERPP, POLAV, POLPE, ECHCG, AEOPO

for dose rate 1,2 l/ha: DATST, FUMOF, GERPP, POLAV, POLLM, POLPE, ECHCG, AEOPO, CONAR

- moderately susceptible (MS)

for dose rate 1,0 l/ha: POLCO, VERPE, CONAR

for dose rate 1,2 l/ha: POLCO, VERPE, PVAZE

- moderately tolerant (MT)

for dose rate 1,0 l/ha: DIGSA, PVAZE

for dose rate 1,2 l/ha: GALAP, DIGSA

tolerant (T)

for dose rate 1,0 l/ha: GALAP, POROL

for dose rate 1,2 l/ha: POROL

There is need to underline that in one trial, DIGSA was tolerant towards dose rate 1,2 l/ha of AE053H/01 and in that case standard product Elumis showed much more better control (MS). SAE053H/01 caused also insufficient (tolerant) susceptibility for GALAP at dose rate 1,0 l/ha and for POROL at both doses rates.

What is more the Applicant presented for some weeds too few number of trials and took under consideration also trials from other EPPO climatic zones explaining that SAE053H/01 gave similar levels of control of weed species between trials carried out in the Maritime, North-East and South-East climatic zones. Additionally is some trials number of weeds per m² were below the threshold of 5 weeds per m². Appropriateness of such an approach is for decision of cMS whether above mentioned trials and results should be taken under consideration to prove efficacy of SAE053H/01.

Control of weeds in the SE EPPO climatic zone

The following target weed species were categorized as:

- very susceptible (VS)

for dose rate 1,0 l/ha: ABUTH, AMABL, CHEHY, DATST, THLAR, VERPE

for dose rate 1,2 l/ha: ABUTH, AMABL, CAPBP, CHEAL, CHEHY, DATST, LAMPU, MATIN, POLPE, SINAR, THLAR, VERHE, VERPE

- susceptible (S)

for dose rate 1,0 l/ha: AMARE, CAPBP, CHEAL, LAMPU, MATIN, SINAR, STAAN, VIOAR, SORHA

for dose rate 1,2 l/ha: AMARE, HELAN, HIBTR, POLCO, SOLNI, STAAN, VIOAR, ECHCG, SETPU, SORHA

- moderately susceptible (MS)

for dose rate 1,0 l/ha: AMBEL, HIBTR, POLCO, POLLA, POROL, SOLNI, VERHE, ECHCG, SETPU, SETVI, CIRAR

for dose rate 1,2 l/ha: AMBEL, POLLA, POROL, SETVI, CIRAR, CONAR

- moderately tolerant (MT)

for dose rate 1,0 l/ha: POLPE, CONAR

for dose rate 1,2 l/ha: AGREE, CYNDA

tolerant (T)

for dose rate 1,0 l/ha: AGRRE

There is need to underline that SAE053H/01 caused insufficient (tolerant) susceptibility for AGRRE at dose rate 1,0 l/ha.

What is more the Applicant presented for some weeds too few number of trials and took under consideration also trials from other EPPO climatic zones explaining that SAE053H/01 gave similar levels

of control of weed species between trials carried out in the Maritime, North-East and South-East climatic zones. Additionally in some trials number of weeds per m² were below the threshold of 5 weeds per m². Appropriateness of such an approach is for decision of cMS whether above mentioned trials and results should be taken under consideration to prove efficacy of SAE053H/01.

The applicant presented strategy of resistance management recommended by HRAC.

SAE053H/01 was safe to the crops on which it was applied as no phytotoxicity symptoms were observed in the efficacy and selectivity tests. The product did not cause a negative impact on the yield of maize.

The product SAE053H/01 is to be expected no negative effect on the quality of plants or plant products and transformation processes.

Only cereal crops should be sown in the autumn following harvest of a maize crop on which SAE053H/01 was applied in the spring and in the event of crop failure for any reason of a maize crop on which SAE053H/01 has been applied, only maize should be sown as a replacement crop.

The risk of adverse impact resulting from the post-emergence application of SAE053H/01 at the rate of 1.2 L product/ha was acceptably low when a 5 m buffer zone was observed, with a buffer zone of 3 m when 50% drift reduction nozzles was used or without a buffer zone when 90% drift reduction nozzles was used.

According to the above, the plant protection product SAE053H/01 is recommended to be approved to use according to the table of intended uses for SAE053H/01 (Table 3.1- 1). The evaluation was carried out in accordance with the Uniform Principles.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-1:Acceptability of intended uses

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 expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	AT, BE, CZ, DE, IE, NL, UK, PL, HU, RO, SI, SK	maize	F	Broad-leaved weeds and grasses	foliar spray	12-19 (BBCH)	1	NA	a) 1.2 L/Ha b) 1.2 L/Ha	a) 0.96 + 0.036 b) 0.96 + 0.036	200-400 300	NA	The GAP was originally 1.5 L/Ha, but has been reduced to 1.2 L/Ha for Risk Assessment reasons.	A
2	AT, BE, CZ, DE, IE, NL, UK, HU, RO, SI, SK	maize	F	Broad-leaved weeds and grasses	foliar spray	12-19 (BBCH)	1	NA	a) 1.2 L/Ha b) 1.2 L/Ha	a) 0.96 + 0.036 b) 0.96 + 0.036	200-300	NA	The GAP was originally 1.5 L/Ha, but has been reduced to 1.2 L/Ha for Risk Assessment reasons.	C
3	DE	maize	F	Annual broad-leaved weeds Annual grasses: ECCHG	foliar spray	12-19 (BBCH)	1	NA	a) 1.2 L/Ha b) 1.2 L/Ha	a) 0.96 + 0.036 b) 0.96 + 0.036	200-300	NA	The GAP was originally 1.5 L/Ha, but has been reduced to 1.2 L/Ha for Risk Assessment reasons.	C

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

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

Column 15: zRMS conclusion.

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

3.2 Efficacy data (KCP 6)

Introduction

This document summaries the information related to the efficacy of the plant protection product SAE053H/01 (Kagura) containing mesotrione, which was included onto Annex I of Council Directive 91/414/EEC (Directive 2003/68/EC, 11th July 2003) and approved in accordance with Regulation (EC) No. 1107/2009 by Commission Implementing Regulation (EC) No. 540/2011 (25th May 2011), and nicosulfuron, which was included into Annex I of Council Directive 91/414/EEC (Directive 2008/40/EC, 28th March 2008) and approved in accordance with Regulation (EC) No. 1107/2009 by Commission Implementing Regulation (EC) No. 540/2011 (25th May 2011). As an AIR 3 substance, mesotrione was re-evaluated at EU level and successfully re-approved from 1st June 2017 by Commission Implementing Regulation (EU) 2017/725 (24th April 2017).

The EC final renewal report (SANTE/11654/2016, 23rd March 2017) for the renewal of mesotrione are considered to provide the relevant review information or a reference to where such information can be found.

The SANCO report (SANCO/3780/07 rev 1, 22nd January 2008) for nicosulfuron is considered to provide the relevant review information or a reference to where such information can be found.

The Annex I of the Commission Implementing Regulation (EU) for mesotrione (2017/725) and the Inclusion Directive for nicosulfuron (2008/40/EC) provide specific provisions under Part B which need to be considered by the applicant in the preparation of their of their submission and by the MS prior to granting an authorisation:

Member States need to pay particular attention to the following specific additional points relating to efficacy or other Section 3 data requirements with regard to granting of authorisations of plant protection products containing mesotrione and/or nicosulfuron.

- The protection of non-target plants (mesotrione)
- The protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field no-spray buffer zone (nicosulfuron)

This registration report gives a concise summary of data on the efficacy, crop safety and other Section 3 data points submitted in support of an application for the registration of SAE053H/01, an Oil dispersion (OD) formulation containing 80 g/L mesotrione and 30 g/L nicosulfuron, in EU Central Registration zone countries (AT, BE, CZ, DE, IE, NL, PL, RO, HU, SI, SK, UK) for use as a herbicide for control of annual and perennial broad-leaved and grass weeds in maize.

Description of active substances

Mesotrione is a selective systemic herbicide that was discovered and developed by Syngenta, with first products launched in the USA, Germany and Austria in 2001. Subsequently products containing mesotrione, as sole active substance and in co-formulations with other herbicides, were introduced worldwide for use in maize.

Nicosulfuron is a broad spectrum herbicide that has been widely used for weed control in maize since being first introduced in the early 1990s. Products containing nicosulfuron are approved in the majority of EU countries for use as herbicides in maize.

Mode of action

Mesotrione is a triketone compound and herbicide that is included in HRAC mode of action group F2 (4-HPPD inhibitors), involving inhibition of the p-hydroxyphenylpyruvate dioxygenase (HPPD) enzyme, which is a key enzyme in the biosynthesis of tocopherols and plastoquinone. Plastoquinone is an electron acceptor for the phytoene desaturase reaction in the pathway of carotenoid biosynthesis and also serves as an electron acceptor in PSII. Tocopherols and carotenoids are responsible for the detoxification of reactive oxygen species and scavenging of free radicals in plant tissues, whilst carotenoids also protect chlorophyll from photo-oxidation. Following a mesotrione treatment, carotenoid biosynthesis is inhibited in sensitive plants, resulting in bleaching and necrosis.

Nicosulfuron is a sulfonylurea herbicide that is included in HRAC mode of action group B (ALS-inhibitors), involving inhibition of the acetolactate synthase (ALS) enzyme, which is a key enzyme involved in the first stage of the biosynthesis of branched chain amino acids, including the two amino acids valine and isoleucine that are essential building blocks of proteins and other plant components. Nicosulfuron is a systemic selective herbicide that is rapidly absorbed by the leaves and translocated to the meristematic tissue, with genera specific selective and broad spectrum activity against a relatively wide range of broad-leaved and grass weed species, including grasses that are closely related to maize. The selectivity is due to the ability of maize and other tolerant species to metabolise nicosulfuron into harmless compounds.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-1:Details of the active substances

Active substance	mesotrione	nicosulfuron
Concentration (Unit: g/kg or g/L...)	80 g/L	30 g/L
Chemical group	Triketone	Sulfonylurea
Mode of action	4-HPPD inhibitors (p-hydroxyphenylpyruvate dioxygenase)	ALS inhibitors (acetolactate synthase)
Biological action	Foliar and residual acting post-emergence herbicide	Foliar and residual acting post-emergence herbicide

Description of the plant protection product

SAE053H/01 is an Oil Dispersion (OD) formulation, containing 80 g/L mesotrione and 30 g/L nicosulfuron that is intended for use as a herbicide in maize.

SAE053H/01 is a co-formulation product that combines the complementary and overlapping spectrums of selective herbicide activity of mesotrione and nicosulfuron to give effective control of an extensive range of annual and perennial broad-leaved and grass weeds when applied post-emergence in maize. Both active substances have contact foliar and residual soil herbicide activity, with mesotrione having good activity against susceptible broad-leaved weed species and some activity against certain grass weeds and nicosulfuron giving effective control of susceptible broad-leaved weed species and some major grass weed species.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-2: Simplified table of requested uses for SAE053H/01

Uses		Member States	Requested rates	Comments
Crop(s)	Target(s)			
Maize	Broad-leaved and grass weeds	AT, BE, CZ, DE, IE, NL, UK, PL, HU, RO, SI, SK	1.0-1.2 L/ha	Maximum 1 application per crop. Application in spring when crop is within growth stage range of 12-19 (BBCH). Application volume range of 200-400 L/ha water

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

Description of the target pests

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-3:
Glossary of pests mentioned in the dossier

EPPO code	Scientific name	Common name
ABUTH	<i>Abutilon theophrasti</i>	Indian mallow
AEOPPO	<i>Aegopodium podagraria</i>	Ground elder
AGRRE	<i>Elymus repens</i>	Common couchgrass
AMABL	<i>Amaranthus blitoides</i>	Mat amaranth
AMARE	<i>Amaranthus retroflexus</i>	Common amaranth
AMBEL	<i>Ambrosia artemisiifolia</i>	Common ragweed
BRSNW	<i>Brassica napus</i>	Winter oilseed rape
CAPBP	<i>Capsella bursa-pastoris</i>	Sherpherd's purse
CENCY	<i>Cyanus segetum</i>	Cornflower
CHEAL	<i>Chenopodium album</i>	Fat-hen
CHEHY	<i>Chenopodium hybridum</i>	Maple-leaf goosefoot
CHEPO	<i>Lipandra polysperma</i>	Many-seeded goosefoot
CHESS	<i>Chenopodium</i> spp.	Goosefoot species
CIRAR	<i>Cirsium arvense</i>	Creeping thistle
CONAR	<i>Convolvulus arvensis</i>	Field bindweed
CYNDA	<i>Cynodon dactylon</i>	Bermuda grass
DATST	<i>Datura stramonium</i>	Thorn apple
DIGSA	<i>Digitaria sanguinalis</i>	Hairy crabgrass
ECHCG	<i>Echinochloa crus-galli</i>	Barnyard grass
FUMOF	<i>Fumaria officinalis</i>	Common fumitory
GAETE	<i>Galeopsis tetrahit</i>	Common hemp-nettle
GALAP	<i>Gallium aparine</i>	Cleavers
GASPA	<i>Galinsoga parviflora</i>	Gallant soldier
GERPP	<i>Geranium purpureum</i>	Little robin
GERPU	<i>Geranium pusillum</i>	Small-flowered cranesbill
HELAN	<i>Helianthus annuus</i>	Sunflower
HIBTR	<i>Hibiscus trionum</i>	Bladder hibiscus
LAMAM	<i>Lamium amplexicaule</i>	Henbit dead-nettle
LAMPU	<i>Lamium purpureum</i>	Red dead-nettle
LAMSS	<i>Lamium</i> spp.	Dead-nettle species
MATCH	<i>Matricaria chamomilla</i>	Scented mayweed
MATIN	<i>Tripleurospermum inodorum</i>	Scentless mayweed
MATMA	<i>Tripleurospermum maritimum</i>	False mayweed
MATSS	<i>Matricaria</i> spp.	Mayweed species
MERAN	<i>Mercurialis annua</i>	Annual mercury
MYOAR	<i>Myosotis arvensis</i>	Field forget-me-not
PAPRH	<i>Papaver rhoeas</i>	Common poppy
POAAN	<i>Poa annua</i>	Annual meadowgrass
POLAV	<i>Polygonum aviculare</i>	Common knotgrass
POLCO	<i>Fallopia convolvulus</i>	Black bindweed
POLLA	<i>Persicaria lapathifolia</i>	Pale persicaria
POLLM	<i>Persicaria maculata</i>	Spotted knotweed
POLPE	<i>Persicaria maculosa</i>	Redshank
POROL	<i>Portulaca oleraceae</i>	Common purslane

EPPO code	Scientific name	Common name
PVAZE	<i>Pavonia zeylanica</i>	-
RAPRA	<i>Raphanus raphanistrum</i>	Runch
SETPU	<i>Setaria pumila</i>	Yellow foxtail
SETSS	<i>Setaria</i> spp.	Foxtail species
SETVI	<i>Setaria viridis</i>	Green foxtail
SINAR	<i>Sinapsis arvensis</i>	Charlock
SOLNI	<i>Solanum nigrum</i>	Black nightshade
SORHA	<i>Sorghum halepense</i>	Johnson grass
SPRAR	<i>Spergula arvensis</i>	Corn spurrey
STAAN	<i>Stachys annua</i>	Annual woundwort
STEME	<i>Stellaria media</i>	Common chickweed
TAROF	<i>Taraxacum officinale</i>	Common dandelion
THLAR	<i>Thlaspi arvense</i>	Field pennycress
URTDI	<i>Urtica dioica</i>	Common nettle
VERHE	<i>Veronica hederifolia</i>	Ivy-leaved speedwell
VERPE	<i>Veronica persica</i>	Common speedwell
VIOAR	<i>Viola arvensis</i>	Field pansy

Whilst the majority of weeds that occur in maize crops are annuals, perennial broad-leaved and grass weed species can also be present and particularly problematic and warranting control. Amongst the most common annual weed species occurring in maize crops in Europe are *Amaranthus* spp., *Chenopodium* spp., *Polygonum* spp., *Solanum nigrum*, *Echinochloa crus-galli* and *Setaria* spp.. Widespread weed species occurring in the warmer climatic zones of Southern Europe, but which are spreading progressively into Central and Northern Europe include *Datura* spp. and *Portulaca oleracea*.

The major maize growing regions in Europe are generally in warmer, higher rainfall areas and on more fertile soils, where the potential for build-up in the soil weed seed bank is high. Maize is sown at a low seed rate and wide row spacings. Therefore, with low plant densities and relatively slow initial plant growth, the crop is particularly vulnerable to competition from weeds during the early stages of development, from germination to when the crop has 10-12 leaves and before the canopy is well-developed, which is typically up to 4-6 weeks after emergence.

Weeds compete with maize for water, light, nutrients and space, causing reductions in yield quantity and quality and can also be host to pests and diseases, creating a bridge for carry over between crops. The extent of reductions in yield depends on the particular weed species, the weed density, the length of the period of competition and the availability of water and nutrients.

Weed infestation can also have an impact on the quality of harvested crop, with potential negative effects on the nutritional qualities of forage and seed, and the presence of certain weeds that are be poisonous to livestock can be a major problem in silage produced from the crop. Therefore, effective early season weed management is of major importance in maize production.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-4: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
Maize	AT, BE, CZ, DE, IE, NL, UK, PL, HU, RO, SI, SK	-	Broad-leaved and grass weeds	AT, BE, CZ, DE, IE, NL, UK, PL, HU, RO, SI, SK	-

Compliance with the Uniform Principles

This overall assessment has been performed according to the uniform principles. All summarized data are from trials carried out to GEP and in accordance with relevant EPPO guidelines.

Information on trials submitted (3.2 Efficacy data)

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-5: Presentation of trials (efficacy trials)

Crop(s)*	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)			GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime zone	North-east zone	South-east zone		
Maize (post-emergence)	Broad-leaved and grass weeds	Belgium	2018	MED + E	2 (2)	-		GEP	
		Bulgaria	2014	MED + E	-	-	1 (1)	GEP	
			2018	MED + F	-	-	1 (1)	GEP	
		Czech Republic	2014	MED + E	2 (2)	-	-	GEP	
			2015	E	1 (1)	-	-	GEP	
				MED + E	3 (3)	-	-	GEP	
		France	2018	MED + E	5 (5)	-	-	GEP	
		Germany	2018	MED + E	4 (4)			GEP	
		Hungary	2014	MED + E	-	-	1 (1)	GEP	
			2015	MED + E	-	-	5 (5)	GEP	
			2016	MED + E	-	-	2 (2)	GEP	
		Poland	2014	MED + E	-	4 (4)	-	GEP	
			2015	MED + E	-	7 (7)	-	GEP	
			2016	MED + E	-	5 (5)	-	GEP	
		Romania	2014	MED + E	-	-	1 (1)	GEP	
			2015	MED + E	-	-	5 (5)	GEP	
			2016	MED + E	-	-	3 (3)	GEP	
		Slovakia	2018	MED + E	-	-	2 (2)	GEP	
		United Kingdom	2015	MED + E	3 (3)	-	-	GEP	
			2018	MED + E	3 (3)			GEP	
TOTAL		-	2014-18	MED + E	22 (22)	16 (16)	21 (21)		
		-	2015	E	1 (1)	-	-		

* According to the GAP table.

** MED = minimum effective dose trials, E = efficacy trials

*** GEP: Good Experimental Practices.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-6:
Presentation of reference standards used in trials in maize (efficacy trials)

Reference standard	Country(ies) where the product is registered ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate (/ha) ⁽³⁾	Application rate in trials (per treatment) (/ha)	Remark ⁽⁴⁾
				Type ⁽²⁾	Concentration of a.s.			
Elumis	BE	10383P/B	mesotrione + nicosulfuron	OD	75g/L + 30g/L	1.5 L	0.5 L, 1.0 L, 1.5 L, 2.0 L	
	CZ	4757-0				1.0-1.5 L		
	DE	006960-00				1.5 L		
	FR	2100111				1.5 L		
	UK	15800				1.5 L		
	PL	R-61/2014				1.0-1.5 L		
	BG	1151-2/25.10.2013 r.				1.3-2.0 L / 1.0 + 0.7 L or 1.3 + 0.7 L		
	HU	04.2/1283-2/2013				1.0-2.0 L		
	RO	006PC/20.12.2011				1.0-1.5		
	SK	14-11-1420						
Callisto 4 SC	HU	04.2/660-2/2016	mesotrione	SC	480 g/L	0.25-0.35 L	0.35 L	
Callisto 480 SC	RO	2156/11.10.2002	mesotrione	SC	480 g/L	0.2-0.3 L	0.35 L	
	BG	01053-III3/02.03.2010 r.				0.2 L (post-em) 0.3-0.4 L (pre-em)	0.4 L	
Callisto 100 SC	PL	R-25/2009	mesotrione	SC	100 g/L	1.0-1.5 L	1.5 L	
Temsa SC	CZ	5147-0	mesotrione	SC	100 g/L	1.5 L	1.5 L	

(1) only on use(s) applied for (with the test product).

(2) e.g. WP (wetable powder), EC (emulsifiable concentrate), etc.

(3) dose(s) / dose range authorized on that use in the country.

(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.).

Comments of zRMS:	<p>This report summarizes the information concerning the efficacy of the plant protection product SAE053H/01. The product contains 80 g/l of mesotrion and 30 g/l of nicosulfuron and is formulated as an oil dispersion (OD). It is used as herbicide in maize. The reports and data were submitted to support the evaluation of the SAE053H/01 product authorization in AT, BE, CZ, DE, IE, NL, UK, HU, RO, SI, SK and PL.</p> <p>The active substance nicosulfuron is included in the Annex to Commission Implementing Regulation (EU) No 540/2011 containing the active substances approved for use in plant protection products under Regulation (EC) No 1107/2009 with the expiration of approval on 31/12/2021.</p> <p>According to general provisions applying to all substances listed in the Annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances, specific provisions of Regulation (EU) No 540/2011 were as follows:</p> <p>PART A:</p> <p>Only uses as herbicide may be authorised.</p> <p>PART B:</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on nicosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> - the potential exposure of the aquatic environment to metabolite DUDN when it is applied in regions with vulnerable soil conditions, - the protection of aquatic plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones, - the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field no-spray buffer zone, - the protection of groundwater and surface water under vulnerable soil and climatic conditions. <p>The active substance mesotrion is included in the Annex to Commission Implementing Regulation (EU) No 540/2011 containing the active substances approved for use in plant protection products under Regulation (EC) No 1107/2009 with the expiration of approval on 31/05/2032.</p> <p>According to general provisions applying to all substances listed in the Annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances, specific provisions of Regulation (EU) No 540/2011 were as follows:</p> <p>Only use as herbicide may be authorised.</p> <p>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mesotrione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account.</p>
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3.2.1 Preliminary tests (KCP 6.1)

Preliminary range finding tests are not reported as products containing mesotrione and/or nicosulfuron, either in co-formulation or as the sole active substance, have been approved for the control of weeds in

maize for many years, and the herbicidal activity of both mesotrione and nicosulfuron has been widely researched and proven in commercial use in countries across the EU.

The combination of mesotrione and nicosulfuron in SAE053H/01 is justified on the basis of the complementary and overlapping selective herbicidal activities of the two active substances giving effective broad spectrum control of a wide range of annual and perennial broad-leaved and grass weed species, including the majority of those that widely occur in maize crops.

The ratio of the two active substances in SAE053H/01 is almost identical to the content and ratio of the same active substances in an approved formulation that is current registered for use as a herbicide in maize in the majority of EU countries, including those relevant to this application for the approval of SAE053H/01 in the EU Central Registration zone. It is therefore considered that proven effective control of a wide spectrum of weeds by this approved product in commercial practice provides full justification of the same combination and very similar ratio of the two active substances in SAE053H/01.

Study Comments: 3.2.1 dRR point 3.2.1	EN: Lack of studies.
EN: Evaluator conclusion: Preliminary range finding tests are not reported. The active substances mesotrione and nicosulfuron have been well known, and used in many authorised products with a known range of action.	

3.2.2 Minimum effective dose (KCP 6.2)

Fifty-nine (59) of the 60 trials carried out in the Maritime, North-east and South-east EPPO climatic zones between 2014 and 2018 were established in order to determine the minimum effective dose for the control of annual and perennial broad-leaved and grass weed species in maize. In all of these trials, SAE053H/01 was tested at a range of rates (0.75 L, 1.2 L and 1.5 L product/ha, 0.75 L, 1.0 L, 1.2 L and 1.5 L product/ha or 1.0 L and 1.5 L product/ha).

Details of these trials are included in Section 3.2.3.

A summary of mean percentage efficacy of SAE053H/01 applied at a range of rates against individual weed species at late assessment timings across these trials in maize is given in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-7.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-7: Dose justification: mean overall percentage efficacy of SAE053H/01 applied at a range of rates against individual weeds at late assessment timings across trials in maize

Target	EPPO climatic zone	No. of trials		Untreated-plants/m ² (or % ground cover)	Mean % efficacy of SAE053H/01			
					60-154 DA-A			
					0.75 L/ha	1.0 L/ha	1.2 L/ha	1.5 L/ha
Annual broad-leaved weeds								
ABUTH	South-east	1	Mean	16.0	100	100	100	100
AMABL	South-east	1	Mean	8.0	90.0	100	100	100
AMARE	Maritime	2	Mean	8.5	94.9	98.5	100	100
			Min-Max	6.0-11.0	93.8-96.0	97.0-100	100-100	100-100
			SD	-	1.56	2.12	0.00	0.00
	North-east	1	Mean	11.0	46.3	67.5	77.5	85.0
	South-east	4	Mean	13.2	75.3	83.9	92.8	94.6
			Min-Max	7.8-18.0	68.5-81.3	71.3-96.3	86.3-98.8	85.7-100
			SD	-	5.88	10.58	5.17	5.19
		1	Mean	7.8	92.5	-	95.0	100
AMBEL	South-east	3	Mean	13.5	73.7	79.4	82.2	89.2
			Min-Max	8.0-20.0	57.5-99.8	66.3-99.5	65.0-99.0	77.5-100
			SD	-	22.82	17.65	17.00	11.27

Target	EPPO climatic zone	No. of trials		<i>Untreated-plants/m² (or % ground cover)</i>	Mean % efficacy of SAE053H/01			
					60-154 DA-A			
					0.75 L/ha	1.0 L/ha	1.2 L/ha	1.5 L/ha
		1	Mean	10.5	70.5	-	75.0	75.8
BRSNW	Maritime	1	Mean	10	100	100	100	100
	North-east	1	Mean	5.0	100	100	100	100

Target	EPPO climatic zone	No. of trials		Untreated-plants/m ² (or % ground cover)	Mean % efficacy of SAE053H/01			
					60-154 DA-A			
					0.75 L/ha	1.0 L/ha	1.2 L/ha	1.5 L/ha
CAPBP	North-east	2	Mean	12.5	93.8	100	100	100
			Min-Max	9.0-16.0	87.5-100	100-100	100-100	100-100
			SD	-	8.84	0.00	0.00	0.00
		2	Mean	9.5	100	-	100	100
			Min-Max	8.0-11.0	100-100	-	100-100	100-100
			SD	-	0.00	-	0.00	0.00
	South-east	1	Mean	6.3	81.3	92.5	100	100
CENCY	North-east	1	Mean	8.0	88.8	-	99.3	99.9
CHEAL	Maritime	17	Mean	31.0	91.7	95.3	95.8	96.2
			Min-Max	8.0-143.0	50.0-100	80.0-100	80.0-100	80.0-100
			SD	-	13.55	7.3	6.66	6.3
		2	Mean	49.8	83.2	-	99.1	100
			Min-Max	38.5-61.0	82.5-83.8	-	98.8-99.4	100-100
			SD	-	0.92	-	0.49	0.00
	North-east	12	Mean	30.6	86.1	91.0	93.2	95.6
			Min-Max	5.0-159.0	51.3-100	58.8-100	68.8-100	78.8-100
			SD	-	18.05	15.68	11.93	8.06
		3	Mean	15.3	97.5	-	98.6	100
			Min-Max	13.8-17.0	93.9-100	-	95.8-100	99.9-100
			SD	-	3.18	-	2.45	0.08
	South-east	9	Mean	10.8	83.9	90.6	95.3	96.9
			Min-Max	5.0-20.0	65.0-100	71.3-100	83.8-100	90.9-100
			SD	-	23.54	9.88	6.13	3.84
		2	Mean	11.0	88.8	-	95.0	98.8
			Min-Max	7.0-15.0	82.5-95	-	92.5-97.5	97.5-100
			SD	-	8.84	-	3.54	1.77
		3	Mean	14.0	-	92.5	-	95.4
			Min-Max	10.0-20.0	-	85.5-100	-	91.3-100
			SD	-	-	7.13	-	4.37
CHEHY	Maritime	1	Mean	7.0	95.0	100	100	100
	South-east	1	Mean	10.0	-	100	-	100
CHEPO	Maritime	1	Mean	27.3	81.3	-	98.8	100
DATST	Maritime	2	Mean	7.0	80.0	89.9	95.0	96.3
			Min-Max	6.0-8.0	60.0-100	80.0-99.8	90.0-100	92.5-100
			SD	-	28.28	14.00	7.07	5.30
	South-east	2	Mean	102.5	100	100	100	100
			Min-Max	85.0-120	100-100	100-100	100-100	100-100
			SD	-	0.00	0.00	0.00	0.00
FUMOF	Maritime	1	Mean	12.0	85.0	82.5	82.5	85.0
	North-east	1	Mean	6.0	70.0	-	85.0	90.0
GAETE	North-east	1	Mean	14.0	96.5	100	100	100
GALAP	Maritime	2	Mean	18.5	17.5	24.0	62.5	81.3
			Min-Max	18.0-19.0	15.0-20.0	21.7-26.3	50.0-75.0	76.3-86.3
			SD	-	3.54	3.25	17.68	7.07
GASPA	North-east	2	Mean	8.0	62.5	73.8	87.5	100
			Min-Max	15.0	78.2	85.2	95.0	96.3
			SD	10.0-20.0	68.8-87.5	73.8-96.5	90.0-100	92.5-100
GERPP	Maritime	1	Mean	-	13.22	16.05	7.07	5.30
GERPU	North-east	1	Mean	11.0	82.5	91.3	88.8	94.5
		1	Mean	14.7	0.0	5.0	12.5	18.8
HELAN	South-east	1	Mean	12.0	86.3	-	92.5	98.5
			Mean	6.0	96.0	-	95.0	97.5

Target	EPPO climatic zone	No. of trials		Untreated-plants/m ² (or % ground cover)	Mean % efficacy of SAE053H/01			
					60-154 DA-A			
					0.75 L/ha	1.0 L/ha	1.2 L/ha	1.5 L/ha
HIBTR	South-east	5	Mean	10.9	83.3	86.4	91.5	93.2
			Min-Max	5.0-17.5	61.0-100.0	71.8-100	77.5-100	86.3-100
			SD	-	15.40	12.70	9.50	5.70
		1	Mean	18.0	90.0	-	98.8	96.3
		2	Mean	14.0	-	85.7	-	92.9
			Min-Max	11.0-16.0	-	84.3-87.0	-	92.0-93.8
			SD	-	-	1.91	-	1.27
LAMAM	North-east	1*	Mean	6.0	96.3	-	100	100
LAMPU	Maritime	1	Mean	41.0	100	100	100	100
		1	Mean	79.0	88.8	-	99.9	100
	North-east	1	Mean	8.0	100	-	100	100
	South-east	1	Mean	5.8	81.3	87.5	98.8	100
MATCH	Maritime	1	Mean	32.0	100	100	100	100
	North-east	1	Mean	15.0	100	100	100	100
MATIN	North-east	5	Mean	9.4	78.5	89.1	95.5	99.1
			Min-Max	5.0-12.0	61.3-100	78.8-100	91.3-100	95.3-100
			SD	-	19.73	10.18	4.18	2.10
	South-east	1	Mean	7.8	81.3	96.3	98.8	100
MATMA	Maritime	2	Mean	30.3	85.6	-	99.4	100
			Min-Max	24.5-36.0	85.0-86.3	-	99.0-99.8	100.0-100
			SD	-	0.88	-	0.53	0.00
MERAN	Maritime	1	Mean	15.0	97.5	100	100	100
MYOAR	North-east	1	Mean	7.0	100	-	100	100
PAPRH	North-east	1	Mean	8.0	76.3	-	83.8	87.5
POLAV	Maritime	2	Mean	6.5	86.9	88.2	89.8	89.4
			Min-Max	5.0-8.0	82.5-91.3	81.3-95.0	82.5-97.0	80.0-98.8
			SD	-	6.22	9.69	10.25	13.29
	North-east	1	Mean	7.0	31.3	52.5	67.5	76.3
POLCO	Maritime	3	Mean	14.3	80.5	80.7	86.7	88.3
			Min-Max	9.0-17.0	70.0-99.0	70.0-99.5	80.0-97.5	75.0-100
			SD	-	16.07	16.38	9.46	12.58
	North-east	1	Mean	39.5	61.3	-	81.3	90.0
		3	Mean	11.3	43	63.4	80.9	85.9
			Min-Max	8.0-14.0	33.8-58.8	46.3-77.5	71.3-88.8	76.3-91.3
			SD	-	13.77	15.81	8.86	8.31
		1	Mean	12.0	63.8	-	83.8	95.0
	South-east	3	Mean	11	72.8	80.2	86.1	88.5
			Min-Max	10.0-12.0	71.0-74.5	77.5-85.0	83.8-87.5	85.3-90.8
			SD	-	1.76	4.19	2.01	2.87
		1	Mean	11.8	60.0	-	71.3	87.5
POLLA	North-east	1	Mean	5.0	80.0	87.5	100	100
	South-east	1	Mean	6.0	86.3	89.5	91.0	81.3
POLLM	Maritime	1	Mean	31.3	82.6	-	93.9	98.7
POLPE	Maritime	1	Mean	20.0	100	100	97.5	100
	North-east	1	Mean	(7.0)	68.8	-	77.5	87.5
		1	Mean	11.8	92.5	-	95.0	97.5
	South-east	1	Mean	7.0	-	67.8	-	77.8
POROL	Maritime	1	Mean	65.0	22.5	25.0	27.5	75.0
	South-east	1	Mean	5.0	60.0	56.3	72.5	86.0
RAPRA	North-east	1	Mean	24.0	95.8	100	100	100

Target	EPPO climatic zone	No. of trials		Untreated-plants/m ² (or % ground cover)	Mean % efficacy of SAE053H/01			
					60-154 DA-A			
					0.75 L/ha	1.0 L/ha	1.2 L/ha	1.5 L/ha
SINAR	North-east	2	Mean	9.0	76.9	86.7	92.0	93.8
			Min-Max	8.0-10.0	68.8-85.0	77.5-95.8	84.0-100	87.5-100
			SD	-	11.45	12.94	11.31	8.84
	South-east	2	Mean	11.0	85.3	90.7	95.3	96.3
			Min-Max	5.0-17.0	70.5-100	81.3-100	90.5-100	92.5-100
			SD	-	20.86	13.22	6.72	5.30
SOLNI	Maritime	4	Mean	19.4	95.2	96.9	98.7	99.2
			Min-Max	5.0-57.0	87.5-100	88.8-100	95.0-100	96.8-100
			SD	-	5.42	5.42	2.47	1.60
	South-east	1	Mean	20.8	85.0	-	98.5	100
		1	Mean	9.5	100	100	100	100
		1	Mean	7.8	92.5	-	95.0	97.5
SPRAR	North-east	1	Mean	20.0	100	100	100	100
STAAN	South-east	1	Mean	21.2	94.3	99.3	99.5	99.8
STEME	Maritime	3	Mean	14.7	94.4	95.8	93.8	95.0
			Min-Max	6.0-23.0	83.8-100	87.5-100	81.3-100	85.0-100
			SD	-	9.16	7.22	10.80	8.66
	North-east	3	Mean	6.3	99.1	-	99.9	100
			Min-Max	5.0- 8.0	97.5-100	-	99.8-100	100-100
			SD	-	1.43	-	0.14	0.00
THLAR	North-east	2	Mean	9.5	100	100	100	100
			Min-Max	9.0-10.0	100-100	100-100	100-100	100-100
			SD	-	0.00	0.00	0.00	0.00
		2	Mean	9.1	100	-	100	100
			Min-Max	5.3-13.0	100-100	-	100-100	100-100
			SD	-	0.00	-	0.00	0.00
	South-east	1	Mean	5.5	82.5	97.5	100	100
VERHE	North-east	2	Mean	10.5	84.4	-	88.1	95.0
			Min-Max	8.0-13.0	68.8-100	-	76.3-100	90.0-100
			SD	-	22.10	-	16.79	7.07
	South-east	1	Mean	7.5	72.5	85.0	98.8	100
VERPE	Maritime	4	Mean	21.3	76.6	87.5	92.5	94.4
			Min-Max	13.0-39.0	6.3-100	50.0-100	70.0-100	77.5-100
			SD	-	46.88	25.00	15.00	11.25
	South-east	1	Mean	10.0	84.5	97.0	99.0	99.0
VIOAR	North-east	2	Mean	11.5	66.3	74.4	94.2	100
			Min-Max	6.0-17.0	65.0-67.5	71.3-77.5	93.8-94.5	100-100
			SD	-	1.77	4.38	0.49	0.00
	South-east	1	Mean	5.5	62.5	86.3	95.0	97.5
Annual grass weeds								
DIGSA	Maritime	3	Mean	69.7	27.5	44.6	45.9	70.0
			Min-Max	15.0-118	0.0-61.3	3.8-76.3	2.5-88.8	58.8-88.8
			SD	-	31.12	37.11	43.15	16.36

Target	EPPO climatic zone	No. of trials		<i>Untreated-plants/m² (or % ground cover)</i>	Mean % efficacy of SAE053H/01			
					60-154 DA-A			
					0.75 L/ha	1.0 L/ha	1.2 L/ha	1.5 L/ha
ECHCG	Maritime	6	Mean	21.8	83.3	90.7	93.4	97.4
			Min-Max	6.0-39.0	40.0-96.8	70.0-96.8	80.0-100	90.0-100
			SD	-	21.60	10.31	8.02	4.02
		2	Mean	87.8	81.9	-	97.9	100
			Min-Max	89.5-96.0	81.3-82.6	-	97.5-98.3	100-100
			SD	-	0.93	-	0.55	0.00
	North-east	7	Mean	58.5	65.7	77.6	88.2	94.2
			Min-Max	5.0-172.0	46.3-100	58.8-100	71.3-100	77.5-100
			SD	-	23.42	17.29	10.54	8.21
		4	Mean	9.6	81.9	-	94.7	99.8
			Min-Max	5.5-16.0	67.6-98.8	-	88.8-100	99.6-100
			SD	-	16.06	-	6.13	0.19
	South-east	6	Mean	21.1	54.4	76.1	86.1	91.3
			Min-Max	17.0-25.0	25.0-75.0	58.8-100	65.0-100	78.8-100
			SD	-	19.82	13.79	11.60	7.83
		3	Mean	11.3	83.3	-	89.5	91.9
			Min-Max	7.0-19.0	71.3-93.8	-	82.5-96.0	83.8-97.0
			SD	-	11.35	-	6.78	6.76
		1	Mean	25.0	-	87.3	-	91.0
SETPU	South-east	1	Mean	118.0	35.0	73.8	75.0	93.8
SETVI	South-east	6	Mean	15.6	62.9	78.9	83.4	88.6
			Min-Max	5.0-30.0	52.5-72.5	53.8-92.5	57.5-95.0	77.5-98.8
			SD	-	8.60	13.63	13.40	7.00
		1	Mean	6.0	87.5	-	90.0	95.0
		1	Mean	13.0	-	78.0	-	90.3
Perennial broad-leaved weeds								
AEOPO	Maritime	1	Mean	16.0	50.0	80.0	80.0	90.0
CIRAR	North-east	1	Mean	8.0	41.3	57.5	71.3	73.8
	South-east	5	Mean	11.6	67.4	76.8	86.2	88.5
			Min-Max	6.0-26.3	30.0-87.5	52.5-90.0	80.5-97.5	85.8-90.0
			SD	-	22.54	14.68	6.90	1.70
CONAR	Maritime	2	Mean	8.5	75.0	76.3	80.0	77.5
			Min-Max	8.0-9.0	62.5-87.5	70.0-82.5	80.0-80.0	72.5-82.5
			SD	-	17.68	8.84	0.00	7.07
	North-east	1	Mean	12.0	100	100	100	100
	South-east	2	Mean	6.9	71.7	65.2	79.4	84.4
			Min-Max	5.0-8.8	47.5-95.8	56.3-74.0	61.3-97.5	72.5-96.3
SD			-	34.15	12.52	25.60	16.83	
PVAZE	Maritime	1	Mean	10.0	43.8	62.5	88.8	98.0
TAROF	North-east	1	Mean	9.0	77.5	-	85.0	95.3
Perennial grass weeds								
AGRRE	North-east	2	Mean	11.0	57.6	65.7	81.3	90.1
			Min-Max	10.0-12.0	48.8-66.3	62.5-68.8	77.5-85.0	88.8-91.3
			SD	-	12.37	4.45	5.30	1.77
	South-east	2	Mean	23	-	55.0	-	80.1
			Min-Max	20.0-26.0	-	40.0-70.0	-	75.3-84.8
			SD	-	-	21.21	-	6.72
		1*	Mean	5.5	68.8	78.8	82.5	93.8
CYNDA	South-east	1	Mean	12.3	43.8	-	50.0	50.0

Target	EPPO climatic zone	No. of trials		<i>Untreated-plants/m² (or % ground cover)</i>	Mean % efficacy of SAE053H/01			
					60-154 DA-A			
					0.75 L/ha	1.0 L/ha	1.2 L/ha	1.5 L/ha
SORHA	South-east	2	Mean	15.5	73.2	89.2	90.1	92.3
			Min-Max	11.0-20.0	68.8-77.5	88.8-89.5	86.3-93.8	91.3-93.3
			SD	-	6.15	0.49	5.30	1.41
		3	Mean	159.7	-	85.2	-	89.9
			Min-Max	26.0-318	-	80.3-88.5	-	89.5-90.2
			SD	-	-	4.34	-	0.34
		1	Mean	6.5 (4.0)	89.6	-	88.5	90.8

*data from earlier assessment timings where weed populations in untreated control reduced to below 5 plants/m² by the later assessment timing

Pronounced rate related responses were apparent with respect to control of many of the weed species on which data were generated.

Overall, for many of the main weeds on which data were generated, the minimum effective rate of SAE053H/01 required to consistently give optimum control is shown to be between 1.0 L and 1.2 L product/ha. This included annual broad-leaved weed species (CAPBP, CRESS, DATST, HIBTR, LAMPU, MATIN, SINAR, VERPE), a perennial broad-leaved weed species (CIRAR) and perennial grass weed species (CYNDA, SORHA).

For other weed species, the minimum effective rate of SAE053H/01 required to consistently give optimum control is shown to be between 1.2 L and 1.5 L product/ha. This included annual broad-leaved weed species (AMASS, GALAP, GERSS, POLAV, POLCO, POLPE, POLLA, POLLM, POROL, VERHE, VIOAR), annual grass weed species (DIGSA, ECHCG, SETSS) and a perennial grass weed species (AGRRE).

Whilst no rate related responses were apparent with respect to some of the other weed species on which data were generated, with no distinct differences in efficacy between any of the rates tested and the lowest rate of 0.75 L product/ha giving effective control, a range of different annual broad-leaved weed species typically occur and warrant control in maize crops and therefore the rate of a herbicide to be applied should be that required to give effective control of all weeds present.

Summary and conclusions on the minimum effective dose

Across trials, the efficacy of SAE053H/01 has been evaluated under a wide range of climatic conditions and agronomic practices fully representing those in maize growing regions of EU Central Registration zone countries relevant to this submission. Data to demonstrate minimum effective dose for SAE053H/01 in maize are presented for a range of annual and perennial weed broad-leaved and grass weed species known to be susceptible to approved products containing mesotrione and nicosulfuron and for which label claims for control are supported for SAE053H/01, and including many of the main widespread occurring and problematic weed species that occur in maize in Europe. Populations of these weed species and growth stages at application across trials are considered to be fully representative of those in maize crops in relevant EU Central Registration zone countries.

Where data were generated on individual weed species in two or three EPPO climatic zones, the minimum effective dose was in most cases shown to be the same between zones. It is therefore reasonable to conclude that for specific weed species where data were only generated in one or two climatic zones, the minimum effective dose would be the same in all 3 climatic zones relevant to the EU Central Registration zone.

Based on presented data, it is therefore reasonable to conclude that rates within the range of 1.0-1.2 L product/ha are fully justified as the minimum effective doses required to give consistent control of many of the main susceptible annual and perennial broad-leaved and grass weeds for which label claims for control are supported for SAE053H/01 in maize, with the 1.0 L product/ha rate sufficient to give effective control of more susceptible species, whilst rates of up to 1.2 L product/ha rate will give sufficient control of other species.

Study Comments: 3.2.2 dRR point 3.2.2	EN: Studies are acceptable. The claimed dose rate is 1,0 – 1,2 l of SAE053H/01/ha
EN: Evaluator conclusion: The claimed dose rate is 1,0 – 1,2 l of product/ha. The minimum effective dose were tested in maize through the Maritime, SE and NE climatic EPPO zones. The range of 1,0 - 1,2 L product/ha gives control of many of the main susceptible annual and perennial broad-leaved and grass weeds. The 1.0 L product/ha rate gives effective control of more susceptible species, whilst higher rates of up to 1,2 or 1,5 L product/ha rate are needed to give optimum control of other species. The dose rate of 1,0 – 1,2 l of product/ha showed the best efficacy in all mentioned above climatic EPPO zones.	

3.2.3 Efficacy tests (KCP 6.2)

A total of 60 trials carried out between 2014 and 2018 generated data on the efficacy of SAE053H/01 applied post-emergence at the lowest and/or highest rates in the proposed label range of 1.0-1.5 L product/ha against a wide range of broad-leaved and grass weed species in maize. Of these trials, 23 were carried out in the Maritime climatic zone, 16 were carried out in the North-east climatic zone and 21 were carried out in the South-east climatic zone.

All efficacy trials were carried out by organisations that are officially recognised as competent to carry out efficacy testing in accordance with European Commission Directive 93/71/EEC by the authorities in the relevant countries.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-8: Details on trial methodology (efficacy trials)

Guidelines	General guidelines	EPPO PP1/226 (2), EPPO PP1/241 (1), EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (3/4)
	Specific guidelines	EPPO PP 1/50 (3), CEB Method M046
Experimental design	Plot design	RCBD (60)
	Plot size	16-30 m ²
	Number of replications	4 (60)
Crop	Trials per crop	Maize (60)
	Varieties per crop	Activate (1), Ambrosini (1), Beethoven (1), Cannavaro (1), Capuzzi (1), Cathy (1), Cranio (1), DKC 3203 (1), DKC 3350 (1), DKC 3511 (1), DKC 5031 (1), DKC 4541 (1), DKC 4590 (2), DK 5830 (1), ES Pallazzo (1), F376 (1), Fabregas (1), Fehér nyolcsoros (1), Finkas (2), Kadryl (1), Kongres (1), KWS 6471 (1), KWS Stabil (1), LG30 212 (1), LG 30.220 (1), LG 32.16 (2), LG3350 (1), LG3352 (1), Limagrain 30.315 (1), Luigi (1), Mantilla (1), Mas 19.H (1), Mikado (1), NK Falkone (1), Format (1), NK Pako (1), Olt (1), Opoka (1), P7892 (1), P8523 (1), P8816 (1), Phileaxx (1), Pioneer P0725 (1), Pioneer 8400 (1), PO105 (1), PR37N01 (1), PR38A79 (1), PR39D81 (1), Ricardinio (1), Ronaldinio (1), Ronaldis (1), Sevenus (1), Suarez (1), Sumberto (1), SY Feeditop (1), ZP 341 (1), ZP Dalmac (1)
Application	Crop stage (BBCH) at application	Post-emergence from 10 to 18 (BBCH)
Application	Weed stage (BBCH) and population at application	Annual broad-leaved weeds ABUTH (1): from 10 to 13 (BBCH), 16.0 plants/m ² , AMASS (9): from 00 to 16 (BBCH), 0 (1) or 5.0-100.0 (8) plants/m ² , AMBEL (4): from 10 to 16 (BBCH), 8.0-27.0 plants/m ² , BRNN (2): from 10 to 51 (BBCH), 5.0-7.0 plants/m ² , CAPBP (5): from 12 to 39 (BBCH), 3.0-15.0 plants/m ² , CENCY (1): 15 (BBCH), 6.0 plants/m ² , CHESS (51): from 00 to 51 (BBCH), 0 (2) or 2.0-159.0 (49) plants/m ² ,

		<p>DATST (6): from 00 to 16 (BBCH), 0 (1) or 9.0-120.0 (5) plants/m², FUMOF (2): from 12 to 13 (BBCH), 5.0-13.0 plants/m², GAETE (1): from 10 to 14 (BBCH), 25.0 plants/m², GALAP (3): from 12 to 25 (BBCH), 6.0-24.0 plants/m², GASPA (2): from 12 to 15 (BBCH), 10.0 plants/m², GERSS (2): from 12 to 14 (BBCH), 7.0-34.0 plants/m², HELAN (1): from 14 to 16 (BBCH), 15.5 plants/m², HIBTR (8): from 00 to 15 (BBCH), 0 (1) or 5.0-18.0 (7) plants/m², LAMSS (5): from 12 to 16 (BBCH), 5.0-80.3 plants/m², MATSS (10): from 10 to 53 (BBCH), 5.0-34.8 plants/m², MERAN (1): from 14 to 21 (BBCH), 28.0 plants/m², MYOAR (1): 13 (BBCH), 8.0 plants/m², PAPRH (1): 13 (BBCH), 6.0 plants/m², POLAV (3): from 10 to 31 (BBCH), 5.0-8.0 plants/m², POLCO (13): from 10 to 31 (BBCH), 2.0-39.8 plants/m², POLLA (2): from 11 to 31 (BBCH), 5.0-9.5 plants/m², POLLN (1): 14 (BBCH), 32 plants/m², POLPE (5): from 12 to 16 (BBCH), 5.0-20.0 plants/m², POROL (2): from 14 to 18 (BBCH), 10.0-65.0 plants/m², RAPRA (1): from 10 to 14 (BBCH), 32.0 plants/m², SINAR (4): from 10 to 51 (BBCH), 5.0-17.0 plants/m², SOLNI (9): from 00 to 35 (BBCH), 0 (1) or 1.0-57.0 (8) plants/m², SPRAR (1): from 11 to 16 (BBCH), 20.0 plants/m², STAAN (2): from 12 to 16 (BBCH), 15.5-94.8 plants/m², STEME (7): from 00 to 33 (BBCH), 0 (1) or 4.0-23.0 plants/m² (6), THLAR (6): from 10 to 55 (BBCH), 5.0-17.5 plants/m², VERHE (3): from 12 to 13 (BBCH), 6.0-7.5 plants/m², VERPE (5): from 00 to 63 (BBCH), 0 (1) or 7.0-38.0 plants/m² (4), VIOAR (7): from 12 to 20 (BBCH), 4.0-46.0 plants/m²</p> <p>Annual grass weeds DIGSA (3): from 14 to 23 (BBCH), 40.0-76.0 plants/m², ECHCG (31): from 00 to 45 (BBCH), 0 (2) or 1.0-483.0 plants/m² (29), SETSS (10): from 10 to 23 (BBCH), 2.0-118.0 plants/m²</p> <p>Perennial broad-leaved weeds AEOPO (1): from 12 to 14 (BBCH), 6.0 plants/m², CIRAR (6): from 10 to 32 (BBCH), 5.0-24.8 plants/m², CONAR (5): from 12 to 51 (BBCH), 2.0-12.5 plants/m², PVAZE (1): from 11 to 12 (BBCH), 2.0 plants/m², TAROF (1): 15 (BBCH), 6.0 plants/m²</p> <p>Perennial grass weeds AGRRE (5): from 11 to 59 (BBCH), 6.8-21.0 plants/m², CYNDA (1): from 18 to 22 (BBCH), 11.5 plants/m², SORHA (6): from 11 to 22 (BBCH), 5.3-318 plants/m²</p>
	Number of applications	1 (all trials)
	Spray volumes	200 L/ha (33), 250 L/ha (4), 300 L/ha (23)
Assessments	Assessment types	Visual % weed control, % weed ground cover, number of weeds/m ² Phytotoxicity, crop vigour

Agronomic practices in the cultivation of maize are considered to be sufficiently similar across countries within the Central Registration zone for data generated across all trials to be fully supportive of demonstrating the efficacy of SAE053H/01 in all countries relevant to this submission.

Populations of susceptible broad-leaved and grass weed species on which data have been generated in trials are considered to be sufficiently similar between EU countries relevant to this submission for the data generated in all trials to be fully representative and supportive of demonstrating the efficacy of SAE053H/01 across all EU Central Registration zone countries relevant to this submission.

Justification for the use of biological efficacy data included in this dossier is made according to EPPO PP 1/241(1) "Guidance on comparable climates".

Efficacy trials from which data are summarized in this dossier were carried out in the following EPPO climatic zones:

Maritime: Belgium, Czech Republic, Germany, Maritime regions of France, United Kingdom

North-east: Poland

South-east: Bulgaria, Hungary, Romania, Slovakia

Trials carried out in the Maritime climatic zone have been conducted in areas where climatic conditions are representative of those in Austria, Belgium, Czech Republic, Germany, Ireland, Netherlands and the United Kingdom. Data generated in these trials are therefore fully supportive towards demonstrating the efficacy of SAE053H/01 in the EU Central Registration zone with respect to these countries.

All trials carried out in the North-east climatic zone have been conducted in Poland and data generated in these trials are therefore fully supportive towards demonstrating the efficacy of SAE053H/01 in the EU Central Registration zone with respect to this country.

Trials carried out in the South-east climatic zone have been conducted in areas where climatic conditions are representative of those in Hungary, Romania, Slovenia and Slovakia and data generated in these trials are therefore fully supportive towards demonstrating the efficacy of SAE053H/01 in the EU Central Registration zone with respect to these countries.

Comparison of the efficacy of SAE053H/01 with that of the equivalent approved product (Elumis)

SAE053H/01 is an Oil Dispersion (OD) formulation that contains 80 g/L mesotrione and 30 g/L nicosulfuron, for which the formulation type is the same and the amounts of the active substances are very similar for mesotrione and identical for nicosulfuron to those in the approved product (Elumis, containing 75g + 30 g a.s./L) that is current registered for use as a herbicide in maize in the majority of EU countries, including those relevant to this application for the approval of SAE053H/01 in the EU Central Registration zone. The proposed national label rates are within the range of 1.0-1.2 L product/ha for the use of SAE053H/01 as a herbicide in maize and these correspond or overlap with approved national label rates of the registered Elumis product.

All 60 efficacy trials conducted between 2014 and 2018 included a comparison of the efficacy of SAE053H/01 with that of the registered product (Elumis) when applied at either the lowest and highest label range rates (1.0 L and 1.5 L product/ha) or both for post-emergence control of a wide range of broad-leaved and grass weed species in maize.

Direct comparisons of the efficacy of SAE053H/01 with that of Elumis when applied at the same rates (between 1.0 L and 1.5 L product/ha) against individual weed species at early and late assessment timings across these 60 trials are given in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-9.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-9: Comparison of the efficacy of SAE053H/01 with that of Elumis when applied at the same rates (1.0 L and 1.5 L product/ha against individual weed species in maize at early and late assessment timings

Weed EPPO code	EPPO climatic zone		Early assessment timings					Late assessment timings				
			Number of trials	SAE053H//01 1.0 L/ha	Elumis 1.0 L/ha	SAE053H//01 1.5 L/ha	Elumis 1.5 L/ha	Number of trials	SAE053H//01 1.0 L/ha	Elumis 1.0 L/ha	SAE053H//01 1.5 L/ha	Elumis 1.5 L/ha
Annual broad-leaved weed species												
ABUTH	South-east	Mean	1	100	100	100	100	1	100	100	100	100
AMABL	South-east	Mean	1	100	100	100	100	1	100	100	100	90.0
AMARE	Maritime	Mean	2	97.5	100	100	100	2	98.5	100	100	100
		Min-max		95.0-100	100-100	100-100	100-100		97.0-100	100-100	100-100	100-100
		SD		3.54	0.00	0.00	0.00		2.12	0	0	0
	North-east	Mean	1	78.8	81.3	91.3	93.8	1	67.5	71.3	85.0	86.3
	South-east	Mean	4	94.3	94.0	-	-	4	83.9	86.5	-	-
		Min-max		92.5-98.8	82.5-100	-	-		71.3-96.3	83.8-92.0	-	-
		SD		3.02	8.03	-	-		10.58	3.82	-	-
		Mean	5	-	-	95.1	92.9	5	-	-	95.7	93.2
		Min-max		-	-	77.5-100	75.0-100		-	-	87.5-100	82.5-100
		SD		-	-	9.83	10.42		-	-	5.11	7.26
AMBEL	South-east	Mean	2	80.0	80.0	-	-	3	79.4	73.6	-	-
		Min-max		72.5-87.5	72.5-87.5	-	-		66.3-99.5	42.5-95.8	-	-
		SD		10.61	10.61	-	-		17.65	27.74	-	-
		Mean	3	-	-	89.6	86.8	4	-	-	85.8	79.5
		Min-max		-	-	82.5-96.3	77.5-100		-	-	75.8-100	63.8-99.0
		SD		-	-	6.91	11.77		-	-	11.39	14.87
BRSNW	Maritime	Mean	1	100	100	100	100	1	100	100	100	100
	North-east	Mean	1	69.0	75.0	85.8	80.5	1	100	100	100	100
CAPBP	North-east	Mean	2	100	100	-	-	2	100	100	-	-
		Min-max		100-100	100-100	-	-		100-100	100-100	-	-
		SD		0.00	0.00	-	-		0.00	0.00	-	-
		Mean	4	-	-	99.4	100	4	-	-	100	100
		Min-max		-	-	97.5-100	100-100		-	-	100-100	100-100
		SD		-	-	1.25	0.00		-	-	0.00	0.00
	South-east	Mean	1	87.5	86.3	100	100	1	92.5	88.8	100	100
CENCY	North-east	Mean	1	-	-	95.0	93.8	1	-	-	99.9	100

Weed EPPO code	EPPO climatic zone		Early assessment timings					Late assessment timings				
			Number of trials	SAE053H//01 1.0 L/ha	Elumis 1.0 L/ha	SAE053H//01 1.5 L/ha	Elumis 1.5 L/ha	Number of trials	SAE053H//01 1.0 L/ha	Elumis 1.0 L/ha	SAE053H//01 1.5 L/ha	Elumis 1.5 L/ha
CHEAL	Maritime	Mean	17	94.3	94.2	-	-	17	95.3	94.2	-	-
		Min-max		66.3-100	70.0-100	-	-		80.0-100	50-100	-	-
		SD		9.38	9.61	-	-		7.30	12.28	-	-
		Mean	19			96.6	99.8	19	-	-	94.7	98.3
		Min-max				80.0-100	99.6-99.9		-	-	68.8-100	90.0-100
		SD				6.06	0.22		-	-	8.61	4.08
	North-east	Mean	12	92.3	90.3	-	-	12	91.0	85.5	-	-
		Min-max		72.5-100	67.5-100	-	-		58.8-100	48.8-100	-	-
		SD		10.00	10.16	-	-		15.68	18.32	-	-
		Mean	15	-	-	96.0	97.3	15	-	-	96.5	96.3
		Min-max		-	-	82.5-100.0	85.0-100.0		-	-	78.8-100	77.5-100.0
		SD		-	-	6.68	4.57		-	-	7.37	7.42
	South-east	Mean	12	94.8	93.0	-	-	12	91.1	90.4	-	-
		Min-max		80.5-100	81.3-100	-	-		71.3-100	81.3-100	-	-
		SD		6.01	7.71	-	-		9.00	6.93	-	-
		Mean	11	-	-	96.9	96.4	11	-	-	97.3	96.2
		Min-max		-	-	80.0-100	77.5-100		-	-	90.8-100	88.3-100
		SD		-	-	6.01	6.89		-	-	3.56	4.33
CHEHY	Maritime	Mean	1	100	100	100	100	-	-	-	-	-
	South-east	Mean	1	100	100	100	100	1	100	100	100	100
CHEPO	Maritime	Mean	1	-	-	99.9	98.2	1	-	-	100	100
DATST	Maritime	Mean	2	85.0	88.8	91.2	92.5	2	89.9	91.3	96.3	98.3
		Min-max		70.0-100	77.5-100	82.5-99.8	85.0-100		80.0-99.8	82.5-100	92.5-100	96.5-100
		SD		21.21	15.91	12.23	10.61		14.00	12.37	5.30	2.47
	South-east	Mean	3	100	100	-	-	3	100	100	-	-
		Min-max		100-100	100-100	-	-		100-100	100-100	-	-
		SD		0.00	0.00	-	-		0.00	0.00	-	-
		Mean	3	-	-	99.3	99.3	3	-	-	99.4	99.4
		Min-max		-	-	98.0-100	98.0-100		-	-	98.3-100	98.3-100
		SD		-	-	1.15	1.15		-	-	1.01	1.01
FUMOF	Maritime	Mean	1	97.3	96.5	95.8	96.5	1	82.5	86.2	85.0	81.3
	North-east	Mean	1	-	-	93.8	93.8	1	-	-	90.0	91.3
GAETE	North-east	Mean	1	100	100	100	100	1	100	100	100	100

Weed EPPO code	EPPO climatic zone		Early assessment timings					Late assessment timings				
			Number of trials	SAE053H//01 1.0 L/ha	Elumis 1.0 L/ha	SAE053H//01 1.5 L/ha	Elumis 1.5 L/ha	Number of trials	SAE053H//01 1.0 L/ha	Elumis 1.0 L/ha	SAE053H//01 1.5 L/ha	Elumis 1.5 L/ha
GALAP	Maritime	Mean	2	50.0	70.7	73.8	75.0	2	24.0	68.8	81.3	69.6
		Min-max		50.0-50.0	66.3-75.0	71.3-76.3	75.0-75.0		21.7-26.3	62.5-75.0	76.3-86.3	58.3-80.8
		SD		0.00	6.15	3.54	0.00		3.25	8.84	7.07	15.91
	North-east	Mean	1	100	100	100	100	1	73.8	67.5	100	97.5
GASPA	North-east	Mean	2	89.4	89.4	96.9	91.3	2	85.2	80.0	96.3	95.0
		Min-max		78.8-100	78.8-100	93.8-100	82.5-100		73.8-96.5	72.5-87.5	92.5-100	90.0-100
		SD		14.99	14.99	4.38	12.37		16.05	10.61	5.30	7.07
	Maritime	Mean	1	91.3	76.3	94.5	81.3	-	-	-	-	-
GERPP	North-east	Mean	1	17.5	21.3	-	-	1	5.0	11.3	-	-
		Mean		-	-	61.9	66.3		-	-	58.7	61.7
		Min-max		-	-	31.1-92.5	33.8-98.8		-	-	18.8-98.5	23.8-99.5
	South-east	SD	2	-	-	43.27	45.93	2	-	-	56.36	53.53
HELAN	South-east	Mean	1	-	-	96.0	97.3	1	-	-	97.5	97.8
HIBTR	South-east	Mean	7	69.3	76.5	-	-	7	86.2	86.8	-	-
		Min-max		12.5-86.3	35.0-88.5	-	-		71.8-100	76.5-100	-	-
		SD		26.18	19.39	-	-		10.39	7.62	-	-
	North-east	Mean	6	-	-	86.1	90.9	6	-	-	93.7	94.7
		Min-max		-	-	50.0-100	73.8-100		-	-	86.3-100	91.8-100
		SD		-	-	19.03	10.06		-	-	5.29	2.91
LAMAM	North-east	Mean	1	-	-	100	100	-	-	-	-	-
LAMPU	Maritime	Mean	1	90.0	81.3	-	-	1	100	100	-	-
		Mean	2	-	-	97.5	99.3	2	-	-	100	100
		Min-max		-	-	95.0-100	99.0-99.6		-	-	100-100	100-100
		SD		-	-	3.54	0.45		-	-	0.00	0.00
	North-east	Mean	1	-	-	100	100	1	-	-	100	100
	South-east	Mean	1	82.5	81.3	100	100	1	87.5	83.8	100	100
MATCH	Maritime	Mean	1	100	100	100	100	1	100	100	100	100
	North-east	Mean	1	89.5	32.5	100	85.5	1	100	100	100	100
MATIN	North-east	Mean	5	82.6	67.9	90.1	85.0	5	87.5	79.4	99.1	97.5
		Min-max		73.8-100	22.5-96.5	77.3-100	71.0-100		78.8-100	40.0-100	95.3 - 100	87.5 - 100
		SD		11.48	31.26	10.41	13.03		10.18	24.42	2.10	5.59
	South-east	Mean	1	91.3	86.3	100	98.8	1	96.3	88.8	100	98.8
MATMA	Maritime	Mean	2	-	-	99.9	99.8	2	-	-	100	100
		Min-max		-	-	99.9-99.9	99.8-99.9		-	-	100-100	100-100
		SD		-	-	0.00	0.13		-	-	0.00	0.00

Weed EPPO code	EPPO climatic zone		Early assessment timings					Late assessment timings				
			Number of trials	SAE053H//01 1.0 L/ha	Elumis 1.0 L/ha	SAE053H//01 1.5 L/ha	Elumis 1.5 L/ha	Number of trials	SAE053H//01 1.0 L/ha	Elumis 1.0 L/ha	SAE053H//01 1.5 L/ha	Elumis 1.5 L/ha
MERAN	Maritime	Mean	1	95.8	90.0	95.3	96.5	1	100	97.5	100	97.5
MYOAR	North-east	Mean	1	-	-	100	100	1	-	-	100	100
PAPRH	North-east	Mean	1	-	-	90.0	91.3	1	-	-	87.5	90.0
POLAV	Maritime	Mean	2	87.8	82.2	92.0	92.9	2	88.2	80.4	89.4	92.9
		Min-max		78.0-97.5	67.5-96.8	85.0-99.0	88.0-97.8		81.3-95.0	67.5-93.3	80.0-98.8	88.8-97.0
		SD		13.79	20.72	9.90	6.93		9.69	18.24	13.29	5.80
	North-east	Mean	1	52.5	20.0	80.0	68.8	1	52.5	35.0	76.3	65.0
POLCO	Maritime	Mean	4	74.9	71.9	-	-	3	80.7	71.7	-	-
		Min-max		60.0-99.5	50.4-97.5	-	-		70.0-99.5	50.0-97.5	-	-
		SD		18.93	19.51	-	-		16.36	24.02	-	-
		Mean	5	-	-	91.0	90.0	4	-	-	88.8	89.4
		Min-max		-	-	70.0-100	80.0-100		-	-	75.0-100	80.0-100
		SD		-	-	12.45	7.07		-	-	10.31	8.26
	North-east	Mean	2	75.0	56.9	-	-	3	63.4	49.6	-	-
		Min-max		55.0-95.0	22.5-91.3	-	-		46.3-77.5	32.5-60.0	-	-
		SD		28.28	48.65	-	-		15.81	14.92	-	-
		Mean	3	-	-	91.3	81.4	4	-	-	88.2	77.2
		Min-max		-	-	81.3-100	66.3-99.0		-	-	76.3-95.0	68.8-91.3
		SD		-	-	9.41	16.50		-	-	8.18	9.77
	South-east	Mean	3	87.2	91.1	-	-	3	80.2	81.8	-	-
		Min-max		78.5-92.5	82.3-100	-	-		77.5-85.0	78.0-88.0	-	-
		SD		7.57	8.85	-	-		4.19	5.39	-	-
		Mean	4	-	-	94.4	94.4	4	-	-	88.3	87.8
		Min-max		-	-	91.3-100	92.5-100		-	-	85.3-90.8	85.5-90.0
		SD		-	-	3.88	3.75		-	-	2.40	1.94
POLLA	North-east	Mean	1	93.8	95.0	100	100	1	87.5	88.8	100	100
	South-east	Mean	1	25.0	15.0	72.5	40.0	1	89.5	93.5	81.3	85.0
POLLM	Maritime	Mean	1	-	-	96.8	95.4	1	-	-	98.7	97.8
POLPE	Maritime	Mean	2	84.4	87.5	89.4	91.9	1	100	100	100	97.5
		Min-max		70.0-98.8	75.0-100	78.8-100	83.8-100		-	-	-	-
		SD		20.36	17.68	14.99	11.46		-	-	-	-
	North-east	Mean	-	-	-	-	-	1	-	-	87.5	91.3
	South-east	Mean	1	67.8	71.3	-	-	1	67.8	67.3	-	-
		Mean	1	-	-	100	100	1	-	-	97.5	95.0

Weed EPPO code	EPPO climatic zone		Early assessment timings					Late assessment timings				
			Number of trials	SAE053H//01 1.0 L/ha	Elumis 1.0 L/ha	SAE053H//01 1.5 L/ha	Elumis 1.5 L/ha	Number of trials	SAE053H//01 1.0 L/ha	Elumis 1.0 L/ha	SAE053H//01 1.5 L/ha	Elumis 1.5 L/ha
POROL	Maritime	Mean	1	36.3	53.8	58.8	73.8	1	25.0	21.3	75.0	83.8
	South-east	Mean	-	-	-	-	-	1	56.3	45.0	86.0	70.0
RAPRA	North-east	Mean	1	100	85.5	100	88.8	1	100	90.0	100	97.3
SINAR	North-east	Mean	2	100	99.4	100	100	2	86.7	79.4	93.8	90.0
		Min-max		100-100	98.8-100	100-100	100.0-100		77.5-95.8	71.3-87.5	87.5-100	80.-100
		SD		0.00	0.85	0.00	0.00		12.94	11.46	8.84	14.14
	South-east	Mean	2	92.4	92.3	97.9	97.5	2	90.7	90.9	96.3	96.4
		Min-max		84.8-100	84.5-100	95.8-100	95.0-100		81.3-100	81.8-100	92.5-100	92.8-100
		SD		10.75	10.96	2.97	3.54		13.22	12.87	5.30	5.09
SOLNI	Maritime	Mean	5	92.2	91.7	-	-	4	96.9	96.2	-	-
		Min-max		77.5-100	77.5-100	-	-		88.8-100	85.0-100	-	-
		SD		10.74	11.33	-	-		5.42	7.47	-	-
		Mean	6	-	-	95.1	95.1	5	-	-	99.4	99.3
		Min-max		-	-	77.5-100	78.8-100		-	-	96.8-100	96.3-100
		SD		-	-	8.95	8.51		-	-	1.43	1.65
	South-east	Mean	1	77.5	66.3	-	-	1	100	98.8	-	-
		Mean	2	-	-	82.5	77.5	2	-	-	98.8	97.5
		Min-max		-	-	75.0-90.0	72.5-82.5		-	-	97.5-100	95.0-100
SPRAR	North-east	SD	1	-	-	10.61	7.07	2	-	-	1.77	3.50
		Mean		100	99.5	100	100		100	100	100	100
		Mean		82.5	83.8	-	-		99.3	97.3	-	-
		Mean		-	-	91.5	87.3		-	-	99.8	97.0
STAAAN	South-east	Min-max	2	-	-	86.3-96.8	78.8-95.8	1	-	-	-	-
		SD		-	-	7.39	11.92		-	-	-	-
	Maritime	Mean		98.8	99.0	98.9	98.3		95.8	94.7	95.0	95.0
		Min-max		96.5-100	97.3-100	96.8-100	95.0-100		87.5-100	84.3-100	85.0-100	85.0-100
		SD		2.02	1.50	1.85	2.89		7.22	9.01	8.66	8.66
	North-east	Mean	1	100	100	-	-	-	-	-	-	-
		Mean	3	-	-	100	100	3	-	-	100	100
		Min-max		-	-	100-100	100-100		-	-	100-100	100-100
		SD		-	-	0.00	0.00		-	-	0.00	0.00

Weed EPPO code	EPPO climatic zone		Early assessment timings					Late assessment timings				
			Number of trials	SAE053H//01 1.0 L/ha	Elumis 1.0 L/ha	SAE053H//01 1.5 L/ha	Elumis 1.5 L/ha	Number of trials	SAE053H//01 1.0 L/ha	Elumis 1.0 L/ha	SAE053H//01 1.5 L/ha	Elumis 1.5 L/ha
THLAR	North-east	Mean	3	100	99.9	-	-	2	100	100	-	-
		Min-max		100-100	99.8-100	-	-		100 - 100	100 - 100	-	-
		SD		0.00	0.12	-	-		0.00	0.00	-	-
	North-east	Mean	5	-	-	100	100	4	-	-	100	100
		Min-max		-	-	100-100	100-100		-	-	100-100	100-100
		SD		-	-	0.00	0.00		-	-	0.00	0.00
	South-east	Mean	1	95.0	91.3	100	100	1	97.5	93.8	100	100
VERHE	North-east	Mean	2	-	-	94.6	98.6	2	-	-	95.0	99.8
		Min-max		-	-	90.0-99.3	97.5-99.7		-	-	90.0-100	99.7-100
		SD		-	-	6.55	1.54		-	-	7.07	0.23
	South-east	Mean	1	82.5	80.0	98.8	97.5	1	85.0	83.8	100	100
VERPE	Maritime	Mean	4	63.8	64.7	74.7	70.3	4	87.5	89.1	94.4	94.7
		Min-max		7.7-100	11.8-96.8	17.5-100	6.0-100		50.0-100	56.3-100	7.5-100	78.8-100
		SD		41.57	37.21	38.55	43.67		25.0	21.88	11.25	10.63
	South-east	Mean	1	100	97.0	100	98.0	1	97.0	89.0	99.0	95.0
VIOAR	North-east	Mean	2	86.3	85.7	-	-	2	74.4	70.7	-	-
		Min-max		72.5-100	71.3-100	-	-		71.3-77.5	63.8-77.5	-	-
		SD		19.45	20.29	-	-		4.38	9.69	-	-
		Mean	6	-	-	99.8	98.5	5	-	-	100	97.0
		Min-max		-	-	98.5-100	95.0-100		-	-	100-100	91.5-100
		SD		-	-	0.61	2.00		-	-	0.00	4.21
	South-east	Mean	1	83.8	75.0	96.3	95.0	1	86.3	80.0	97.5	96.3
Annual grass weed species												
DIGSA	Maritime	Mean	3	60.4	72.4	75.0	85.3	3	44.6	55.4	70.0	85.6
		Min-max		11.3-93.5	45.0-93.5	55.0-95.0	71.3-97.0		3.8-76.3	35.0-67.5	58.8-88.8	78.8-90.8
		SD		43.35	24.87	20.00	12.99		37.11	17.79	16.36	6.17
ECHCG	Maritime	Mean	7	90.1	91.0	-	-	6	90.7	89.3	-	-
		Min-max		80.0-97.0	70.0-100	-	-		70.0-96.8	90.0-99.0	-	-
		SD		6.34	10.40	-	-		10.31	15.29	-	-
		Mean	9	-	-	99.3	97.8	8	-	-	98.0	96.4
		Min-max		-	-	97.3-100	90.0-100		-	-	90.0-100	85.0-100
		SD		-	-	0.98	3.34		-	-	3.61	5.70

Weed EPPO code	EPPO climatic zone		Early assessment timings					Late assessment timings				
			Number of trials	SAE053H//01 1.0 L/ha	Elumis 1.0 L/ha	SAE053H//01 1.5 L/ha	Elumis 1.5 L/ha	Number of trials	SAE053H//01 1.0 L/ha	Elumis 1.0 L/ha	SAE053H//01 1.5 L/ha	Elumis 1.5 L/ha
ECHCG	North-east	Mean	8	78.7	78.2	-	-	7	77.6	76.9	-	-
		Min-max		61.3-90.0	60.0-94.3	-	-		58.8-100	55.0-100	-	-
		SD		9.83	10.57	-	-		17.29	17.46	-	-
		Mean	12	-	-	95.1	91.2	11	-	-	96.2	90.6
		Min-max		-	-	84.3-100	62.5-99.3		-	-	77.5-100	57.5-100
		SD		-	-	4.59	10.01		-	-	6.98	13.86
	South-east	Mean	7	83.7	82.3	-	-	7	77.7	74.5	-	-
		Min-max		72.5-100	65.0-92.5	-	-		58.8-100	65.0-87.5	-	-
		SD		9.96	11.20	-	-		13.28	7.81	-	-
		Mean	9	-	-	92.3	90.1	9	-	-	91.2	88.7
		Min-max		-	-	72.6-100	70.0-100		-	-	78.8-100	78.8-100
		SD		-	-	8.72	8.85		-	-	7.05	6.04
SETPU	South-east	Mean	1	81.3	81.3	95.0	95.8	1	73.8	50.0	93.8	86.3
SETVI	South-east	Mean	8	78.4	76.4	-	-	7	78.8	77.1	-	-
		Min-max		26.3-93.8	18.8-97.4	-	-		53.8-92.5	67.5-81.8	-	-
		SD		21.84	25.34	-	-		12.45	4.63	-	-
		Mean	8	-	-	89.0	85.7	7	-	-	89.5	87.4
		Min-max		-	-	70.0-98.0	57.5-100		-	-	77.5-98.8	77.5-92.6
		SD		-	-	10.69	15.05		-	-	6.83	4.90
Perennial broad-leaved weed species												
AEOPO	Maritime	Mean	1	95.0	90.0	100	99.0	1	80.0	70.0	90.0	90.0
CIRAR	North-east	Mean	1	83.8	73.8	91.3	91.3	1	57.5	38.8	73.8	65.0
	South-east	Mean	5	65.4	59.0	79.2	77.8	5	76.8	70.6	88.5	86.6
		Min-max		23.8-94.5	17.5-92.5	57.5-95.8	53.8-95.0		52.5-90.0	50.0-88.5	85.8-90.0	73.8-96.3
		SD		27.73	29.03	18.23	18.36		14.68	17.61	1.70	8.14
CONAR	Maritime	Mean	2	84.8	90.0	82.7	88.1	2	76.3	83.2	77.5	80.7
		Min-max		73.8-95.8	85.0-95.0	68.8-96.5	78.8-97.3		70.0-82.5	82.5-83.8	72.5-82.5	78.8-82.5
		SD		15.56	7.07	19.59	13.08		8.85	0.92	7.07	2.62
	North-east	Mean	1	68.8	41.3	65.0	75.8	1	77.5	62.0	100	99.8
CONAR	South-east	Mean	1	58.8	70.0	68.8	67.5	2	65.2	80.4	84.4	82.6
		Min-max	-	-	-	-	56.3-74.0		65.0-95.8	72.5-96.3	66.3-98.8	
		SD	-	-	-	-	12.52		21.78	16.83	22.98	
PVAZE	Maritime	Mean	-	-	-	-	-	1	62.5	98.0	98.0	98.0
TAROF	North-east	Mean	1	-	-	91.3	92.4	1	-	-	95.3	90.0

Weed EPPO code	EPPO climatic zone		Early assessment timings					Late assessment timings				
			Number of trials	SAE053H//01 1.0 L/ha	Elumis 1.0 L/ha	SAE053H//01 1.5 L/ha	Elumis 1.5 L/ha	Number of trials	SAE053H//01 1.0 L/ha	Elumis 1.0 L/ha	SAE053H//01 1.5 L/ha	Elumis 1.5 L/ha
Perennial grass weed species												
AGRRE	North-east	Mean	2	88.8	82.6	97.9	94.4	2	65.7	61.3	90.1	87.5
		Min-max		83.8-93.8	73.8-91.3	95.8-100	88.8-100.0		62.5-68.8	61.3-61.3	88.8 - 91.3	87.5 - 87.5
		SD		7.07	12.37	2.97	7.92		4.45	0.00	1.77	0.00
	South-east	Mean	3	38.3	41.7	-	-	2	55.0	73.7	-	-
		Min-max		20.0-60.0	10.0-66.3	-	-		40.0-70.0	71.3-76.0	-	-
		SD		20.21	28.81	-	-		21.21	3.32	-	-
		Mean	1	-	-	66.3	11.3	-	-	-	-	-
CYNDA	South-east	Mean	1	-	-	66.3	69.0	1	-	-	50.0	55.0
SORHA	South-east	Mean	5	87.7	88.9	-	-	5	84.8	86.6	-	-
		Min-max		74.4-93.8	80.7-96.5	-	-		78.8-89.5	81.3-91.8	-	-
		SD		7.94	5.73	-	-		10.43	3.75	-	-
		Mean	3	-	-	96.6	88.5	3	-	-	91.8	85.2
		Min-max		-	-	94.0-98.5	78.3-97.3		-	-	90.8-93.3	72.3-93.3
		SD		-	-	2.33	9.61		-	-	1.32	11.32

When applied at the same rates, the efficacy of SAE053H/01 was comparable to that of Elumis in the overall majority of cases against weed species on which data have been generated. In the very few cases where significant differences occurred, neither SAE053H/01 or Elumis consistently gave the higher levels of control.

In addition to data summarised on the efficacy of SAE053H/01 in this dossier, label claims for control of susceptible weed species by SAE053H/01 applied at rates within the range of 1.0-1.2 L product/ha are therefore considered to be further supported for those weed species for which claims for control are supported on national labels of the approved Elumis product applied at equivalent rates in countries relevant to this submission.

Efficacy against weeds

A total of 60 trials carried out between 2014 and 2018 generated data on the efficacy of SAE053H/01 applied across the range of 0.75-1.5 L product/ha against a wide range of annual and perennial broad-leaved and grass weed species in maize.

A summary of the mean percentage efficacy of SAE053H/01 applied at the lowest and highest rates in the proposed range of 1.0-1.5 L product/ha against all annual and perennial broad-leaved and grass weeds on which data were generated, at early and late assessments across trials in maize in each of the climatic zones is given in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-10.

Direct comparisons of mean percentage efficacy of SAE053H/01 applied at the lowest and highest rates in the proposed range of 1.0-1.5 L product/ha against annual and perennial broad-leaved and grass weeds in maize to that of the standard reference product Elumis applied at the same rates across trials are given in the previous table (Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-9).

Direct comparisons of mean percentage efficacy of SAE053H/01 applied at the highest rate in the proposed label range of 1.0-1.5 L product/ha against annual and perennial broad-leaved and grass weeds in maize to that of Elumis applied at the higher rate of 2.0 L product/ha and of standard reference products containing straight mesotrione, where included across trials, are given in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-11.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-10: Mean overall percentage efficacy of SAE053H/01 applied at the lowest and highest rates in the proposed range of 1.0-1.5 L product/ha against weed species at assessments carried out at early and late assessment timings across trials on maize

Weed species	EPO climatic zone (total no.trials)	SAE053H/01 application rate (L prod/ha)	Early assessment timings (2-5 weeks after application)					Late assessment timings (11-22 weeks after application)				
			No. of trials	Untreated (plants/m ²)		% efficacy		No. of trials	Untreated (plants/m ²)		% efficacy	
				Mean	Min-Max	Mean	Min-Max		Mean	Min-Max	Mean	Min-Max
Annual broad-leaved weed species												
ABUTH	South-east (1)	1.0	1	16.0	-	100	-	1	16.0	-	100	-
		1.5	1	16.0	-	100	-	1	16.0	-	100	-
AMABL	South-east (1)	1.0	1	6.0	-	100	-	1	6.0	-	100	-
		1.5	1	8.0	-	100	-	1	8.0	-	100	-
AMARE	Maritime (2)	1.0	2	7.0	5.0-9.0	97.5	95.0-100	2	8.5	6.0-11.0	98.5	97.0-100
		1.5	2	7.0	5.0-9.0	100	100-100	2	8.5	6.0-11.0	100	100-100
	North-east (1)	1.0	1	8.0	-	78.8	-	1	11.0	-	67.5	-
		1.5	1	8.0	-	91.3	-	1	11.0	-	85.0	-
	South-east (5)	1.0	4	23.7	7.8-60.0	94.3	92.5-98.8	4	13.2	7.8-18.0	83.9	71.3-96.3
		1.5	5	20.6	7.8-60.0	95.1	77.5-100	5	12.1	7.8-18.0	95.7	87.5-100
AMBEL	South-east (4)	1.0	2	14.0	8.0-20.0	80.0	72.5-87.5	3	13.5	8.0-20.0	79.4	66.3-99.5
		1.5	3	14.1	8.0-20.0	89.6	82.5-96.3	4	12.8	8.0-20.0	85.8	75.8-100
BRSNW	Maritime (1)	1.0	1	10.0	-	100	-	1	10.0	-	100	-
		1.5	1	10.0	-	100	-	1	10.0	-	100	-
	North-east (1)	1.0	1	5.0	-	69.0	-	1	5.0	-	100	-
		1.5	1	5.0	-	85.8	-	1	5.0	-	100	-
CAPBP	North-east (4)	1.0	2	11.5	9.0-14.0	100	100-100	2	12.5	-	100	100-100
		1.5	4	10.6	8.0-14.0	99.4	97.4-5-100	4	11.0	8.0-16.0	100	100-100
	South-east (1)	1.0	1	6.3	-	87.5	-	1	6.3	-	92.5	-
		1.5	1	6.3	-	100	-	1	6.3	-	100	-
CENCY	North-east (1)	1.5	1	7.0	-	95.0	-	1	8.0	-	99.9	-
CHEAL	Maritime (19)	1.0	17	32.3	6.0-143.0	94.3	66.3-100	17	31.0	8.0-143.0	95.3	80.0-100
		1.5	19	34.1	6.0-1143.0	96.8	71.3-100	19	33.0	8.0-143.0	96.6	80.0-100
	North-east (15)	1.0	12	32.1	5.0-159.0	92.3	72.5-100	12	30.6	5.0-159.0	91.0	58.8-100
		1.5	15	28.2	5.0-159.0	96.0	82.5-100	15	27.6	5.0-159.0	96.5	78.8-100
	South-east (14)	1.0	12	12.1	5.0-35.0	94.8	80.5-100	12	11.6	5.0-20.0	91.1	71.3-100
		1.5	14	12.0	5.0-35.0	97.0	80.0-100	14	11.5	5.0-20.0	96.9	90.8-100

Weed species	EPPO climatic zone (total no.trials)	SAE053H/01 application rate (L prod/ha)	Early assessment timings (2-5 weeks after application)					Late assessment timings (11-22 weeks after application)				
			No. of trials	Untreated (plants/m²)		% efficacy		No. of trials	Untreated (plants/m²)		% efficacy	
				Mean	Min-Max	Mean	Min-Max		Mean	Min-Max	Mean	Min-Max
CHEHY	Maritime (1)	1.0	1	7.0	-	100	-	-	-	-	-	-
		1.5	1	7.0	-	100	-	-	-	-	-	-
	South-east (1)	1.0	1	10.0	-	100	-	1	10.0	-	100	-
		1.5	1	10.0	-	100	-	1	10.0	-	100	-
CHEPO	Maritime (1)	1.5	1	28.3	-	99.9	-	1	27.3	-	100	-
DATST	Maritime (2)	1.0	2	10.0	7.0-13.0	85.0	70.0-100	1	7.0	6.0-8.0	89.9	80.0-99.8
		1.5	2	10.0	7.0-13.0	91.2	82.5-99.8	2	7.0	6.0-8.0	96.3	92.5-100
	South-east (4)	1.0	3	71.3	9.0-120.0	100	100-100	3	71.3	9.0-120.0	100	100-100
		1.5	4	56.8	9.0-120.0	99.5	98.0-100	4	55.2	6.8-120.0	99.6	98.3-100
FUMOF	Maritime (1)	1.0	1	12.0	-	97.3	-	1	12.0	-	82.5	-
		1.5	1	12.0	-	95.8	-	1	12.0	-	85.0	-
	North-east (1)	1.5	1	6.0	-	93.8	-	1	6.0	-	90.0	-
GAETE	North-east (1)	1.0	1	14.0	-	100	-	1	14.0	-	100	-
		1.5	1	14.0	-	100	-	1	14.0	-	100	-
GALAP	Maritime (2)	1.0	2	17.0	15.0-19.0	50.0	50.0-50.0	2	18.5	18.0-19.0	24.0	21.7-26.3
		1.5	2	17.0	15.0-17.0	73.8	71.3-76.3	2	18.5	18.0-19.0	81.3	76.3-86.3
	North-east (1)	1.0	1	7.0	-	100	-	1	8.0	-	73.8	-
		1.5	1	7.0	-	100	-	1	8.0	-	100	-
GASPA	North-east (2)	1.0	2	13.0	10.0-16.0	89.4	78.8-100	2	15.0	10.0-20.0	85.2	73.8-96.5
		1.5	2	13.0	10.0-16.0	96.9	93.8-100	2	15.0	10.0-20.0	96.3	92.5-100
GERPP	Maritime (1)	1.0	1	11.0	-	91.3	-	-	-	-	-	-
		1.5	1	11.0	-	94.5	-	-	-	-	-	-
GERPU	North-east (2)	1.0	1	12.0	-	17.5	-	1	14.7	-	5.0	-
		1.5	2	11.0	10.0-12.0	61.9	31.1-92.5	2	13.4	12.0-14.7	58.7	18.8-98.5
HELAN	South-east (1)	1.5	1	10.5	-	96.0	-	1	6.5	-	97.5	-
HIBTR	South-east (8)	1.0	7	9.3	6.0-15.0	69.3	12.5-86.3	7	11.6	5.0-17.5	86.2	71.8-100
		1.5	8	9.9	6.0-15.0	88.8	50.0-100	8	10.9	5.0-17.5	93.7	86.3-100
LAMAM	North-east (1)	1.5	1	5.5	-	100	-	-	-	-	-	-

Weed species	EPPO climatic zone (total no.trials)	SAE053H/01 application rate (L prod/ha)	Early assessment timings (2-5 weeks after application)					Late assessment timings (11-22 weeks after application)				
			No. of trials	Untreated (plants/m ²)		% efficacy		No. of trials	Untreated (plants/m ²)		% efficacy	
				Mean	Min-Max	Mean	Min-Max		Mean	Min-Max	Mean	Min-Max
LAMPU	Maritime (2)	1.0	1	41.0	-	90.0	-	1	41.0	-	100	-
		1.5	2	60.4	41.0-79.8	97.5	95.0-100	2	60.0	41.0-79.0	100	100-100
	North-east (1)	1.5	1	8.0	-	100	-	1	8.0	-	100	-
	South-east (1)	1.0	1	5.8	-	82.5	-	1	5.8	-	87.5	-
		1.5	1	5.8	-	100	-	1	5.8	-	100	-
MATCH	Maritime (1)	1.0	1	10.0	-	100	-	1	10.0	-	100	-
		1.5	1	10.0	-	100	-	1	10.0	-	100	-
	North-east (1)	1.0	1	17.0	-	89.5	-	1	15.0	-	100	-
		1.5	1	17.0	-	100	-	1	15.0	-	100	-
MATIN	North-east (5)	1.0	5	9.0	5.0-11.0	82.6	73.8-100	5	9.4	5.0-12.0	87.5	78.8-100
		1.5	5	9.0	5.0-11.0	90.1	77.3-100	5	9.4	5.0-12.0	99.1	95.3-100
	South-east (1)	1.0	1	7.8	-	91.3	-	1	7.8	-	96.3	-
		1.5	1	7.8	-	100	-	1	7.8	-	100	-
MATMA	Maritime (2)	1.5	2	29.8	24.0-35.5	99.9	99.9-99.9	2	30.3	24.5-36.0	100	100-100
MERAN	Maritime (1)	1.0	1	20.0	-	95.8	-	1	15.0	-	100	-
		1.5	1	20.0	-	95.3	-	1	15.0	-	100	-
MYOAR	North-east (1)	1.5	1	9.0	-	100	-	1	7.0	-	100	-
PAPRH	North-east (1)	1.5	1	7.0	-	90.0	-	1	8.0	-	87.5	-
POLAV	Maritime (2)	1.0	2	6.5	5.0-8.0	87.8	78.0-97.5	2	6.5	5.0-8.0	88.2	81.3-95.0
		1.5	2	6.5	5.0-8.0	92.0	85.0-99.0	2	6.5	5.0-8.0	89.4	80.0-98.8
	North-east (1)	1.0	1	7.0	-	52.5	-	1	7.0	-	52.5	-
		1.5	1	7.0	-	80.0	-	1	7.0	-	76.3	-
POLCO	Maritime (5)	1.0	4	11.0	6.0-17.0	74.9	60.0-99.5	3	14.3	9.0-17.0	80.7	70.0-99.5
		1.5	5	16.6	6.0-38.8	91.0	70.0-100	4	20.6	9.0-39.5	88.8	75.0-100
	North-east (4)	1.0	2	12.0	12.0-12.0	75.0	55.0-95.0	3	11.3	8.0-14.0	63.4	46.3-77.5
		1.5	3	12.0	12.0-12.0	91.3	81.3-100	4	11.5	8.0-14.0	88.2	76.3-95.0
	South-east (4)	1.0	3	8.0	7.0-9.0	87.2	78.5-92.5	3	11.0	10.0-12.0	80.2	77.5-85.0
		1.5	4	9.4	7.0-13.5	94.4	91.3-100	4	11.2	10.0-12.0	88.3	85.3-90.8
POLLA	North-east (1)	1.0	1	5.0	-	93.8	-	1	5.0	-	87.5	-
		1.5	1	5.0	-	100	-	1	5.0	-	100	-
	South-east	1.0	1	8.3	-	25.0	-	1	6.0	-	89.5	-

Weed species	EPPO climatic zone (total no.trials) (1)	SAE053H/01 application rate (L prod/ha)	Early assessment timings (2-5 weeks after application)					Late assessment timings (11-22 weeks after application)				
			No. of trials	Untreated (plants/m ²)		% efficacy		No. of trials	Untreated (plants/m ²)		% efficacy	
				Mean	Min-Max	Mean	Min-Max		Mean	Min-Max	Mean	Min-Max
		1.5	1	8.3	-	72.5	-	1	6.0	-	81.3	-
POLLM	Maritime (1)	1.5	1	33.3	-	96.8	-	1	31.3	-	98.7	-
POLPE	Maritime (2)	1.0	2	13.0	6.0-20.0	84.4	70.0-98.8	1	20.0	-	100	-
		1.5	2	13.0	6.0-20.0	89.4	78.8-100	1	20.0	-	100	-
	North-east (1)	1.5	-	-	-	-	-	1	7.0	-	87.5	-
	South-east (2)	1.0	1	5.0	-	71.3	-	1	7.0	-	67.3	-
		1.5	2	9.3	5.0-13.5	88.3	76.5-100	2	9.4	7.0-11.8	87.7	77.8-97.5
POROL	Maritime (1)	1.0	1	65.0	-	36.3	-	1	65.0	-	5.0	-
		1.5	1	65.0	-	58.8	-	1	65.0	-	75.0	-
	South-east (1)	1.0	-	-	-	-	-	1	5.0	-	56.3	-
		1.5	-	-	-	-	-	1	5.0	-	86.0	-
RAPRA	North-east (1)	1.0	1	24.0	-	100	-	1	24.0	-	100	-
		1.5	1	24.0	-	100	-	1	24.0	-	100	-
SINAR	North-east (2)	1.0	2	8.0	6.0-10.0	100	100-100	2	9.0	8.0-10.0	86.7	77.5-95.8
		1.5	2	8.0	6.0-10.0	100	100-100	1	9.0	8.0-10.0	93.8	87.5-100
	South-east (2)	1.0	2	10.5	6.0-15.0	92.4	84.8-100	2	11.0	5.0-17.0	90.7	81.3-100
		1.5	2	10.5	6.0-15.0	97.9	95.8-100	2	11.0	5.0-17.0	96.3	92.5-100
SOLNI	Maritime (7)	1.0	5	23.8	8.0-55.0	92.2	77.5-100	4	19.4	5.0-57.0	96.9	88.8-100
		1.5	6	23.4	8.0-55.0	95.1	77.5-100	5	19.6	5.0-57.0	99.4	96.8-100
	South-east (2)	1.0	1	7.8	-	77.5	-	1	9.5	-	100	-
		1.5	2	7.9	7.8-8.0	82.5	75.0-90.0	2	8.6	7.8-8.5	98.8	97.5-100
SPRAR	North-east (1)	1.0	1	20.0	-	100	-	1	20.0	-	100	-
		1.5	1	20.0	-	100	-	1	20.0	-	100	-
STAAN	South-east (2)	1.0	1	7.0	-	82.5	-	1	21.2	-	99.3	-
		1.5	2	11.8	7.0-16.5	91.5	86.3-96.8	1	21.2	-	99.8	-
STEME	Maritime (3)	1.0	3	13.7	7.0-23.0	98.8	96.5-100	3	14.7	6.0-23.0	95.8	87.5-100
		1.5	3	13.7	7.0-23.0	98.9	96.8-100	3	14.7	6.0-23.0	95.0	85.0-100
	North-east (4)	1.0	1	7.0	-	100	-	-	-	-	-	-
		1.5	3	7.3	6.8-8.0	100	100-100	3	6.3	5.0-8.0	100	100-100
THLAR	North-east (5)	1.0	3	10.3	6.0-16.0	100	100-100	2	9.5	9.0-10.0	100	100-100
		1.5	5	10.3	6.0-16.0	100	100-100	4	9.3	5.3-13.0	100	100-100
	South-east (1)	1.0	1	5.5	-	95.0	-	1	5.5	-	97.5	-
		1.5	1	5.5	-	100	-	1	5.5	-	100	-

Weed species	EPPO climatic zone (total no.trials)	SAE053H//01 application rate (L prod/ha)	Early assessment timings (2-5 weeks after application)					Late assessment timings (11-22 weeks after application)				
			No. of trials	Untreated (plants/m²)		% efficacy		No. of trials	Untreated (plants/m²)		% efficacy	
				Mean	Min-Max	Mean	Min-Max		Mean	Min-Max	Mean	Min-Max
VERHE	North-east (2)	1.5	2	9.1	9.0-9.3	94.6	90.0-99.3	2	10.5	8.0-13.0	95.0	90.0-100
	South-east (1)	1.0	1	7.5	-	82.5	-	1	7.5	-	85.0	-
		1.5	1	7.5	-	98.8	-	1	7.5	-	100	-
VERPE	Maritime (4)	1.0	4	19.4	9.0-39.0	63.8	7.7-100	4	21.3	13.0-39.0	87.5	50.0-100
		1.5	4	19.4	9.0-39.0	74.7	17.5-100	4	21.3	13.0-39.0	94.4	77.5-100
	South-east (1)	1.0	1	9.0	-	100	-	1	10.0	-	97.0	-
		1.5	1	9.0	-	100	-	1	10.0	-	99.9	-
		VIOAR	North-east (6)	1.0	2	7.5	6.0-9.0	86.3	72.5-100	2	11.5	6.0-17.0
1.5	6			18.5	5.5-69.8	99.8	98.5-100	5	22.0	6.0-62.0	100	100-100
South-east (1)	1.0		1	5.5	-	83.8	-	1	5.5	-	86.3	-
	1.5		1	5.5	-	96.3	-	1	5.5	-	97.5	-
	Annual grass weed species											
DIGSA	Maritime (3)	1.0	3	67.3	15.0-111.0	60.4	11.3-93.5	3	69.7	15.0-118.0	44.6	3.8-76.3
		1.5	3	67.3	15.0-111.0	75.0	55.0-95.0	3	69.7	15.0-118.0	70.0	58.8-88.8
ECHCG	Maritime (9)	1.0	7	18.7	6.0-37.0	90.1	80.0-97.0	6	21.8	6.0-39.0	90.7	70.0-96.8
		1.5	9	38.3	6.0-96.0	99.3	97.3-100	8	34.2	6.0-99.0	98.0	90.0-100
	North-east (12)	1.0	8	86.0	5.0-420.0	78.2	61.3-90.0	7	58.5	5.0-172.0	77.6	58.8-100
		1.5	12	60.2	5.0-420.0	95.1	84.3-100	11	40.7	5.0-172.0	96.2	77.5-100
	South-east (10)	1.0	7	20.7	15.0-25.0	83.7	72.5-100	7	21.7	17.0-25.0	77.7	58.8-100
		1.5	10	18.4	7.0-25.0	92.6	72.6-100	10	18.6	7.0-25.0	91.2	78.8-100
SETPU	South-east (1)	1.0	1	118.0	-	81.3	-	1	118.0	-	73.8	-
		1.5	1	118.0	-	95.0	-	1	118.0	-	93.8	-
SETVI	South-east (9)	1.0	8	11.9	5.0-21.0	78.4	26.3-93.8	7	15.3	5.0-30.0	78.8	53.8-92.5
		1.5	9	11.3	5.0-21.0	89.3	70.0-98.0	8	14.2	5.0-30.0	89.6	77.5-98.8
Perennial broad-leaved weed species												
AEOPO	Maritime (1)	1.0	1	10.0	-	95.0	-	1	16.0	-	80.0	-
		1.5	1	10.0	-	100	-	1	16.0	-	90.0	-
CIRAR	North-east (1)	1.0	1	7.0	-	83.8	-	1	8.0	-	57.5	-
		1.5	1	7.0	-	91.3	-	1	8.0	-	73.8	-
	South-east (5)	1.0	5	13.3	6.0-27.0	65.4	23.8-94.5	5	11.6	6.0-26.3	76.8	52.5-90.0
		1.5	5	13.3	6.0-27.0	79.2	57.5-95.8	5	11.6	6.0-26.3	88.5	85.8-90.0

Weed species	EPPO climatic zone (total no.trials)	SAE053H/01 application rate (L prod/ha)	Early assessment timings (2-5 weeks after application)					Late assessment timings (11-22 weeks after application)				
			No. of trials	Untreated (plants/m ²)		% efficacy		No. of trials	Untreated (plants/m ²)		% efficacy	
				Mean	Min-Max	Mean	Min-Max		Mean	Min-Max	Mean	Min-Max
CONAR	Maritime (2)	1.0	2	10.0	9.0-11.0	84.8	73.8-95.8	2	10.0	9.0-11.0	76.3	70.0-82.5
		1.5	2	10.0	9.0-11.0	82.7	68.8-96.5	2	10.0	9.0-11.0	77.5	72.5-82.5
	North-east (1)	1.0	1	12.0	-	68.8	-	1	12.0	-	100	-
		1.5	1	12.0	-	65.0	-	1	12.0	-	100	-
	South-east (2)	1.0	1	18.0	-	58.8	-	2	6.9	5.0-8.8	65.2	56.3-74.0
		1.5	1	18.0	-	68.8	-	2	6.9	5.0-8.8	84.4	72.5-96.3
PVAZE	Maritime (1)	1.0	-	-	-	-	-	1	10.0	-	62.5	-
		1.5	-	-	-	-	-	1	10.0	-	98.0	-
TAROF	North-east (1)	1.5	1	8.0	-	91.3	-	1	9.0	-	95.3	-
Perennial grass weed species												
AGRRE	North-east (2)	1.0	2	10.0	10.0-10.0	88.8	83.8-93.8	2	11.0	10.0-12.0	65.7	62.5-68.8
		1.5	2	10.0	10.0-10.0	97.9	95.8-100	2	11.0	10.0-12.0	90.1	88.8-91.3
	South-east (3)	1.0	3	14.5	6.5-20.0	38.3	20.0-60.0	2	23.0	20.0-26.0	55.0	40.0-70.0
		1.5	3	14.5	6.5-20.0	63.8	48.8-76.3	2	23.0	20.0-26.0	80.1	75.3-84.8
CYNDA	South-east (1)	1.5	1	11.5	-	66.3	-	1	12.3	-	50.0	-
SORHA	South-east (6)	1.0	5	95.6	11.0-318.0	87.7	74.4-93.8	5	102.0	11.0-318.0	84.8	78.8-89.5
		1.5	6	80.7	6.0-318.0	94.7	87.5-98.5	6	86.1	6.5-318.0	91.1	89.5-93.3

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-11: Direct comparisons of mean percentage efficacy of SAE053H/01 applied at the highest rate in the proposed range of 1.0-1.5 L product/ha against individual weed species to that of Elumis applied at the higher rate of 2.0 L product/ha and of standard reference products containing straight mesotrione, where included across trials in maize

		Direct comparison of efficacy of SAE053H/01 at 1.5 L product/ha to that of standard reference products											
		Early assessment timings						Late assessment timings					
Product		No. of trials	SAE053H/01	Elumis	Callisto 100 SC / Temsa SC	Callisto 4 SC/ Callisto 480 SC		No. of trials	SAE053H/01	Elumis	Callisto 100 SC / Temsa SC	Callisto 4 SC/ Callisto 480 SC	
Active substances			mesotrione + nicosulfuron	mesotrione + nicosulfuron	mesotrione	mesotrione			mesotrione + nicosulfuron	mesotrione + nicosulfuron	mesotrione	mesotrione	mesotrione
Rate/ha product (a.s.)			1.5 (120+45)	2.0 (225+90)	1.0* (100) 1.5 (150)	0.35 (168)	0.4 (192)		1.5 (120+45)	2.0 (225+90)	1.0* (100) 1.5 (150)	0.35 (168)	0.4 (192)
Weed species	EPPO climatic zone		Mean	Mean	Mean	Mean	Mean		Mean	Mean	Mean	Mean	Mean
Annual broad-leaved weed species													
AMARE	South-east	1	77.5			65.0		1	100			85.0	
AMBEL	South-east	1	90.0			83.0		1	75.8			73.8	
CAPBP	North-east	1	100		100*			1	100		100*		
CENCY	North-east	1	93.8		99.5*			1	100		100*		
CHEAL	Maritime	2	99.8		96.6			2	100		99.2		
	North-east	3	98.0		99.0*			3	100		100*		
	South-east	3	97.3	96.2				3	95.4	96.9			
		1	100			92.5		1	97.5			90.0	
		1	80.0				67.5	1	100				87.5
CHEHY	South-east	1	100	100			1	100	100				
CHEPO	Maritime	1	99.9		96.8			1	100		98.8		
DATST	South-east	1	100	100				1	100	100			
		1	98.0			98.0		1	98.3			98.3	
FUMOF	North-east	1	93.8		83.8*			1	91.3		80.0*		
GERPU	North-east	1	92.5		95.0*			1	98.5		95.8*		
HELAN	South-east	1	97.3			95.0		1	97.8			96.0	
HIBTR	South-east	2	93.7	92.4				2	92.9	96.9			
		1	100			100		1	96.3			93.8	
LAMAM	North-east	1	100		97.5*								
LAMPU	Maritime	1	100		98.7			1	100		99.9		
	North-east	1	100		100*			1	100		100*		
MATMA	Maritime	2	99.9		98.1			1	100		99.8		

		Direct comparison of efficacy of SAE053H/01 at 1.5 L product/ha to that of standard reference products											
		Early assessment timings						Late assessment timings					
Product		No. of trials	SAE053H/01	Elumis	Callisto 100 SC / Temsa SC	Callisto 4 SC/ Callisto 480 SC		No. of trials	SAE053H/01	Elumis	Callisto 100 SC / Temsa SC	Callisto 4 SC/ Callisto 480 SC	
Active substances			mesotrione + nicosulfuron	mesotrione + nicosulfuron	mesotrione	mesotrione			mesotrione + nicosulfuron	mesotrione + nicosulfuron	mesotrione	mesotrione	mesotrione
Rate/ha product (a.s.)			1.5 (120+45)	2.0 (225+90)	1.0* (100) 1.5 (150)	0.35 (168)	0.4 (192)		1.5 (120+45)	2.0 (225+90)	1.0* (100) 1.5 (150)	0.35 (168)	0.4 (192)
Weed species	EPPO climatic zone		Mean	Mean	Mean	Mean	Mean		Mean	Mean	Mean	Mean	Mean
PAPRH	North-east	1	90.0		86.3*			1	87.5		81.3*		
POLCO	Maritime	1	90.0		87.5			1	90.0		88.8		
	North-east	1	92.5		93.8*			1	95.0		95.8*		
	South-east	1	91.3			41.3		1	87.5			40.0	
POLLM	Maritime	1	96.8		93.9			1	98.7		96.4		
POLPE	North-east							1	87.5		76.3*		
	South-east	1	76.5	88.3				1	77.8	84.8			
		1	100			93.8		1	97.5			90.0	
SOLNI	Maritime	1	99.3		95.6			1	100		98.3		
	South-east	1	75.0				62.5	1	97.5				82.5
STAAN	South-east	1	96.8			96.0							
STEME	North-east	2	100		99.9*			3	100		100*		
THLAR	North-east	2	100		100*			2	100		100*		
VERHE	North-east	2	94.6		94.4*			2	95.0		100*		
VIOAR	North-east	4	99.6		97.9*			3	100		100*		
Annual grass weed species													
ECHCG	Maritime	2	99.5		97.0			2	100		99.3		
	North-east	4	96.8		96.3*			4	99.8		95.7*		
	South-east	1	99.5	98.5				1	97.0	93.3			
		2	92.1			73.8		2	90.4			69.5	
		1	72.6				0	1	92.5				0
SETVI	South-east	1	91.8	95.3			1	90.3	91.8				
		1	70.0				0	1	95.0				0
Perennial broad-leaved weed species													
TAROF	North-east	1	91.3		78.8*			1	95.3		75.0*		
Perennial grass weed species													
AGRRE	South-east	2	62.6	82.6				2	80.1	91.9			

		Direct comparison of efficacy of SAE053H/01 at 1.5 L product/ha to that of standard reference products											
		Early assessment timings						Late assessment timings					
Product		No. of trials	SAE053H/01	Elumis	Callisto 100 SC / Temsa SC	Callisto 4 SC/ Callisto 480 SC		No. of trials	SAE053H/01	Elumis	Callisto 100 SC / Temsa SC	Callisto 4 SC/ Callisto 480 SC	
Active substances			mesotrione + nicosulfuron	mesotrione + nicosulfuron	mesotrione	mesotrione			mesotrione + nicosulfuron	mesotrione + nicosulfuron	mesotrione	mesotrione	mesotriorn e
Rate/ha product (a.s.)			1.5 (120+45)	2.0 (225+90)	1.0* (100) 1.5 (150)	0.35 (168)	0.4 (192)		1.5 (120+45)	2.0 (225+90)	1.0* (100) 1.5 (150)	0.35 (168)	0.4 (192)
Weed species	EPPO climatic zone		Mean	Mean	Mean	Mean	Mean		Mean	Mean	Mean	Mean	Mean
CYNDA	South-east	1	66.3				40.0	1	50.0				20.0
SORHA	South-east	3	92.8	96.9				3	90.5	92.7			
		1	94.0			30.0		1	90.8			20.0	

In the overall majority of cases, SAE053H/01 applied at the lowest and/or highest rates in the range of 1.0-1.5 L product/ha gave consistently effective control of the wide range of annual and perennial broad-leaved and grass weed species on which data have been generated across trials.

SAE053H/01 applied at the lowest and highest rates in the range of 1.0-1.5 L product/ha gave consistently comparable levels of control compared to those given by the standard reference product Elumis when applied at the same rates. Elumis is approved for broad spectrum control of weeds in maize in all Central Registration zone countries relevant to this submission at rates or ranges of rates between 1.0 L and 1.5 L product/ha, with the exceptions of Hungary (label rate range of 1.3-2.0 L product/ha) and Romania (label rate range of 1.0-2.0 L product/ha).

The efficacy of SAE053H/01 applied at 1.5 L product/ha was similar or only slightly lower compared to that of Elumis applied at the higher rate of 2.0 L product/ha, where included in some of the trials carried out in the South-east climatic zone, with this being the maximum rate in label ranges currently approved in Hungary and Romania.

The efficacy of SAE053H/01 applied at 1.5 L product/ha was similar to or slightly higher than that of these standard reference products containing straight mesotrione against all other weed species on which data were generated in trials that included comparison with these standard reference products.

The above trials demonstrate the equivalent dose-to-dose efficacy of SAE053H/01 versus the standard treatments.

Summary and conclusions on efficacy

Across trials, the efficacy of SAE053H/01 has been evaluated under a wide range of climatic conditions and agronomic practices fully representing those in maize growing regions of EU Central Registration zone countries relevant to this submission. Data to demonstrate the efficacy of SAE053H/01 in maize are presented for a range of annual and perennial weed broad-leaved and grass weed species, including many of the main widespread occurring and problematic weed species that occur in maize in Europe.

Across trials, applications were made between May and June. Single applications of SAE053H/01 were made when crop growth stages were within the range of 10-18 (BBCH), with all or some crop within the proposed label range of 12-19 (BBCH) for the application of SAE053H/01 on all trials.

Between trials, SAE053H/01 was applied in water volumes of between 200 and 300 L/ha and therefore fully representative of the proposed 200-400 L/ha label range.

SAE053H/01 generally gave similar levels of control of individual weed species between climatic zones, where data were generated in 2 or 3 of the zones. It is therefore reasonable to consider that the efficacy of SAE053H/01 is sufficiently similar between climatic zones for data generated in any one of the climatic zones to provide supportive evidence of efficacy in the other climatic zones relevant to countries within the EU Registration zone.

All weed species for which label claims are supported for control by SAE053H/01 are known to be susceptible to the equivalent registered product containing mesotrione and nicosulfuron, the majority of which have specific for control supported on the label of this product in least one of the EU Central Registration zone countries relevant to this submission. Based on demonstrated comparability between the efficacy of SAE053H/01 and that of the equivalent approved product across trials, label claims for control of susceptible weed species by SAE053H/01 are considered to be further supported for those weed species for which claims for control are supported on national labels of the approved product.

A summary of numbers of trials generating data on individual weed species and their relative susceptibilities to SAE053H/01 applied at the lowest and highest rates within the proposed range of 1.0-1.5 L product/ha, as demonstrated by data across trials, is given in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-12 .

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-12:
Overall summary of label claims for control of individual weed species supported for SAE053H/01

Weed species EPPO code	Relevant CEU countries where equivalent approved product has specific label claims for control at national label rates***	No. of trials with supportive efficacy data for SAE053H/01 (1.0 L / 1.5 L product/ha rates)			Susceptibility rating demonstrated by data for SAE053H/01	
		EPPO climatic zone			1.0 L product/ha rate	1.5 L product/ha rate
		Maritime	North-east	South-east		
Annual broad-leaved weed species						
ABUTH	RO, SI	-	-	1/1	HS	HS
AMASS	AT, CZ, DE, IE, UK, PL, RO, SI, SK	2/2	1/1	5/6	S	HS
AMBEL	SI, SK	-	-	3/4	MS	S
BRSNW	AT, DE, IE, UK, PL, SI	1/1	1/1	-	HS	HS
CAPBP	AT, DE, IE, NL, UK, PL, SI	-	2/4	1/1	S	HS
CENCY	-	-	0/1	-	-	(HS*)
CHESS	AT, CZ, DE, IE, NL, UK, PL, RO, SI, SK	19/21	12/15	13/15	S	HS
DATST	RO, SI, SK	2/2	-	3/4	HS	HS
FUMOF	AT, DE, IE, UK, PL, SI	1/1	0/1	-	S	S
GAETE	AT, DE, IE, UK, SI	-	1/1	-	HS	HS
GALAP	AT, DE, IE, UK, PL, SI	2/2	1/1	-	MS	S
GASPA	AT, DE, NL, PL, SI	-	2/2	-	S	HS
GERSS	AT, NL, PL	1/1	1/2	-	S	S
HELAN	SI	-	-	0/1	-	HS
HIBTR	SK	-	-	7/8	MS	S
LAMSS	AT, CZ, DE, IE, UK, PL, SI, SK	1/2	0/2	1/1	S	HS
MATSS	AT, CZ, DE, IE, UK, PL, SI, SK	1/3	6/6	1/1	S	HS
MERAN	AT, DE	1/1	-	-	HS (MS**)	HS (MS**)
MYOAR	SI	-	0/1	-	-	S
PAPRH	RO	-	0/1	-	-	(S*)
POLAV	AT, DE, IE, UK, PL, SK	2/2	1/1	-	MT	MS
POLCO	AT, CZ, DE, IE, UK, PL, RO, SI, SK	4/5	3/4	3/4	MS	S
POLLA	AT, DE, IE, UK, PL, RO	-	1/1	1/1	S	S
POLLM	-	0/1	-	-	-	(HS*)
POLPE	AT, DE, IE, NL, UK, PL, RO	2/2	0/1	1/2	MS	S
POROL	RO	1/1	-	1/1	T	MS
RAPRA	SI	-	1/1	-	HS	HS
SINAR	RO, SI	-	2/2	2/2	S	HS
SOLNI	AT, DE, IE, NL, UK, RO, SI, SK	6/7	-	1/2	HS	HS
SPRAR	-	-	1/1	-	(HS*)	(HS*)
STAAN	-	-	-	1/2	HS	HS
STEME	AT, DE, IE, NL, UK, PL, RO, SI, SK	3/3	1/4	-	HS	HS
THLAR	AT, DE, PL, SI	-	3/5	1/1	HS	HS
VERHE	-	-	0/2	1/1	(S*)	HS
VERPE	AT, CZ, DE, IE, UK, RO, SI, SK	4/4	-	1/1	S	HS
VIOAR	AT, DE, IE, NL, UK, PL	-	2/6	1/1	S	HS
Annual grass weed species						
DIGSA	NL, SI	3/3	-	-	MT	MS
ECHCG	AT, CZ, DE, IE, NL UK, PL, RO, SI, SK	7/9	8/12	7/10	S	HS
SETSS	AT, DE, NL, RO, SK	-	-	9/10	MS	S

* Limited or inconsistent data, no label claim proposed for control

** Limited data, label claim adjusted taking into account susceptibility rating for the equivalent approved product (Elumis) supported on national labels

*** Information on individual weed species with claims for control on the Elumis labels could not be sourced for Belgium or Hungary and are therefore missing from the label

Label claim	Control level range (%)
Tolerant (T)	0-49.9
Moderately tolerant (MT)	50-74.9
Moderately susceptible (MS)	75-84.9
Susceptible (S)	85-94.9
Highly susceptible (HS)	95-100

Study Comments: 3.2.3 dRR point 3.2.3	
EN: Evaluator conclusion:	
<u>Control of weeds in the North-east EPPO climatic zone (Poland)</u>	
The applicant submitted 16 trials carried out in 2014, 2015 and 2016 on <i>Zea mays</i> (BBCH 12-18 – Principal growth stage 1: Leaf development) in Poland.	
The minimal number of an individual weed per m ² in the trials should be 5, to include such trials in the assessment. In the following reports the number of weeds per m ² were not adequate, so those trials were excluded from the assessment:	
S14 – 02857-02: CAPBP - 4 pl. m ²	
S14 – 02857-02: VIOAR - 4 pl. m ²	
STEME - 4 pl. m ²	
VERHE - 4 pl. m ²	
BTD – 15 – 21145 – PL13: POLCO - 2 pl. m ²	
SRY – 16 26183 – PL10: GALAP – 2,5 pl. m ²	
What is more, for following weeds the Applicant presented only one trial per weed: AMARE, BRSNW, CENCY, FUMOF, GAETE, GALAP, LAMAM, LAMPU, MATCH, MYOAR, PAPRH,	

POLAV, POLLA, POLPE, RAPRA, SPRAR, CIRAR, CONAR, TAROF. The data from one trial for one weed species are not sufficient to prove the effectiveness of the product.

Efficacy trials were carried out by organisations that are officially recognised as competent to carry out efficacy testing in accordance with Regulation (EC) 284/2013 by the authorities in the relevant countries. All trials have been conducted according to GEP.

The efficacy trials were designed, conducted and reported according to the following EPPO guidelines:

1. PP 1/226 Number of efficacy trials;
2. PP 1/181 (4) Conduct and reporting of efficacy evaluation trials including good experimental practice.
3. PP 1/135 (3/4) Phytotoxicity assessment
4. PP 1/50 (3) Weeds in maize
6. PP 1/152(4) Design and analysis of efficacy evaluation trials

Results of experiments (data on effectiveness) are contained in Appendix 3 to the BAD.

Trials were conducted in Poland (NE EPPO climatic zone). Trials were of randomized block design with a minimum of four replicates. Details on trial sites, applications are contained in Appendix 2 to the BAD. The susceptibility of weeds were evaluated according to the criteria presented below, established for PL.

Weed species are classified as:

susceptible (S) –	85%
moderately susceptible (MS) -	70-85%
moderately tolerant (MT)	60 -70%
tolerant (T)	< 60%

The tested herbicide was applied at the rates: 0,75 l/ha, 1,0 l/ha, 1,2 l/ha, 1,5 l/ha of SAE053H/01 (spray volume 200 – 300 l/ha) in *Zea mays* as a single post-emergence application against weeds. In accordance with GAP table results are presented below for two rates: 1,0 l/ha; 1,2 l/ha.

Efficacy against annual broad – leaves weeds species in maize 2 – 5 weeks after application and – 11 - 22 weeks after application:

CAPBP – 2 trials 1,0 l/ha, mean efficacy 100 % and 100%
CAPBP – 4 trials, 1,2 l/ha, mean efficacy 100% and 100%
CHEAL – 12 trials, 1,0 l/ha, mean efficacy 92,3% and 91,0%
CHEAL – 15 trials, 1,2 l/ha, mean efficacy 94,7 % and 94,8%
GASPA – 2 trials 1,0 l/ha, mean efficacy 89,4% and 85,2%
GASPA – 2 trials, 1,2 l/ha, mean efficacy 90,3% and 95,95%
GERPU - 1 trial 1,0 l/ha, mean efficacy 17,5% and 5,0%
GERPU – 2 trials, 1,2 l/ha, mean efficacy 55,95% and 66,7%
MATIN - 5 trials 1,0 l/ha, mean efficacy 82,6% and 87,5%
MATIN – 5 trials, 1,2 l/ha, mean efficacy 82,8% and 95,6%
POLCO - 3 trials, 1,0 l/ha, mean efficacy 75,0% and 63,4%
POLCO - 4 trial, 1,2 l/ha, mean efficacy 85,65% and 83,3%
SINAR - 2 trials, 1,0 l/ha, mean efficacy 100% and 93,8%
SINAR - 2 trials, 1,2 l/ha, mean efficacy 96,9% and 96,0%
STEME - 1 trial, 1,0 l/ha, mean efficacy 100%
STEME- 3 trials, 1,2 l/ha, mean efficacy 97,9% and 100%
THLAR - 3 trials, 1,0 l/ha, mean efficacy 100% and 100%
THLAR- 5 trials, 1,2 l/ha, mean efficacy 96,6% and 100%
VERHE - 2 trials, 1,2 l/ha, mean efficacy 89,4% and 88,4%
VIOAR - 2 trials, 1,0 l/ha, mean efficacy 86,3% and 74,4%
VIOAR- 6 trials, 1,2 l/ha, mean efficacy 97,3% and 98,9%

Efficacy against annual grass weeds species in maize 2 – 5 weeks after application and – 11 - 22 weeks after application:

ECHCG - 8 trials, 1,0 l/ha, mean efficacy 78,2% and 77,6%
ECHCG- 12 trials, 1,2 l/ha, mean efficacy 85,3% and 92,7%

Efficacy against perennial grass weeds species in maize 2 – 5 weeks after application and – 11 - 22 weeks after application:

AGRRE- 2 trials, 1,0 l/ha, mean efficacy 88,8% and 65,7%
AGRRE- 2 trials, 1,2 l/ha, mean efficacy 85,95% and 90,5%

2 - 22 weeks after application the following target weed species were categorized as:

- susceptible (S)

for dose rate 1,0 l/ha: CAPBP, CHEAL, GASPA, MATIN, SINAR, THLAR,

for dose rate 1,2 l/ha: CAPBP, CHEAL, GASPA, MATIN, SINAR, STEME, THLAR, VERHE,
VIOAR, ECHCG, AGRRE

- moderately susceptible (MS)

for dose rate 1,0 l/ha: VIOAR, ECHCG, AGRRE

for dose rate 1,2 l/ha: POLCO

- moderately tolerant (MT)

for dose rate 1,0 l/ha: POLCO

for dose rate 1,2 l/ha: GERPU

SAE053H/01 caused insufficient (tolerant) susceptibility for GERPU at dose rate 1,0 l/ha. On the dose rate 1,2 l/ha the weed appeared only moderately tolerant. There is a need to make an appropriate label statement.

The following weeds mentioned above have the great competitive potential for maize: CHEAL, GASPA, MATIN, SINAR, ECHCG, AGRRE. For those weeds, at least 4 trials should be presented to confirm properly efficacy against these weeds. For GASPA, SINAR and AGRRE the applicant presented only 2 trials. Nevertheless the efficacy for these weeds at both dose rates 1.0 l/ha and 1,2 l/ha was consistent and high and on the same level or better than standard product - Elumis applied at dose rate 1,5 l/ha (g a. s. 112,5 + 45). That is why presented in that way efficacy for these weeds should be considered appropriate.

To sum up, it might be concluded that the application of SAE053H/01 at 1,0 l/ha and 1,2l/ha dose rates (spray volume 200 - 300 l/ha), post-emergence provides benefit against weeds in maize comparable or better with standard products: Elumis, Calisto 100 SC. The dose rate 1,2 l/ha gave better control of AGREE, ECHCG and POLCO.

Control of weeds in the Maritime EPPO climatic zone

The applicant submitted 23 trials carried out in 2014, 2015 and 2018 in *Zea mays* (BBCH 10-19 - Principal growth stage 1: Leaf development)) in BE, CZ, DE, FR,UK.

Efficacy trials were carried out by organisations that are officially recognised as competent to carry out efficacy testing in accordance with Regulation (EC) 284/2013 by the authorities in the relevant countries. All trials have been conducted according to GEP.

The efficacy trials were designed, conducted and reported according to the following EPPO guidelines:

1. PP 1/226 Number of efficacy trials;
2. PP 1/181 (4) Conduct and reporting of efficacy evaluation trials including good experimental practice.
3. PP 1/135 (3/4) Phytotoxicity assessment
4. PP 1/50 (3) Weeds in maize
6. PP 1/152(4) Design and analysis of efficacy evaluation trials

7. CEB method M046 Désherbage du maïs (French, Belgian trials)

Results of experiments (data on effectiveness) are contained in Appendix 3 to the BAD. Trials were conducted in BE, CZ, DE, FR, UK (Maritime EPPO climatic zone). Trials were of randomized block design with a minimum of four replicates. Details on trial sites, applications are contained in Appendix 2 to the BAD.

Weed species are classified as:

very susceptible (VS) -	95 - 100%
susceptible (S) -	85 - 94,9%
moderately susceptible (MS) -	70 - 84,9%
moderately tolerant (MT) -	50 - 69,9%
tolerant (T)	< 49,9%

The tested herbicide was applied at the rates: 0,75 l/ha, 1,0 l/ha, 1,2 l/ha, 1,5 l/ha of SAE053H/01 (spray volume 200 – 300 l/ha) in *Zea mays* as a single post emergence application against weeds. In accordance with GAP table results are presented below for two rates: 1,0 l/ha, 1,2 l/ha.

Efficacy against annual broad – leaves weeds species in maize 2 – 5 weeks after application and – 11 - 22 weeks after application:

AMARE – 2 trials, 1,0 l/ha, mean efficacy 97,5% and 98,5%
AMARE – 2 trials, 1,2 l/ha, mean efficacy 100% and 100%
BRSNW – 1 trial, 1,0 l/ha, mean efficacy 100% and 100%
BRSNW – 1 trial, 1,2 l/ha, mean efficacy 96,9% and 100%
CHEAL – 17 trials, 1,0 l/ha, mean efficacy 94,3% and 95,3%
CHEAL – 19 trials, 1,2 l/ha, mean efficacy 93,5 % and 96,6%
CHEHY - 1 trial, 1,0 l/ha, mean efficacy 100%
CHEHY – 1 trial, 1,2 l/ha, mean efficacy 100%
CHEPO - 1 trial, 1,2 l/ha, mean efficacy 95,75% and 98,75%
DATST - 2 trials, 1,0 l/ha, mean efficacy 85% and 89,9%
DATST – 2 trials, 1,2 l/ha, mean efficacy 91,6 % and 90%
FUMOF – 1 trial, 1,0 l/ha, mean efficacy 97,3% and 85,2%
FUMOF – 1 trial, 1,2 l/ha, mean efficacy 97,1% and 89,4%
GALAP - 2 trials, 1,0 l/ha, mean efficacy 50,0% and 24,0%
GALAP – 2 trial, 1,2 l/ha, mean efficacy 74,4% and 62,5%
GERPP - 1 trial 1,0 l/ha, mean efficacy 91,3%
GERPP – 1 trial, 1,2 l/ha, mean efficacy 88,8%
LAMPU - 1 trial, 1,0 l/ha, mean efficacy 90% and 100%
LAMPU – 2 trails, 1,2 l/ha, mean efficacy 96,4% and 99,92%
MATCH - 1 trial 1,0 l/ha, mean efficacy 100% and 100%
MATCH – 1 trial, 1,2 l/ha, mean efficacy 99% and 100%
MATMA – 2 trials, 1,2 l/ha, mean efficacy 97,25% and % 99,05
MERAN – 1 trial, 1,0 l/ha, mean efficacy 95,8% and 100%
MERAN – 1 trial, 1,2 l/ha, mean efficacy 84,5% and 100%
POLAV - 2 trials, 1,0 l/ha, mean efficacy 87,8% and 88,2%
POLAV - 2 trial, 1,2 l/ha, mean efficacy 82,6% and 88,95%
POLCO - 4 trials, 1,0 l/ha, mean efficacy 74,9% and 80,7%
POLCO - 5 trials, 1,2 l/ha, mean efficacy 82,4% and 85,0%
POLLN - 1 trial, 1,2 l/ha, mean efficacy 88,3% and 93,3%
POLPE - 2 trials, 1,0 l/ha, mean efficacy 84,4% and 100%
POLPE - 2 trials, 1,2 l/ha, mean efficacy 79,7% and 98,15%
POROL – 1 trial, 1,0 l/ha, mean efficacy 36,3% and 5,0%
POROL – 1 trial, 1,2 l/ha, mean efficacy 47,55% and 30,65%
SOLNI - 5 trials, 1,0 l/ha, mean efficacy 92,2% and 96,9%
SOLNI - 6 trials, 1,2 l/ha, mean efficacy 94,65% and 98,02%

STEME - 3 trials, 1,0 l/ha, mean efficacy 98,8% and 95,8%
STEME - 3 trials, 1,2 l/ha, mean efficacy 98,61% and 94,4%
VERPE - 4 trials, 1,0 l/ha, mean efficacy 63,8% and 87,5%
VERPE - 4 trials, 1,2 l/ha, mean efficacy 64,0% and 95,0%

Efficacy against annual grass weeds species in maize 2 – 5 weeks after application and – 11 - 22 weeks after application:

DIGSA- 3 trials, 1,0 l/ha, mean efficacy 60,4% and 44,6%
DIGSA- 3 trials, 1,2 l/ha, mean efficacy 65% and % 46,9%
ECHCG - 7 trials, 1,0 l/ha, mean efficacy 90,1% and 90,7%
ECHCG- 7 trials, 1,2 l/ha, mean efficacy 92,1% and 95,2%

Efficacy against perennial broad – leaved weeds species in maize 2 – 5 weeks after application and – 11 - 22 weeks after application:

AEOPO- 1 trial, 1,0 l/ha, mean efficacy 95,0% and 80,0%
AEOPO- 1 trial, 1,2 l/ha, mean efficacy 97,5% and 80,0 2%
CONAR- 2 trials, 1,0 l/ha, mean efficacy 84,8% and 76,3%
CONAR- 2 trials, 1,2 l/ha, mean efficacy 93,3% and 85,32%
PVAZE- 1 trial, 1,0 l/ha, mean efficacy 75,65% and 62,5%
PVAZE- 1 trial, 1,2 l/ha, mean efficacy 78,15% and 88,8%

2 - 22 weeks after application the following target weed species were categorized as:

- very susceptible (VS)

for dose rate 1,0 l/ha: AMARE, BRSNW, CHEAL, CHEHY, LAMPU, MATCH, MERAN, SOLNI, STEME

for dose rate 1,2 l/ha: AMARE, BRSNW, CHEAL, CHEHY, CHEPO, LAMPU, MATCH, MATMA, MERAN, SOLNI, STEME

- susceptible (S)

for dose rate 1,0 l/ha: DATST, FUMOF, GERPP, POLAV, POLPE, ECHCG, AEOPO

for dose rate 1,2 l/ha: DATST, FUMOF, GERPP, POLAV, POLLM, POLPE, ECHCG, AEOPO, CONAR

- moderately susceptible (MS)

for dose rate 1,0 l/ha: POLCO, VERPE, CONAR

for dose rate 1,2 l/ha: POLCO, VERPE, PVAZE

- moderately tolerant (MT)

for dose rate 1,0 l/ha: DIGSA, PVAZE

for dose rate 1,2 l/ha: GALAP, DIGSA

tolerant (T)

for dose rate 1,0 l/ha: GALAP, POROL

for dose rate 1,2 l/ha: POROL

To sum up, there is need to underline that in one trial, DIGSA was tolerant towards dose rate 1,2 l/ha of AE053H/01 and in that case standard product Elumis showed much more better control (MS). SAE053H/01 caused also insufficient (tolerant) susceptibility for GALAP at dose rate 1,0 l/ha and for POROL at both doses rates.

Moreover, in the following efficacy trials the number of weeds per m², at the time of application was very low (below the threshold of 5 weeds per m²):

BTD – 15-21145 – CZ04: CHEHY - 2 pl. m²

ECHCG – 1,0 pl. m²

POLCO – 4,3 pl. m²

SOLNI – 1.0 pl. m²

BTD – 15-21145 – GB01: PVAZE – 2 pl. m²

BTD – 18- 33653 – FR04: DATST – 4 pl. m²

POLPE – 2 pl. m²

SOLNI – 4 pl. m²

BTD – 18-33653 – DE09: ECHCG – 1 pl. m²

Additionally, for following weeds the Applicant presented only one trial per weed: BRSNW, CHEHY, CHEPO, FUMOF, GERPP, LAMPU (1,0 l/ha), MATCH, MERAN, POLLM, POROL, AEOPPO, PVAZE. The data from one trial for one weed species are not sufficient to prove the effectiveness of the product. It is for decision of cMS whether above mentioned trials and results should be taken under consideration to prove efficacy of SAE053H/01.

The following weeds mention above have the great competitive potential for maize: AMARE, CHEAL, GALAP, MATCH, MATMA, POLPE, SOLNI, ECHCG, CONAR. For those weeds, at least 4 trials should be presented to properly confirm efficacy against these weeds. The Applicant presented only 2 or 1 trial for AMARE, GALAP, MATCH, MATMA, POLPE, CONAR, what might be not sufficient number of trials to confirm efficacy of the product.

What is more for many weeds the Applicant presented data on efficacy for one or two climatic zones. The applicant concluded that, SAE053H/01 gave similar levels of control of weed species between trials carried out in the Maritime, North-East and South-East climatic zones. It is also for decision of cMS whether above mentioned approach should be taken under consideration to prove efficacy of SAE053H/01.

Control of weeds in the SE EPPO climatic zone

The applicant submitted 21 trials carried out in 2014, 2015, 2016 and 2018 in *Zea mays* (BBCH 10-17 - Principal growth stage 1: Leaf development)) in Romania, Hungary, Slovakia, Bulgaria. Efficacy trials were carried out by organisations that are officially recognised as competent to carry out efficacy testing in accordance with Regulation (EC) 284/2013 by the authorities in the relevant countries. All trials have been conducted according to GEP.

The efficacy trials were designed, conducted and reported according to the following EPPO guidelines:

1. PP 1/226 Number of efficacy trials;
2. PP 1/181 (4) Conduct and reporting of efficacy evaluation trials including good experimental practice.
3. PP 1/135 (3/4) Phytotoxicity assessment
4. PP 1/50 (3) Weeds in maize
6. PP 1/152(4) Design and analysis of efficacy evaluation trials

Results of experiments (data on effectiveness) are contained in Appendix 3 to the BAD.

Trials were conducted in Romania, Hungary, Slovakia, Bulgaria (SE EPPO Zone). Trials were of randomized block design with a minimum of four replicates. Details on trial sites, applications are contained in Appendix 2 to the BAD.

Weed species are classified as:

very susceptible (VS) -	95 - 100%
susceptible (S) -	85 - 94,9%
moderately susceptible (MS) -	70 - 84,9%
moderately tolerant (MT) -	50 - 69,9%
tolerant (T)	< 49,9%

The tested herbicide was applied at the rates: 0,75 l/ha, 1,0 l/ha, 1,2 l/ha, 1,5 l/ha and 1,85 l/ha of SAE053H/01 (spray volume 200 – 300 l/ha) in *Zea mays* as a single post-emergence application against weeds. In accordance with GAP table results are presented below for two rates: 1,0 l/ha, 1,2 l/ha.

Efficacy against annual broad – leaves weeds species in maize 2 – 5 weeks after application and – 11 - 22 weeks after application:

ABUTH – 1 trial, 1,0 l/ha, mean efficacy 100% and 100%
ABUTH – 1 trial, 1,2 l/ha, mean efficacy 98,9% and 100%
AMABL – 1 trial, 1,0 l/ha, mean efficacy 100% and 100%
AMABL – 1 trial, 1,2 l/ha, mean efficacy 100% and 100%

AMARE – 4 trials, 1,0 l/ha, mean efficacy 94,3% and 83,9%
AMARE – 5 trials, 1,2 l/ha, mean efficacy 89,55% and 95,04%
AMBEL – 3 trials, 1,0 l/ha, mean efficacy 80% and 79,4%
AMBEL – 4 trials, 1,2 l/ha, mean efficacy 83,6% and 82,2%
CAPBP – 1 trial, 1,0 l/ha, mean efficacy 87,5% and 92,5%
CAPBP – 1 trial, 1,2 l/ha, mean efficacy 98,75% and 100%
CHEAL – 12 trials, 1,0 l/ha, mean efficacy 94,8% and 91,1%
CHEAL – 11 trials, 1,2 l/ha, mean efficacy 95,3% and 96,4%
CHEHY – 1 trial, 1,0 l/ha, mean efficacy 100% and 100%
CHEHY – 1 trial, 1,2 l/ha, mean efficacy 100% and 100%
DATST – 3 trials, 1,0 l/ha, mean efficacy 100% and 100%
DATST – 3 trials, 1,2 l/ha, mean efficacy 97,85 % and 99,3%
HELAN – 1 trial, 1,2 l/ha, mean efficacy 94,05% and 94,75%
HIBTR – 7 trials, 1,0 l/ha, mean efficacy 69,3% and 86,2%
HIBTR – 6 trials, 1,2 l/ha, mean efficacy 84,8% and 92,0%
LAMPU – 1 trial, 1,0 l/ha, mean efficacy 82,5% and 87,5%
LAMPU – 1 trial, 1,2 l/ha, mean efficacy 96,3% and 98,8%
MATIN- 1 trial 1,0 l/ha, mean efficacy 91,3% and 96,3%
MATIN- 1 trial, 1,2 l/ha, mean efficacy 98,15% and 98,8%
POLCO – 3 trials, 1,0 l/ha, mean efficacy 87,2% and 80,2%
POLCO – 4 trials, 1,2 l/ha, mean efficacy 85,96% and 85,02%
POLLA – 1 trial, 1,0 l/ha, mean efficacy 25% and 89,5%
POLLA – 1 trial, 1,2 l/ha, mean efficacy 60,85% and 76,3%
POLPE – 1 trial, 1,0 l/ha, mean efficacy 71,3% and 67,3%
POLPE – 1 trials, 1,2 l/ha, mean efficacy 100% and 98,75%
POROL – 1 trial, 1,0 l/ha, mean efficacy 73,8% and 67,55%
POROL – 1 trial, 1,2 l/ha, mean efficacy 83,75% and 78,75%
SINAR – 2 trials, 1,0 l/ha, mean efficacy 92,4% and 90,7%
SINAR – 2 trials, 1,2 l/ha, mean efficacy 96,15% and 95,5%
SOLNI – 1 trial, 1,0 l/ha, mean efficacy 73,75% and 93,5%
SOLNI – 2 trials, 1,2 l/ha, mean efficacy 74,07% and 95,6%
STAAN – 1 trial, 1,0 l/ha, mean efficacy 82,5% and 99,3%
STAAN – 2 trials, 1,2 l/ha, mean efficacy 87,4% and 96,9%
THLAR – 1 trial, 1,0 l/ha, mean efficacy 95,0% and 97,5%
THLAR – 1 trial, 1,2 l/ha, mean efficacy 100% and 100%
VERHE – 1 trial, 1,0 l/ha, mean efficacy 82,5% and 85%
VERHE – 1 trial, 1,2 l/ha, mean efficacy 95,0% and 98,15%
VERPE – 1 trial, 1,0 l/ha, mean efficacy 100% and 97,0%
VERPE – 1 trial, 1,2 l/ha, mean efficacy 99,0% and 99,5%
VIOAR – 1 trial, 1,0 l/ha, mean efficacy 83,8% and 86,3%
VIOAR – 1 trial, 1,2 l/ha, mean efficacy 90,9% and 94,4%

Efficacy against annual grass weeds species in maize 2 – 5 weeks after application and – 11 - 22 weeks after application:

ECHCG – 7 trials, 1,0 l/ha, mean efficacy 83,7% and 77,7%
ECHCG – 9 trials, 1,2 l/ha, mean efficacy 87,2% and 89,0%
SETPU – 1 trial, 1,0 l/ha, mean efficacy 81,3% and 73,8%
SETPU – 1 trial, 1,2 l/ha, mean efficacy 92,0% and 81,25%
SETVI – 8 trials, 1,0 l/ha, mean efficacy 78,4% and 78,8%
SETVI – 7 trials, 1,2 l/ha, mean efficacy 81,7% and 86,2%

Efficacy against perennial broad – leaved weeds species in maize 2 – 5 weeks after application and – 11 - 22 weeks after application:

CIRAR – 5 trials, 1,0 l/ha, mean efficacy 65,4% and 76,8%
CIRAR – 5 trials, 1,2 l/ha, mean efficacy 71,0% and 82,4%
CONAR – 2 trials, 1,0 l/ha, mean efficacy 61,3% and 71,0%

CONAR- 2 trials, 1,2 l/ha, mean efficacy 66,0% and 80,8%

Efficacy against perennial grass weeds species in maize 2 – 5 weeks after application and – 11 - 22 weeks after application:

AGRRE- 3 trials, 1,0 l/ha, mean efficacy 38,3% and 55,0%

AGRRE- 1 trial, 1,2 l/ha, mean efficacy 33,15% and 90,6%

CYNDA- 1 trial, 1,2 l/ha, mean efficacy 67,5% and 55,0%

SORHA- 6 trials, 1,0 l/ha, mean efficacy 87,7% and 84,8%

SORHA- 3 trials, 1,2 l/ha, mean efficacy 94,65% and 91,8%

2 - 22 weeks after application the following target weed species were categorized as:

- very susceptible (VS)

for dose rate 1,0 l/ha: ABUTH, AMABL, CHEHY, DATST, THLAR, VERPE

for dose rate 1,2 l/ha: ABUTH, AMABL, CAPBP, CHEAL, CHEHY, DATST, LAMPU, MATIN, POLPE, SINAR, THLAR, VERHE, VERPE

- susceptible (S)

for dose rate 1,0 l/ha: AMARE, CAPBP, CHEAL, LAMPU, MATIN, SINAR, STAAN, VIOAR, SORHA

for dose rate 1,2 l/ha: AMARE, HELAN, HIBTR, POLCO, SOLNI, STAAN, VIOAR, ECHCG, SETPU, SORHA

- moderately susceptible (MS)

for dose rate 1,0 l/ha: AMBEL, HIBTR, POLCO, POLLA, POROL, SOLNI, VERHE, ECHCG, SETPU, SETVI, CIRAR

for dose rate 1,2 l/ha: AMBEL, POLLA, POROL, SETVI, CIRAR, CONAR

- moderately tolerant (MT)

for dose rate 1,0 l/ha: POLPE, CONAR

for dose rate 1,2 l/ha: AGREE, CYNDA

tolerant (T)

for dose rate 1,0 l/ha: AGRRE

To sum up, there is need to underline that SAE053H/01 caused insufficient (tolerant) susceptibility for AGRRE at dose rate 1,0 l/ha.

Moreover, in the following efficacy trials the number of weeds per m², at the time of application was very low (below the threshold of 5 weeds per m²):

BTD – 15-21145 – HU15: HELAN - 2 pl. m²

SRY – 16-26183 – HU04: CHEAL – 4 pl. m²

SRY – 16-26183 – HU05: CONAR – 2 pl. m²

SRY – 16-26183 – RO03: SETVI – 4,25 pl. m²

Additionally, for following weeds the Applicant presented only one trial per weed: CAPBP, CHEHY, HELAN, LAMPU, POLLA, POROL, THLAR, VERHE, VERPE, VIOAR, SETPU, CYNDA. The data from one trial for one weed species are not sufficient to prove the effectiveness of the product. It is for decision of cMS whether above mentioned trials and results should be taken under consideration to prove efficacy of SAE053H/01.

The following weeds mention above have the great competitive potential for maize: ABUTH, AMABL, MATIN, SINAR, POLPE, SOLNI. For those weeds, at least 4 trials should be presented to properly confirm efficacy against these weeds. The Applicant presented only 2 or 1 trial for ABUTH, AMABL, MATIN, POLPE, what might be not sufficient number of trials to confirm efficacy of the product.

What is more for many weeds the Applicant presented data on efficacy for one or two climatic zones. The applicant concluded that, SAE053H/01 gave similar levels of control of weed species between trials carried out in the Maritime, North-east and South-east climatic zones. . It is also for decision of cMS whether above mentioned approach should be taken under consideration to prove efficacy of SAE053H/01.

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

EPPO guideline number	Title
EPPO guideline PP 1/213 (4)	Resistance Risk Analysis

SAE053H/01 is an OD formulation containing the active substances mesotrione and nicosulfuron, both of which have different herbicidal modes of action and are approved and included in products registered for use as herbicides in maize within the European Union.

SAE053H/01 is proposed to be applied at rates within the range of 1.0-1.2 L product/ha, with one application per crop made when the growth stage of the crop is within range of 12-19 (BBCH) and in water volumes of 200-400 L/ha. The actual application rate to be used is dependent on the weeds to be controlled, with the lowest rate of 1.0 L product/ha sufficient to give effective control of some more susceptible annual broad-leaved weed species and the higher rate of 1.2 L product/ha giving consistent control of other susceptible annual broad-leaved weed species, annual grass weed species and perennial broad-leaved and grass weed species.

Mesotrione is a triketone compound and herbicide that is included in HRAC mode of action group F2 (4-HPPD inhibitors), involving inhibition of the p-hydroxyphenylpyruvate dioxygenase (HPPD) enzyme, which is a key enzyme in the biosynthesis of tocopherols and plastoquinone. Plastoquinone is an electron acceptor for the phytoene desaturase reaction in the pathway of carotenoid biosynthesis and also serves as an electron acceptor in PSII. The maize crop is naturally tolerant of mesotrione due to rapid metabolism into inactive compounds mediated by cytochrome-P450-oxygenase whilst sensitive weed species cannot metabolise mesotrione in this way. Despite widespread use of herbicides containing mesotrione for control of weeds in maize and also other herbicides in HRAC mode of action group F2 in other crops for a number of years, cases of resistance to this mode of action are relatively low.

Nicosulfuron is a sulfonylurea herbicide that is included in HRAC mode of action group B (ALS-inhibitors) for which the mode of action involves inhibition of the enzyme acetolactate synthase (ALS), which is involved in branched chain amino acid biosynthesis and the first common enzyme in the pathway leading to valine and isoleucine that are essential building blocks of proteins and other plant components. Nicosulfuron is a systemic selective herbicide that is rapidly absorbed by the leaves and translocated to the meristematic tissue, with genera specific selective and broad spectrum activity against a relatively wide range of broad-leaved and grass weed species, including grasses that are closely related to maize. The selectivity is due to the ability of maize and other tolerant species to metabolise nicosulfuron into harmless compounds. Since the introduction of the first sulfonylurea herbicides, followed by a range of further HRAC mode of action group B (ALS inhibitors) active substances, there has been a steady increase in the number of reported cases of resistance to this mode of action, with relatively high numbers of recorded cases of developed resistance to this mode of action worldwide, occurring in a wide range of different broad-leaved and grass weed species. However, ALS inhibitor herbicides, including nicosulfuron, remain a key chemical group for control of weeds in maize, with the risk of resistance arising or becoming widespread realised through the use of effective resistance management strategy, including application in combination with herbicides with other modes of action.

With no cases of resistance in Europe to date involving multiple resistance between HRAC mode of action group B and group F2 herbicides, the combination of mesotrione with nicosulfuron provides an effective resistance management tool.

For the risk of resistance with respect to broad-leaved and grass weeds, weed species differ in their propensity to develop resistance to herbicides and the risk of resistance developing to a herbicide in annual and perennial broad-leaved and grass weed species, for which claims for control are supported for SAE053H/01, therefore range from **low** to **high**. With respect to the active substances involved, the risk of resistance arising to mesotrione is low whilst that for nicosulfuron is **high**. However, as SAE053H/01 is a co-formulated mixture containing two active ingredients with different modes of actions that have overlapping and complementary activity, the overall risk of resistance arising from the use of such a co-formulation is considered to be **medium** as they reduce the exposure and hence selection pressure on the weeds. Control of weeds in maize crops in commercial practice typically involves more than one application of a herbicide and tank mixtures of herbicides, utilising multiple active substances with different modes of action and cultural control methods (including ploughing prior to sowing and mechanical weeding) can also be utilised and contribute to an overall strategy for control of weeds in maize. The risk of resistance associated with agronomic practices is therefore considered to be **low**. Based on available criteria, the calculated overall risk of resistance arising from the use of SAE053H/01 ranges from **low-medium risk (1-3)**, dependent on the risk associated with the individual weed species.

The risk management strategy to reduce the risk of resistance developing to mesotrione or nicosulfuron from the use of SAE053H/01 is based on Good Agricultural Practices (GAP) and current measures advocated by HRAC including correctly identifying the problem for which a herbicide is required, application at the label recommended rate at the correct time of year and to the weed at the correct stage of growth, utilisation of chemistry with different herbicidal modes of action and non-chemical methods of control (including soil management and crop rotation) dependent upon the situation and to routinely check the performance of the crop protection product to ensure adequate efficacy is achieved.

Further to these measures, the risk management strategy to reduce the risk of resistance developing directly from the use of SAE053H/01 is specifically based on:

- The combination of mesotrione and nicosulfuron, both with different herbicidal modes of action
- Maximum of one application per season
- Maintaining the recommended label rates as those shown to give effective control
- Application to be made when weeds are at the most susceptible stages of development
- Use in sequences with herbicides with different modes of action
- Use of herbicides with different modes of action in subsequent seasons
- Good agronomical practices: crop rotations, soil management work, etc.

This should ensure there is no adverse shift in the sensitivity of weed populations to the product.

Furthermore, with the proposed conditions of use for SAE053H/01 and taking the right precautions by following relevant HRAC guidance and Good Agricultural Practice, the low to moderate risk of resistance arising to mesotrione or nicosulfuron for SAE053H/01 with an unrestricted use pattern is further reduced to a low and acceptable level.

Study Comments: 3.3 dRR point 3.3	EN: Strategy is acceptable.
EN: Evaluator conclusion: The applicant proposed to maintain HRAC recommendations for avoiding the appearances of more resistances. The label statement should recommend: the use of a suitable product with an alternative mode of action, not use products with similar mode of action on the same field during several years,	

treat weeds at the most susceptible stages of development, while actively growing as well as there should be practiced integrated weed management.

169 weed species have evolved resistance towards HRAC group 2 (previous group B), globally. Among them 9 weed species are reported to exhibit resistance to nicosulfuron in Europe.

Three weed species have evolved resistance towards to HRAC group 27 (previous group F2) but none of them in Europe.

3.4 Adverse effects (KCP 6.4)

In addition to assessments for phytotoxicity having been carried out on all 60 efficacy trials, 23 crop selectivity trials have been conducted between 2014 and 2018 specifically to evaluate crop safety and potential adverse impact on crop yield and quality following the application of SAE053H/01 at the highest proposed label rate of 1.2 L product/ha or at the slightly higher rates of 1.5 and 1.85 L product/ha, and also at twice these rates (3.0 L or 3.7 L product/ha) to simulate sprayer overlap, in maize.

Information on trials submitted (3.4 Crop selectivity data)

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-1: Presentation of trials (crop selectivity trials)

Crop*	Country	Type of trial**	Number of trials			Years	GEP, non-GEP, official***	Comments (any other relevant information)
			Maritime zone	North-east zone	South-east zone			
Maize	Belgium	S + Y + Q	2	-	-	2018	GEP	
	Bulgaria	S + Y + Q	-	-	1	2014	GEP	
	Czech Republic	S + Y + Q	1	-	-	2014	GEP	
			1	-	-	2015	GEP	
	France	S + Y + Q	2	-	-	2018	GEP	
	Germany	S + Y + Q	2	-	-	2018	GEP	
	Hungary	S + Y + Q	-	-	1	2014	GEP	
			-	-	3	2015	GEP	
	Poland	S + Y + Q	-	2	-	2014	GEP	
			-	3	-	2015	GEP	
	Romania	S + Y + Q	-	-	1	2014	GEP	
			-	-	2	2015	GEP	
	United Kingdom	S	1	-	-	2015	GEP	
		S + Y + Q	1	-	-	2015	GEP	
TOTAL	-	S + Y + Q	9	5	8	2014-18	-	-
		S	1	-	-	2015		

* According to the GAP table.

** S = selectivity trial, Y = trial with yield assessment, Q = trial with quality assessment

*** Official: carried out by a national official organisation

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-2:
Presentation of reference standards used in trials in maize (crop selectivity trials)

Reference standard	Country(ies) where the product is registered ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application Rate (/ha) ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
				Type ⁽²⁾	Concentration of a.s.			
Elumis	UK	15800	mesotrione + nicosulfuron	OD	75 g/L + 30 g/L	1.5 L	1.5 L, 2.0 L, 3.0 L, 4.0 L	
	CZ	4757-0				1.0-1.5 L		
	BE	10383P/B				1.5 L		
	DE	006960-00				1.5 L		
	FR	2100111				1.5 L		
	PL	R-61/2014				1.0-1.5 L		
	RO	006PC/20.12.2011				1.0-2.0 L		
	HU	04.2/1283-2/2013				1.3-2.0 L / 1.0 + 0.7 L or 1.3 + 0.7 L		
	BG	1151-2/25.10.2013 r.				L		
Callisto 4 SC / Callisto 480 SC	HU	04.2/660-2/2016	mesotrione	SC	480 g/L	0.25-0.35 L	0.35 L, 0.7 L	
	RO	2156/11.10.2002				0.2-0.3 L		
	BG	01053-III/3/02.03.2010 r.				0.2 L (post-em) 0.3-0.4 L (pre-em)		
Callisto 100 SC	PL	R-25/2009	mesotrione	SC	100 g/L	1.0-1.5 L	1.5 L, 3.0 L	
Temsa SC	CZ	5147-0	mesotrione	SC	100 g/L	1.5 L	1.5 L, 3.0 L	

(1) only on use(s) applied for (with the test product).

(2) e.g. WP (wetable powder), EC (emulsifiable concentrate), etc.

(3) dose(s) / dose range authorized on that use in the country.

(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.).

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Assessments for phytotoxic symptoms and other effects on crop growth and development have been carried out on all 60 trials conducted between 2014 and 2018 that generated data on the efficacy of SAE053H/01 applied at rates up to and including the highest proposed label rate of 1.5 L product/ha against weeds in maize.

Details of the materials and methods used in all efficacy trials summarized in support of demonstrating crop safety in maize are given in Section 3.2.3.

Assessments for phytotoxic symptoms and other effects on crop growth and development have also been carried out on 23 crop selectivity trials carried out between 2014 and 2018 for the specific purpose of generating data on the crop safety of SAE053H/01 applied at the rate of 1.5 L product/ha or at the slightly higher rate of 1.85 L product/ha, and also at twice these rates (3.0 L or 3.7 L product/ha) to simulate sprayer overlap, in maize.

All crop selectivity trials were carried out by organisations that are officially recognised as competent to carry out efficacy testing in accordance with European Commission Directive 93/71/EEC by the authorities in the relevant countries.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-3: Details on trial methodology (crop selectivity trials)

Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (3/4)
	Specific guidelines	EPPO PP1/50 (3)
Experimental design	Plot design	RCBD (23)
	Plot size	16-42 m ²
	Number of replications	4 (23)
Crop	Trials per crop	Grain maize (19) Forage maize (3) Maize for ethanol production (1)
	Varieties per crop	Activate (1), Alexandra Duo (1), Ambrosini (1), Crossman (1), DKC4490 (1), ES Watson (1), Grizzly (1), Grosso (1), Karimba (1), Kroissans (1), LBS 4378 (1), LG 30.273 (1), Lucius (1),Milanno (1), P8523 (1), PO105 (1), Rywal (1), Suarze (1), Subito (1), SY Cardone (1), SY Ondino (1), SY Respect (1), TK202 (1)
Application	Crop stage (BBCH)* at application	Post-emergence from 12 to 20 (BBCH)
	Number of applications	1 (all trials)
	Spray volumes	200 L/ha (17), 300 L/ha (6)
Assessment	Assessment types	Phytotoxicity, crop stunting, crop vigour, crop biomass, crop yield, grain moisture content, grain starch content, thousand grain weight, grain hectolitre weight, silage moisture content, silage dry matter content, plant moisture content

Between trials, SAE053H/01 was applied in water volumes of between 200 and 300 L/ha and therefore fully representative of the proposed 200-400 L/ha label range.

Agronomic practices in the cultivation of maize are considered to be sufficiently similar across countries within the Central Registration zone for data generated across all trials to be fully supportive of demonstrating the crop safety of SAE053H/01 in all countries relevant to this submission.

Justification for the use of crop safety data included in this dossier is made according to EPPO PP 1/241(1) "Guidance on comparable climates".

Crop selectivity trials from which data are summarized in this dossier were carried out in the following EPPO climatic zones:

Maritime: Belgium, Czech Republic, Maritime regions of France, Germany, United Kingdom

North-east: Poland

South-east: Bulgaria, Hungary, Romania

Trials carried out in the Maritime climatic zone have been conducted in areas where climatic conditions are representative of those in Austria, Belgium, Czech Republic, Germany, Ireland, Netherlands and the United Kingdom. Data generated in these trials are therefore fully supportive towards demonstrating the crop safety of SAE053H/01 in the EU Central Registration zone with respect to this country.

Trials carried out in the North-east climatic zone have all been conducted in Poland and data generated in these trials are therefore fully supportive towards demonstrating the crop safety of SAE053H/01 in the EU Central Registration zone with respect to this country.

Trials carried out in the South-east climatic zone have been conducted in areas where climatic conditions are representative of those in Hungary, Romania, Slovenia and Slovakia. Data generated in these trials are therefore fully supportive towards demonstrating the crop safety of SAE053H/01 in the EU Central Registration zone with respect to these countries.

Overall summaries of the crop safety of SAE053H/01 across trials carried out in maize are given in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-4 (Crop selectivity trials) and Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-5 (Efficacy trials).

[illegible]

EPPO Climatic zone	Timing	Levels of phytotoxicity	Number of trials											
			SAE053H/01				Elumis				Callisto 100 SC / Temsa SC (3 trials)		Callisto 4 SC / Callisto 480 SC (3 trials)	
			(20 trials)		(3 trials)		(20 trials)		(3 trials)		1.5 L/ha (150 g a.s./ha)	3.0 L/ha (300 g a.s./ha)	0.35 L/ha (168 g a.s./ha)	0.7 L/ha (336 g a.s./ha)
			1.5 L/ha (120 + 45 g a.s./ha)	3.0 L/ha (240 + 90 g a.s./ha)	1.85 L/ha (148 + 55.5 g a.s./ha)	3.7 L/ha (296 + 111 g a.s./ha)	1.5 L/ha (112.5+45 g a.s./ha)	3.0 L/ha (240 + 90 g a.s./ha)	2.0 L/ha (150 + 60 g a.s./ha)	4.0 L/ha (300 + 120 g a.s./ha)				
South- east (8 trials)	Maximum level of symptoms recorded	0%	5	3	1	-	4	3	-	-	-	-	3	3
		0.1-5%	-	1	2	2	1	1	2	1	-	-	-	-
		>5-10%	-	1	-	-	-	1	1	-	-	-	-	-
		>10-15%	-	-	-	1	-	-	-	2	-	-	-	-
		>15%	-	-	-	-	-	-	-	-	-	-	-	-
	Final assessment timings	0%	5	5	3	3	5	5	3	3	-	-	3	3
		0.1-5%	-	-	-	-	-	-	-	-	-	-	-	-
		>5-10%	-	-	-	-	-	-	-	-	-	-	-	-
		>10-15%	-	-	-	-	-	-	-	-	-	-	-	-
		>15%	-	-	-	-	-	-	-	-	-	-	-	-

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-5: Overall summary of the crop safety of SAE053H/01 across all efficacy trials carried out in maize

EPPO climatic zone	Timing	Levels of phytotoxicity	Number of trials					
			SAE053H/01 (60 trials)	Elumis		Callisto 4 SC / Callisto 480 SC		Callisto 100 SC / Temsa SC (6 trials)
				(56 trials)	(4 trials)	(2 trials)	(1 trial)	
			1.5 L/ha (120+45 g a.s./ha)	1.5 L/ha (112.5 + 45 g a.s./ha)	2 L/ha (150 + 60 g a.s./ha)	0.35 L/ha (168 g a.s./ha)	0.4 L/ha (192 g a.s./ha)	1.0 / 1.5 L/ha (100 / 150 g a.s./ha)
Maritime (23 trials)	Maximum level of symptoms recorded	0%	17	17	-	-	-	2
		0.1-5%	-	-	-	-	-	-
		>5-10%	2	3	-	-	-	-
		>10-15%	-	1	-	-	-	-
		>15%	4	2	-	-	-	-
	Final assessment timings	0%	20	20	-	-	-	2
		0.1-5%	1	1	-	-	-	-
		>5-10%	-	-	-	-	-	-
		>10-15%	1	1	-	-	-	-
		>15%	1	1	-	-	-	-

EPPO climatic zone	Timing	Levels of phytotoxicity	Number of trials					
			SAE053H/01 (60 trials)	Elumis		Callisto 4 SC / Callisto 480 SC		Callisto 100 SC / Temsa SC (6 trials)
				(56 trials)	(4 trials)	(2 trials)	(1 trial)	
				1.5 L/ha (120+45 g a.s./ha)	2 L/ha (150 + 60 g a.s./ha)	0.35 L/ha (168 g a.s./ha)	0.4 L/ha (192 g a.s./ha)	
North-east (16 trials)	Maximum level of symptoms recorded	0%	16	16	-	-	-	4
		0.1-5%	-	-	-	-	-	-
		>5-10%	-	-	-	-	-	-
		>10-15%	-	-	-	-	-	-
		>15%	-	-	-	-	-	-
	Final assessment timings	0%	16	16	-	-	-	4
		0.1-5%	-	-	-	-	-	-
		>5-10%	-	-	-	-	-	-
		>10-15%	-	-	-	-	-	-
		>15%	-	-	-	-	-	-
South-east (21 trials)	Maximum level of symptoms recorded	0%	17	14	3	2	1	-
		0.1-5%	2	2	-	-	-	-
		>5-10%	1	-	1	-	-	-
		>10-15%	-	-	-	-	-	-
		>15%	1	1	-	-	-	-
	Final assessment timings	0%	21	17	4	2	1	-
		0.1-5%	-	-	-	-	-	-
		>5-10%	-	-	-	-	-	-
		>10-15%	-	-	-	-	-	-
		>15%	-	-	-	-	-	-

SAE053H/01 applied at the rate of 1.5 L product/ha, or the higher rate of 1.85 L product/ha in 1 crop selectivity trial, caused no phytotoxic symptoms or other adverse effects on crop growth on 50 of the 60 efficacy trials or on 18 of the 23 crop selectivity trials. On 7 of the other 10 efficacy trials and all of the other 5 crop selectivity trials, SAE053H/01 applied at the rate of 1.5 L product/ha, or the higher rate of 1.85 L product/ha in 2 of the crop selectivity trials, caused only relatively low levels of phytotoxicity and/or effects on crop growth and development, with symptoms including chlorosis, necrosis, bleaching, discoloration, crop vigour and biomass reductions and stunting. In all cases these symptoms were transient, occurring soon after application and no longer apparent at later assessment timings.

The SAE053H/01 labels will include precautionary statements informing that transitory phytotoxicity and/or reductions in crop vigour may sometimes occur following application but that these effects are generally transient and do not result in subsequent reductions in crop yield.

Therefore, SAE053H/01 applied at the rate of 1.5 L product/ha, or the higher rate of 1.85 L product/ha in 3 trials, only caused more severe and permanent phytotoxicity on 3 of 83 trials. These were 3 efficacy trials carried out in 2015 in the Maritime climatic zone (all in the UK), in which SAE053H/01 applied at the rate of 1.5 L product/ha caused moderate crop stunting on all 3 trials and moderate levels of chlorosis on 2 of the trials, with the symptoms being relatively persistent and still evident at final assessment timings.

Climatic conditions in the UK were particularly variable in the spring of the year when these 3 trials were conducted, including the periods proceeding and following application in the areas where all trials were carried out. This included sudden changes from unseasonably low to above average temperatures, periods with no or low rainfall, intermittent storms with heavy rainfall over a short time and also strong winds. It is considered that these pronounced fluctuations or extremities in one or more of these climatic factors caused the crops to become stressed and therefore more susceptible to the potential for pesticide treatments to cause phytotoxicity and effects on crop growth. The severity and persistence of the symptoms caused by SAE053H/01 applied at the rate of 1.5 L product/ha on these trials are therefore considered to have been attributable to crop stress.

The SAE053H/01 labels will include precautionary statements informing that more severe phytotoxicity and reductions in crop vigour may occur if application is made to crops suffering from stress (caused by extremes of temperature, waterlogging, drought, physical damage, etc.) and that this should be avoided.

SAE053H/01 applied at more than twice the highest proposed label rate (3.0 L product/ha) to simulate sprayer overlap, or the even higher rate of 3.7 L product/ha in 3 trials, caused no phytotoxic symptoms or other adverse effects on crop growth on 14 of the 23 crop selectivity trials. On 8 of the other 9 trials, SAE053H/01 applied at more than twice the highest proposed label rate (3.0 L product/ha), or the even higher rate of 3.7 L product/ha in 3 of the trials, caused only relatively low levels phytotoxicity and/or effects on crop growth and development, with symptoms including chlorosis, bleaching, leaf curling, crop vigour reductions and stunting. In all cases these symptoms were transient, occurring soon after application and no longer apparent at later assessment timings.

Therefore, SAE053H/01 at more than twice the highest proposed label rate (3.0 L product/ha) to simulate sprayer overlap, or the even higher rate of 3.7 L product/ha in 3 trials, only caused more severe and permanent phytotoxicity on 1 of 23 trials. This was 1 of the crop selectivity trials carried out in 2015 in the Maritime climatic zone (in the UK), in which SAE053H/01 applied at more than twice the highest proposed label rate (3.0 L product/ha) caused severe crop stunting, with the symptoms being relatively persistent and still evident at the final assessment timing.

In addition to precautionary statements informing that more severe phytotoxicity and reductions in crop vigour may occur if application is made to crops suffering from stress, the SAE053H/01 labels will also include a statement advising to avoid sprayer overlap.

Summary and conclusions on phytotoxicity

Across trials, the crop safety of SAE053H/01 has been tested under a wide range of climatic conditions and agronomic practices fully representing those in maize growing regions of EU Central Registration zone countries relevant to this submission. Trials have been carried out on an extensive range of different commercial varieties of maize, representing those that are currently widely grown in relevant countries in the EU Central Registration zone.

Single applications of SAE053H/01 were made when crop growth stages were within the range of 10-20 (BBCH), with all or some crop within the proposed label range of 12-19 (BBCH) for the application of SAE053H/01, on all trials.

In the overall majority of cases, SAE053H/01 applied at more than twice the highest proposed label rate of 1.2 L - the rates of 1.5 L product/ha or 1.85 L product/ha (60 trials), and also at twice these rates (3.0 L or 3.7 L product/ha), on 23 crop selectivity trials, caused either no phytotoxicity or only low and transient levels of symptoms. SAE053H/01 caused higher and more persistent levels of phytotoxic symptoms on only 3 of the 83 trials and the equivalent standard reference product also caused similar levels of the same effects on these trials. The more severe phytotoxicity on these trials was attributed to the crop being under stress due to unseasonal fluctuations or extremes in climatic conditions both before and following application. The SAE053H/01 labels will include precautionary statements informing that more severe phytotoxicity and reductions in crop vigour may occur if application is made to crops suffering from stress (caused by extremes of temperature, waterlogging, drought, physical damage, etc.) and that this should be avoided.

SAE053H/01 is a similar formulation and contains almost equivalent amounts of mesotrione and nicosulfuron to an approved standard reference product (Elumis) that is registered for application in maize at rates overlapping the 1.0-1.2 L product/ha label range proposed for SAE053H/01 and in some countries at higher rates. The proven crop safety of this approved product through extensive commercial use and similar levels of symptoms and effects caused by Elumis and SAE053H/01 in the trials summarized here is therefore considered to provide further supportive evidence of the crop safety of SAE053H/01.

Therefore, based on the absence of phytotoxic symptoms or effects on crop growth and development or only very low and transient levels of symptoms or effects across trials, it is reasonable to conclude that a single application of SAE053H/01 at up to the highest rate in the proposed range of 1.0-1.2 L product/ha, and when applied according to label recommendations (including not to apply to crops under stress), is crop safe on maize.

Study Comments: 3.4.1 dRR point 3.4.1	Studies are acceptable.
Phytotoxicity symptoms were checked in selectivity trials: n=10 for Maritime climatic zone, n=5 for NE climatic zone, n=8 for SE climatic zone and in efficacy trials: n=23 for Maritime climatic zone, n=16 for NE climatic zone, n=21 for SE climatic zone SAE053H/01 was applied at the rate of 1,5 L product/ha, 3,0 L product/ha, 1,85 L product/ha nad 3,7 L product/ha. In 7 efficacy trials and 5 crop selectivity trials, SAE053H/01 applied at the rate of 1,5 L product/ha, or the higher rate of 1,85 L product/ha and in 8 trials, SAE053H/01 applied at 3.0 L product/ha or of 3.7 L product/ha caused only relatively low levels of phytotoxicity and/or effects on crop growth and development: chlorosis, necrosis, bleaching, discoloration, crop vigour, biomass reductions and stunting. In all cases these symptoms were transient.	

Simultaneously in 3 efficacy trials, SAE053H/01 applied at the rate of 1.5 L product/ha, or the rate of 1.85 L and in 1 trial, SAE053H/01 applied at 3.0 L product/ha or of 3.7 L product/ha carried out in 2015 in the Maritime climatic zone (all in the UK) caused more severe and permanent phytotoxicity evident at final assessment timings. The reason of such phenomenon might be explained by the unfavorable climatic conditions in the spring of the year when these 3 trials were conducted: sudden changes from unseasonably low to above average temperatures, periods with no or low rainfall, intermittent storms with heavy rainfall over a short time, strong winds. These climatic factors might have caused the crops to become stressed and therefore more susceptible to the potential for pesticide treatments to cause phytotoxicity and effects on crop growth.

The label needs to contain information that transitory phytotoxicity and/or reductions in crop vigour may sometimes occur following application and that these effects are transient. In relation to more severe phytotoxicity and reductions in crop vigour causes, the label needs to contain additional information that may occur if application is made to crops suffering from stress caused by extremes of temperature, waterlogging, drought, physical damage, etc and that this should be avoided as well as spray overlap.

It might be concluded that crop safety of FH-044 application in maize can be claimed.

3.4.2 Effects on yield of treated plants or plant products (KCP 6.4.2)

A total of 22 of the 23 crop selectivity trials carried out between 2014 and 2018 generated data on crop yield at normal commercial harvest following a single application of SAE053H/01 at either the rate of 1.5 L product/ha or at the higher rate of 1.85 L product/ha, and also at twice these rates (3.0 L or 3.7 L product/ha) to simulate sprayer overlap, in the absence of weeds in maize.

Of these trials, 9 were carried out in the Maritime climatic zone, 5 were carried out in the North-east climatic zone and 8 were carried out in the South-east climatic zone, with 18 on crops for grain production, 3 on crops for silage production and 1 was carried out a crop for ethanol production.

On these trials, single applications of SAE053H/01 were made when crop growth stages were within the range of 12-20 (BBCH) and within or overlapping on the proposed label range of 12-19 (BBCH) for the application of SAE053H/01.

A comparison of levels of phytotoxicity to crop yield on 9 of the 10 crop selectivity trials carried out in maize on which SAE053H/01 caused phytotoxic symptoms or effects on crop growth and development is given in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-6.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-6: Comparison of levels of phytotoxicity to crop yield in 9 of the 10 crop selectivity trials carried out on maize in which SAE053H/01 caused phytotoxicity

EPPO climatic zone	Trial no.	Variety	Product	Max. level of phyto. (%) (timing)		Yield in the untreated control (t/ha)	Crop yield (as % of untreated)	
				>1N rate	>2N rate		>1N rate	>2N rate
Maritime	BTD-15-21149-GB01	Activate	SAE053H/01	0	61.3 (23 DA-A)	No yield evaluation carried out	-	-
			Elumis	2.5 (23 DA-A)	11.3 (23 DA-A)		-	-
	BTD-18-33654-FR01	Kroissans	SAE053H/01	5.3 (7 DA-A)	5.8 (7 DA-A)	31.36 (silage)	98.5	96.3
			Elumis	3.8 (7 DA-A)	5.0 (7 DA-A)		98.3	99.2
	BTD-18-33655-FR01	LBS 4378	SAE053H/01	7.3 (7 DA-A)	10.0 (7 DA-A)	14.4 (grain)	104.8	100.6
			Elumis	5.0 (7 DA-A)	12.0 (7 DA-A)		101.7	102.5
North-east	S14-02865-01	Ambrosini	SAE053H/01	2.0 (15 DA-A)	10.0 (15 DA-A)	5.0 (grain)	90.0	86.0
			Elumis	0	0		82.0	80.0
			Callisto 100 SC	0	10.0 (15 DA-A)		92.0	84.0
	S14-02865-02	Rywal	SAE053H/01	0.7 (15 DA-A)	1.7 (15 DA-A)	3.7 (grain)	125.8	119.7
			Elumis	0	0		115.6	114.8
			Callisto 100 SC	0	2.0 (15 DA-A)		118.6	118.9
South-east	S14-02868-01	Alexandra Duo	SAE053H/01	0	1.3 (17 DA-A)	9.0 (grain)	106.2	89.8
			Elumis	0.8 (17 DA-A)	0.8 (17 DA-A)		115.3	107.3
			Callisto 4 SC	0	0		101.4	110
	BTD-15-21149-RO11	Suarez	SAE053H/01	0	10.0 (14 DA-A)	7.0 (grain)	101.7	100.6
			Elumis	0	10.0 (14 DA-A)		101.6	100.3
	BTD-15-21149-HU07	Lucius	SAE053H/01 (1.85 L product/ha)	1.3 (14 DA-A)	4.0 (14 DA-A)	10.9 (grain)	99.5	93.2
			Elumis (2.0 L product/ha)	6.5 (14 DA-A)	11.3 (14 DA-A)		97.7	94.3

Eppo climatic zone	Trial no.	Variety	Product	Max. level of phyto. (%) (timing)		Yield in the untreated control (t/ha)	Crop yield (as % of untreated)	
				>1N rate	>2N rate		>1N rate	>2N rate
South-east	BTD-15-21149-HU08	TK 202	SAE053H/01 (1.85 L product/ha)	0	4.0 (14 DA-A)	6.9 (grain)	110.4	107.4
			Elumis (2.0 L product/ha)	2.5 (14 DA-A)	5.0 (14 DA-A)		113.9	122.1
	BTD-15-21149-RO10	P8523	SAE053H/01 (1.85 L product/ha)	4.0 (14 DA-A)	13.5 (14 DA-A)	5.5 (grain)	101.1	99.1
			Elumis (2.0 L product/ha)	4.0 (14 DA-A)	14.0 (14 DA-A)		104.2	104.5

On the one crop selectivity trial in which SAE053H/01 caused more severe and persistent adverse effects on crop growth and development (stunting) but only when applied at twice the highest proposed label rate (3.0 L product/ha), evaluations of yield could not be carried out due to an oversight by the grower.

On the other 9 crop selectivity trials on which SAE053H/01 applied at the rate of 1.5 L product/ha or the higher rate of 1.85 L product/ha, and/or at twice these rates (3.0 L or 3.7 L product/ha), caused relatively low and transient levels of phytotoxic symptoms, there were no corresponding significant reductions in crop yield.

Whilst SAE053H/01 and the standard reference product gave relatively pronounced but non-significant reductions in crop yield, compared to the untreated control, in 1 of these 9 trials, crop yield within this trial was variable and differences in the reductions in yield given by different treatments did not correspond to differences in the low and transient phytotoxic symptoms that occurred earlier in the season on this trial.

Summary and conclusions on impact on crop yield

Across trials, the potential impact of SAE053H/01 on crop yield has been tested under a wide range of climatic conditions and agronomic practices fully representing those in maize growing regions of EU Central Registration zone countries relevant to this submission. Trials have been carried out on an extensive range of different commercial varieties of maize, representing those that are currently widely grown in relevant countries in the EU Central Registration zone.

SAE053H/01 applied at the at rates of 1.5 L product/ha or the slightly higher rate of 1.85 L product/ha, and also at twice these rates (3.0 L or 3.7 L product/ha), caused no consistent or significant effects on crop yield on any of the 22 crop selectivity trials on which evaluations were carried out, including those where SAE053H/01 and standard reference products caused relatively low and transient phytotoxicity earlier in the season.

Additionally, SAE053H/01 is a similar formulation and contains almost equivalent amounts of mesotrione and nicosulfuron to an approved standard reference product (Elumis) that is registered for application in maize at rates overlapping the 1.0-1.2 L product/ha range proposed for SAE053H/01 and also at rates of up to 2.0 L product/ha in some countries. The proven crop safety of this approved product through extensive commercial use and similar levels of symptoms and effects caused by Elumis and SAE053H/01 in the trials summarized here is therefore considered to provide further supportive evidence of the crop safety and absence of adverse impact on crop yield of SAE053H/01 at the highest recommended label rate of 1.2 L product/ha.

Based on the absence of pronounced or significant effects across trials, it is therefore reasonable to conclude that a single application of SAE053H/01 at up to the highest rate in the proposed range of 1.0-1.2 L product/ha, and applied according to label recommendations, has no adverse impact on crop yield in maize.

Study Comments: 3.4.2 dRR point: 3.4.2	Studies are acceptable
The applicant presented data obtained from 22 trials carried out in NE and Maritime and SE EPPO zones. SAE053H/01 at the rates 1N and 2N had no negative effect on the yield of maize.	

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

A total of 22 of the 23 crop selectivity trials carried out between 2014 and 2018 generated data on quality parameters of the harvested produce at normal commercial harvest following a single application of SAE053H/01 at either the rate of 1.5 L product/ha or at the even higher rate of 1.85 L product/ha, and also at twice these rates (3.0 L or 3.7 L product/ha) to simulate sprayer overlap, in the absence of weeds in maize.

Of these trials, 9 were carried out in the Maritime climatic zone, 5 were carried out in the North-east climatic zone and 8 were carried out in the South-east climatic zone, with 18 on crops for grain production, 3 on crops for silage production and 1 was carried out a crop for ethanol production.

On these trials, single applications of SAE053H/01 were made when crop growth stages were within the range of 12-20 (BBCH) and within or overlapping on the proposed label range of 12-19 (BBCH) for the application of SAE053H/01.

A comparison of levels of phytotoxicity to yield quality parameters on 9 of the 10 crop selectivity trials carried out in maize on which SAE053H/01 caused phytotoxic symptoms or effects on crop growth and development is given in Table **Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-7**.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-7: Comparison of levels of phytotoxicity to yield quality parameters in 9 of the 10 crop selectivity trials carried out on maize in which SAE053H/01 caused phytotoxicity

EPPO climatic zone	Trial no.	Variety	Product	Max. level of phyto. (%) (timing)		Quality parameter	Quality parameter in the untreated control	Quality parameter (as % of untreated)	
				1.5L/ha rate	3.0 L/ha rate			1.5L/ha rate	3.0 L/ha rate
Maritime	BTD-15-21149-GB01	Activate	SAE053H/01	0	61.3 (23 DA-A)	No quality parameter evaluations carried out	-	-	
			Elumis	2.5 (23 DA-A)	11.3 (23 DA-A)		-	-	
	BTD-18-33654-FR01	Kroissans	SAE053H/01	5.3 (7 DA-A)	5.8 (7 DA-A)	Silage dry matter content (%)	38.13	99.9	97.8
			Elumis	3.8 (7 DA-A)	5.0 (7 DA-A)			99.5	106.3
	BTD-18-33655-FR01	LBS 4378	SAE053H/01	7.3 (7 DA-A)	10.0 (7 DA-A)	Grain moisture content (%)	24.0	100.2	99.8
			Elumis	5.0 (7 DA-A)	12.0 (7 DA-A)			100.0	99.4
North-east	S14-02865-01	Ambrosini	SAE053H/01	2.0 (15 DA-A)	10.0 (15 DA-A)	Grain moisture content (%)	14.9	106.2	109.5
			Elumis	0	0			109.0	108.8
			Callisto 100 SC	0	10.0 (15 DA-A)			106.0	114.4
			SAE053H/01	2.0 (15 DA-A)	10.0 (15 DA-A)	TGW (g)	426	95.3	96.2
			Elumis	0	0			99.5	98.6
			Callisto 100 SC	0	10.0 (15 DA-A)			99.6	97.6
			SAE053H/01	2.0 (15 DA-A)	10.0 (15 DA-A)	HLW (kg/hL)	70.1	98.8	98.4
			Elumis	0	0			98.1	98.5
			Callisto 100 SC	0	10.0 (15 DA-A)			99.2	97.9
			SAE053H/01	2.0 (15 DA-A)	10.0 (15 DA-A)	Starch content (%)	70.0	99.9	100.0
			Elumis	0	0			99.8	100.0
			Callisto 100 SC	0	10.0 (15 DA-A)			100.3	100.5

EPPO climatic zone	Trial no.	Variety	Product	Max. level of phyto. (%) (timing)		Quality parameter	Quality parameter in the untreated control	Quality parameter (as % of untreated)	
				1.5L/ha rate	3.0 L/ha rate			1.5L/ha rate	3.0 L/ha rate
North-east	S14-02865-02	Rywal	SAE053H/01	0.7 (15 DA-A)	1.7 (15 DA-A)	Grain moisture content (%)	23.5	99.4	98.9
			Elumis	0	0			97.4	99.7
			Callisto 100 SC	0	2.0 (15 DA-A)			94.4	97.2
			SAE053H/01	0.7 (15 DA-A)	1.7 (15 DA-A)	TGW (g)	351.8	101.7	104.4
			Elumis	0	0			102.1	103.7
			Callisto 100 SC	0	2.0 (15 DA-A)			103.6	101.7
			SAE053H/01	0.7 (15 DA-A)	1.7 (15 DA-A)	HLW (kg/hL)	76.7	98.1	100.7
			Elumis	0	0			99.0	99.5
			Callisto 100 SC	0	2.0 (15 DA-A)			101.0	99.8
			SAE053H/01	0.7 (15 DA-A)	1.7 (15 DA-A)	Starch content (%)	70.1	100.9	100.6
			Elumis	0	0			100.2	100.3
			Callisto 100 SC	0	2.0 (15 DA-A)			101.2	100.3
South-east	S14-02868-01	Alexandra Duo	SAE053H/01	0	1.3 (17 DA-A)	Grain moisture content (%)	25.3	100.3	97.2
			Elumis	0.8 (17 DA-A)	0.8 (17 DA-A)			96.3	98.6
			Callisto 4 SC	0	0			100.5	99.3
			SAE053H/01	0	1.3 (17 DA-A)	TGW (g)	344	99.4	106.4
			Elumis	0.8 (17 DA-A)	0.8 (17 DA-A)			100.6	104.4
			Callisto 4 SC	0	0			101.6	101.6
			SAE053H/01	0	1.3 (17 DA-A)	HLW (kg/hL)	74.0	101.1	101.5
			Elumis	0.8 (17 DA-A)	0.8 (17 DA-A)			100.1	101.5
			Callisto 4 SC	0	0			100.1	99.9
			SAE053H/01	0	1.3 (17 DA-A)	Starch content (%)	57.0	96.9	93.5
			Elumis	0.8 (17 DA-A)	0.8 (17 DA-A)			91.4	94.5
			Callisto 4 SC	0	0			94.0	94.2

EPPO climatic zone	Trial no.	Variety	Product	Max. level of phyto. (%) (timing)		Quality parameter	Quality parameter in the untreated control	Quality parameter (as % of untreated)	
				1.5L/ha rate	3.0 L/ha rate			1.5L/ha rate	3.0 L/ha rate
South-east	BTD-15-21149-RO11	Suarez	SAE053H/01	0	10.0 (14 DA-A)	Grain moisture content (%)	19.1	100.5	101.0
			Elumis	0	10.0 (14 DA-A)			100.5	104.2
			SAE053H/01	0	10.0 (14 DA-A)	TGW (g)	299.9	110.3	107.2
			Elumis	0	10.0 (14 DA-A)			108.7	113.3
			SAE053H/01	0	10.0 (14 DA-A)	HLW (kg/hL)	80.3	102.5	102.2
			Elumis	0	10.0 (14 DA-A)			100.6	99.6
	BTD-15-21149-HU07	Lucius	SAE053H/01 (1.85 L product/ha)	1.3 (14 DA-A)	4.0 (14 DA-A)	Grain moisture content (%)	14.4	99.3	100.7
			Elumis (2.0 L product/ha)	6.5 (14 DA-A)	11.3 (14 DA-A)			100.0	100.0
	BTD-15-21149-HU08	TK 202	SAE053H/01 (1.85 L product/ha)	0	4.0 (14 DA-A)	Grain moisture content (%)	20.5	98.7	100.8
			Elumis (2.0 L product/ha)	2.5 (14 DA-A)	5.0 (14 DA-A)			101.0	100.8
	BTD-15-21149-RO10	P8523	SAE053H/01 (1.85 L product/ha)	4.0 (14 DA-A)	13.5 (14 DA-A)	Grain moisture content (%)	17.4	100.0	102.3
			Elumis (2.0 L product/ha)	4.0 (14 DA-A)	14.0 (14 DA-A)			99.4	100.0
			SAE053H/01 (1.85 L product/ha)	4.0 (14 DA-A)	13.5 (14 DA-A)	TGW (g)	301.0	110.3	107.2
			Elumis (2.0 L product/ha)	4.0 (14 DA-A)	14.0 (14 DA-A)			108.6	113.3
			SAE053H/01 (1.85 L product/ha)	4.0 (14 DA-A)	13.5 (14 DA-A)	HLW (kg/hL)	79.5	99.0	99.6
			Elumis (2.0 L product/ha)	4.0 (14 DA-A)	14.0 (14 DA-A)			101.1	100.6

On the one crop selectivity trial in which SAE053H/01 caused severe and persistent adverse effects on crop growth and development (stunting) but only when applied at twice the highest proposed label rate (3.0 L product/ha), evaluations of yield and therefore also grain quality could not be carried out due to an oversight by the grower.

On the other 9 crop selectivity trials on which SAE053H/01 applied at the rate of 1.5 L product/ha or the higher rate of 1.85 L product/ha, and/or at twice these rates (3.0 L or 3.7 L product/ha), caused relatively low and transient levels of phytotoxic symptoms, there were no corresponding consistent or significant reductions in the various grain quality parameters (moisture content, TGW, HLW, starch content) or silage quality (dry matter content), where evaluated, or silage quality (dry matter content).

Summary and conclusions on impact on quality of plants and plant products

Across trials, the potential impact of SAE053H/01 on the quality of the harvested produce has been tested under a wide range of climatic conditions and agronomic practices fully representing those in maize growing regions of EU Central Registration zone countries relevant to this submission. Trials have been carried out on an extensive range of different commercial varieties of maize, representing those that are currently widely grown in relevant countries in the EU Central Registration zone.

SAE053H/01 applied at the at the rate of 1.5 L product/ha or the even higher rate of 1.85 L product/ha, and also at twice these rates (3.0 L or 3.7 L product/ha), caused no consistent or significant effects on quality of the harvested produce on any of the 22 crop selectivity trials on which evaluations were carried out, including those where SAE053H/01 and standard reference products caused relatively low and transient phytotoxicity earlier in the season.

Additionally, SAE053H/01 is a similar formulation and contains almost equivalent amounts of mesotrione and nicosulfuron to an approved standard reference product (Elumis) that is registered for application in maize at rates overlapping the 1.0-1.2 L product/ha label range proposed for SAE053H/01 and in some countries at higher rates. The proven crop safety of this approved product through extensive commercial use and similar levels of symptoms and effects caused by Elumis and SAE053H/01 in the trials summarized here is therefore considered to provide further supportive evidence of the crop safety and absence of adverse impact on quality of plants and plant products of SAE053H/01.

Based on the absence of pronounced or significant effects across trials, it is therefore reasonable to conclude that a single application of SAE053H/01 at up to the highest rate in the proposed range of 1.0-1.2 L product/ha, and applied according to label recommendations, has no adverse impact on the quality of plants or plant products in maize.

Study Comments: 3.4.3 dRR point: 3.4.3	Studies are acceptable
The applicant presented data obtained from 22 trials carried out in NE, Maritime and SE EPPO zones. The following yield quality parameters were checked: Silage dry matter content (%), Grain moisture content (%), TGW (g), HLW (kg/hL), Starch content (%). It might be concluded that a single application of SAE053H/01 at the proposed range of 1.0-1.2 L product/ha has no adverse impact on the quality of plants or plant products in maize.	

3.4.4 Effects on transformation processes (KCP 6.4.4)

Whilst there are no major transformation processes applicable to forage or grain maize, products containing mesotrione or nicosulfuron as the sole active substance or together in co-formulations have been approved and extensively used as herbicides in maize across EU countries for many years and are well proven to have no negative impact on any relevant processing procedures.

On this basis, no data are presented or considered necessary to demonstrate the absence of adverse effects of SAE053H/01 on transformation processes in maize.

It is therefore reasonable to conclude that the application of SAE053H/01 at up to the highest rate in the proposed range of 1.0-1.2 L product/ha and according to other label recommendations on maize has no effects on relevant processing procedures.

Study Comments: 3.4.4 dRR point: 3.4.4	Explanations are acceptable
The applicant presented no data on effects on transformation processes taking note that there are no major transformation processes applicable to forage or grain maize, products containing mesotrione or nicosulfuron as the sole active substance or together in co-formulations have been approved and extensively used as herbicides in maize across EU countries for many years and are well proven to have no negative impact on any relevant processing procedures. The explanations are acceptable.	

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

Products containing mesotrione or nicosulfuron as the sole active substance or together in co-formulations have been approved and extensively used as herbicides in maize across EU countries for many years and are well proven to have no adverse effects on the viability of progeny seed.

On this basis, no data are presented or considered necessary to demonstrate the absence of adverse effects of SAE053H/01 on seed viability in maize.

It is therefore reasonable to conclude that SAE053H/01 applied up to the highest rate in the proposed range of 1.0-1.2 L product/ha and according to label recommendations has no adverse impact on the viability of the progeny seed and can safely be applied on maize intended for seed production.

Study Comments: 3.4.5 dRR point: 3.4.5	Explanations are acceptable
The applicant presented no data on impact on treated plants or plant parts to be used for propagation taking note that Products containing mesotrione or nicosulfuron have been using for many years and are well proven to have no adverse effects on the viability of progeny seed. The explanations are acceptable.	

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

3.5.1 Impact on succeeding crops (KCP 6.5.1)

SAE053H/01 contains two active substances. Of these, mesotrione is primarily a contact acting herbicide with some residual soil activity and uptake by plants via the roots and low to moderate persistence in the soil ($DT_{50} = 4.3-28.7$ days¹). Nicosulfuron has both contact and residual soil activity and whilst also having low to moderate persistence in the soil (1st order $DT_{50S} = 8.6-63.3$ days), two of the soil metabolites of nicosulfuron (ADMP, ASMD) have similar toxicity to plants as nicosulfuron and ASMD at least has medium to high persistence in the soil ($DT_{50\text{ lab}} = 90.5-268.5$ days)². The risk of adverse impact of SAE053H/01 on succeeding crops is therefore relatively high due to relatively slow degradation of nicosulfuron and its metabolites in the soil.

One greenhouse pot study (Study number: S16-02421) carried out in 2016 in Germany generated data on the impact of SAE053H/01 on a representative range of monocotyledonous and dicotyledonous crop species sown following application to the soil at a range of concentrations in the range of 0.00469-1.5 L product/ha.

This study was carried out by an organisation that is officially recognised as competent to carry out efficacy testing in accordance with European Commission Directive 93/71/EEC by the authority in the relevant country.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-1: Details on trial methodology (Seedling emergence and seedling growth test)

Guidelines	General guidelines	EPPO PP1/135 (4)
	Specific guidelines	OECD Guideline 208 (Seedling Emergence and Seedling Growth Test) EPPO guideline PP 1/207(2) Effects on succeeding crops
Experimental design	Plot design	RCBD
	Plot size	One pot (15 cm diameter)
	Number of replications	5 (ALLCE, AVESA and LOLPE), 10 (all other species)
Crop	Crops tested	Onion (ALLCE), Oats (AVESA), English ryegrass (LOLPE), Maize (ZEAMX), Sugar beet (BEAVX), White cabbage (BRSOL), Turnip (BRSRR), Cucumber (CUMSA), Soybean (GLXMA), Lettuce (LACSA)
Application	Crop stage (BBCH)* at application	Pre-sowing
	Number of applications	1
	Spray volumes	200 L/ha
Assessment	Assessment types	Phytotoxicity, seedling emergence, plant mortality, shoot dry weight

The test was carried out under protected conditions in a glass greenhouse equipped with artificial lighting maintained on a cycle of 16 hours of light and 8 hours of dark. For the duration of the study, temperatures were within the range of 20.7-45.7°C, relative humidity was in the range of 27.3-90.4% and light intensity was in the range of 14882-21063 lux.

In this study, the most sensitive endpoint was shoot dry weight and as ER_{10} values were not calculated, NOER values for shoot dry weight are used for the following risk assessment calculations. A summary of NOER for SAE053H/01 based on shoot dry weight from this study is given in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-2.

¹ Peer review of the pesticide risk assessment of the active substance mesotrione. EFSA Journal 07 March 2016.

² Conclusions of the peer review of the pesticide risk assessment of the active substance nicosulfuron. EFSA Scientific Report (2007) 120, 1-91

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-2: Effect rates (NOER) determined for SAE053H/01 based on shoot dry weight (21 days after 50% emergence of untreated control) in OECD 208 seedling emergence and seedling growth test

Crop species (EPPO code)	NOER values (based on shoot dry weight)				
	SAE053H	mesotrione		nicosulfuron	
	L product/ha	g a.s./ha	mg/kg soil*	g a.s./ha	mg/kg soil*
Monocotyledonous plant species					
ALLCE	≥0.09375	≥7.5	≥0.01	≥2.8125	≥0.0038
AVESA	≥1.5	≥120	≥0.16	≥45	≥0.06
LOLPE	>0.375	>30	>0.04	>16.875	>0.0225
ZEAMX	≥1.5	≥120	≥0.16	≥45	≥0.02
Dicotyledonous plant species					
BEAVX	0.00938	0.7504	0.0010	0.2814	0.0004
BRSOL	0.00938	0.7504	0.0010	0.2814	0.0004
BRSRR	0.09375	7.5	0.01	2.8125	0.0038
CUMSA	<0.09375	<7.5	<0.01	<2.8125	<0.0038
GLXMA	≥1.5	≥120	≥0.16	≥45	≥0.02
LACSA	0.09375	7.5	0.01	2.8125	0.0038

*The NOER (g a.s./ha) values are converted to concentration in the soil (mg/kg soil) by using the equation below (assuming an even distribution of chemical in the top 5cm of soil and an average soil bulk density of 1.5 g/cm):

$$\frac{\text{g a.s./ha (NOER)}}{100 \times 5 \text{ (soil depth)} \times 1.5 \text{ (bulk density dry soil)}} = \text{mg a.s./kg of soil}$$

For the following risk assessment, PEC_{soil} values (as summarized in dRR Part B Section 8, KCP 9.1.3) are calculated for mesotrione and nicosulfuron based on a single application of SAE053H/01 at the label rate of 1.5 L product/ha (120 g mesotrione/ha + 45 g nicosulfuron/ha) for distribution to a soil depth of 5 cm (representative of minimum cultivation) and to a soil depth of 20cm (representative of deep cultivation).

Following the EPPO guideline Standard PP 1/207(2) 'Effects on succeeding crops', the calculated TER (Toxicity Exposure Ratio) values for all plant species based on Predicted Environmental Concentration in soil (PEC_{soil}) for mesotrione and nicosulfuron and effect rates (NOER) on plant emergence and seedling growth are given in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-3 (with minimum cultivation, for soil depth of 5cm) and Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-4 (with deep cultivation to a soil depth of 20cm) for mesotrione in the soil and in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-5 (with minimum cultivation, for soil depth of 5cm) and Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-6 (with deep cultivation to a soil depth of 20cm) for nicosulfuron in the soil.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-3: TERs for mesotrione for representative succeeding crop types based on NOER and PEC_{soil} values for distribution to soil depth of 5 cm (representative of minimum cultivation)

DA-A (PEC _{soil} for 5 cm soil depth in mg/kg soil)		TER=NOER/PEC _{soil} to 5 cm soil depth									
Plant species	NOER (mg/kg soil)	0d (0.160)	1 d (0.157)	2 d (0.154)	4 d (0.148)	7 d (0.139)	14 d (0.121)	21 d (0.105)	28 d (0.091)	50 d (0.058)	100 d (0.021)
Monocotyledonous crop types											
ALLCE	≥ 0.01	0.06	0.06	0.06	0.07	0.07	0.08	0.10	0.11	0.17	0.48
AVESA	≥ 0.16	1.00	1.02	1.04	1.08	1.15	1.32	1.52	1.76	2.76	7.62
LOLPE	> 0.04	0.25	0.25	0.26	0.27	0.29	0.33	0.38	0.44	0.69	1.90
ZEAMX	≥ 0.16	1.00	1.02	1.04	1.08	1.15	1.32	1.52	1.76	2.76	7.62
Dicotyledonous crop types											
BEAVX	0.001	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.02	0.05
BRSOL	0.001	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.02	0.05
BRSRR	0.01	0.06	0.06	0.06	0.07	0.07	0.08	0.10	0.11	0.17	0.48
CUMSA	< 0.01	0.06	0.06	0.06	0.07	0.07	0.08	0.10	0.11	0.17	0.48
GLXMA	≥ 0.16	1.00	1.02	1.04	1.08	1.15	1.32	1.52	1.76	2.76	7.62
LACSA	0.01	0.06	0.06	0.06	0.07	0.07	0.08	0.10	0.11	0.17	0.48

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-4: TERs for mesotrione for representative succeeding crop types based on NOER and PEC_{soil} values for distribution to soil depth of 20 cm (representative of deep cultivation)

DA-A (PEC _{soil} for 20 cm soil depth in mg/kg soil)		TER=NOER/PEC _{soil} to 20 cm soil depth									
Plant species	NOER (mg/kg soil)	0d (0.040)	1 d (0.039)	2 d (0.039)	4 d (0.037)	7 d (0.035)	14 d (0.030)	21 d (0.026)	28 d (0.023)	50 d (0.015)	100 d (0.005)
Monocotyledonous crop types											
ALLCE	≥ 0.01	0.25	0.25	0.26	0.27	0.29	0.33	0.38	0.44	0.69	1.90
AVESA	≥ 0.16	4.00	4.08	4.16	4.32	4.60	5.29	6.10	7.03	11.03	30.48
LOLPE	> 0.04	1.00	1.02	1.04	1.08	1.15	1.32	1.52	1.76	2.76	7.62
ZEAMX	≥ 0.16	4.00	4.08	4.16	4.32	4.60	5.29	6.10	7.03	11.03	30.48
Dicotyledonous crop types											
BEAVX	0.001	0.03	0.03	0.03	0.03	0.03	0.03	0.04	0.04	0.07	0.19
BRSOL	0.001	0.03	0.03	0.03	0.03	0.03	0.03	0.04	0.04	0.07	0.19
BRSRR	0.01	0.25	0.25	0.26	0.27	0.29	0.33	0.38	0.44	0.69	1.90
CUMSA	< 0.01	0.25	0.25	0.26	0.27	0.29	0.33	0.38	0.44	0.69	1.90
GLXMA	≥ 0.16	4.00	4.08	4.16	4.32	4.60	5.29	6.10	7.03	11.03	30.48
LACSA	0.01	0.25	0.25	0.26	0.27	0.29	0.33	0.38	0.44	0.69	1.90

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-5: TERs for nicosulfuron for representative succeeding crop types based on NOER and PEC_{soil} values for distribution to soil depth of 5 cm (representative of minimum cultivation)

DA-A (PEC _{soil} for 5 cm soil depth in mg/kg soil)		TER=NOER/PEC _{soil} to 5 cm soil depth									
Plant species	NOER (mg/kg soil)	0d (0.060)	1 d (0.059)	2 d (0.059)	4 d (0.057)	7 d (0.055)	14 d (0.051)	21 d (0.047)	28 d (0.044)	50 d (0.034)	100 d (0.019)
Monocotyledonous plant species											
ALLCE	≥ 0.0038	0.06	0.06	0.06	0.07	0.07	0.07	0.08	0.09	0.11	0.20
AVESA	≥ 0.06	1.00	1.02	1.02	1.05	1.09	1.18	1.28	1.36	1.76	3.16
LOLPE	> 0.0225	0.25	0.25	0.25	0.26	0.27	0.29	0.32	0.34	0.44	0.79
ZEAMX	≥ 0.06	1.00	1.02	1.02	1.05	1.09	1.18	1.28	1.36	1.76	3.16
Dicotyledonous plant species											
BEAVX	0.0004	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.02
BRSOL	0.0004	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.02
BRSRR	0.0038	0.06	0.06	0.06	0.07	0.07	0.07	0.08	0.09	0.11	0.20
CUMSA	< 0.0038	0.06	0.06	0.06	0.07	0.07	0.07	0.08	0.09	0.11	0.20
GLXMA	≥ 0.06	1.00	1.02	1.02	1.05	1.09	1.18	1.28	1.36	1.76	3.16
LACSA	0.0038	0.06	0.06	0.06	0.07	0.07	0.07	0.08	0.09	0.11	0.20

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-6: TERs for nicosulfuron for representative succeeding crop types based on NOER and PEC_{soil} values for distribution to soil depth of 20 cm (representative of deep cultivation)

DA-A (PEC _{soil} for 20 cm soil depth in mg/kg soil)		TER=NOER/PEC _{soil} to 20 cm soil depth									
		0d	1 d	2 d	4 d	7 d	14 d	21 d	28 d	50 d	100 d
Plant species	NOER (mg/kg soil)	0.015	0.015	0.015	0.014	0.014	0.013	0.012	0.011	0.009	0.005
Monocotyledonous crop types											
ALLCE	≥ 0.0038	0.25	0.26	0.26	0.27	0.28	0.30	0.32	0.35	0.45	0.80
AVESA	≥ 0.06	4.00	4.07	4.07	4.21	4.36	4.71	5.11	5.45	7.06	12.63
LOLPE	> 0.0225	1.00	1.02	1.02	1.05	1.09	1.18	1.28	1.36	1.76	3.16
ZEAMX	≥ 0.06	4.00	4.07	4.07	4.21	4.36	4.71	5.11	5.45	7.06	12.63
Dicotyledonous crop types											
BEAVX	0.0004	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.04	0.05	0.08
BRSOL	0.0004	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.04	0.05	0.08
BRSRR	0.0038	0.25	0.26	0.26	0.27	0.28	0.30	0.32	0.35	0.45	0.80
CUMSA	< 0.0038	0.25	0.26	0.26	0.27	0.28	0.30	0.32	0.35	0.45	0.80
GLXMA	≥ 0.06	4.00	4.07	4.07	4.21	4.36	4.71	5.11	5.45	7.06	12.63
LACSA	0.0038	0.25	0.26	0.26	0.27	0.28	0.30	0.32	0.35	0.45	0.80

With relatively high residual soil activity, there is therefore potential risk of adverse impact to crops sown or planted following the application of SAE053H/01 at the rate of 1.5 L product/ha on a maize crop. However, TERs calculated for both mesotrione and nicosulfuron based on PEC_{soil} values and NOER values from the OECD 208 seedling emergence and seedling growth test are above the trigger value of 1.0 for two of the monocotyledonous crop types (AVESA and ZEAMX) and one of the dicotyledonous crop types (GLXMA) included in the study and that these can therefore safely be sown from 1 day following application onwards following shallow cultivation to a depth of at least 5 cm and also that one other monocotyledonous crop type (LOLPE) included in the study can safely be sown from 1 day following application onwards providing the soil is first deep cultivated to a minimum depth of at least 20 cm.

Based on the close similarities in the susceptibility of different cereal crop types to residual soil activity of selective herbicides such as mesotrione and nicosulfuron, it is considered the risk assessment showing that AVESA can be safely sown from 1 day following the application of SAE053H/01 at the proposed label rate of 1.2 L product/ha it is reasonable to consider that other cereal crops types can also be sown following the same interval.

Summary and conclusions on potential impact on succeeding crops

Based on risk assessments using TERs calculated from PEC_{soil} values and the NOER data from this seedling emergence and seedling growth test and also the safe sowing intervals for succeeding crops established for the equivalent registered product containing mesotrione and nicosulfuron the following label restrictions are proposed for replacement and succeeding crops following the application of SAE053H/01 at up to the highest proposed label rate of 1.2 L product/ha on maize. These are also in accordance with recommendations regarding succeeding crops in the EFSA Scientific Report (2007) 120, 1-91, Conclusion on the peer review of nicosulfuron.

In the event of crop failure for any reason of a maize crop on which SAE053H/01 has been applied, only maize should be sown as a replacement crop.

Only cereal crops should be sown in the autumn following harvest of a maize crop on which SAE053H/01 was applied in the spring. All crop types can safely be sown in the spring of the year following application with no restrictions.

The risk of adverse impact on replacement or succeeding crops sown or planted following a single application of SAE053H/01 at the proposed label rate of 1.2 L product/ha on maize are considered to be minimal and therefore acceptable, when these proposed label restrictions are observed.

Study Comments: 3.5.1 dRR point: 3.5.1	Studies are acceptable
<p>The risk of adverse impact of SAE053H/01 on succeeding crops comes from residual soil activity and low to moderate persistence in the soil of nicosulfuron and as a result a slow degradation of nicosulfuron and its metabolites in the soil.</p> <p>The applicant presented data obtained from 1 greenhouse trial carried out in Germany, in line with OECD Guideline 208 Seedling Emergence and Seedling Growth Test and EPPO guideline PP 1/207(2) Effects on succeeding crops on a representative range of monocotyledonous and dicotyledonous crop types.</p> <p>Assessment of adverse impact of SAE053H/01 on succeeding crops of were obtained by calculation of TER (Toxicity Exposure Ratio) values for all plant species based on Predicted Environmental Concentration in soil (PEC_{soil}) for mesotrione and nicosulfuron and effect rates (NOER) on plant emergence and seedling growth.</p> <p>Taking under consideration results of the test, on the label the information need to be that only cereal crops should be sown in the autumn following harvest of a maize crop on which SAE053H/01 was</p>	

applied in the spring and in the event of crop failure for any reason of a maize crop on which SAE053H/01 has been applied, only maize should be sown as a replacement crop.

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

Mesotrione and nicosulfuron, as the active substances in SAE053H/01, are herbicides and therefore pose a potential risk with regard to adverse impact on other plants, including adjacent crops.

Vapour drift following volatilisation and direct spray drift are the two sources of potential damage to other plants including adjacent crops.

After spray application of SAE053H/01, mesotrione and nicosulfuron will be present initially as a deposit in an essentially aqueous environment on the foliage surface and on the soil surface. As the water volatilizes the deposit will contain the active ingredients in a mixture of non-volatile components of the formulation. From this deposit there is the potential for the active ingredients to volatilize and with air movement affect other plants, including adjacent crops, away from the area of application.

Both mesotrione and nicosulfuron have low volatility as demonstrated by the vapour pressure and Henry's Law constant for pure materials given in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-7.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-7: Vapour pressure and Henry's Law constant

Active ingredient	Vapour pressure	Henry's Law Constant	Interpretation
Mesotrione ³	<5.7 x 10 ⁻⁶ Pa at 20°C (99.7% pure)	<5.1 x 10 ⁻⁷ Pa m ³ / mol at 20°C	Non-volatile
Nicosulfuron ⁴	< 8 x 10 ⁻¹⁰ Pa at 25°C	1.48 x 10 ⁻¹¹ Pa m ³ mol ⁻¹ at 25°C	Non-volatile

So whilst the transfer of mesotrione and nicosulfuron is theoretically possible, and indeed there will be very low concentrations of the active substances above the spray deposit, in practice the actual concentrations will be negligible. What little active component present as vapour above the treated crop that does exist will be diluted in the air space reducing the concentration further to a point where it becomes insignificant.

The main risk to other plants including adjacent crops when SAE053H/01 is applied to maize therefore comes from direct spray drift.

Two greenhouse pot studies carried out in 2016 in Germany generated data on the impact of SAE053H/01 on a representative range of monocotyledonous and dicotyledonous crop types, when applied pre-sowing (OECD 208 seedling emergence and seedling growth test, Study number: S16-02421) or early post-emergence (OECD 227 Vegetative vigour test, Study number: S14-04353).

The materials and methods used in the OECD 208 seedling emergence and seedling growth test are given in Section 3.5.1.

The OECD 227 study was carried out by an organisation that is officially recognised as competent to carry out efficacy testing in accordance with European Commission Directive 93/71/EEC by the authority in the relevant country.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-8: Details on trial methodology (Vegetative vigour test)

³ Peer review of the pesticide risk assessment of the active substance mesotrione. EFSA Journal 07 March 2016

⁴ Conclusions of the peer review of the pesticide risk assessment of the active substance nicosulfuron. EFSA Scientific Report (2007) 120, 1-91

Guidelines	General guidelines	EPPO PP1/135 (4)
	Specific guidelines	OECD Guideline 227 (Vegetative vigour test) EPPO guideline PP 1/256(1) Effects on adjacent crops
Experimental design	Plot design	RCBD
	Plot size	One pot (15 cm diameter)
	Number of replications	5 (ALLCE, AVESA and LOLPE), 10 (all other species)
Crop	Crops tested	Onion (ALLCE), Oats (AVESA), English ryegrass (LOLPE), Maize (ZEAMX), Sugar beet (BEAVX), White cabbage (BRSOL), Turnip (BRSRR), Cucumber (CUMSA), Soybean (GLXMA), Lettuce (LACSA)
Application	Crop stage (BBCH)* at application	Post-emergence 12-13 BBCH (all crop types)
	Number of applications	1
	Spray volumes	200 L/ha
Assessment	Assessment types	Phytotoxicity, seedling mortality, plant mortality, shoot dry weight

The test was carried out under protected conditions in a glass greenhouse equipped with artificial lighting maintained on a cycle of 16 hours of light and 8 hours of dark. For the duration of the study, temperatures were within the range of 13.7-34.4°C, relative humidity was in the range of 12.5-89.7% and light intensity was in the range of 13250-15573 lux.

In both the OECD 208 seedling emergence and seedling growth and OECD 227 vegetative vigour studies, the most sensitive endpoint was shown to be shoot dry weight. A summary of effect values (ER₅₀) for SAE053H/01 based on shoot dry weight from both studies is given in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-9.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-9: Effect rates (ER₅₀ values) determined for SAE053H/01 applied pre-sowing and early post-emergence based on reductions in shoot dry weight on a range of different crop types

Crop (EPPO code)	ER ₅₀ values			
	Seedling emergence (OECD 208 test)		Vegetative vigour (OECD 227 test)	
	L product/ha	g a.s./ha (mesotrione+ nicosulfuron)	L product/ha	g a.s./ha (mesotrione+ nicosulfuron)
Monocotyledonous plant species				
ALLCE	≥0.09375*	≥7.5 + 2.8125*	0.83757	67.0056 + 25.1271
AVESA	>1.5	>120 + 45	0.64671	51.7368 + 19.4013
LOLPE	>0.375	>30 + 11.25	0.2101	16.808 + 6.303
ZEAMX	>1.5	>120 + 45	>1.5	>120 + 45
Dicotyledonous plant species				
BEAVX	<0.09375*	<7.5 + 2.8125*	>0.00938	0.7504 + 0.2814
BRSOL	0.0577	4.616 + 1.731	0.03221	2.5768 + 0.9663
BRSSR	0.1605	12.84 + 4.185	0.02913	2.3304 + 0.8739
CUMSA	0.5838	46.704 + 17.514	0.04374	3.4992 + 1.3122
GLXMA	>1.5	>120 + 45	0.22718	18.1744 + 6.8154
LACSA	0.0994	7.952 + 2.982	0.00847	0.6776 + 0.2541

*The ER₅₀ could not be calculated as no clear dose response, therefore the more sensitive LOER endpoint is given

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the *BBA (2000)*⁵ from the spray-drift predictions of *Ganzelmeier & Rautmann (2000)*⁶. For a single application to maize, 2.77 % of the application rate is assumed to reach areas at 1 m from the edge of the crop (worst-case scenario). At the rate 1.5 L product/ha for SAE053H/01, (120 g mesotrione + 45 g nicosulfuron/ha) the maximum off-field predicted environmental rate (PER_{off-field}) is 0.04155 L product/ha (3.3 g mesotrione + 1.2 g nicosulfuron/ha) at 1 m from the edge of the area of application.

The lowest endpoints with respect to ER₅₀ values for the most sensitive crop species included in the tests, for pre-emergence effects (on BRSOL) and post-emergence effects (on LACSA), are compared to the off-field Predicted Environmental Rates (PER) resulting from application of SAE053H/01 at the rate of 1.5 L product/ha in Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-10. The risk is acceptable if the PER is below the ER₅₀ (TER>1).

⁵ BBA (2000) Bundesanzeiger Jg. 52 (Official Gazette), Nr 100, S. 9879-9880 (25.05.2000) Bekanntmachung über die Abtrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden. Public domain.

⁶ Ganzelmeier H., Rautmann D. (2000) Drift, drift-reducing sprayers and sprayer testing. Aspects of Applied Biology 57, 2000, Pesticide Application. Public domain.

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-10: Refined risk assessment for impact on other plants including adjacent crops outside the area of application when SAE053H/01 is applied at the rate of 1.5 L product/ha, based on the most sensitive crop types (based on shoot dry weight) for pre-emergence and early post-emergence exposure

Effect endpoint	Most sensitive crop species (EPPO code)	ER ₅₀ values	Distance [m]	% drift (90th percentile estimates by BBA)	Exposure PER _{off-field} [L/ha]	TER _{off-field}
Seedling emergence	BRSOL	0.0577 L/ha	1	2.77	0.04155	1.4
			3	0.95	0.01425	4.0
			5	0.57	0.00855	6.7
			10	0.29	0.00435	13.3
Vegetative vigour	LACSA	0.00847 L/ha	1	2.77	0.04155	0.2
			3	0.95	0.01425	0.6
			5	0.57	0.00855	1.0
			10	0.29	0.00435	1.9

TER values at a distance of 1 m from the area of application exceed the trigger value of 1.0 for pre-emergence effects on the most sensitive crop type tested (BRSOL) in the seedling emergence test but are below the trigger value of 1.0 for distances of up to 5 m away from the area of application for post-emergence effects on the most sensitive crop species tested (LACSA) in the vegetative vigour test.

Summary and conclusions on potential impact on adjacent crops

Both mesotrione and nicosulfuron have relatively low volatility and therefore the risk to other plants including adjacent crops from volatilisation and air movement away from the area of application can be considered to be negligible when SAE053H/01 is applied at up to the highest proposed label rate of 1.2 L product/ha and risk is therefore primarily that associated with spray drift.

Based on the data generated on pre- and post-emergence sensitivity of the range of different crop types to SAE053H/01 in these tests, TER values calculated from ER₅₀ values for the most sensitive crop type tested (LACSA for post-emergence sensitivity) were below the trigger value of 1.0 up to a distance of 5 m from the area of application. Therefore, for this most sensitive crop species, the risk of adverse impact resulting from the post-emergence application of SAE053H/01 at the highest proposed label rate of 1.2 L product/ha is acceptably low when a 5 m buffer zone is observed, with a buffer zone of 3 m when 50% drift reduction nozzles are used or without a buffer zone when 90% drift reduction nozzles are used.

The risk of adverse impact on other plants including adjacent crops when SAE053H/01 is applied in maize at up to the highest proposed label rate of 1.2 L product/ha, and according to label recommendations including those to reduce drift, is minimal and therefore acceptable.

Study Comments: 3.5.1 dRR point: 3.5.1	Studies are acceptable
Both mesotrione and nicosulfuron have low volatility so, the main risk to other plants including adjacent crops when SAE053H/01 is applied to maize comes from direct spray drift. The applicant presented data obtained from 2 greenhouse trials carried out in Germany, in line with OECD Guideline 227 (Vegetative vigour test) and EPPO guideline PP 1/256(1) Effects on adjacent crops on a representative range of monocotyledonous and dicotyledonous crop types. Assessment of adverse impact of SAE053H/01 on other plants including adjacent crops were obtained by calculation of TER (Toxicity Exposure Ratio) values. The risk of adverse impact resulting from the post-emergence application of SAE053H/01 at the rate of 1.2 L product/ha was acceptably low when a 5 m buffer zone was observed, with a buffer zone of 3 m when 50% drift reduction nozzles was used or without a buffer zone when 90% drift reduction nozzles was used.	

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

Detailed studies on the possible adverse effects to beneficial and other non-target organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

3.6 Other/special studies

No additional studies are summarised.

3.7 List of test facilities including the corresponding certificates

Table Błąd! Użyj karty Narzędzia główne, aby zastosować Heading 2 do tekstu, który ma się tutaj pojawić.-1:List of test facilities

Test facility	Country	Certificate (Yes or No)
AGRITEC Research, Breeding & Services Ltd.	CZ	Yes
Agrofil-SZMI Kft.	HU	Yes
AgroProspect SRL	RO	Yes
Eurofins Agrosience Services	BG	Yes
	DE	Yes
	HU	Yes
	RO	Yes
	PL	Yes
Gemerprodukt Valice OVD	SK	Yes
Staphyt	BE	Yes
	BG	Yes
	CZ	Yes
	DE	Yes
	FR	Yes
	HU	Yes
	PL	Yes
	RO	Yes
	UK	Yes

Appendix 1: List of data submitted in support of the evaluation

List of data submitted and relied on

Annex point	Author	Year	Title Source (where different from company) Company report No. GLP or GEP status (Y/N) Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6/01	Eurofins Agrosience Services	2019	Biological Assessment Dossier for SAE053H/01 (KAGURA) Sumi Agro Europe Limited -,- n/a Unpublished <u>This is CONFIDENTIAL INFORMATION</u>	Y	Sumi Agro Europe