

REGISTRATION REPORT
Part B
Section 3
Efficacy Data and Information

Concise summary

Product name: ASAHI MAX

Product code: ARY-0469-04

Chemical active substance:

Sodium 5-nitroguaiacolate, 3g/L

Sodium o-nitrophenolate, 6g/L

Sodium p-nitrophenolate, 9g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT
(authorization)

Applicant: Asahi Chemical Europe s.r.o.

Submission date: June 2022

MS Finalisation date: March 2023 (initial Core Assessment)

June 2023 (final Core Assessment)

Version history

When	What
June 2022	Initial version of dRR for submission to zRMS
December 2022	Update table 3.2-13 (MED for sugar beet)
March 2023	<p>Initial zRMS assessment</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.</p>
June 2023	<p>Final report (Core Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments received from the CMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded.</p>

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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. Textual changes were done using grey highlights in the text. The parts of the text amended or added by the zRMS evaluator are highlighted in grey, whereas the parts struck off are visibly marked with the grey font.

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

Abstract

Abstract of the evaluation, by the zRMS:

This application has been submitted for the authorization of new product Asahi Max (product code: ARY-0469-04) in Poland. Asahi Max contains three active substances: sodium p-nitrophenolate (0,9% w/w), sodium o-nitrophenolate (0,6% w/w) and sodium 5-nitroguaiacolate (0,3% w/w). This product is intended to use as a plant growth regulator in winter wheat, winter oilseed rape and sugar beet.

3 efficacy trials were carried out in France. France belongs to the Maritime EPPO climatic zone and is not considered the neighboring country for Poland. Because the application concerns the registration of Asahi Max only in Poland, the trial results from France have been removed from the overall calculation.

MED

The results from efficacy trials have been presented to determine minimum effective dose of Asahi Max used as plant growth regulator. It can be considered that dose rate of 0,2 l/ha is minimum effective dose for all intended crops.

Efficacy

Based on the submitted trial results, it can be concluded that Asahi Max applied at 0,2 l/ha can be recommended to use as plant growth regulator for sugar beet, winter wheat and winter oilseed rape. The positive effect was visible especially in case of germination and the quality or quantity parameters of yield.

Selectivity

No special selectivity trials have been presented. The results from efficacy trials show that Asahi Max is safe for sugar beet, winter wheat and winter oilseed rape. Slight phytotoxicity symptoms were noted in 3 out of 9 efficacy trials on sugar beet. However, these symptoms were transient and no negative impact on yield was noted. The reference product caused similar effect. No special warning on the product label is necessary.

Table 3.1-1: 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	PL	Winter oilseed rape	F	Plant growth regulator, number of pods per plant, number of seeds per plant, higher lignification of pods	Spray	BBCH 29-69 (spring)	2	7	a) 0.2 b) 0.4	a) 0.6 1.2 1.8 b) 1.2 2.4 3.6	200- 500	28		A
2	PL	Winter wheat	F	Plant growth regulator, number of tillers and ears, portion above the sieves, germination energy	Spray	BBCH 21-49 (spring)	1	-	a) 0.2 b) 0.2	0.6 1.2 1.8	200- 300	28		A
3	PL	Sugar beet	F	Plant growth regulator, effect on higher yield of sugar, lower content of unwanted sodium.	Spray	BBCH 12-49 (spring-summer)	2 3	7	a) 0.2 b) 0.4 0.6	a) 0.6 1.2 1.8 b) 1.2 2.4 3.6	200- 500	15		A
Minor uses according to Article 51 (field uses)														
1	PL	Mustard, spring rape, turnip rape, camelina, garden radish, poppy, linseed, hemp, sunflower, borage.	F	Plant growth regulator, number of pods per plant, number of seeds per plant, higher lignification of pods.	Spray	BBCH 29-69 (spring)	2	7	c) 0.2 d) 0.4	0.6 1.2 1.8	200- 500	28	Crops registered as a minor crops on the base of art 51.	n.r.
2	PL	Spring rye, spelt, emmer wheat,	F	Plant growth regulator, number of tillers and	Spray	BBCH 21-49 (spring)	1	-	c) 0.2 d) 0.2	0.6	200- 300	28	Crops registered as a minor crops	n.r.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate 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			
		small spelt, durum wheat.		ears, portion above the sieves, germination energy.						1.2 1.8			on the base of art 51.	
3	PL	Fodder beet, red beet, swede, turnip.	F	Plant growth regulator, effect on higher yield.	Spray	BBCH 12-49 (spring-summer)	3	7	c) 0.2 d) 0.6	0.6 1.2 1.8	200- 500	15	Crops registered as a minor crops on the base of art 51.	n.r.

* 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, Fnp: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gnp: 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 summarises the information related to the efficacy of the plant protection product Asahi Max containing sodium *p*-nitrophenolate, sodium *o*-nitrophenolate and sodium 5-nitroguaiacolate, which were included into Annex I of Council Directive 91/414/EEC (Directive 2009/11/EC, 18th February 2009) and approved in accordance with Regulation (EC) No. 1107/2009 by Commission Implementing Regulation (EC) No. 540/2011 (25th May 2011).

The EFSA Scientific Report (2008; 191) and SANCO report (SANCO/210/08 rev. 2, 17 May 2013) for sodium *p*-nitrophenolate, sodium *o*-nitrophenolate and sodium 5-nitroguaiacolate are considered to provide the relevant review information or a reference to where such information can be found.

The Annex I of the Inclusion Directives for sodium *p*-nitrophenolate, sodium *o*-nitrophenolate and sodium 5-nitroguaiacolate (2009/11/EC) provides 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:

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on sodium *p*-nitrophenolate, sodium *o*-nitrophenolate and sodium 5-nitroguaiacolate and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 may 2013 shall be taken into account.

There are no specific additional points that Member States need to pay particular attention to with regard to granting of authorisations of plant protection products containing sodium *p*-nitrophenolate, sodium *o*-nitrophenolate or sodium 5-nitroguaiacolate relating to efficacy or other Section 3 data requirements.

The objective of this Biological Assessment Dossier is to provide data on the efficacy, crop safety and other Annex III Section 3 data points in support of the registration of Asahi Max, a soluble concentrate (SL) formulation containing 0.9% w/w sodium *p*-nitrophenolate, 0.6 % w/w sodium *o*-nitrophenolate and 0.3 % w/w sodium 5-nitroguaiacolate in the EU Central Registration zone for use as a growth regulator in oilseed rape, sugar beet and winter wheat.

Description of active substances

Sodium *p*-nitrophenolate, sodium *o*-nitrophenolate and sodium 5-nitroguaiacolate are well known since the 50's of the previous century. In the beginning, they were used as a medicine against tuberculosis, but after popularization of penicillin, they lost their significance in this respect. It was later discovered that these active substances can regulate the growth processes in the plant organisms as well.

Sodium *p*-nitrophenolate, sodium *o*-nitrophenolate and sodium 5-nitroguaiacolate belong to the class of nitrophenolate plant growth regulators. Sodium *p*-nitrophenolate, sodium *o*-nitrophenolate and sodium 5-nitroguaiacolate are absorbed through leaves and translocated in plants systemically. DAR (volume 3, Annex B, part 1, B3.1.6 Mode of action, November 2007) list the functions stated below:

- They act as plant growth stimulators, that accelerates the cytoplasmic streaming which conducts to a better assimilation of nutrients and to their easier translocation toward the fructifications organs
- prolongs the auxin activity by inhibition of IAA (indolylacetic acid) oxydases and at the same time inhibits ABA (abscissic acid) induced abscission of the fruits
- increase the nitrate reductase activity

DAR (volume 3, Annex B, part 1, B3.1.6 Mode of action, November 2007) also mentions, that increase of resistance against fungicidal and bacterial diseases is suggested through activation of mechanical and chemical barriers involved in the plant defence system, but there is not enough proof for this action.

In April 2020 was submitted the application for Renewal of approval for active substances, where newly elicitor effect was added. In April 2021 was submitted an updated Mode of action for sodium *p*-nitrophenolate, sodium *o*-nitrophenolate and sodium 5-nitroguaiacolate, where new studies annnowledge

was presented. Application of Asahi Max prolong auxin activity by increase in PPO (polyphenol oxidase) activity and reduction of IAA oxidase activity. Increased synthesis of auxin in treated plants is based on upregulation of ERF1091 gene known as the master switch of auxin biosynthetic enzymes ASA1 and YUC2. Increase in auxin content is directly involved in lignin biosynthesis and increased lignification of cell walls. Nitrophenols are also involved in reduction of biotic and abiotic stress via increased activity of antioxidant enzymes and reduced activity of reactive oxygen species. Exogenously applied nitrophenol compounds elicit a huge variety of plant actions and thus have various MoAs which cannot be distinguished or deduced in detail but synergistically result in better plant health and growth.

Table 3.2-1: Details of the active substance

Active substance(s)	Sodium <i>p</i> -nitrophenolate	Sodium <i>o</i> -nitrophenolate	Sodium 5-nitroguaiacolate
Concentration (Unit: g/Kg or g/L...)	9 %	6 %	3 %
Chemical group	Sodium nitrocompound		
Mode of action	Plant growth regulator; absorbed through leaves and translocated in plants systemically		
Biological action	Acceleration the cytoplasmic streaming, prolongation the auxin activity by inhibition of IAA (indolylacetic acid) oxydases, inhibition of ABA (abscissic acid), increase the nitrate reductase activity		

Description of the plant protection product

Asahi Max is a soluble concentrate (SL) formulation containing 0.9% w/w sodium *p*-nitrophenolate, 0.6 % w/w sodium *o*-nitrophenolate and 0.3 % w/w sodium 5-nitroguaiacolate intended to use as plant growth regulator in oilseed rape, sugar beet and winter wheat.

Asahi Max is also recommended to be used under biotic and abiotic stress conditions, unfavorable for plant growth and development. Asahi Max acts positively on enzyme metabolism, regulates rooting, tillering, development of branches, flowering, fruit set and fruit growth. It increases the production of auxins in plants and stimulates cytoplasmic streaming, thus promoting higher yields and higher quality crops. Treated plants show better growth and development of the pollen tube, better accumulation of biomass and greater efficiency of the photosynthetic system, water status, integrity of membranes and lignification of cell walls.

Asahi Max is an innovative formulation (three-times higher concentration of active substances) compared to currently registered product Asahi SL. The plant growth regulator Asahi SL has been known and used for a number of years in various EU countries and many other parts of the world in the cultivation of many species of plants such as: oilseed rape, sugar beet, sunflower, potato, corn, fruit trees, olives, grapevine, vegetables and other crops.

Table 3.2-2: Simplified table of requested uses for Asahi Max

Uses		Member States	Requested rate	Comments
Crops	Targets			
Oilseed rape	None (Plant growth regulator)	PL	0.2 L/ha	Maximum 2 applications per season, minimum interval between applications 7 days. Application in spring at crop BBCH 29-69.
Winter wheat	None (Plant growth regulator)	PL	0.2 L/ha	Maximum 1 application per season, in spring at crop BBCH 21-49.
Sugar beet	None (Plant growth regulator)	PL	0.2 L/ha	Maximum 2 applications per season, minimum interval between applications 7 days. Application in spring/summer at crop BBCH 12-49.

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

Table 3.2-3: 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
Oilseed rape	PL	-	Plant growth regulator	PL	-
Winter wheat	PL	-	Plant growth regulator	PL	-
Sugar beet	PL	-	Plant growth regulator	PL	-

Compliance with the Uniform Principles

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

Information on trials submitted (3.2 Efficacy data)

Table 3.2-4: 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	North-East		
Sugar beet	Plant growth regulator	Germany	2008	P + E	1 (1)	-	GEP	
		Poland	2008-2009	P + E + MED	-	8 (8)	GEP	
TOTAL	-	-	2008-2009	-	1 (1)	8 (8)	-	
Oilseed rape	Plant growth regulator	Germany	2008	P + E MED	3 (3)	-	GEP	
		Poland	2008-2009	P + E + MED	-	8 (8)	GEP	
TOTAL	-	-	2020-2021	-	3 (3)	8 (8)	-	

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	North-East		
Winter wheat	Plant growth regulator	Czech Republic	2010	P + E	3 (3)	-	GEP	
		Germany	2021	P + E	1 (1)	-	GEP	
			2011	E MED	3 (3)	-		
		France	2011	E MED	3 (3)	-		
		Poland	2021	P + E	-	2 (2)	GEP	
			2011	E MED	-	2 (2)		
TOTAL	-	-	2020-2021	-	10 (7) 7 (4)	4 (4)	-	

* According to the GAP table

** MED = minimum effective dose, E = efficacy trial, P = preliminary trials

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

Table 3.2-5: Presentation of reference standards used in trials (efficacy trials)

Crop (s)	Reference standard	Country (ie s) where the product is registered (1)	Authorisation number	Active substance	Formulation		Registered appl'n rate (3)	Appl'n rate in trials (per treatment)	Remark (4)
					Type (2)	Concentration of a.s.			
Sugar beet	Asahi SL	DE	00A070-00	sodium <i>p</i> -nitrophenolate + sodium <i>o</i> -nitrophenolate + sodium 5-nitroguauacolate	SL	0.9 0.3 % + 0.6 0.2 % + 0.3 0.1 %	0.6 L	0.3 L, 0.6 L	-
		PL	R-62/2012				0.6 L	0.3 L, 0.6 L	-
	Atonik	PL	868/2001				0.5-1.0 L or 0.1-0.2 % v/v	0.6 L	not registered anymore
Oilseed rape	Asahi SL	DE	00A070-00	sodium <i>p</i> -nitrophenolate + sodium <i>o</i> -nitrophenolate + sodium 5-nitroguauacolate	SL	0.9 0.3 % + 0.6 0.2 % + 0.3 0.1 %	0.6 L	0.3 L, 0.6 L	-
		PL	R-62/2012				0.6 L	0.3 L, 0.6 L	-
	Atonik	PL	868/2001				0.5-1.0 L or 0.1-0.2 % v/v	0.6 L	not registered anymore
Winter wheat	Asahi SL	DE	00A070-00	sodium <i>p</i> -nitrophenolate + sodium <i>o</i> -nitrophenolate + sodium 5-nitroguauacolate	SL	0.9 0.3 % + 0.6 0.2 % + 0.3 0.1 %	0.6 L	0.3 L, 0.6 L	-
		PL	R-62/2012				0.6 L	0.3 L, 0.6 L	-
	Stabilan 750 SL	PL	R-284/2014	Chlormequat chloride	SL	750	1.2-2.0 L	1.5 L, 2.0 L	not registered anymore
	Cycoel CS-BASF	FR	7400815		SL	460	2.0 L	2.0 L	not registered

Crop (s)	Reference standard	Country(ies) where the product is registered ⁽¹⁾	Authorisation number	Active substance	Formulation		Registered appl'n rate ⁽³⁾	Appl'n rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
									anymore
		DE	not registered				-	2.0 L	-
	CCC720	DE	034046-60		SL	720	0.7-2.1 L	1.5 L	not registered anymore

(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.)

3.2.1 Preliminary tests (KCP 6.1)

Products containing sodium *p*-nitrophenolate, sodium *o*-nitrophenolate and sodium 5-nitroguaiacolate have been approved and used for a number of years in various EU countries as a plant growth regulators in crops such as: oilseed rape, sugar beet, winter wheat, orchards, vegetables and many other plants. The range and scope of activity of sodium *p*-nitrophenolate, sodium *o*-nitrophenolate and sodium 5-nitroguaiacolate is therefore well established from research and commercial use and data from preliminary screening tests and not considered to be necessary to include here.

Asahi Max is a formulation containing 0.9% w/w sodium *p*-nitrophenolate, 0.6 % w/w sodium *o*-nitrophenolate and 0.3 % w/w sodium 5-nitroguaiacolate and this is an exactly three-times higher concentration of the same active substances at an identical ratio as in the approved product Asahi SL (0.3% w/w sodium *p*-nitrophenolate, 0.2 % w/w sodium *o*-nitrophenolate and 0.1 % w/w sodium 5-nitroguaiacolate) that is currently registered for use as a plant growth regulator in various crops and EU countries, including those relevant for this application for the approval of Asahi Max in the EU Central Registration zone. Identical product to Asahi Max is for a long time registered in Greece (since 1978), Cyprus and newly in Bulgaria (2019). The proposed label rate of 0.2 L product/ha for the use of Asahi Max as a plant growth regulator in oilseed rape, sugar beet and winter wheat is consistent with the approved label rate of 0.6 L product/ha of the registered Asahi SL product in terms of amounts and ratio of the three active substances. Asahi SL at the approved label rate of 0.6 L product/ha and Asahi Max at the proposed label rate of 0.2 L product/ha gave comparable efficacy and crop safety, as demonstrated by data summarized in Sections 3.2.1.1 and 3.2.1.2. It is therefore considered that the approved ratio of the active substances of Asahi SL provides full justification of the same ratio of the three active substances in Asahi Max. Furthermore, it is considered that data generated with Asahi SL are fully supportive of the proposed label claim of Asahi Max.

3.2.1.1 Comparison of the efficacy of Asahi Max to that of Asahi SL

In order to present ~~comparability~~ comparability between Asahi Max and Asahi SL and to support the label claims of Asahi Max as a plant growth regulator, a comparison of the results of Asahi Max applied at the proposed label rate of 0.2 L product/ha with that of Asahi SL applied at the approved label rate of 0.6 L product/ha (both at 1.8 g sodium *p*-nitrophenolate/ha, 1.2 g sodium *o*-nitrophenolate/ha and 0.6 g sodium 5-nitroguaiacolate/ha) is summarised and evaluated in this section. On this basis, the currently registered product, Asahi SL, will support label claims of Asahi Max for use as a plant growth regulator in sugar beet, oilseed rape and winter wheat.

3.2.1.1.1 Sugar beet

A total of 9 efficacy trials carried out between 2008 and 2009 have generated data in support of demonstrating comparability of the efficacy of Asahi Max at the proposed label rate of 0.2 L product/ha

with that of Asahi SL at the approved label rate of 0.6 L product/ha (both at 1.8 g sodium *p*-nitrophenolate/ha, 1.2 g sodium *o*-nitrophenolate/ha and 0.6 g sodium 5-nitroguaiacolate/ha).

Of these trials, 1 was carried out in the Maritime EPPO climatic zone (Germany) and 8 were carried out in the North-East EPPO climatic zone (all in Poland).

Across these 9 trials, 2 applications of Asahi Max and Asahi SL were made when the crop growth stages were within the range of 10 to 14 (BBCH) at first application timings and from 12 to 18 (BBCH) at second application timings. Intervals between applications were within the range of 9-15 days.

Efficacy was determined based on a regulating effect on plant population, seedling weight, crop yield and yield quality improvements.

An overall summary of the efficacy (at various assessment types) of Asahi Max applied at the proposed label rate of 0.2 L product/ha to that of Asahi SL applied at the approved label rate of 0.6 L product/ha (expressed as % relative to the untreated control) across trials in each of the EPPO climatic zones is given in Table 3.2-6.

Table 3.2-6: Comparison of overall efficacy of Asahi Max to that of Asahi SL at various assessment types across all trials carried out in sugar beet

EPPO climatic zone	No. of trials	Untreated	Mean efficacy (as % relative to untreated)		Asahi Max compared to Asahi SL#
			Asahi Max	Asahi SL	
			0.2 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	
			A1+A2	A1+A2	
Plant population (thousand plants/ha)					
114-146 DAA2 (before harvest)					
Maritime	1*	7.2	90.7	98.7	1 trial =
North-East	8	97.7	99.0	99.9	8 trials =
		75.7-111.1	80.6-106.6	95.1-105.1	
Seedling weight (g/plant)					
9 DAA1					
Maritime	1	4.3	83.7	83.7	1 trial =
16-26 DAA2					
North-East	7	143.4	133.8	125.3	7 trials =
		13.5-269.2	100.7-195.1	100.4-191.2	
Root yield (t/ha)					
Maritime	1	93.0	103.8	99.0	1 trial =
North-East	7	67.6	111.3	110.1	7 trials =
		45.0-103.1	101.6-132.7	104.9-122.8	
Sugar content (%)					
Maritime	1	18.3	100.5	100.1	1 trial =
North-East	8	17.0	100.9	100.4	8 trials =
		15.7-18.7	99.1-104.9	97.9-103.7	
Biological sugar yield (t/ha)					
Maritime	1	17.0	104.4	99.3	1 trial =
North-East	6	12.2	113.9	111.1	6 trials =
		9.2-17.0	103.4-132.8	102.5-123.3	
Technological sugar yield (t/ha)					
North-East	6	8.0	137.8	133.0	6 trials =
		2.3-15.9	103.2-200.0	106.4-196.0	
N content (mmol/1000g)					
Maritime	1	16.6	87.5	85.6	1 trial =
North-East	3	21.2	95.6	91.0	3 trials =
		19.4-22.8	83.6-102.2	85.9-94.0	
	1**	0.6	166.4	100.0	1 trial =
K content (mmol/1000g)					
Maritime	1	37.8	98.0	97.5	1 trial =
North-East	4	46.4	98.6	100.6	4 trials =
		35.8-55.9	92.3-106.4	88.2-107.9	
Na content (mmol/1000g)					
Maritime	1	4.2	92.4	102.6	1 trial =

North-East	4	7.4	99.8	101.0	3 trials = 1 trial <
		3.7-11.0	76.5-116.4	69.9-126.1	

No of trials where >, < or =, based on statistically significant differences at 95% confidence level

*In trial EUR_MNN_BEAVA_DE_2771 the mean plant population for all treatments and untreated is markedly lower than the mean plant population from the other 8 trials and therefore data from this trial are presented separately and need to be taken with caution

**In trial EUR_MNN_BEAVA_PL_3293 the mean N content for all treatments and untreated is markedly lower from the mean N content from the other 3 trials and therefore data from this trial are presented separately and need to be taken with caution

The overall efficacy of Asahi Max applied at the proposed label rate of 0.2 L product/ha was comparable to that of Asahi SL applied at the approved label rate of 0.6 L product/ha (both at 1.8 g sodium *p*-nitrophenolate/ha, 1.2 g sodium *o*-nitrophenolate/ha and 0.6 g sodium 5-nitroguaiacolate/ha) within the Maritime and North-East EPPO climatic zones. Differences in the individual trials were not statistically significant on all of the trials.

On the basis of demonstrating comparability of the efficacy of Asahi Max to that of Asahi SL, containing the same amounts of all three active substances when applied at 0.2 L and 0.6 L product/ha respectively, the efficacy of the currently registered product, Asahi SL, can support label claims of Asahi Max for use as a plant growth regulator in sugar beet.

Comments of zRMS:

9 efficacy trials (conducted in Poland and Germany) have been submitted to present comparability of Asahi Max and Asahi SL. Taking into account all results, no significant differences are visible between both products. Asahi Max and Asahi SL have positive effects on quality and quantity parameters of yield, especially root yield and sugar content. Plant population was on similar level for both products. The trials conducted with Asahi SL can support registration of Asahi Max in sugar beet.

3.2.1.1.2 Oilseed rape

A total of 11 efficacy trials carried out between 2008 and 2009 in winter oilseed rape have generated data in support of demonstrating comparability of the efficacy of Asahi Max at the proposed label rate of 0.2 L product/ha with that of Asahi SL at the approved label rate of 0.6 L product/ha (both at 1.8 g sodium *p*-nitrophenolate/ha, 1.2 g sodium *o*-nitrophenolate/ha and 0.6 g sodium 5-nitroguaiacolate/ha).

Of these trials, 3 were carried out in the Maritime EPPO climatic zone (all in Germany) and 8 were carried out in the North-East EPPO climatic zone (all in Poland).

Across these 11 trials, 2 applications of Asahi Max and Asahi SL were made when the crop growth stages were within the range of 17 to 35 (BBCH) at first application timings and from 31 to 57 (BBCH) at second application timings. Intervals between applications were within the range of 10-16 days.

Efficacy was determined based on a regulating effect on plant population, plant height, number of branches, pods per plant and seeds per pod, thickness of pod coats, crop yield and yield quality improvements.

An overall summary of the efficacy (at various assessment types) of Asahi Max applied at the proposed label rate of 0.2 L product/ha to that of Asahi SL applied at the approved label rate of 0.6 L product/ha (expressed as % relative to the untreated control) across trials in each of the EPPO climatic zones is given in Table 3.2-7 3.2-7.

Table 3.2-7: Comparison of overall efficacy of Asahi Max to that of Asahi SL at various assessment types across all trials carried out in oilseed rape

EPPO climatic zone	No. of trials	Untreated	Mean efficacy (as % relative to untreated)		Asahi Max compared to Asahi SL#
			Asahi Max	Asahi SL	
			0.2 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	
			A1+A2	A1+A2	
Plant population (plants/m ²)					
	3	61.1	103.5	101.0	3 trials =

EPPO climatic zone	No. of trials	Untreated	Mean efficacy (as % relative to untreated)		Asahi Max compared to Asahi SL#
			Asahi Max	Asahi SL	
			0.2 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	
			A1+A2	A1+A2	
North-East		56.0-70.7	95.8-109.3	90.9-109.3	
Plant height (cm)					
North-East	7	145.6	99.9	98.9	7 trials =
		122.4-168.2	91.3-105.4	92.6-101.3	
Number of branches (branch/plant)					
Maritime	3	6.6	102.3	103.7	3 trials =
		6.0-7.2	94.7-114.1	97.2-111.3	
North-East	6	5.4	113.5	118.5	6 trials =
		4.2-6.7	79.1-81.0-128.0	111.9-128.0	
Number of pods (pods/plant)					
Maritime	3	149.3	98.9	105.3	3 trials =
		110.5-177.4	90.3-114.2	101.3-111.0	
North-East	5	132.3	112.6	110.0	5 trials =
		74.8-223.5	94.0-157.6	103.6-121.3	
	1*	17.0	104.4	99.3	1 trial =

EPPO climatic zone	No. of trials	Untreated	Mean efficacy (as % relative to untreated)		Asahi Max compared to Asahi SL#
			Asahi Max	Asahi SL	
			0.2 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	
			A1+A2	A1+A2	
Number of seeds (seeds/pod)					
Maritime	3	25.1	99.0	102.0	3 trials =
		24.2-26.6	95.2-102.6	97.7-104.2	
North-East	6	23.3	109.1	106.9	6 trials =
		19.5-26.0	100.1-121.8	98.7-113.6	
Thickness of pod coats (n/d)					
North-East	2	39.8	104.0	101.1	2 trials =
		33.3-46.2	103.6-104.3	100.0-102.1	
Crop yield (t/ha)					
Maritime	3	3.2	100.8	103.8	3 trials =
		2.5-4.0	97.3-104.9	97.9-107.5	
North-East	8	3.4	120.5	127.7	8 trials =
		2.1-5.7	100.7-168.1	102.3-187.0	
TGW (g)					
Maritime	3	4.4	100.6	100.8	3 trials =
		4.0-4.8	99.8-102.0	100.2-101.9	
North-East	8	4.7	108.0	107.4	8 trials =
		3.8-5.9	99.3-123.8	100.0-121.4	
Oil content (%)					
Maritime	3	44.3	99.6	100.0	3 trials =
		37.9-48.2	99.0-100.1	99.7-100.4	
North-East	6	34.7	110.5	109.8	6 trials =
		25.7-45.2	98.3-128.8	99.3-123.0	
Oil yield (dt/ha)					
North-East	2	21.3	104.3	108.8	2 trials =
		19.2-23.3	99.5-109.0	104.7-112.9	

No of trials where >, < or =, based on statistically significant differences at 95% confidence level

*In trial EUR_MNN_BRSNW_PL_3038 the mean pods number for all treatments and the untreated is markedly higher than the mean pods number from the other 8 trials and therefore data from this trial are presented separately and need to be taken with caution

The overall efficacy of Asahi Max as a plant growth regulator applied at the proposed label rate of 0.2 L product/ha was comparable to that of Asahi SL applied at the approved label rate of 0.6 L product/ha (both at 1.8 g sodium *p*-nitrophenolate/ha, 1.2 g sodium *o*-nitrophenolate/ha and 0.6 g sodium 5-nitroguaiacolate/ha) within the Maritime and North-East EPPO climatic zones for the majority of the tested parameters. Differences in the individual trials were not statistically significant on all of the trials.

On the basis of demonstrating comparability of the efficacy of Asahi Max to that of Asahi SL, containing the same amounts of all three active substances when applied at 0.2 L and 0.6 L product/ha respectively, the efficacy of the currently registered product, Asahi SL, can support label claims of Asahi Max for use as a plant growth regulator in oilseed rape.

Comments of zRMS:

11 efficacy trials (from Poland and Germany) have been submitted to present comparability of Asahi Max and Asahi SL in winter oilseed rape. The trials show that the both products achieved similar results. Positive impact of test products was visible in case of quality and quantity parameters of yield (oil content, TGW). Also number of seeds was higher for both products. Taking into account the presented results, the trials with Asahi SL can support registration of Asahi Max in winter oilseed rape.

3.2.1.1.3 Winter wheat

Six (6) of the 14 11 efficacy trials carried out between 2010 and 2021 in winter wheat have generated data in support of demonstrating comparability of the efficacy of Asahi Max at the proposed label rate of 0.2 L product/ha with that of Asahi SL at the approved label rate of 0.6 L product/ha (both at 1.8 g sodium *p*-nitrophenolate/ha, 1.2 g sodium *o*-nitrophenolate/ha and 0.6 g sodium 5-nitroguaiacolate/ha).

Of these trials, 4 were carried out in the Maritime EPPO climatic zone (3 in Czech Republic and 1 in Germany) and 2 were carried out in the North-East EPPO climatic zone (both in Poland).

Across these 6 trials, single application of Asahi Max and Asahi SL was made when the crop growth stages were within the range of 24 to 32 (BBCH).

Efficacy was determined based on a regulating effect on plant population, plant height, weight and length of the roots, number of tillers per plant, ears per square meter and grain per ear, tiller length, supporting effect against lodging, crop yield and yield quality improvements.

An overall summary of the efficacy (at various assessment types) of Asahi Max applied at the proposed label rate of 0.2 L product/ha to that of Asahi SL applied at the approved label rate of 0.6 L product/ha (expressed as % relative to the untreated control) across trials in each of the EPPO climatic zones is given in Table 3.2-8. An overall efficacy (based on distribution of the yield between different grain size grades) of Asahi Max applied at the proposed label rate of 0.2 L product/ha to that of Asahi SL applied at the approved label rate of 0.6 L product/ha across trials in the Maritime EPPO climatic zone is given in Table 3.2-9

Table 3.2-8: Comparison of overall efficacy of Asahi Max to that of Asahi SL at various assessment types across all trials carried out in winter wheat

across all trials carried out in winter wheat					
EPPO climatic zone	No. of trials	Untreated	Mean efficacy (as % relative to untreated)		Asahi Max compared to Asahi SL#
			Asahi Max	Asahi SL	
			0.2 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	
Plant population (plants/m ²)					
Maritime	3	346.8	100.0	99.4	3 trials =
		298.5-432.0	98.4-101.1	96.8-101.0	
Plant height (cm)					
14-21 DAA					
Maritime	3	45.4	99.6	100.1	3 trials =
		42.7-49.3	99.3-100.0	99.2-100.5	
62-96 DAA					
Maritime	1	95.2	98.2	99.1	1 trial =
North-East	2	72.9	95.8	97.2	1 trial >
		69.4-76.4	95.4-96.1	97.0-97.5	1 trial =
Length of the roots (cm)					
Maritime	1	9.8	99.0	96.9	1 trial =
North-East	2	6.1	127.2	115.7	2 trials >
		6.0-6.1	123.3-131.1	115.0-116.4	
Weight of the roots (g)					
Maritime	1	0.1	82.5	85.8	1 trial =
North-East	2	0.7	131.9	117.4	2 trials >
		0.7-0.7	131.4-132.4	116.2-118.6	
Number of tillers (tillers/plant)					
Maritime	4	2.5	111.0	108.7	4 trials =
		0.9-5.0	94.0-129.5	95.5-125.3	
North-East	2	3.2	104.6	104.6	2 trials =
		2.8-3.6	103.6-105.6	103.6-105.6	
Number of ears (ears/plant)					
Maritime	4	496.9	101.5	98.8	1 trial >
		377.5-689.0	97.5-103.9	92.5-104.5	3 trials =
North-East	2	589.8	100.1	100.0	2 trials =
		584.3-595.2	100.1-100.1	100.0-100.0	
Number of grains (grains/ear)					
Maritime	2	31.6	105.8	108.9	2 trials =
		27.3-36.0	104.2-107.3	107.3-110.4	
	1*	428.8	101.1	102.5	1 trial =

EPPO climatic zone	No. of trials	Untreated	Mean efficacy (as % relative to untreated)		Asahi Max compared to Asahi SL#
			Asahi Max	Asahi SL	
			0.2 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	
Tiller length (cm)					
Leading tiller					
Maritime	1	39.4	100.3	98.7	1 trial =
North-East	2	24.4	104.3	105.7	1 trial >
		23.6-25.1	103.8-104.8	105.1-106.4	1 trial =
2nd tiller					
Maritime	1	34.4	100.6	100.0	1 trial =
North-East	2	20.4	104.2	101.0	1 trial =
		19.5-21.2	104.1-104.2	100.9-101	1 trial <
3rd tiller					
Maritime	1	24.9	99.6	104.0	1 trial =
North-East	2	15.8	102.5	99.7	1 trial =
		15.4-16.2	101.3-103.7	99.4-100.0	1 trial <
Lodging area (%)					
Maritime	1	3.9	0**	0**	1 trial =
Crop yield (t/ha)					
Maritime	4	5.9	103.1	101.6	3 trials =
		3.6-8.1	99.9-107.1	92.7-107.1	1 trial <
North-East	2	7.1	102.2	101.6	2 trials =
		7.0-7.2	101.8-102.6	101.4-101.8	
TGW (g)					
Maritime	4	40.5	100.7	99.2	3 trials =
		35.3-46.4	95.9-104.4	91.9-102.6	1 trial n/d
North-East	2	37.3	101.7	101.9	2 trials =
		33.9-40.6	100.4-103.0	100.5-103.2	
HLW (kg/hl)					
Maritime	2	75.5	99.4	99.9	1 trial =
		74.6-76.3	98.7-100.2	99.2-100.6	1 trial <
Protein content (%)					
Maritime	3	12.7	99.8	100.0	1 trial =
		11.0-13.8	99.5-100.0	99.2-100.8	1 trial < 1 trial n/d
North-East	2	14.0	102.6	101.4	2 trials =
		12.7-15.3	102.0-103.1	101.3-101.6	
Starch content (%)					
Maritime	3	62.1	100.5	98.7	2 trials >
		56.2-68.2	99.9-101.3	97.9-99.7	1 trial =
Sedimentation index (ml)					
Maritime	2	37.4	105.6	93.1	2 trials >
		32.0-42.8	100.0-111.1	92.4-93.8	
Hagberg falling number (s)					
Maritime	2	250.1	112.0	95.6	1 trial >
		237.0-263.3	100.8-123.1	83.2-108.0	1 trial =
Germination energy (%)					
Maritime	3	81.8	128.8	129.7	1 trial >
		54.0-98.5	100.0-185.2	99.5-185.2	2 trials =
Germination test (%)					
Maritime	3	83.2	128.5	128.3	2 trials =
		55.0-99.5	99.5-181.8	100.0-181.8	1 trial <

No of trials where >, < or =, based on statistically significant differences at 95% confidence level

*In trial EUR_MNN_TRZAW_CZ_4104 the mean grains number for all treatments and the untreated is markedly higher than the mean grains number from the other 2 trials and therefore data from this trial are presented separately and need to be taken with caution

**Data presented as % of lodging area

Table 3.2-9: Comparison of overall efficacy (based on distribution of the yield between different grain size grades) across all trials carried out in winter wheat

EPPO climatic zone	No. of trials	Grain size grade	Mean % distribution between grain size categories			Asahi Max compared to Asahi SL#
			<i>Untreated</i>	Asahi Max	Asahi SL	
				0.2 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	
North-East	3	>2.5 mm	85.2	87.5	87.8	1 trial =
			80.0-90.0	79.0-97.0	79.1-97.1	2 trials <
		2.5-2.2 mm	11.2	8.9	8.8	1 trial >
			9.0-15.3	2.0-15.8	2.2-15.7	1 trial =
		<2.2 mm	3.6	3.7	3.4	1 trial n/d
			1.0-5.0	1.0-5.2	0.7-5.2	2 trials =
						1 trial <

No of trials where >, < or =, based on statistically significant differences at 95% confidence level

The overall efficacy of Asahi Max as a plant growth regulator applied at the proposed label rate of 0.2 L product/ha was comparable to that of Asahi SL applied at the approved label rate of 0.6 L product/ha (both at 1.8 g sodium *p*-nitrophenolate/ha, 1.2 g sodium *o*-nitrophenolate/ha and 0.6 g sodium 5-nitroguaiacolate/ha) within the Maritime and North-East EPPO climatic zones for the majority of the tested parameters. Differences in the individual trials were not statistically significant on majority of the trials.

On the basis of demonstrating comparability of the efficacy of Asahi Max to that of Asahi SL, containing the same amounts of all three active substances when applied at 0.2 L and 0.6 L product/ha respectively, the efficacy of the currently registered product, Asahi SL, can support label claims of Asahi Max for use as a plant growth regulator in winter wheat.

Comments of zRMS:

6 efficacy trials (from Poland, Germany and Czech Republic) have been submitted to show comparability of Asahi Max and Asahi SL in winter wheat. The test products achieved positive impact on germination energy and quality parameters of yield (protein and starch content, TGW). No symptoms of lodging were noted in the submitted trials. Moreover, better results have been observed for number of grains and ears per plant on treated objectives. Taking into account comparability of trial results, the trials conducted with Asahi SL can support registration of Asahi Max in winter wheat.

3.2.1.2 Comparison of the crop safety of Asahi Max to that of Asahi SL

In order to present comparability between Asahi Max and Asahi SL and to support the crop safety of Asahi Max, a comparison of the results of Asahi Max applied at the proposed label rate of 0.2 L product/ha with that of Asahi SL applied at the approved label rate of 0.6 L product/ha (both at 1.8 g sodium *p*-nitrophenolate/ha, 1.2 g sodium *o*-nitrophenolate/ha and 0.6 g sodium 5-nitroguaiacolate/ha), is summarised and evaluated in this section. On this basis, the currently registered product, Asahi SL, will support the crop safety of Asahi Max for use as a plant growth regulator in sugar beet, oilseed rape and winter wheat.

3.2.1.2.1 Sugar beet

A total of 9 efficacy trials carried out between 2008 and 2009 in sugar beet included a comparison of crop safety of Asahi Max at the proposed label rate of 0.2 L product/ha with that of Asahi SL at the approved label rate of 0.6 L product/ha (both at 1.8 g sodium *p*-nitrophenolate/ha, 1.2 g sodium *o*-nitrophenolate/ha and 0.6 g sodium 5-nitroguaiacolate/ha).

Of these trials, 1 was carried out in the Maritime EPPO climatic zone (Germany) and 8 were carried out in the North-East EPPO climatic zone (all in Poland).

Across these 9 trials, 2 applications of Asahi Max and Asahi SL were made when the crop growth stages were within the range of 10 to 14 (BBCH) at first application timing and from 12 to 18 (BBCH) at second application timing. Intervals between applications were within the range of 9-15 days.

An overall summary of the crop safety of Asahi Max and Asahi SL across trials carried out in sugar beet is given in Table 3.2-10.

Table 3.2-10: Overall summary of the crop safety of Asahi Max with that of Asahi SL on 8 9 trials carried out in sugar beet

EPPO climatic zone (no. of trials)	Timing	Levels of phytotoxicity	Number of trials	
			Asahi Max 0.2 L/ha (3.6 g a.i./ha)	Asahi SL 0.6 L/ha (3.6 g a.i./ha)
			A1+A2	A1+A2
Maritime (1 trial)	Maximum level of symptoms recorded	0	1	1
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-
	Final assessment timings	0	1	1
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-
North- East (8 trials)	Maximum level of symptoms recorded	0	8 5	8 5
		0.1% to 5%	3	3
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-
	Final assessment timings	0	8	8
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-

Asahi Max applied at the proposed label rate of 0.2 L product/ha and Asahi SL applied at the approved label rate of 0.6 L product/ha (both at 1.8 g sodium *p*-nitrophenolate/ha, 1.2 g sodium *o*-nitrophenolate/ha and 0.6 g sodium 5-nitroguaiacolate/ha) caused no phytotoxicity on any of the 9 efficacy trials.

On the basis of demonstrating comparability of crop safety of Asahi Max with that of Asahi SL, containing the same amounts of all three active substances when applied at 0.2 L and 0.6 L product/ha respectively, the proven crop safety of the currently registered product, Asahi SL, can support demonstration of the crop safety of Asahi Max for use as a plant growth regulator in sugar beet.

3.2.1.2.2 Oilseed rape

A total of 11 efficacy trials carried out between 2008 and 2009 in winter oilseed rape included a comparison of crop safety of Asahi Max at the proposed label rate of 0.2 L product/ha with that of Asahi SL at the approved label rate of 0.6 L product/ha (both at 1.8 g sodium *p*-nitrophenolate/ha, 1.2 g sodium *o*-nitrophenolate/ha and 0.6 g sodium 5-nitroguaiacolate/ha).

Of these trials, 3 were carried out in the Maritime EPPO climatic zone (all in Germany) and 8 were carried out in the North- East EPPO climatic zone (all in Poland).

Across these 11 trials, 2 applications of Asahi Max and Asahi SL were made when the crop growth stages were within the range of 17 to 35 (BBCH) at first application timings and from 31 to 57 (BBCH) at second application timings. Intervals between applications were within the range of 10-16 days.

An overall summary of the crop safety of Asahi Max and Asahi SL across trials carried out in winter oilseed rape is given in Table 3.2-11.

Table 3.2-11: Overall summary of the crop safety of Asahi Max with that of Asahi SL on 11 trials carried out in winter oilseed rape

EPPO climatic zone (no. of trials)	Timing	Levels of phytotoxicity	Number of trials	
			Asahi Max	Asahi SL
			0.2 L/ha (3.6 g a.i./ha) A1+A2	0.6 L/ha (3.6 g a.i./ha) A1+A2
Maritime (3 trials)	Maximum level of symptoms recorded	0	3	3
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-
	Final assessment timings	0	3	3
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-
North- East (8 trials)	Maximum level of symptoms recorded	0	8	8
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-
	Final assessment timings	0	8	8
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-

Asahi Max applied at the proposed label rate of 0.2 L product/ha and Asahi SL applied at the approved label rate of 0.6 L product/ha (both at 1.8 g sodium *p*-nitrophenolate/ha, 1.2 g sodium *o*-nitrophenolate/ha and 0.6 g sodium 5-nitroguaiacolate/ha) caused no phytotoxicity or other adverse effects on the crop on any of the 11 efficacy trials.

On the basis of demonstrating comparability of crop safety of Asahi Max with that of Asahi SL, containing the same amounts of all three active substances when applied at 0.2 L and 0.6 L product/ha respectively, the proven crop safety of the currently registered product, Asahi SL, can support demonstration of the crop safety of Asahi Max for use as a plant growth regulator in oilseed rape.

3.2.1.2.3 Winter wheat

Six (6) of the 11 efficacy trials carried out between 2010 and 2021 in winter wheat included a comparison of the crop safety of Asahi Max at the proposed label rate of 0.2 L product/ha with that of Asahi SL at the approved label rate of 0.6 L product/ha (both at 1.8 g sodium *p*-nitrophenolate/ha, 1.2 g sodium *o*-nitrophenolate/ha and 0.6 g sodium 5-nitroguaiacolate/ha).

Of these trials, 4 were carried out in the Maritime EPPO climatic zone (3 in Czech Republic and 1 in Germany) and 2 were carried out in the North-East EPPO climatic zone (both in Poland).

Across these 6 trials, single application of Asahi Max and Asahi SL was made when the crop growth stages were within the range of 24 to 32 (BBCH).

An overall summary of the crop safety of Asahi Max and Asahi SL across trials carried out in winter wheat is given in Table 3.2-12.

Table 3.2-12: Overall summary of the crop safety of Asahi Max with that of Asahi SL on 6 trials carried out in winter wheat

EPPO climatic zone (no. of trials)	Timing	Levels of phytotoxicity	Number of trials	
			Asahi Max	Asahi SL
			0.2 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)
Maritime (4 trials)	Maximum level of symptoms recorded	0	4	4
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-
	Final assessment timings	0	4	4
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-
North- East (2 trials)	Maximum level of symptoms recorded	0	2	2
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-
	Final assessment timings	0	2	2
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-

Asahi Max applied at the proposed label rate of 0.2 L product/ha and Asahi SL applied at the approved label rate of 0.6 L product/ha (both at 1.8 g sodium *p*-nitrophenolate/ha, 1.2 g sodium *o*-nitrophenolate/ha and 0.6 g sodium 5-nitroguaiacolate/ha) caused no phytotoxicity or other adverse effects on the crop on any of the 6 efficacy trials.

On the basis of demonstrating comparability of crop safety of Asahi Max with that of Asahi SL, containing the same amounts of all three active substances when applied at 0.2 L and 0.6 L product/ha respectively, the proven crop safety of the currently registered product, Asahi SL, can support demonstration of the crop safety of Asahi Max for use as a plant growth regulator in winter wheat.

Comments of zRMS:

Slight phytotoxic symptoms were observed in 3 out of 9 trials on sugar beet (smaller plants, discolouration on the leaves, plants with small spoon shaped leaves, small elapsing deformation on plants) in case of both products. Because these deformations were small and no negative impact on yield was detected, the level of symptoms can be described as acceptable. Furthermore, Asahi Max and Asahi SL are safe for sugar beet, winter wheat and winter oilseed rape.

3.2.2 Minimum effective dose (KCP 6.2)

Eight (8) Five (5) of the 14 11 efficacy trials carried out in winter wheat between 2008 and 2009 in 2011 generated data on the efficacy of Asahi Max applied at the proposed label rate of 0.2 L product/ha and also at the lower rate of 0.1 L product/ha, representing 50% of the proposed label rate. Data from these trials are summarised in support of justifying the minimum effective dose rate of Asahi Max for use as a plant growth regulator.

Additionally, 8 of the a total of 9 efficacy trials carried out in sugar beet between 2008 and 2009 and a total of 11 efficacy trials carried out in oilseed rape between 2008 and 2009 generated data on the efficacy of Asahi SL applied at the approved label rate of 0.6 L product/ha and also at the lower rate of 0.3 L product/ha, representing 50% of the approved label rate. Based on data presented in Section 3.2.1.1 that demonstrates comparability of the efficacy of Asahi Max and Asahi SL, both providing the same amount of the three active substances when applied at 0.2 L and 0.6 L product/ha respectively, minimum

effective dose justification with Asahi SL is considered as fully supportive to justify the minimum effective dose rate of Asahi Max for use as a plant growth regulator in sugar beet and oilseed rape.

Furthermore, Asahi SL is already registered across countries in Europe at the same amounts of the same active ingredients/ha as the proposed label rate of Asahi Max, so the minimum effective dose for these products was already proven.

3.2.2.1 Minimum effective dose in sugar beet

Eight (8) A total of the 9 carried out between 2008 and 2009 generated data on the efficacy of 3 2 applications of Asahi SL at 0.3 L and 0.6 L product/ha is sugar beet. Data from these trials are summarised in support of justification of the minimum effective of Asahi Max for use as a plant growth regulator. Based on data presented in Section 3.2.1.1 that demonstrates comparability of the efficacy of Asahi Max and Asahi SL, both providing the same amount of the three active substances when applied at 0.2 L and 0.6 L product/ha respectively, minimum effective dose justification with Asahi SL is considered as fully supportive to justify the minimum effective dose rate of Asahi Max for use as a plant growth regulator.

All of these trials Of these trials, 1 was carried out in the Maritime EPPO climatic zone (Germany) and 8 were carried out in the North-east EPPO climatic zone (all in Poland).

Across these 8 9 trials, 3 2 applications of Asahi SL were made when the crop growth stages were within the range of 10 to 14 (BBCH) at first application timings, and from 12 to 18 (BBCH) at second application timings and from 14 to 32 (BBCH) at third application timings. Intervals between applications were within the range of 7-15 days.

Efficacy was determined based on a regulating effect on plant population, seedling weight, crop yield and yield quality improvements.

A summary of mean percentage efficacy (at various assessment types) of 3 2 applications of Asahi SL at 0.3 L and 0.6 L product/ha (expressed as % relative to the untreated control) across all trials in sugar beet is given in Table 3.2-13.

Table 3.2-13: Dose justification; mean overall percentage efficacy of Asahi SL applied at 0.3 L and 0.6 L product/ha at various assessment types across all trials carried out in sugar beet

Products and at various assessment types across all trials carried out in sugar beet					
EPPO climatic zone	No. of trials	Untreated	Mean efficacy (as % relative to untreated)		Statistical comparison 0.6 L to 0.3 L/ha (no. of trials)/#
			Asahi SL	Asahi SL	
			0.3 L/ha (1.8 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	
			A1+A2+A3	A1+A2+A3	
Plant population (thousand plants/ha) at 101-133 DAA3					
North-east	8	97.8	99.7	99.3	8 trials =
		75.7-111.1	95.1-107.9	90.3-102.6	
Seedling weight (g/plant) at 7-14 DAA3					
North-east	7	143.4	126.2	133.5	7 trials =
		13.5-269.2	100.6-165.5	100.9-199.8	
Root yield (t/ha)					
North-east	7	67.6	106.6	113.0	2 trials > 5 trials =
		45.0-103.1	100.4-110.0	104.7-126.3	
Sugar content (%)					
North-east	8	17.0	99.2	100.0	8 trials =
		15.7-18.7	95.6-102.4	96.3-104.9	
Biological sugar yield (t/ha)					
North-east	6	12.2	106.5	114.3	2 trials > 4 trials =
		9.2-17	100.9-112.4	106.7-128.4	
Technological sugar yield (t/ha)					
North-east	6	8.2	106.2	140.6	2 trials > 4 trials =
		2.3-15.9	95.2-116	98.1-221.7	
N content (mmol/1000g)					
North-east	3	21.2	95.1	94.5	3 trials =
		19.4-22.8	75.4-107.9	92.3-98.7	
	1*	0.6	132.8	83.2	1 trial =

EPPO climatic zone	No. of trials	Untreated	Mean efficacy (as % relative to untreated)		Statistical comparison 0.6 L to 0.3 L/ha (no. of trials)#
			Asahi SL	Asahi SL	
			0.3 L/ha (1.8 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	
			A1+A2+A3	A1+A2+A3	
K content (mmol/1000g)					
North- east	4	46.4	99.7	99.9	4 trials =
		35.8-55.9	96.5-103.2	92.9-107.9	

EPPO climatic zone	No. of trials	Untreated	Mean efficacy (as % relative to untreated)		Statistical comparison 0.6 L to 0.3 L/ha (no. of trials)#
			Asahi SL	Asahi SL	
			0.3 L/ha (1.8 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	
			A1+A2+A3	A1+A2+A3	
Na content (mmol/1000g)					
North-east	4	7.4	99.7	102.7	3 trials = 1 trial <
		3.7-11.1	69.5-130.5	66.8-139.2	

No of trials where >, < or =, based on statistically significant differences at 95% confidence level

* In trial EUR_MNN_BEAVA_PL_3293 the mean N content for all treatments is significantly different from the mean N content from the other 3 trials and therefore data from this trial are presented separately and need to be taken with caution

EPPO climatic zone	No. of trials	Untreated	Mean efficacy (as % relative to untreated)		Statistical comparison 0.6 L to 0.3 L/ha (no. of trials)#
			Asahi SL	Asahi SL	
			0.3 L/ha (1.8 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	
			A1+A2	A1+A2	
Plant population (thousand plants/ha) at 114-146 DAA2					
Maritime	1*	7.2	97.0	98.7	1 trial =
North-east	8	97.8	98.7	99.9	8 trials =
		75.7-111.1	88.3-105.0	95.1-105.1	
Seedling weight (g/plant) at 16-26 DAA2					
North-east	7	143.4	120.8	125.3	7 trials =
		13.5-269.2	100.4-165.4	100.4-191.2	
Root yield (t/ha)					
Maritime	1	93.0	102.0	99.0	1 trial =
North-east	7	67.6	103.3	110.1	1 trial >
		45.0-103.1	99.7-109.0	104.9-122.8	6 trials =
Sugar content (%)					
Maritime	1	18.3	99.3	100.1	1 trial =
North-east	8	17.0	99.4	100.4	8 trials =
		15.7-18.7	96.8-101.9	97.9-103.7	
Biological sugar yield (t/ha)					
Maritime	1	17.0	101.6	99.3	1 trial =
North-east	6	12.2	103.1	111.1	2 trials >
		9.2-17.0	96.6-110.9	102.5-123.3	4 trials =
Technological sugar yield (t/ha)					
North-east	6	8.0	115.4	133.0	2 trials >
		2.3-15.9	101.7-152.2	106.4-196.0	4 trials =
N content (mmol/1000g)					
Maritime	1	16.6	96.1	85.6	1 trial =
North-east	3	21.2	91.9	91.0	3 trials =
		19.4-22.8	91.2-93.4	85.9-94.0	
	1**	0.6	100.0	100.0	1 trial =
K content (mmol/1000g)					
Maritime	1	37.8	99.6	97.5	1 trial =
North-east	4	46.4	98.2	100.6	4 trials =
		35.8-55.9	91.3-103.3	88.2-107.9	
Na content (mmol/1000g)					
Maritime	1	4.2	102.1	102.6	1 trial =
North-east	4	7.4	92.5	101.0	3 trials =
		3.7-11.0	78.3-106.3	69.9-126.1	1 trial <

No of trials where >, < or =, based on statistically significant differences at 95% confidence level

* In trial EUR_MNN_BEAVA_DE_2771 the mean plant population for all treatments and the untreated is significantly different from the mean plant population from the other 8 trials and therefore data from this trial need to be taken with caution

** In trial EUR_MNN_BEAVA_PL_3293 the mean N content for all treatments is significantly different from the mean N content from the other 3 trials and therefore data from this trial are presented separately and need to be taken with caution

Data generated in trials carried out across North-east EPPO climatic zone clearly show the efficacy based on seedling weight, crop yield and biological and technological sugar yield of Asahi SL applied at 0.6 L product/ha in sugar beet to be generally higher compared to that of lower rate of 0.3 L product/ha, although the differences were not always statistically significant.

Data generated in trial carried in Maritime EPPO climatic zone clearly show the efficacy based on N content of Asahi SL applied at 0.6 L product/ha in sugar beet to be generally higher compared to that of lower rate of 0.3 L product/ha, although the differences were statistically not significant. Data generated in trials carried out across North-East EPPO climatic zone clearly show the efficacy based on seedling weight, root yield, biological and technological sugar yield and Na content of Asahi SL applied at 0.6 L product/ha in sugar beet to be generally higher compared to that of lower rate of 0.3 L product/ha, although the differences were not always statistically significant.

Based on the presented data and on the comparability of the efficacy of Asahi Max and that of Asahi SL, when applied at 0.2 L and 0.6 L product/ha rates respectively, it is therefore reasonable to conclude that the proposed label rate of 0.2 L product/ha is fully justified as the minimum effective dose rate of Asahi Max for use as a plant growth regulator.

Comments of zRMS:

9 trials have been submitted to determine minimum effective dose in sugar beet. Based on the comparability of Asahi SL and Asahi Max, two dose rates of 0,3 and 0,6 l/ha of Asahi SL were tested in two applications. The biological and technological sugar yield was visible higher after applied of 0,6 l/ha. Also the positive impact on seedling weight, root yield and content of sodium were noted in the submitted trials. The presented results show that dose rate of 0,6 l/ha is justified as minimum effective dose.

Taking into account comparability of both products, it can be considered that Asahi Max at 0,2 l/ha is acceptable as MED in sugar beet.

3.2.2.2 Minimum effective dose in oilseed rape

A total of 11 trials carried out between 2008 and 2009 generated data on the efficacy of 2 applications of Asahi SL at 0.3 L and 0.6 L product/ha in winter oilseed rape. Data from these trials are summarised in support of justification of the minimum effective dose of Asahi Max for use as a plant growth regulator. Based on data presented in Section 3.2.1.1 that demonstrates comparability of the efficacy of Asahi Max and Asahi SL, both providing the same amount of the three active substances when applied at 0.2 L and 0.6 L product/ha respectively, minimum effective dose justification with Asahi SL is considered as fully supportive to justify the minimum effective dose rate of Asahi Max for use as a plant growth regulator.

Of these trials, 3 were carried out in the Maritime EPPO climatic zone (all in Germany) and 8 were carried out in the North-East EPPO climatic zone (all in Poland).

Across these 11 trials, 2 applications of Asahi SL were made when the crop growth stages were within the range of 17 to 35 (BBCH) at first application timings and from 31 to 57 (BBCH) at second application timings. Intervals between applications were within the range of 10-16 days.

Whilst no data has been generated in support of justifying the minimum effective dose in spring oilseed rape, plant physiology, agronomic practices and susceptibility to plant growth regulators can be considered to be very similar between winter and spring oilseed rape. Data from trials carried out in winter oilseed rape are therefore considered to be supportive of justifying the minimum effective dose of Asahi Max in spring oilseed rape.

Efficacy was determined based on a regulating effect on plant population, plant height, number of branches, pods per plant and seeds per pod, thickness of pod coats, crop yield and yield quality improvements.

A summary of mean percentage efficacy (at various assessment types) of 2 applications of Asahi SL at 0.3 L and 0.6 L product/ha (expressed as % relative to the untreated control) across all trials in winter oilseed rape is given in Table 3.2-14.

Table 3.2-14: Dose justification; mean overall percentage efficacy of Asahi SL applied at 0.3 L and 0.6 L product/ha at various assessment types across all trials carried out in winter oilseed rape

Production at various assessment types across all trials carried out in winter oilseed rape					
EPPO climatic zone	No. of trials	Untreated	Mean efficacy (as % relative to untreated)		Statistical comparison 0.6 L to 0.3 L/ha (no. of trials)#
			Asahi SL	Asahi SL	
			0.3 L/ha (1.8 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	
			A1+A2+A3	A1+A2+A3	
Plant population (plants/m ²)					
North-East	3	61.1	110.1	101.0	3 trials =
		56.0-70.7	103.3-122.9	90.9-109.3	
Plant height (cm)					
North-East	7	145.6	100.0	98.9	7 trials =
		122.4-168.2	93.0-102.9	92.6-101.3	
Number of branches (branches/plant)					
Maritime	3	6.6	99.9	103.7	3 trials =
		6.0-7.2	93.3-108.8	97.2-111.3	
North-East	6	5.4	106.3	118.4	2 trial > 5 trials =
		4.2-6.7	97.4 97.9-113.3	111.9 115.0-128.0	
Number of pods (pods/plant)					
Maritime	3	149.3	106.9	105.3	3 trials =
		110.5-177.4	102.0-110.2	101.3-111.0	
North-East	5	132.3	107.7	110.0	2 trials >
		74.8-223.5	97.1-126.6	103.6-121.3	3 trials =
	1*	695.4	103.0	131.2	1 trial =
Number of seeds (seeds/pod)					
Maritime	3	25.1	97.7	102.0	3 trials =
		24.2-26.6	92.1-102.1	97.7-104.2	
North-East	6	23.3	105.6	106.9	1 trial >
		19.5-26	96.3-120.6	98.7-113.6	5 trials =
Thickness of pod coats (n/d)					
North-East	2	39.8	98.7	101.1	2 trials =
		33.3-46.2	98.3-99.1	100.0-102.1	
Crop yield (t/ha)					
Maritime	3	3.2	103.1	103.8	3 trials =
		2.5-4.0	99.6-106.2	97.9-107.5	
North-East	8	3.4	121.8	127.7	2 trials >
		2.1-5.7	101.5-167.1	102.3-187.0	6 trials =
TGW (g)					
Maritime	3	4.4	100.6	100.8	3 trials =
		4.0-4.8	99.4-102.8	100.2-101.9	
North-East	8	4.7	104.7	107.4	1 trial >
		3.8-5.9	96.3-119.0	100.0-121.4	7 trials =
Oil content (%)					
Maritime	3	44.3	100.1	100.0	3 trials =
		37.9-48.2	99.9-100.4	99.7-100.4	
North-East	6	34.7	102.6	109.8	3 trials >
		25.7-45.2	99.5-103.9	99.3-123.0	3 trials =
Oil yield (%)					
North-East	2	21.3	106.6	108.8	2 trials =
		19.2-23.3	104.2-109.0	104.7-112.9	

No of trials where >, < or =, based on statistically significant differences at 95% confidence level

* In trial EUR_MNN_BRSNW_PL_3038 the mean pods number for all treatments and the untreated is markedly higher than the mean pods number from the other 8 trials and therefore data from this trial are presented separately and need to be taken with caution

Data generated in trials carried out across Maritime and/or North-East EPPO climatic zone show the efficacy based on an increase of number of branches, pods and seeds, crop yield, TGW and oil content of Asahi SL applied at 0.6 L product/ha in winter oilseed rape to be generally higher compared to that of lower rate of 0.3 L product/ha.

Based on the presented data and on the comparability of the efficacy of Asahi Max and that of Asahi SL, when applied at 0.2 L and 0.6 L product/ha rates respectively, it is therefore reasonable to conclude

that the proposed label rate of 0.2 L product/ha is fully justified as the minimum effective dose rate of Asahi Max for use as a plant growth regulator.

Comments of zRMS:

11 efficacy trials have been submitted to determine minimum effective dose in winter oilseed rape. Asahi SL was tested at two dose rate: 0,3 l/ha (0,5N) and 0,6 l/ha (1N). No significant differences between dose rates were noted for the quantity and quality parameters of yield. Overall, higher efficacy was visible after application of 0,6 l/ha in case of number of branches and number of seeds. Similar results have been achieved for the rest of parameters. Based on the comparability of the efficacy of Asahi Max and Asahi SL, the dose rates of 0,2 l/ha corresponds to the dose of 0,6 l/ha.
Taking into account all trials, Asahi Max at dose rate of 0,2 l/ha can be considered MED in winter oilseed rape.

3.2.2.3 Minimum effective dose in winter wheat

Eight (8) ~~5~~ of the ~~14~~ **11** efficacy trials carried out between 2010 and 2021 generated data on the efficacy of single application of Asahi Max at 0.1 L and 0.2 L product/ha in winter wheat. Data from these trials are summarised in support of justification of the minimum effective of Asahi Max for use as a plant growth regulator.

Of these trials, ~~6~~ **3** were carried out in the Maritime EPPO climatic zone (~~3~~ **all** in Germany ~~and 3 in France~~) and 2 were carried out in the North-East EPPO climatic zone (both in Poland).

Across these ~~8~~ **5** trials, single application of Asahi Max was made when the crop growth stages were within the range of 29-30 to 31 (BBCH).

Efficacy was determined based on a regulating effect on plant population, plant height, weight and length of the roots, weight above ground part of the plant, number of tillers per plant, ears per square meter and grain per ear, tiller and internod length, supporting effect against lodging, crop yield and yield quality improvements.

A summary of mean percentage efficacy (at various assessment types) of single application of Asahi Max at 0.1 L and 0.2 L product/ha (expressed as % relative to the untreated control) across ~~8~~ **5** trials in winter wheat is given in Table 3.2-15.

A summary of mean percentage efficacy (based on lodging reduction) of single application of Asahi Max at 0.1 L and 0.2 L product/ha (expressed on various assessment parameters) across 2 trials in winter wheat is given in Table 3.2-16.

Table 3.2-15: Dose justification; mean overall percentage efficacy of Asahi Max applied at 0.1 L and 0.2 L product/ha at various assessment types across all trials carried out in winter wheat

EPPO climatic zone	No. of trials	Untreated	Mean efficacy (as % relative to untreated)		Statistical comparison 0.2 L to 0.1 L/ha (no. of trials)#
			Asahi Max		
			0.1 L/ha (1.8 g a.i./ha)	0.2 L/ha (3.6 g a.i./ha)	
Plant height (cm)***					
14-23 DAA					
North-East	3 2	64.7	99.5	99.8	2 trials =
		64.3-65.1	99.2-99.7	99.4-100.2	
43-83 DAA					
Maritime	6 3	89.8 90.9	100.7 102.2	100.6 100.9	6 3 trials =
		66.6-105.7	98.5-106.9	98.6-105.0	
		88.0-95.5	99.8-106.9		
Length of the roots (cm)					
Maritime	6 3	6.9 6.0	100.1 99.6	99.7 96.4	6 3 trials =
		5.4-9.4 6.7	94.0-105.4 97.0-101.7	93.3-105.4 101.9	
North-East	2	14.8	98.2	93.7	1 trial =
		9.9-19.7	93.4-103.0	89.3-98.0	1 trial <
Weight of the roots (g)					
Maritime	6 3	23.7 3.2	96.3 96.6	96.2 93.8	6 3 trials =

EPPO climatic zone	No. of trials	Untreated	Mean efficacy (as % relative to untreated)		Statistical comparison 0.2 L to 0.1 L/ha (no. of trials)#
			Asahi Max		
			0.1 L/ha (1.8 g a.i./ha)	0.2 L/ha (3.6 g a.i./ha)	
		2.0-56.3 4.4	90.1-106.4 93.1-102.1	86.1-106.8	
North-East	2	7.3	91.7	98.4	2 trials =
		4.8-9.7	87.5-95.9	85.4-111.3	
Weight above ground part of the plant (g)					
North-East	2	10.9	110.4	97.5	2 trials =
		8.3-13.5	106.0-114.8	92.8-102.2	
Number of tillers (tiller/plant)					
Maritime	6 3	3.4 2.3	93.1 93.5	98.0 95.4	6 3 trials =
		2.1-6.0 2.5	84.0-104.8	90.5-113.2 100.0	
North-East	2	4.4	92.1	90.9	1 trial = 1 trial <
		4.3-4.4	81.8-102.3	79.5-102.3	
Number of ears (ear/m ²)					
Maritime	6 3	447.8 408.0	100.0 102.9	100.8 104.5	6 3 trials =
		303-526	87.1-118.2	95.8 99.8-109.2	
North-East	1	569.8	98.7	100.5	1 trial =
	1*	40.7	105.7	104.2	1 trial =
Tiller length (cm)***					
Leading tiller					
Maritime	6 3	61.6 70.5	100.2 102.0	101.4 102.9	6 3 trials =
		40.8 68.5-73.6	97.6 100.9-102.9	99.4 102.0-103.5	
North-East	2	76.4	99.4	99.0	2 trials
		71.0-81.8	96.5-102.4	96.3-101.7	
2nd tiller					
Maritime	6 3	56.5 66.8	100.8 102.0	101.5 102.5	6 3 trials =
		35.4 64.4-70.8	98.1 101.1-103.1	100.0 101.8-103.1	
North-East	2	56.1	98.8	101.6	1 trial >
		55.7-56.4	98.0-99.6	98.4-104.8	1 trial =
3rd tiller					
Maritime	3	59.8	103.8	102.7	3 trials =
		57.0-64.1	102.7-104.5	100.7-104.4	
North-East	2	10.5	115.9	112.4	1 trial >
		8.8-12.1	94.2-137.5	79.3-145.5	1 trial =
Internode length (cm)***					
Lenght of I internode					
North-East	2	9.8	99.2	101.5	6 trials =
		8.5-11.0	97.3-101.2	101.2-101.8	
Lenght of II internode					
North-East	2	12.8	102.5	105.0	6 trials =
		11.3-14.2	101.4-103.5	102.1-108.0	
Lenght of II internode					
North-East	2	19.0	100.3	102.6	3 trials =
		18.1-19.8	99.0-101.7	101.1-104.0	
Crop yield (t/ha)					
Maritime	6 3	9.3 8.3	100.9 100.8	101.7 101.9	6 3 trials =
		7.3-12.8	99.3-102.2	97.9-104.1	
		7.7-9.5	99.8-101.9		
North-East	2	7.9	105.6	98.9	2 trials =
		6.2-9.6	100.0-111.3	96.8-101.0	
TGW (g)					
Maritime	6 3	50.2 49.8	100.9 100.2	100.7 101.5	6 3 trials =
		44.2-58.5	98.8-102.5 101.6	99.5 99.8-102.4	
		47.0-52.8			
North-East	2	38.5	99.0	101.2	2 trials =
		37.1-39.8	93.5-104.5	97.8-104.5	
HLW (kg/hl)					
Maritime	3	77.7	101.2	100.2	3 trials =
		73.9-81.1	99.8-102.4	99.2-101.0	
	2	63.7	103.6	103.6	2 trials =

EPPO climatic zone	No. of trials	Untreated	Mean efficacy (as % relative to untreated)		Statistical comparison 0.2 L to 0.1 L/ha (no. of trials)#
			Asahi Max		
			0.1 L/ha (1.8 g a.i./ha)	0.2 L/ha (3.6 g a.i./ha)	
North-East		63.2-64.1	98.6-108.5	99.8-107.4	
Protein content (%)					
Maritime	3	14.3	94.9	100.4	3 trials =
		13.4-16.2	85.2-100	100.2-100.7	
North-East	2	13.0	100.5	100.5	2 trials =
		11.3-14.6	99.3-101.8	99.3-101.8	
Gluten content (%)					
North-East	2	28.2	99.4	98.7	2 trials =
		25.4-30.9	98.4-100.3	98.4-99.0	
Grain grading (% of the grain >2.5mm)**					
North-East	2	28.2	99.4	98.7	2 trials =
		25.4-30.9	98.4-100.3	98.4-99.0	

No of trials where >, < or =, based on statistically significant differences at 95% confidence level

*In trial EUR_MNN_TRZAW_4609 the mean ears number for all treatments and the untreated is markedly lower than the mean ears number from the other 7 trials and therefore data from this trial are presented separately and need to be taken with caution

**Results for all treatments and the untreated presented as % of the yield above grain grade size 2.5 mm

***The aim of the product is to support effects against lodging not by reducing the plant height and tiller or internode length but by improving the plant growth and strength, therefore these results need to be taken with caution

Table 3.2-16: Dose justification; mean overall percentage efficacy (based on lodging reduction) of Asahi Max applied at 0.1 L and 0.2 L product/ha across 2 trials carried out in winter wheat

EPPO zone	No. of trials	Lodging parameter (unit)	Untreated	Mean		Statistical comparison 0.2 L to 0.1 L/ha#
				Asahi Max		
				0.1 L/ha (1.8 g a.i./ha)	0.2 L/ha (3.6 g a.i./ha)	
Maritime	1	Lodging area (%)	86.3	80.0	61.3	=
		Lodging angle (°)	31.3	42.5	40.0	=
	1	Lodging (% area without lodging)	81.3	87.5	86.3	=
		Lodging (% area with lodging less than 45°)	17.5	12.5	12.5	=
		Lodging (% area with lodging more than 45°)	1.3	0.0	1.3	=

>, < or =, based on statistically significant differences at 95% confidence level

Data generated in trials carried out across Maritime and/or North-East EPPO climatic zone not show clear rate related response with respect to the efficacy of Asahi Max. However, based on data presented in Section 3.2.1.1 that demonstrates comparability of the efficacy of Asahi Max and Asahi SL, both providing the same amount of the three active substances when applied at 0.2 L and 0.6 L product/ha respectively, and on fact that Asahi SL is already registered across countries in Europe at the same amounts of the same active ingredients/ha as the proposed label rate of Asahi Max, so the minimum effective dose for these products was already proven.

It is therefore reasonable to conclude that the proposed label rate of 0.2 L product/ha is fully justified as the minimum effective dose rate of Asahi Max for use as a plant growth regulator.

Comments of zRMS:

5 efficacy trials have been submitted to determine minimum effective dose in winter wheat. Asahi Max was tested at two dose rates: 0,1 l/ha (0,5N) and 0,2 l/ha (1N). No significant differences between dose rates were noted for the quality and quantity parameters of yield. Also comparable results have been achieved for the rest of parameters. Slight higher effectiveness was detected at dose rate of 0,2 l/ha in case of weight of the roots (in Polish trials) and number of ears. However, the comparable product Asahi SL containing the same amount of all active substances is already authorized in winter wheat at minimum recommended dose rate of 0,6 l/ha. Taking into account all trials, Asahi Max at dose rate of 0,2 l/ha can be considered MED in winter wheat.

3.2.3 Efficacy tests (KCP 6.2)

A total of 34 efficacy trials carried out between 2008 and 2021 have generated data on the efficacy of Asahi Max applied at the proposed label rate of 0.2 L product/ha for use as a plant growth regulator in sugar beet (9 trials), oilseed rape (11 trials) and winter wheat (14 trials).

3.2.3.1 Efficacy in sugar beet

A total of 9 trials carried out between 2008 and 2009 have generated data on the efficacy of 2 applications of Asahi Max applied the proposed label rate of 0.2 L product/ha for use as a plant growth regulator in sugar beet. Of these trials, 1 was carried out in the Maritime EPPO climatic zone (Germany) and 8 were carried out in the North-East EPPO climatic zone (all in Poland).

All efficacy trials were carried out by organisations that are officially recognised as competent to carry out efficacy testing in accordance with Regulation (EU) 284/2013 by the authorities in the relevant countries.

Table 3.2-17: Details on trial methodology (efficacy trials on sugar beet)

Guidelines	General guidelines	EPPO PP1/152 (3), EPPO PP1/181 (3), EPPO PP1/135 (3), EPPO PP1/214 (1)
	Specific guidelines	-
Experimental design	Plot design	RCBD (9)
	Plot size	27-66 m ² (9)
	Number of replications	5 (1) 6 (8)
Crop	Trials per crop	Sugar beet (9)
	Varieties per crop	Aldona (2), Felicita (1), Kujawska (1), Jagoda (2), Jantar (1), Nabucco (1), Ezperanza (1)

Application	Crop stage (BBCH) at application	A1: from 10 to 12-14 (BBCH) A2: from 12 to 16-18 (BBCH) A3: from 14-15 to 15-32 (BBCH)
	Number of applications	2 (1) 3 (8)
	Spray volumes	300 L/ha (9)
Assessments	Assessment types	Plant population, seedling weight, phytotoxicity, root yield and yield quality parameters (sugar content, biological and technological sugar yield, N, K and Na content)
	Assessment dates	up to 171 DAA2 or 138 DAA3
Other relevant information	e.g. Natural / artificial inoculation	Not relevant
	e.g. Field / Greenhouse	Field

Agronomic practices in the cultivation of sugar beet are considered to be sufficiently similar across Germany and Poland within the Central Registration zone for data generated across all trials to be fully supportive of demonstrating the efficacy of Asahi Max in Poland.

Across trials, the efficacy of Asahi Max has been evaluated under a wide range of climatic conditions, agronomic practices considered to fully represent those in sugar beet growing regions in Poland.

Trials have been carried out on a wide range of different sugar beet cultivars, many of which are still grown commercially, that are considered to be representative of those in Poland.

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”.

The trial carried out in the Maritime EPPO climatic zone has been conducted in Germany and data generated in this trial are therefore fully supportive towards demonstrating the efficacy of Asahi Max in Poland.

Trials carried out in the North-East EPPO climatic zone have all been conducted in Poland and data generated in these trials are therefore fully supportive towards demonstrating the efficacy of Asahi Max in Poland.

Applications on all efficacy trials were made using small plot sprayers designed to simulate application using commercial sprayers representative of those used to apply plant growth regulators in sugar beet.

On 8 of these trials, ~~multiple (2 and 3)~~ 2 applications of the treatments were made when the crop growth stages were within the range of 11 to 14 (BBCH) at first application timings, from 12 to 18 (BBCH) at second application timings ~~and from 14 to 32 (BBCH) at third application timings~~ and therefore fully representative of the proposed label range for the application of Asahi Max. In two of these 8 trials the growth stage was outside the label range at the first of the three application timings. At this timing, the crop stage was in the range of 11-14 (BBCH) but with the majority of the crop at 12 (BBCH) and therefore still representative of the proposed label range. On the other 1 trial, application of the first treatment was made when the crop growth stage was at 10 (BBCH) and therefore slightly outside of the proposed label range for the application of Asahi Max. However, intervals between applications were within the range of 7-15 days and therefore representative of the minimum proposed label interval of 7 days. Therefore, all trials are considered as valid.

The standard reference products were applied according to the label recommendations.

Across trials, treatments were applied in water volumes of 300 L/ha and therefore fully representative and supportive of the proposed 200-500 L/ha label range for the application of Asahi Max.

Efficacy was determined based on a regulating effect on plant population, seedling weight, crop yield and yield quality improvements.

~~The label claim proposes 3 applications of Asahi Max in sugar beet, therefore data on the efficacy of 3 applications of Asahi SL applied at the approved label rate of 0.6 L product/ha in sugar beet, that were~~

~~generated in 8 of the efficacy trials carried out between 2008 and 2009 are presented as well. Based on data presented in Section 3.2.1.1 that demonstrates comparability of the efficacy of Asahi Max and Asahi SL, both providing the same amount of the three active substances when applied at 0.2 L and 0.6 L product/ha respectively, efficacy testing with Asahi SL is considered as fully supportive to justify the proposed label claim of 3 applications of Asahi Max at 0.2 L product/ha for use as a plant growth regulator.~~

An overall summary of the efficacy (at various assessment types) of 2 applications of Asahi Max applied at the proposed label rate of 0.2 L product/ha ~~and/or 3 applications of Asahi SL applied at the approved label rate of 0.6 L product/ha (expressed as % relative to the untreated control)~~ across trials in each of the EPPO climatic zone is given in Table 3.2-18.

Table 3.2-18: Mean overall percentage efficacy (based on various assessment timings) of 2 applications of Asahi Max applied at the proposed label rate of 0.2 L product/ha and/or 3 applications of Asahi SL applied at the approved label rate of 0.6 L product/ha across trials on sugar beet in all climatic zones

EPPO climatic zone	No. of trials		UTC with hand weeding	UTC with herbicide spraying	Mean efficacy (as % relative to UTC with hand weeding)			Mean efficacy as % relative to UTC with herbicide spraying)			No of trials where Asahi Max is >, <, = compared to Atonik SL#	No of trials where Asahi SL is >, <, = compared to Atonik SL#
					Asahi Max	Asahi SL	SRP Atonik SL	Asahi Max	Asahi SL	SRP Atonik SL		
					0.2 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	0.2 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)		
					A1+A2	A1+A2+A3	A1+A2	A1+A2	A1+A2+A3	A1+A2		
Plant population (thousand plants/ha) at 114-146 DAA2/101-133 DAA3												
Maritime	1*	Mean	6.9	7.2	94.5	-	-	90.7	-	-	-	-
North- East	8	Mean	98.7	97.7	97.6	98.4	98.7	99.0	99.7	99.9	8 trials =	8 trials =
		Min-Max	81.7-111.1	75.7-111.1	79.8-102.8	89.4-104.8	87.5-108.3	80.6-106.6	90.3-102.6	88.3-104.4		
Seedling weight (g/plant)												
9 DAA1												
Maritime	1	Mean	6.7	4.3	53.7	-	-	83.7	-	-	-	-
16-26 DAA2/7-14 DAA3												
North- East	7	Mean	172.1	143.4	107.6	106.7	108.6	133.8	133.5	130.8	7 trials =	7 trials =
		Min-Max	16.8-271.2	13.5-269.2	93.3-131.2	95.9-122	97.4-126.6	100.7-195.1	100.9-199.8	100.6-190.5		
Phytotoxicity (1- 9 scale)												
Maximum level of symptoms recorded												
North- East	2	Mean	1.0	2.8	170.0	150.0	175.0	60.7	54.0	62.4	2 trials =	2 trials =
		Min-Max	1.0-1.0	2.5-3.0	120.0-220.0	120.0-180.0	120.0-230.0	48.0-73.3	48.0-60.0	48.0-76.7		
	1**	Mean	0.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	1 trial =	1 trial =
Final assessment timings												
North- East	2	Mean	1.0	1.4	100.0	100.0	100.0	71.8	71.8	71.8	2 trials =	2 trials =
		Min-Max	1.0-1.0	1.3-1.5	100.0-100.0	100.0-100.0	100.0-100.0	66.7-76.9	66.7-76.9	66.7-76.9		
	1**	Mean	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1 trial =	1 trial =
Root yield (t/ha)												
Maritime	1	Mean	97.8	93.0	98.7	-	-	103.8	-	-	-	-
North- East	7	Mean	73.2	67.6	103.5	105.2	103.4	111.3	113.0	110.7	6 trials = 1 trial <	7 trials =
		Min-Max	48.6-120.3	45.0-103.1	93.3-124.2	93.5-118.3	89.2-121.8	101.6-132.7	104.7-126.3	103.1-130.1		
Sugar content (%)												
Maritime	1	Mean	18.3	18.3	100.5	-	-	100.5	-	-	-	-
North- East	8	Mean	16.8	17.0	101.9	101.0	100.4	100.9	100.0	99.9	8 trials =	8 trials =
		Min-Max	15.8-18.1	15.7-18.7	99.4-106.9	98.1-106.9	97.9-105.7	99.1-104.9	96.3-104.9	95.9-103.7		
Biological sugar yield (t/ha)												
Maritime	1	Mean	17.9	17.0	99.1	-	-	104.4	-	-	-	-
North- East	6	Mean	13.1	12.2	106.8	107.3	105.1	113.9	114.3	112.4	-	6 trials =

EPPO climatic zone	No. of trials		UTC with hand weeding	UTC with herbicide spraying	Mean efficacy (as % relative to UTC with hand weeding)			Mean efficacy as % relative to UTC with herbicide spraying)			No of trials where Asahi Max is >, <, = compared to Atonik SL#	No of trials where Asahi SL is >, <, = compared to Atonik SL#
					Asahi Max	Asahi SL	SRP Atonik SL	Asahi Max	Asahi SL	SRP Atonik SL		
					0.2 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	0.2 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)		
					A1+A2	A1+A2+A3	A1+A2	A1+A2	A1+A2+A3	A1+A2		
		Min-Max	9.9-20.0	9.2-17.0	92.5-124.2	91-120.2	90.5-122.6	103.4-132.8	106.7-128.4	102.6-131.0	5 trials = 1 trial <	

EPPO climatic zone	No. of trials		UTC with hand weeding	UTC with herbicide spraying	Mean efficacy (as % relative to UTC with hand weeding)			Mean efficacy as % relative to UTC with herbicide spraying)			No of trials where Asahi Max is >, <, = compared to Atonik SL#	No of trials where Asahi SL is >, <, = compared to Atonik SL#
					Asahi Max	Asahi SL	SRP Atonik SL	Asahi Max	Asahi SL	SRP Atonik SL		
					0.2 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	0.2 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)		
					A1+A2	A1+A2+A3	A1+A2	A1+A2	A1+A2+A3	A1+A2		
Technological sugar yield (t/ha)												
North-East	6	Mean	9.0	8.0	119.6	124.2	114.1	137.8	143.3	131.2	5 trials = 1 trial <	6 trials =
		Min-Max	2.9-18.6	2.3-15.9	93.1-166.7	91.3-175.9	91.3-156.7	103.2-200	105.7-221.7	101.6-188		
N content (mmol/1000g)												
Maritime	1	Mean	13.2	16.6	110.3	-	-	87.5	-	-	-	-
North-East	3	Mean	19.2	21.2	105.5	105.1	113.2	95.6	94.5	101.8	3 trials =	3 trials =
		Min-Max	16.6-22.2	19.4-22.8	104.3-107.2	95.5-118.4	106.3-126.6	83.6-102.2	92.3-98.7	98.7-103.5		
	1***	Mean	0.6	0.6	166.4	83.2	116.8	166.4	83.2	116.8	1 trial =	1 trial =
K content (mmol/1000g)												
Maritime	1	Mean	38.0	37.8	104.8	-	-	98.0	-	-	-	-
North-East	4	Mean	46.7	46.4	97.6	98.9	103.0	98.6	99.9	104.1	4 trials =	4 trials =
		Min-Max	37.6-57.3	35.8-55.9	94.4-101.4	95.8-102.7	98.2-111.6	92.3-106.4	92.9-107.9	95.9-117.1		
Na content (mmol/1000g)												
Maritime	1	Mean	3.7	4.2	97.5	-	-	92.4	-	-	-	-
North-East	4	Mean	5.6	7.4	120.5	127.7	100.0	99.8	102.7	85.8	1 trial > 3 trials =	1 trial > 3 trials =
		Min-Max	4.2-7.5	3.7-11	100.5-146.6	95.7-213.3	83.9-114.0	76.5-116.4	66.8-139.2	57.6-118.4		

based on statistically significant differences at 95% confidence level

** In trial EUR_MNN_BEAVA_DE_2771 the mean plant population for all treatments and the untreated is significantly different from the mean plant population from the other 8 trials and therefore data from this trial need to be taken with caution

** Data expressed as mean % symptoms, as for the untreated control no phytotoxicity symptoms were observed (0%) and therefore calculating of % relative to the untreated control was not possible

*** In trial EUR_MNN_BEAVA_PL_3293 the mean N content for all treatments is significantly different from the mean N content from the other 3 trials and therefore data from this trial are presented separately and need to be taken with caution

Two applications of Asahi Max at the proposed label rate of 0.2 L product/ha gave effective performance across most of the trials carried out in Maritime and North-East EPPO climatic zones based on plant population, seedling weight, phytotoxicity symptoms reduction, root yield, biological and technological sugar yield, and N, K and Na content. Limited effect of two applications of Asahi Max at the proposed label rate of 0.2 L product/ha could be proven on sugar content and K and Na content. However, although no overall mean Na content reduction was noted across these trials, significant increase was noted for the overall mean technological sugar yield. Additionally it is reasonable to conclude that the proposed label rate of 0.2 L product/ha of Asahi Max affects those parameters as well as this was proven in practice for many years for the approved Asahi SL.

Consistently, 3 applications of Asahi SL at the approved label rate of 0.6 L product/ha gave more effective performance (based at various assessment types) across most of the trials carried out in the North-East EPPO climatic zones. Based on data presented in Section 3.2.1.1 that demonstrates comparability between the efficacy of Asahi Max and that of Asahi SL, both containing the same amount of three the same active substances when applied at 0.2 L and 0.6 L product/ha respectively, as well as experience through commercial use of Asahi SL, data for Asahi SL are summarised in this section, as fully supportive of demonstrating efficacy of 3 applications of Asahi Max in sugar beet.

Results were mostly comparable to those achieved by standard reference product applied at authorised label rate.

Based on the summarized data, it is therefore considered that claims of Asahi Max as a plant growth regulator applied at the proposed label rate of 0.2 L product/ha, at up to a maximum of 3 2 applications per season and according to other label recommendations, are fully supported.

Comments of zRMS:

9 efficacy trials (conducted in Poland and Germany) have been submitted to show positive effect of Asahi Max on sugar beet. Asahi Max at 0,2 l/ha caused increase of seedling weight about 33,8% compared to the untreated objects with herbicide spraying. Slight increase (7,6%) was noted also in case of the untreated check with hand weeding. No visible increase was observed in overall mean plant density, either on the untreated check with herbicide spraying and with hand weeding. Moreover, slight effect on sugar, nitrogen and sodium content was noted for Asahi Max at 0,2 l/ha. The test product caused significant increase of biological and technological sugar yield. The root yield was superior compared to untreated check with herbicide treatment about 11,3%. No significant differences between Asahi Max and Atonik SL were noted.

Taking into account all trial results, Asahi Max at 0,2 l/ha with max 2 applications per season can be recommended as plant growth regulator, especially to improve quality and quantity parameters of sugar beet yield.

3.2.3.2 Efficacy in oilseed rape

A total of 11 trials carried out between 2008 and 2009 have generated data on the efficacy of 2 applications of Asahi Max applied the proposed label rate of 0.2 L product/ha for use as a plant growth regulator in winter oilseed rape. Of these trials, 3 were carried out in the Maritime EPPO climatic zone (all in Germany) and 8 were carried out in the North-East EPPO climatic zone (all in Poland).

All efficacy trials were carried out by organisations that are officially recognised as competent to carry out efficacy testing in accordance with Regulation (EU) 284/2013 by the authorities in the relevant countries.

Table 3.2-19: Details on trial methodology (efficacy trials on oilseed rape)

Guidelines	General guidelines	EPPO PP1/152 (3), EPPO PP1/181 (3), EPPO PP1/135 (3)
	Specific guidelines	-
Experimental design	Plot design	RCBD (11)
	Plot size	20-60 m ² (11)
	Number of replications	5 (3) 6 (8)
Crop	Trials per crop	Winter oilseed rape (11)

	Varieties per crop	Lorenz (1), ES Astrid (1), Elektra (1), Californium (2), Casoar (1), Castille (1), Lisek (1), Vision (1), Nemax (1), Olpop (1)
Application	Crop stage (BBCH) at application	A1: from 17-30 to 31-35 (BBCH) A2: from 31-51 to 52-57 (BBCH)
	Number of applications	2 (11)
	Spray volumes	300 L/ha (11)

Assessments	Assessment types	Plant population, plant height, number of branches, pods per plant and seeds per pod, thickness of pod coats, crop yield and yield quality parameters (TGW, oil content, oil yield), phytotoxicity
	Assessment dates	Up to 159 DAA2
Other relevant information	e.g. Natural / artificial population	Not relevant
	e.g. Field / Greenhouse	Field

Agronomic practices in the cultivation of winter oilseed rape are considered to be sufficiently similar across Germany and Poland within the Central Registration zone for data generated across all trials to be fully supportive of demonstrating the efficacy of Asahi Max in Poland.

Across trials, the efficacy of Asahi Max has been evaluated under a wide range of climatic conditions, agronomic practices considered to fully represent those in winter oilseed rape is grown in Poland.

Trials have been carried out on a wide range of different winter oilseed rape cultivars, many of which are still grown commercially, that are considered to be representative of those in Poland.

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”.

The trial carried out in the Maritime EPPO climatic zone has been conducted in Germany and data generated in this trial are therefore fully supportive towards demonstrating the efficacy of Asahi Max in Poland.

Trials carried out in the North-east EPPO climatic zone have all been conducted in Poland and data generated in these trials are therefore fully supportive towards demonstrating the efficacy of Asahi Max in Poland.

Applications on all efficacy trials were made using small plot sprayers designed to simulate application using commercial sprayers representative of those used to apply plant growth regulators in winter oilseed rape.

On 9 of these trials, multiple (2) applications of the treatments were made when the crop growth stages were within the range of 29 to 35 (BBCH) at first application timings and from 31 to 57 (BBCH) at second application timings and therefore fully representative of the proposed label range for the application of Asahi Max. In two of the trials the growth stage was outside the label range at the first of the two application timings. In 1 of the trials, the crop stage was in the range of 19-31 (BBCH) but with the majority of the crop at 30 (BBCH) and therefore still representative of the proposed label range. On the other 1 trial, application on the first timing was made when the crop growth stage was in the range of 17-30 with the majority of the crop at 19 (BBCH) and therefore slightly outside of the proposed label range for the application of Asahi Max. However, intervals between applications were within the range of 11-16 days and therefore representative of the minimum proposed label interval of 7 days. Therefore, all trials are considered as valid.

The standard reference products were applied according to the label recommendations.

Across trials, treatments were applied in water volumes of 300 L/ha and therefore fully representative and supportive of the proposed 200-500 L/ha label range for the application of Asahi Max.

Whilst no data has been generated in support of demonstrating the efficacy of Asahi Max in spring oilseed rape, plant physiology, agronomic practices and susceptibility to plant growth regulators can be considered to be very similar between winter and spring oilseed rape. Data from trials carried out in winter oilseed rape are therefore considered to be supportive of demonstrating the efficacy of Asahi Max at the proposed label rate of 0.2 L product/ha in spring oilseed rape.

Efficacy was determined based on effect on plant population, plant height, number of branches, pods per plant and seeds per pod, thickness of pod coats, crop yield and yield quality improvements.

An overall summary of the efficacy (at various assessment types) of 2 applications of Asahi Max applied at the proposed label rate of 0.2 L product/ha (expressed as % relative to the untreated control) across trials in each of the EPPO climatic zone is given in Table 3.2-20.

Table 3.2-20: Mean overall percentage efficacy (based on various assessment timings) of 2 applications of Asahi Max applied at the proposed label rate of 0.2 L product/ha across trials on winter oilseed rape in all climatic zones

EPPO climatic zone	No. of trials		UTC with hand weeding (thousand plants/ha)	Mean efficacy (as % relative to untreated)			No of trials where Asahi Max is >, <, = compared to Atonik SL (applied at A1)#	No of trials where Asahi Max is >, <, = compared to Atonik SL (applied at A1+A2)#
				Asahi Max	Atonik SL			
				0.2 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)		
				A1+A2	A1	A1+A2		
Plant population (plants/m ²)								
North- East	2	Mean	63.4	107.3	90.6	-	2 trials =	-
		Min-max	56.0-70.7	105.4-109.3	78.8-102.5	-		
	1	Mean	56.7	95.8	-	119.9	-	1 trial =
Plant height (cm)								
North- East	4	Mean	159.2	101.7	102.8	-	4 trials =	-
		Min-max	142.0-168.2	99.4-105.4	100.0-106.6	-		
	3	Mean	127.5	97.5	-	98.1	-	3 trials =
		Min-max	122.4-134.3	91.3-101.8	-	95.0-99.6		
Number of branches (branches/plant)								
Maritime	3	Mean	6.6	102.3	-	-	-	-
		Min-max	6.0-7.2	94.7-114.1	-	-		
North- East	3	Mean	5.3	108.9 109.5	116.9 117.2	-	3 trials =	-
		Min-max	4.2-7.2	79.1 81.0-124.1	113.6 114.3-121.7	-		
	3	Mean	5.5	117.2	-	113.6	-	3 trials =
		Min-max	4.8-6.7	101.4-128.0	-	95.9-124.0		
Number of pods (pods/plant)								
Maritime	3	Mean	149.3	98.9	-	-	-	-
		Min-max	110.5-177.4	90.3-114.2	-	-		
North- East	2	Mean	194.4	130.8	135.1	-	2 trials =	-
		Min-max	165.2-223.5	103.9-157.6	111.1-159.2	-		
	1*	Mean	695.4	95.1	128.3	-	1 trial =	-
	3	Mean	90.9	100.4	-	99.2	-	3 trials =
		Min-max	74.8-105.4	94.0-103.8	-	91.1-103.3		
Number of seeds (seeds/pod)								
Maritime	3	Mean	25.1	99.0	-	-	-	-
		Min-max	24.2-26.6	95.2-102.6	-	-		
North- East	3	Mean	22.5	110.4	112.2	-	3 trials =	-
		Min-max	19.5-25.7	100.1-121.8	101.7-129.6	-		
	3	Mean	24.1	107.8	-	107.3	-	3 trials =
		Min-max	22.6-26.0	105.5-111.9	-	103.7-111.5		

EPPO climatic zone	No. of trials		UTC with hand weeding (thousand plants/ha)	Mean efficacy (as % relative to untreated)			No of trials where Asahi Max is >, <, = compared to Atonik SL (applied at A1)#	No of trials where Asahi Max is >, <, = compared to Atonik SL (applied at A1+A2)#
				Asahi Max	Atonik SL			
				0.2 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)		
				A1+A2	A1	A1+A2		
Thickness of pod coats (n/d)								
North-East	1	Mean	46.2	104.3	98.9	-	1 trial =	-
	1	Mean	33.3	103.6	-	101.2	-	1 trial =
Crop yield (t/ha)								
Maritime	3	Mean	3.2	100.8	-	-	-	-
		Min-max	2.5-4.0	97.3-104.9	-	-		
North-East	4	Mean	3.5	113.0	117.0	-	4 trials =	-
		Min-max	2.4-4.3	100.7-141.7	102.0-150.0	-		
	4	Mean	3.3	128.1	-	119.7	-	4 trials =
		Min-max	2.1-5.7	109.3-168.1	-	110.8-137.7		
TGW (g)								
Maritime	3	Mean	4.4	100.6	-	-	-	-
		Min-max	4.0-4.8	99.8-102.0	-	-		
North-East	4	Mean	4.7	106.8	102.8	-	4 trials =	-
		Min-max	4.2-5.1	99.3-123.8	98.0-114.3	-		
	4	Mean	4.7	109.3	-	105.2	-	1 trial > 3 trials =
		Min-max	3.8-5.9	102.5-118.4	-	97.5-110.0		
Oil content (%)								
Maritime	3	Mean	44.3	99.6	-	-	-	-
		Min-max	37.9-48.2	99.0-100.1	-	-		
North-East	2	Mean	42.9	98.6	99.6	-	2 trials =	-
		Min-max	40.5-45.2	98.3-98.9	99.4-99.8	-		
	4	Mean	30.7	116.4	-	109.2	-	2 trials > 2 trials =
		Min-max	25.7-40.8	99.6-128.8	-	99.7-114.4		
Oil yield (dt/ha)								
North-East	1	Mean	19.2	99.5	101.0	-	1 trial =	-
	1	Mean	23.3	109.0	-	110.7	-	1 trial =

based on statistically significant differences at 95% confidence level

*In trial EUR_MNN_BRSNW_PL_3038 the mean pods number for all treatments and the untreated is markedly higher than the mean pods number from the other 8 trials and therefore data from this trial are presented separately and need to be taken with caution

Two applications of Asahi Max at the proposed label rate of 0.2 L product/ha gave effective performance across most of the trials carried out in Maritime and North-East EPPO climatic zones based on plant population, number of branches, pods and seeds, crop yield and the yield quality parameters TGW, oil content and oil yield. Limited effect of two applications of Asahi Max at the proposed label rate of 0.2 L product/ha could be proven on plant height and thickness of pod coats. However, number of trials assessing this parameters were mostly limited and based on the comparability of the efficacy of Asahi Max and that of Asahi SL, when applied at 0.2 L and 0.6 L product/ha rates respectively, it is reasonable to conclude that the proposed label rate of 0.2 L product/ha of Asahi Max regulates those parameters as well as this was proven in practice for many years for the approved Asahi SL.

Results were mostly comparable to those achieved by standard reference product applied at authorised label rate.

Based on the summarized data, it is therefore considered that claims of Asahi Max as a plant growth regulator applied at the proposed label rate of 0.2 L product/ha, at up to a maximum of 2 applications per season and according to other label recommendations, are fully supported.

Comments of zRMS:

11 efficacy trials (conducted in Poland and Germany) have been submitted to present positive effect of Asahi Max on winter oilseed rape. Slight increase of 7,3% for plant population was observed in 2 trials. The test product at 0,2 l/ha showed limited effect on plant height. Double application of Asahi Max caused significant increase of branches, pods and seeds compared to untreated objects. Similar yield and level of quality parameters between test and reference products were noted. Asahi Max presented visible superior crop yield in 8 out of 11 trials compared to untreated check. Also slight positive effect was observed in case of TGW and oil content. Taking into account all trial results, Asahi Max at 0,2 l/ha with max 2 applications per season can be recommended as plant growth regulator for winter oilseed rape, especially to improve quality and quantity parameters of yield.

3.2.3.3 Efficacy in winter wheat

A total of ~~14~~ 11 trials carried out between 2010 and 2021 have generated data on the efficacy of single application of Asahi Max applied the proposed label rate of 0.2 L product/ha for use as a plant growth regulator in winter wheat. Of these trials, ~~10~~ 7 were carried out in the Maritime EPPO climatic zone (3 in Czech Republic, ~~and~~ 4 in Germany, ~~3 in France~~) and 4 were carried out in the North-East EPPO climatic zone (all in Poland).

All efficacy trials were carried out by organisations that are officially recognised as competent to carry out efficacy testing in accordance with Regulation (EU) 284/2013 by the authorities in the relevant countries.

Table 3.2-21: Details on trial methodology (efficacy trials on winter wheat)

Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4)
	Specific guidelines	EPPO PP1/144 (3), CEB 91
Experimental design	Plot design	RCBD (14 11)
	Plot size	19,2 12-36.0 m ² (11) n/d (3)
	Number of replications	4 (9) 6 (3 2)
Crop	Trials per crop	Winter wheat (14 11)
	Varieties per crop	Doppio Giallo (2), Durango (1), Snow (1), Akteur (2), Arkadia (1), Banquet (1), Kashmir (1), Ludwig (1), Muszelka (1), Pannonia (1), RGT Reform (1), Tonacja (1), Toras (1)
Application	Crop stage (BBCH) at application	A1: from 24 to 32 (BBCH)
	Number of applications	1 (14 11)
	Spray volumes	200 L/ha (4), 220 L/ha (2), 250 L/ha (3 2), 300 L/ha (5)

Assessments	Assessment types	Plant population, plant height, weight and length of the roots, weight above ground part of the plant, number of tillers per plant, ears per square meter and grain per ear, tiller and internode length, lodging, crop yield and yield quality parameters (TGW, HLW, protein content, starch content, gluten content, sedimentation index, Hagberg falling number, germination test and energy), phytotoxicity
	Assessment dates	Up to 162 DAA
Other relevant information	e.g. Natural / artificial inoculation	Not relevant
	e.g. Field / Greenhouse	Field caged (barriered) arena trials

Agronomic practices in the cultivation of winter wheat are considered to be sufficiently similar across Germany, Czech Republic, ~~France~~ and Poland within the Central Registration zone for data generated across all trials to be fully supportive of demonstrating the efficacy of Asahi Max in Poland.

Across trials, the efficacy of Asahi Max has been evaluated under a wide range of climatic conditions, agronomic practices considered to fully represent those in winter wheat is grown in Poland.

Trials have been carried out on a wide range of different winter wheat cultivars, many of which are still grown commercially, that are considered to be representative of those in Poland.

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”.

The trial carried out in the Maritime EPPO climatic zone has been conducted in Germany, ~~and~~ Czech Republic ~~and the Maritime regions of France~~ and data generated in this trials are therefore fully supportive towards demonstrating the efficacy of Asahi Max in Poland.

Trials carried out in the North-~~e~~East EPPO climatic zone have all been conducted in Poland and data generated in these trials are therefore fully supportive towards demonstrating the efficacy of Asahi Max in Poland.

Applications on all efficacy trials were made using small plot sprayers designed to simulate application using commercial sprayers representative of those used to apply plant growth regulators in winter wheat.

On all of these trials, single application of the treatments were made when the crop growth stages were within the range of 24-32 (BBCH) a and therefore fully representative of the proposed label range for the application of Asahi Max.

The standard reference products were applied according to the label recommendations.

Across trials, treatments were applied in water volumes of 300 L/ha and therefore fully representative and supportive of the proposed 200-300 L/ha label range for the application of Asahi Max.

Efficacy was determined based on effect on plant population, plant height, weight and length of the roots, weight above ground part of the plant, number of tillers per plant, ears per square meter and grain per ear, tiller and internode length, supporting effect against lodging, crop yield and yield quality improvements.

An overall summary of the efficacy (at various assessment types) of single application of Asahi Max applied at the proposed label rate of 0.2 L product/ha (expressed as % relative to the untreated control) across trials in each of the EPPO climatic zone is given in Table 3.2-22.

An overall summary of the efficacy (based on lodging reduction) of single application of Asahi Max applied at the proposed label rate of 0.2 L product/ha (expressed on various assessment parameters) across trials in the Maritime EPPO climatic zone is given in Table 3.2-23.

An overall summary of the efficacy (based on distribution of the yield between different grain size grades) of single application of Asahi Max applied at the proposed label rate of 0.2 L product/ha across trials in each of the EPPO climatic zone is given in Table 3.2-24.

Table 3.2-22: Mean overall percentage efficacy (based on various assessment timings) of single application of Asahi Max applied at the proposed label rate of 0.2 L product/ha across trials on winter wheat in all climatic zones

EPPO climatic zone (total number of trials)	No. of trials		UTC	Mean efficacy (as % relative to untreated)				No of trials where Asahi Max is >, <, = compared to SRP#
				Asahi Max	Standard reference product (SRP)			
				0.2 L/ha (3.6 g a.i./ha)	Cycocel C5 BASF 2.0 L/ha (920 g a.i./ha)	CCC720 / Stabilan 750 SL 1.5 L/ha (1080/1125 g a.i./ha)	Stabilan 750 SL 2.0 L/ha (1500 g a.i./ha)	
Plant population (plants/m²)								
North- East (3)	3	Mean	346.8	100.0	-	-	-	-
		Min-max	298.5-432.0	98.4-101.1	-	-	-	
Plant height (cm)***								
14-23 DAA								
Maritime (3)	3	Mean	45.4	99.6	-	-	-	-
		Min-max	42.7-49.3	99.3-100.0	-	-	-	
North- East (2)	2	Mean	64.7	99.8	-	-	92.0	2 trials <
		Min-max	64.3-65.1	99.4-100.2	-	-	90.8-93.3	
43-83 DAA								
Maritime (7 4)	3	Mean	89.8 90.9	100.6 100.9	92.9 94.0	-	-	2 1 trials = 4 2 trials <
		Min-max	66.6-105.7 88.0-95.5	98.6-105.0	88.8 90.4-97.5	-	-	
	4	Mean	92.0	100.2	-	95.2	-	3 trials = 1 trial <
		Min-max	88.0-95.5	98.2-105.0	-	89.3-98.3	-	
North- East (2)	2	Mean	72.9	95.8	-	92.9	-	2 trials <
		Min-max	69.4-76.4	95.4-96.1	-	92.7-93.2	-	
Length of the roots (cm)								
Maritime (7 4)	3	Mean	6.9 6.0	99.7 96.4	100.7 98.9	-	-	6 3 trials =
		Min-max	5.4-9.4 6.7	93.3-105.4 101.9	97.0-107.7 101.7	-	-	
	4	Mean	7.0	97.0	-	99.0	-	4 trials =
		Min-max	5.4-9.8	93.3-101.9	-	97.0-100.0	-	
North- East (4)	2	Mean	6.1	127.2	-	106.6	-	1 trial = 1 trial <
		Min-max	6.0-6.1	123.3-131.1	-	106.6-106.7	-	
	2	Mean	14.8	93.7	-	-	103.0	2 trials >
		Min-max	9.9-19.7	89.3-98.0	-	-	100.0-106.1	
Weight of the roots (g)								
Maritime (7 4)	3	Mean	23.7 3.2	96.2 93.8	95.5 96.7	-	-	6 3 trials =
		Min-max	2.0-56.3 4.4	86.1-106.8	78.1-111.3 78.2-106.8	-	-	
	4	Mean	2.5	91.0	-	90.1	-	4 trials =
		Min-max	0.1-4.4	82.5-106.8	-	71.8-106.6	-	

EPPO climatic zone (total number of trials)	No. of trials		UTC	Mean efficacy (as % relative to untreated)				No of trials where Asahi Max is >, <, = compared to SRP#
				Asahi Max	Standard reference product (SRP)			
				0.2 L/ha (3.6 g a.i./ha)	Cycocel C5 BASF	CCC720 / Stabilan 750 SL	Stabilan 750 SL	
				2.0 L/ha (920 g a.i./ha)	1.5 L/ha (1080/1125 g a.i./ha)	2.0 L/ha (1500 g a.i./ha)		
North- East (4)	2	Mean	0.7	131.9	-	104.3	-	2 trials =
		Min-max	0.7-0.7	131.4-132.4	-	101.5-107.1	-	
	2	Mean	7.3	98.4	-	-	114.4	2 trials >
		Min-max	4.8-9.7	85.4-111.3	-	-	91.7-137.1	
Weight above part of the plant (g)								
North- East (2)	2	Mean	10.9	97.5	-	-	90.8	2 trials =
		Min-max	8.3-13.5	92.8-102.2	-	-	88.9-92.8	
Number of tillers (tiller/plant)								
Maritime (4)	3	Mean	1.7	116.7	-	-	-	-
		Min-max	0.9-3.1	104.5-129.5	-	-	-	
	3	Mean	2.3	95.4	95.5	96.0	-	3 trials =
		Min-max	0.9-6.0 2.1-2.5	90.5-129.5 100.0	88.0-100.0	-	-	
	4	Mean	2.4	104.3	-	91.9	-	4 trials =
		Min-max	0.9-5.0	90.5-129.5	-	80.0-100.0	-	
North- East (4)	2	Mean	3.2	104.6	-	104.6	-	2 trials =
		Min-max	2.8-3.6	103.6-105.6	-	103.6-105.6	-	
	2	Mean	4.4	90.9	-	-	91.0	2 trials =
		Min-max	4.3-4.4	79.5-102.3	-	-	77.3-104.7	
Number of ears (ear/m2)								
Maritime (4)	3	Mean	484.7	101.7	-	-	-	-
		Min-max	377.5-689.0	97.5-103.9	-	-	-	
	3	Mean	408.0	104.5	102.3	102.6	-	3 trials =
		Min-max	303.0-689.0 526.0	95.8-99.8-109.2	99.4-107.3	-	-	
	4	Mean	458.8	102.8	-	106.8	-	4 trials =
		Min-max	303.0-689.0	97.5-109.2	-	95.2-115.5	-	
North- East (4)	2	Mean	589.8	100.1	-	100.0	-	2 trials =
		Min-max	584.3-595.2	100.1-100.1	-	100-100	-	
	1	Mean	569.8	100.5	-	-	99.5	1 trial =
	1*	Mean	40.7	104.2	-	-	104.7	1 trial =
Number of grains (grain/ear)								
Maritime (3)	2	Mean	31.6	105.8	-	-	-	-
		Min-max	27.3-36	104.2-107.3	-	-	-	

EPPO climatic zone (total number of trials)	No. of trials		UTC	Mean efficacy (as % relative to untreated)				No of trials where Asahi Max is >, <, = compared to SRP#	
				Asahi Max	Standard reference product (SRP)				
					0.2 L/ha (3.6 g a.i./ha)	Cycocel C5 BASF	CCC720 / Stabilan 750 SL		Stabilan 750 SL
						2.0 L/ha (920 g a.i./ha)	1.5 L/ha (1080/1125 g a.i./ha)		2.0 L/ha (1500 g a.i./ha)
	1**	Mean	428.8	101.1	-	-	-	-	

EPPO climatic zone (total number of trials)	No. of trials		UTC	Mean efficacy (as % relative to untreated)				No of trials where Asahi Max is >, <, = compared to SRP#
				Asahi Max	Standard reference product (SRP)			
				0.2 L/ha (3.6 g a.i./ha)	Cycocel C5 BASF 2.0 L/ha (920 g a.i./ha)	CCC720 / Stablan 750 SL 1.5 L/ha (1080/1125 g a.i./ha)	Stablan 750 SL 2.0 L/ha (1500 g a.i./ha)	
Tiller length (cm)***								
Leading tiller								
Maritime (7/4)	3	Mean	61.6 70.5	101.4 102.9	93.6 95.2	-	-	2/1 trials = 4/2 trials <
		Min-max	40.8 68.5-73.6	99.4 102.0-103.5	89.0 94.0-96.7	-	-	
	4	Mean	62.8	102.3	-	95.8	-	1 trial = 3 trials <
		Min-max	39.4-73.6	100.3-103.5	-	94.2-98.2	-	
North- East (4)	2	Mean	24.4	104.3	-	103.1	-	2 trials =
		Min-max	23.6-25.1	103.8-104.8	-	102.5-103.6	-	
	2	Mean	76.4	99.0	-	-	89.3	2 trials <
		Min-max	71.0-81.8	96.3-101.7	-	-	85.5-93.1	
2nd tiller								
Maritime (7/4)	3	Mean	56.5 66.8	101.5 102.5	93.9 94.9	-	-	2/1 trials = 4/2 trials <
		Min-max	35.4 64.4-70.8	100.0 101.8-103.1	89.7-98.6 94.5-95.3	-	-	
	4	Mean	58.7	102.0	-	96.0	-	2 trials = 2 trials <
		Min-max	34.4-70.8	100.6-103.1	-	94.4-99.4	-	
North- East (4)	2	Mean	20.4	104.2	-	94.9	-	2 trials <
		Min-max	19.5-21.2	104.1-104.2	-	94.3-95.4	-	
	2	Mean	56.1	101.6	-	-	87.4	1 trial = 1 trial <
		Min-max	55.7-56.4	98.4-104.8	-	-	83.0-91.7	
3rd tiller								
Maritime (4)	3	Mean	59.8	102.7	95.1	-	-	3 trials <
		Min-max	57-64.1	100.7-104.4	94.6-96.1	-	-	
	4	Mean	51.1	101.9	-	96.8	-	2 trials = 2 trials <
		Min-max	24.9-64.1	99.6-104.4	-	93.3-99.6	-	
North- East (4)	2	Mean	15.8	102.5	-	100.3	-	1 trial = 1 trial <
		Min-max	15.4-16.2	101.3-103.7	-	100-100.6	-	
	2	Mean	10.5	112.4	-	-	104.9	1 trial = 1 trial <
		Min-max	8.8-12.1	79.3-145.5	-	-	43.8-165.9	
Internode length (cm)***								
I internode								
North- East (2)	2	Mean	9.8	101.5	-	-	84.9	2 trials <
		Min-max	8.5-11.0	101.2-101.8	-	-	82.7-87.1	
II internode								

EPPO climatic zone (total number of trials)	No. of trials		UTC	Mean efficacy (as % relative to untreated)				No of trials where Asahi Max is >, <, = compared to SRP#	
				Asahi Max	Standard refrence product (SRP)				
					0.2 L/ha (3.6 g a.i./ha)	Cycocel C5 BASF	CCC720 / Stabilan 750 SL		Stabilan 750 SL
						2.0 L/ha (920 g a.i./ha)	1.5 L/ha (1080/1125 g a.i./ha)		2.0 L/ha (1500 g a.i./ha)
North- East (2)	2	Mean	12.8	105.0	-	-	90.1	2 trials <	
		Min-max	11.3-14.2	102.1-108.0	-	-	83.8-96.5		
III internode									
North- East (2)	2	Mean	19.0	102.6	-	-	89.2	2 trials <	
		Min-max	18.1-19.8	101.1-104.0	-	-	82.8-95.6		

EPPO climatic zone (total number of trials)	No. of trials		UTC	Mean efficacy (as % relative to untreated)				No of trials where Asahi Max is >, <, = compared to SRP#
				Asahi Max	Standard refrence product (SRP)			
				0.2 L/ha (3.6 g a.i./ha)	Cycocel C5 BASF 2.0 L/ha (920 g a.i./ha)	CCC720 / Stabilan 750 SL 1.5 L/ha (1080/1125 g a.i./ha)	Stabilan 750 SL 2.0 L/ha (1500 g a.i./ha)	
Crop yield (t/ha)								
Maritime (40/7)	3	Mean	5.2	104.2	-	-	-	-
		Min-max	3.6-6.8	101.1-107.1	-	-	-	
	6/3	Mean	7.9 8.3	102.5 101.9	104.3 107.4	-	-	5/2 trials = 1 trial <
		Min-max	3.6-12.8 7.7-9.5	97.9-107.1 104.1	99.0 101.9-116.0	-	-	
	4	Mean	6.9	102.6	-	104.7	-	3 trials = 1 trial <
		Min-max	3.6-9.5	97.9-107.1	-	96.5-115.6	-	
North-East (4)	2	Mean	7.1	102.2	-	101.5	-	2 trials =
		Min-max	7.0-7.2	101.8-102.6	-	100.8-102.2	-	
	2	Mean	7.9	98.9	-	-	97.1	2 trials =
		Min-max	6.2-9.6	96.8-101.0	-	-	95.2-99.0	
TGW (g)								
Maritime (40/7)	3	Mean	42.2	99.4	-	-	-	-
		Min-max	38.8-46.4	95.9-101.6	-	-	-	
	6/3	Mean	47.6 49.8	100.3 101.5	98.5 98.7	-	-	6/3 trials =
		Min-max	38.8-58.5 47.0-52.8	95.9 99.8-102.4	96.1-100.4	-	-	
	4	Mean	44.5	101.0	-	100.2	-	1 trial > 2 trials = 1 trial n/d
		Min-max	35.3-52.8	95.9-104.4	-	95.0-107.2	-	
North-East (4)	2	Mean	37.3	101.7	-	101.3	-	2 trials =
		Min-max	33.9-40.6	100.4-103.0	-	100.0-102.6	-	
	2	Mean	38.5	101.2	-	-	100.4	2 trials =
		Min-max	37.1-39.8	97.8-104.5	-	-	96.8-104.0	
HLW (kg/ha)								
Maritime (5/2)	2	Mean	75.5	99.4 99.5	-	-	-	-
		Min-max	74.6-76.3	98.7-100.2	-	-	-	
	3	Mean	77.5	100.0	101.2	-	-	3 trials =
		Min-max	74.6-81.1	98.7-101.0	100.1-102.3	-	-	
North-East (2)	2	Mean	63.7	103.6	-	102.9	-	2 trials =
		Min-max	63.2-64.1	99.8-107.4	-	100.3-105.5	-	

EPPO climatic zone (total number of trials)	No. of trials		UTC	Mean efficacy (as % relative to untreated)				No of trials where Asahi Max is >, <, = compared to SRP#
				Asahi Max	Standard refrence product (SRP)			
				0.2 L/ha (3.6 g a.i./ha)	Cycocel C5 BASF 2.0 L/ha (920 g a.i./ha)	CCC720 / Stabilan 750 SL 1.5 L/ha (1080/1125 g a.i./ha)	Stabilan 750 SL 2.0 L/ha (1500 g a.i./ha)	
Protein content (%)								
Maritime (6)	2	Mean	12.1	99.8	-	-	-	-
		Min-max	11.0-13.2	99.5-100.0	-	-	-	
	3	Mean	13.4	100.1	97.9	-	-	1 trial > 2 trials =
		Min-max	11.0-16.2	99.5-100.7	96.6-99.9	-	-	
	4	Mean	12.9	99.9	-	97.5	-	1 trial > 2 trials = 1 trial n/d
		Min-max	11.0-13.8	99.5-100.2	-	95.0-100.0	-	
North- East (4)	2	Mean	14.0	102.6	-	101.4	-	2 trials =
		Min-max	12.7-15.3	102.0-103.1	-	101.3-101.6	-	
	2	Mean	13.0	100.5	-	-	101.6	2 trials =
		Min-max	11.3-14.6	99.3-101.8	-	-	101.4-101.8	
Starch content (%)								
Maritime (3)	3	Mean	62.1	100.5	-	-	-	-
		Min-max	56.2-68.2	99.9-101.3	-	-	-	
Gluten content (%)								
North- East (2)	2	Mean	28.2	98.7	-	-	100.4	2 trials =
		Min-max	25.4-30.9	98.4-99	-	-	100.3-100.4	
Sedimentation index (ml)								
Maritime (2)	2	Mean	37.4	105.6	-	-	-	-
		Min-max	32.0-42.8	100.0-111.1	-	-	-	
Hagberg falling number (s)								
Maritime (2)	2	Mean	250.1	112.0	-	-	-	-
		Min-max	237.0-263.3	100.8-123.1	-	-	-	
Germination energy (%)								
Maritime (3)	3	Mean	81.8	128.8	-	-	-	-
		Min-max	54.0-98.5	100.0-185.2	-	-	-	
Germination test (%)								
Maritime (3)	3	Mean	83.2	128.5	-	-	-	-
		Min-max	55.0-99.5	99.5-181.8	-	-	-	

based on statistically significant differences at 95% confidence level

*In trial EUR_MNN_TRZAW_4609 the mean ears number for all treatments and the untreated is markedly lower than the mean ears number from the other 13 trials and therefore data from this trial are presented separately and need to be taken with caution

**In trial EUR_MNN_TRZAW_CZ_4104 the mean grains number for all treatments and the untreated is markedly higher than the mean grains number from the other 2 trials and therefore data from this trial are presented separately and need to be taken with caution

***The aim of the product is to support effects against lodging not by reducing the plant height and tiller or internode length but by improving plant growth and strength, therefore these results need to be taken with caution

Table 3.2-23: Mean overall percentage efficacy (based on lodging reduction) of single application of Asahi Max applied at the proposed label rate of 0.2 L product/ha across trials on winter wheat in the Maritime EPPO climatic zone

EPPO climatic zone (total number of trials)	No. of trials	Lodging parameter (unit)	Untreated	Mean			Asahi Max >, <, = compared to SRP#
				Asahi Max	Cycocel C5 BASF	CCC720	
				0.2 L/ha (1.8 g a.i./ha)	2.0 L/ha (920 g a.i./ha)	1.5 L/ha (1080g a.i./ha)	
Maritime (3)	1	Lodging area (%)	3.9	0.0	-	-	-
	1	Lodging area (%)	86.3	80.0 61.3	41.3	33.8	=/ <
	1	Lodging angle (°)	31.3	42.5 40.0	42.5	43.8	= / =
	1	Lodging (% area without lodging)	81.3	87.5	100.0	-	>
	1	Lodging (% area with lodging less than 45°)	17.5	12.5	0.0	-	>
	1	Lodging (% area with lodging more than 45°)	1.3	0.0	0.0	-	=

based on statistically significant differences at 95% confidence level

Table 3.2-24: Mean overall percentage efficacy (based on distribution of the yield between different grain size grades) of single application of Asahi Max applied at the proposed label rate of 0.2 L product/ha across trials on winter wheat in all climatic zones

EPPO climatic zone (total number of trials)	No. of trials	Grain size grade		Untreated	Mean % distribution between grain size categories		No of trials where Asahi Max is >, <, = compared to SRP#
					Asahi Max	Satbilan 750 SL	
					0.2 L/ha (1.8 g a.i./ha)	2.0 L/ha (1500 g a.i./ha)	
Maritime (3)	3	>2.5 mm	Mean	85.2	87.5	-	1 trial >
			Min-max	80.0-90.0	79.0-97.0	-	1 trial =
		2.5-2.2 mm	Mean	11.2	8.9	-	1 trial >
			Min-max	9.0-15.3	2.0-15.8	-	1 trial =
		<2.2 mm	Mean	3.6	3.7	-	1 trial n/d
			Min-max	1.0-5.0	1.0-5.2	-	2 trials =
North-East (2)	2	>2.5 mm	Mean	72.6	73.7	72.7	1 trial <
			Min-max	53.8-91.4	55.5-91.8	53.7-91.6	2 trials =

based on statistically significant differences at 95% confidence level

Single application of Asahi Max at the proposed label rate of 0.2 L product/ha gave effective performance across most of the trials carried out in Maritime and North-East EPPO climatic zones based on lodging, sedimentation index, Hagberg falling number, germination energy and germination test. Limited effect of single application of Asahi Max at the proposed label rate of 0.2 L product/ha could be proven on plant height, length and weight of the roots, weight above ground part of the plant, number of tillers per plant, ears per square meter and grain per ear, tiller and internode length, crop yield, TGW, HLW and protein, starch and gluten content. However, in case of plant height and tiller or internode length, the aim of Asahi Max is to support effects against lodging not by reducing the plant height and tiller or internode length but by improving plant growth and strength, therefore these results need to be taken with caution. Additionally, in case of other parameters, number of trials assessing this parameters were mostly limited and based on the comparability of the efficacy of Asahi Max and that of Asahi SL, when applied at 0.2 L and 0.6 L product/ha rates respectively, it is reasonable to conclude that the proposed label rate of 0.2 L product/ha of Asahi Max regulates those parameters as well as this was proven in practice for many years for the approved Asahi SL.

Results were mostly comparable to those achieved by standard reference product applied at authorised label rates (with the exception of plant height and tiller or internode length, but as mentioned above results of Asahi Max for these parameters need to be taken with caution).

Based on the summarized data, it is therefore considered that claims of Asahi Max as a plant growth regulator applied at the proposed label rate of 0.2 L product/ha per season and according to other label recommendations, are fully supported.

Comments of zRMS:

11 efficacy trials conducted in Poland and the neighboring countries (Germany and Czech Republic) have been submitted to show positive impact of Asahi Max on winter wheat. No significant effect was observed after applied of test product compared to untreated objects in the following parameters: plant height, length and weight of the roots, weight above part of the plant, number of tillers, number of ears, number of grains, tiller length and internode length. Limited efficacy of Asahi Max was detected in case of crop yield and quality parameters of yield. However, the test product improved significantly germination energy and lodging compared to untreated objects and the reference products. Slight better results were visible also in case of sedimentation index and Hagberg falling number.

Taking into account all trial results, Asahi Max at dose rate of 0,2 l/ha once per season can be recommended to use as plant growth regulator, especially to improve germination of seed and to support effects against lodging.

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

The formulation Asahi Max is used as plant growth regulator, and therefore no use towards pest is performed. The resistance of pest is not relevant.

Comments of zRMS:

Accepted. Generally, for prevention of resistance development, the use of resistant varieties, crop-rotation, following good agronomic practice and label recommendations, maintaining plant hygiene, is considered sufficient.

3.4 Adverse effects (KCP 6.4)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

3.4.1.1 Phytotoxicity in sugar beet

Assessments for phytotoxicity and other adverse effects on crop growth and development related to the application of Asahi Max have been carried out at regular intervals following 2 applications of Asahi

Max on a total of 9 efficacy trials conducted between 2008 and 2009 in countries within the Maritime and North-East EPPO climatic zones.

Across these 9 trials, 2 applications of Asahi Max were made when the crop growth stages were within the range of 10 to 14 (BBCH) at first application timings and from 12 to 18 (BBCH) at second application timings. Intervals between applications were within the range of 7-15 day.

Additionally, in 8 of these efficacy trials, assessments for phytotoxicity and other adverse effects on crop growth and development have been carried out at regular intervals following 3 applications of Asahi SL. Based on data presented in Section 3.2.1.2 that demonstrates comparability between the crop safety of Asahi Max and that of Asahi SL, both containing the same amount of the three active substances when applied at 0.2 L and 0.6 L product/ha respectively, efficacy testing with Asahi SL is considered as fully supportive to justify the proposed label claim of 3 applications of Asahi Max at 0.2 L product/ha for use as a plant growth regulator.

Across trials, the crop safety of Asahi Max and/or Asahi SL has been tested under a wide range of climatic and agronomic conditions that are considered to be fully representative of those under which sugar beet are grown in Poland. Trials were carried out on a range of different commercially representative and commonly grown cultivars of sugar beet.

Overall summary of the crop safety of Asahi Max and/or Asahi SL across efficacy trials carried out in sugar beet is given in Table 3.4-1.

Table 3.4-1: Overall summary of the crop safety of Asahi Max and/or Asahi SL across all efficacy trials carried out in sugar beet.

EPPO climatic zone (no. of trials)	Timing	Levels of phytotoxicity related to application of plant growth regulator	Number of trials			
			Asahi Max (9 trials)	Asahi Max (4 trials)	Asahi SL (8 trials)	Atonik SL (8 trials)
			A1+A2	A1+A2	A1+A2+A3	A1+A2
			0.2 L/ha (3.6 g a.i./ha)	0.4 L/ha (7.2 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)
Maritime (1 trial)	Maximum level of symptoms recorded	0%	1	-	-	-
		0.1% to 5%	-	-	-	-
		>5% to 10%	-	-	-	-
		>10% to 5%	-	-	-	-
		>15%	-	-	-	-
	Final assessment timings	0%	1	-	-	-
		0.1% to 5%	-	-	-	-
		>5% to 10%	-	-	-	-
		>10% to 5%	-	-	-	-
		>15%	-	-	-	-
North-East (8 trials)	Maximum level of symptoms recorded	0%	5	1	5	5
		0.1% to 5%	3	3	3	3
		>5% to 10%	-	-	-	-
		>10% to 5%	-	-	-	-
		>15%	-	-	-	-
	Final assessment timings	0%	8	4	8	8
		0.1% to 5%	-	-	-	-
		>5% to 10%	-	-	-	-
		>10% to 5%	-	-	-	-
		>15%	-	-	-	-

Across these trials, Asahi Max applied at the proposed label rate of 0.2 L product/ha in all of these trials, and also at twice this rate (0.4 L product/ha) in 4 of these trials, and Asahi SL applied at the approved label rate of 0.6 L product/ha in 8 of these trials, caused no phytotoxic symptoms or other adverse effects on crop growth and development on any of the efficacy trials carried out in sugar beet.

Based on the absence of effects across trials, it is reasonable to conclude that a up to 3 application of Asahi Max at the proposed label rate of 0.2 L product/ha, and applied according to label recommendations, causes no phytotoxic symptoms in sugar beet.

3.4.1.2 Phytotoxicity in oilseed rape

Assessments for phytotoxicity and other adverse effects on crop growth and development related to the application of Asahi Max have been carried out at regular intervals following 2 applications of Asahi Max on a total of 11 efficacy trials conducted between 2008 and 2009 in countries within the Maritime and North-East EPPO climatic zones.

Across these 11 trials, 2 applications of Asahi Max and Asahi SL were made when the crop growth stages were within the range of 17 to 35 (BBCH) at first application timings and from 31 to 57 (BBCH) at second application timings. Intervals between applications were within the range of 10-16 days.

Whilst no data has been generated in support of demonstrating the crop safety of Asahi Max in spring oilseed rape, plant physiology, agronomic practices and susceptibility to phytotoxicity caused by plant growth regulators can be considered to be very similar between winter and spring oilseed rape. Data from trials carried out in winter oilseed rape are therefore considered to be supportive of demonstrating the crop safety of Asahi Max at the proposed label rate of 0.2 L product/ha in spring oilseed rape.

Across trials, the crop safety of Asahi Max and/or Asahi SL has been tested under a wide range of climatic and agronomic conditions that are considered to be fully representative of those under which winter oilseed rape is grown in Poland. Trials were carried out on a range of different commercially representative and commonly grown cultivars of winter oilseed rape.

Overall summary of the crop safety of Asahi Max and/or Asahi SL across efficacy trials carried out in winter oilseed rape is given in Table 3.4-2.

Table 3.4-2: Overall summary of the crop safety of Asahi Max across all efficacy trials carried out in winter oilseed rape.

EPPO climatic zone (no. of trials)	Timing	Levels of phytotoxicity related to application of plant growth regulator	Number of trials			
			Asahi Max (11 trials)	Asahi Max (4 trials)	Atonik SL (4 trials)	Atonik SL (4 trials)
			A1+A2	A1+A2	A1	A1+A2
			0.2 L/ha (3.6 g a.i./ha)	0.4 L/ha (7.2 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)	0.6 L/ha (3.6 g a.i./ha)
Maritime (3 trials)	Maximum level of symptoms recorded	0%	3	-	-	-
		0.1% to 5%	-	-	-	-
		>5% to 10%	-	-	-	-
		>10% to 5%	-	-	-	-
		>15%	-	-	-	-
	Final assessment timings	0%	3	-	-	-
		0.1% to 5%	-	-	-	-
		>5% to 10%	-	-	-	-
		>10% to 5%	-	-	-	-
		>15%	-	-	-	-
North-East (8 trials)	Maximum level of symptoms recorded	0%	8	4	4	4
		0.1% to 5%	-	-	-	-
		>5% to 10%	-	-	-	-
		>10% to 5%	-	-	-	-
		>15%	-	-	-	-
	Final assessment timings	0%	8	4	4	4
		0.1% to 5%	-	-	-	-
		>5% to 10%	-	-	-	-
		>10% to 5%	-	-	-	-
		>15%	-	-	-	-

Across these trials, Asahi Max applied at the proposed label rate of 0.2 L product/ha in all of these trials, and also at twice this rate (0.4 L product/ha) in 4 of these trials, and Asahi SL applied at the approved label rate of 0.6 L product/ha in 8 of these trials, caused no phytotoxic symptoms or other adverse effects on any of the efficacy trials carried out in winter oilseed rape.

Based on the absence of effects across trials, it is reasonable to conclude that a up to 2 application of Asahi Max at the proposed label rate of 0.2 L product/ha, and applied according to label recommendations, causes no phytotoxic symptoms in oilseed rape.

3.4.1.3 Phytotoxicity in winter wheat

Assessments for phytotoxicity and other adverse effects on crop growth and development related to the application of Asahi Max have been carried out at regular intervals following single application of Asahi Max on a total of 14 11 efficacy trials conducted between 2008 and 2009 in countries within the Maritime and North-East EPPO climatic zones.

Across these 14 11 trials, single application of Asahi Max were made when the crop growth stages were within the range of 24 to 32 (BBCH).

Across trials, the crop safety of Asahi Max and/or Asahi SL has been tested under a wide range of climatic and agronomic conditions that are considered to be fully representative of those under which winter wheat is grown in Poland. Trials were carried out on a range of different commercially representative and commonly grown cultivars of winter wheat.

Overall summary of the crop safety of Asahi Max and/or Asahi SL across efficacy trials carried out in winter wheat is given in Table 3.4-3.

Table 3.4-3: Overall summary of the crop safety of Asahi Max and/or Asahi SL across all efficacy trials carried out in winter wheat.

EPPO climatic zone (no. of trials)	Timing	Levels of phytotoxicity related to application of plant growth regulator	Number of trials				
			Asahi Max (14 11 trials)	Asahi Max (8 5 trials)	Cycoce 1 C5 BASF (6 3 trials)	CCC720 / Stabilan 750 SL (6 trials)	Stabilan 750 SL (8 trials)
			0.2 L/ha (3.6 g a.i./ha)	0.4 L/ha (7.2 g a.i./ha)	2.0 L/ha (920 g a.i./ha)	1.5 L/ha (1080/112 5 g a.i./ha)	2.0 L/ha (1500 g a.i./ha)
Maritime (14 7 trials)	Maximum level of symptoms recorded	0%	14 7	8 3	6 3	4	6
		0.1% to 5%	-	-	-	-	-
		>5% to 10%	-	-	-	-	-
		>10% to 5%	-	-	-	-	-
		>15%	-	-	-	-	-
	Final assessment timings	0%	14 7	8 3	6 3	4	6
		0.1% to 5%	-	-	-	-	-
		>5% to 10%	-	-	-	-	-
		>10% to 5%	-	-	-	-	-
		>15%	-	-	-	-	-
North-East (4 trials)	Maximum level of symptoms recorded	0%	4	2	-	2	2
		0.1% to 5%	-	-	-	-	-
		>5% to 10%	-	-	-	-	-
		>10% to 5%	-	-	-	-	-
		>15%	-	-	-	-	-
	Final assessment timings	0%	4	2	-	2	2
		0.1% to 5%	-	-	-	-	-

EPPO climatic zone (no. of trials)	Timing	Levels of phytotoxicity related to application of plant growth regulator	Number of trials				
			Asahi Max (11 trials)	Asahi Max (5 trials)	Cycoce 1 C5 BASF (3 trials)	CCC720 / Stabilan 750 SL (6 trials)	Stabilan 750 SL (8 trials)
			0.2 L/ha (3.6 g a.i./ha)	0.4 L/ha (7.2 g a.i./ha)	2.0 L/ha (920 g a.i./ha)	1.5 L/ha (1080/112 5 g a.i./ha)	2.0 L/ha (1500 g a.i./ha)
			>5% to 10%	-	-	-	-
			>10% to 5%	-	-	-	-
			>15%	-	-	-	-

Across these trials, Asahi Max applied at the proposed label rate of 0.2 L product/ha in all of these trials, and also at twice this rate (0.4 L product/ha) in 8 of these trials, and Asahi SL applied at the approved label rate of 0.6 L product/ha in 8 of these trials, caused no phytotoxic symptoms or other adverse effects on any of the efficacy trials carried out in winter wheat.

Based on the absence of effects across trials, it is reasonable to conclude that a single application of Asahi Max at the proposed label rate of 0.2 L product/ha, and applied according to label recommendations, causes no phytotoxic symptoms in winter wheat.

Comments of zRMS:

Slight phytotoxicity symptoms were noted in 3 out of 9 efficacy trials on sugar beet: small clapping deformations of beet plants in the trial EUR_MNN_BEAVA_PL_2999, smaller plants and discolouration on the leaves in the trial EUR_MNN_BEAVA_PL_2998, smaller plants more upright and with small spoon-shaped leaves in the trial EUR_MNN_BEAVA_PL_2997. However, these symptoms were transient and no negative impact on yield was presented. The reference product caused similar effect.

No phytotoxicity symptoms were observed after double application of Asahi Max at dose rate of 0,2 l/ha on **sugar beet**, winter oilseed rape and winter wheat in all submitted efficacy trials, either for N and 2N.

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

3.4.2.1 Crop yield in sugar beet

Evaluations of crop yield have been carried out at normal commercial harvest following 2 applications of Asahi Max on a 4 of the 9 efficacy trials conducted in 2008 in North-East EPPO climatic zone (Poland).

Across these 4 trials, 2 applications of Asahi Max were made when the crop growth stages were within the range of 12 to 14 (BBCH) at first application timings and from 12 to 18 (BBCH) at second application timings. Intervals between applications were within the range of 12-15 days.

Across trials, the potential impact of Asahi Max on crop yield has been tested under a wide range of climatic and agronomic conditions that are considered to be fully representative of those under which sugar beet are grown in Poland. Trials were carried out on a range of different commercially representative and commonly grown cultivars of sugar beet.

Two applications of Asahi Max applied at the proposed label rate of 0.2 L product/ha and at twice this rate (0.4 L product/ha) caused no phytotoxic symptoms or pronounced adverse effects on crop yield on 3 of the 4 efficacy trials carried out in sugar beet. On the other 1 trial, crop yield in the untreated check with herbicide spraying was higher than in the trial with handweeding. Taking into account the limited selectivity of herbicide treatments in sugar beet, increased crop yield following herbicide treatment is unexpected and assessment data have therefore been not considered to be valid.

Additionally, as presented in section 3.2.3.1.2.2, three applications of Asahi SL applied at the approved label rate of 0.6 L product/ha caused no phytotoxic symptoms or pronounced adverse effects on crop yield on any of the 8 efficacy trials carried out in sugar beet. Based on data presented in Section 3.2.1.2 that demonstrates comparability between the crop safety of Asahi Max and that of Asahi SL, both containing the same amount of three the same active substances when applied at 0.2 L and 0.6 L product/ha respectively, data for Asahi SL are fully supportive for 3 applications of Asahi Max at proposed label rate of 0.2 L product/ha.

Based on the absence of adverse effects across trials, it is reasonable to conclude that a up to 3 applications of Asahi Max at the proposed label rate of 0.2 L product/ha, and applied according to label recommendations, has no adverse impact on crop yield on sugar beet.

3.4.2.2 Crop yield in oilseed rape

Evaluations of crop yield have been carried out at normal commercial harvest following 2 applications of Asahi Max on a 4 of the 11 efficacy trials conducted in 2008 in North-East EPPO climatic zone (Poland).

Across these 4 trials, 2 applications of Asahi Max were made when the crop growth stages were within the range of 29 to 32 (BBCH) at first application timings and from 51 to 55 (BBCH) at second application timings. Intervals between applications were within the range of 10-16 days.

Across trials, the potential impact of Asahi Max on crop yield has been tested under a wide range of climatic and agronomic conditions that are considered to be fully representative of those under which winter oilseed rape is grown in Poland. Trials were carried out on a range of different commercially representative and commonly grown cultivars of winter oilseed rape.

Whilst no data has been generated in support of demonstrating the absence of adverse impact on crop yield in spring oilseed rape, plant physiology, agronomic practices and susceptibility to phytotoxicity caused by plant growth regulators can be considered to be very similar between winter and spring oilseed rape. Data from trials carried out in winter oilseed rape are therefore considered to be supportive of demonstrating the absence of adverse impact on crop yield of Asahi Max at the proposed label rate of 0.2 L product/ha in spring oilseed rape.

Two applications of Asahi Max applied at the proposed label rate of 0.2 L product/ha and at twice this rate (0.4 L product/ha) caused no pronounced adverse effects on crop yield on any of the 4 efficacy trials carried out in winter oilseed rape.

Based on the absence of adverse effects across trials, it is reasonable to conclude that at up to 2 applications of Asahi Max at the proposed label rate of 0.2 L product/ha, and applied according to label recommendations, has no adverse impact on crop yield on oilseed rape.

3.4.2.3 Crop yield in winter wheat

Evaluations of crop yield have been carried out at normal commercial harvest following single application of Asahi Max on a 8 of the 14 efficacy trials conducted between 2010 and 2021. Of these trials, 6 were carried out in the Maritime EPPO climatic zone (3 in Germany, 3 in France) and 2 were carried out in the North-East climatic zone (Poland).

Across these 8 trials, single application of Asahi Max was made when the crop growth stages were within the range of 29-30 to 31 (BBCH).

Across trials, the potential impact of Asahi Max on crop yield has been tested under a wide range of climatic and agronomic conditions that are considered to be fully representative of those under which winter wheat is grown in Poland. Trials were carried out on a range of different commercially representative and commonly grown cultivars of winter wheat.

Single application of Asahi Max applied at the proposed label rate of 0.2 L product/ha and at twice this rate (0.4 L product/ha) caused no pronounced adverse effects on crop yield on any of the 8 efficacy trials carried out in winter wheat.

Based on the absence of adverse effects across trials, it is reasonable to conclude that single application of Asahi Max at the proposed label rate of 0.2 L product/ha, and applied according to label recommendations, has no adverse impact on crop yield on winter wheat.

Comments of zRMS:

The assessment of effects on yield of treated plants has been provided in the chapter 3.2.3. Asahi Max applied at dose rate of 0,2 l/ha was safe for treated crops and no negative impact on yield was observed. Significant superior results were noted on sugar beet and winter oilseed rape compared to the untreated objects.

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

3.4.3.1 Quality of the harvested roots in sugar beet

Evaluations of quality parameters of the harvested roots have been carried out following 2 applications of Asahi Max on a 4 of the 9 efficacy trials conducted in 2008 in North-east EPPO climatic zone (Poland).

Across these 4 trials, 2 applications of Asahi Max were made when the crop growth stages were within the range of 12 to 14 (BBCH) at first application timings and from 12 to 18 (BBCH) at second application timings. Intervals between applications were within the range of 12-15 days.

Across trials, the potential impact of Asahi Max on quality of the roots has been tested under a wide range of climatic and agronomic conditions that are considered to be fully representative of those under which sugar beet are grown across the EU Central Registration zone. Trials were carried out on a range of different commercially representative and commonly grown cultivars of sugar beet.

Two applications of Asahi Max applied at the proposed label rate of 0.2 L product/ha and at twice this rate (0.4 L product/ha) caused no phytotoxic symptoms or pronounced adverse effects or pronounced adverse effects on various quality of the harvested roots, on any of the trials carried out in sugar beet. On 1 of the trial, biological sugar yield in the untreated check with herbicide spraying was higher than in the trial with handweeding. Taking into account the limited selectivity of herbicide treatments in sugar beet, increased biological sugar yield following herbicide treatment is unexpected and assessment data have therefore been not considered to be valid.

~~Additionally, as presented in section 3.2.3.1.2.2, three applications of Asahi SL applied at the approved label rate of 0.6 L product/ha caused no phytotoxic symptoms or pronounced adverse effects on most of the various quality parameters of the 8 efficacy trials carried out in sugar beet. Based on data presented in Section 3.2.1.2 that demonstrates comparability between the crop safety of Asahi Max and that of Asahi SL, both containing the same amount of three the same active substances when applied at 0.2 L and 0.6 L product/ha respectively, data for Asahi SL are fully supportive for demonstration of the crop safety of 3 applications of Asahi Max at proposed label rate of 0.2 L product/ha.~~

Based on the absence of effects across trials, it is reasonable to conclude that a up to ~~3~~² application of Asahi Max at the proposed label rate of 0.2 L product/ha, and applied according to label recommendations, has no adverse impact on the quality of plants or plant products in sugar beet.

Comments of zRMS:

Based on the trial results presented in chapter *Efficacy tests*, it can be concluded that Asahi Max at dose rate of 0,2 l/ha used at max 2 applications is safe for sugar beet yield. No negative impact on quality parameters of harvested roots was noted in the submitted trials. Higher content of potassium, sodium and ammonium, especially in case of hand weeding, were noted for the test product. No significant differences between test and reference products have been observed in the efficacy trials.

3.4.3.2 Quality of the harvested seeds in oilseed rape

Evaluations of quality parameters of the harvested seeds have been carried out following 2 applications of Asahi Max on a 4 of the 11 efficacy trials conducted in 2008 in North-East EPPO climatic zone (Poland).

Across these 4 trials, 2 applications of Asahi Max were made when the crop growth stages were within the range of 29 to 32 (BBCH) at first application timings and from 51 to 55 (BBCH) at second application timings. Intervals between applications were within the range of 10-16 days.

Across trials, the potential impact of Asahi Max on quality of the seeds has been tested under a wide range of climatic and agronomic conditions that are considered to be fully representative of those under which winter oilseed rape is grown in Poland. Trials were carried out on a range of different commercially representative and commonly grown cultivars of winter oilseed rape.

Whilst no data has been generated in support of demonstrating the absence of adverse impact on the quality of the harvested grain in spring oilseed rape, plant physiology, agronomic practices and susceptibility to phytotoxicity caused by plant growth regulators can be considered to be very similar between winter and spring oilseed rape. Data from trials carried out in winter oilseed rape are therefore considered to be supportive of demonstrating the absence of adverse impact on the quality of the harvested grain of Asahi Max at the proposed label rate of 0.2 L product/ha in spring oilseed rape.

Two applications of Asahi Max applied at the proposed label rate of 0.2 L product/ha and at twice this rate (0.4 L product/ha) caused no phytotoxic symptoms or pronounced adverse effects or pronounced adverse effects on various quality of the harvested seeds, on any of the 4 efficacy trials carried out in winter oilseed rape.

Based on the absence of effects across trials, it is reasonable to conclude that a up to 2 application of Asahi Max at the proposed label rate of 0.2 L product/ha, and applied according to label recommendations, has no adverse impact on the quality of plants or plant products in oilseed rape.

Comments of zRMS:

Based on the trial results presented in chapter *Efficacy tests*, it can be concluded that Asahi Max at dose rate of 0,2 l/ha used at max 2 applications is safe for oilseed rape yield. No negative impact on quality parameters of harvested seeds has been noted in the submitted trials. Higher oil content and TGW were visible for treated objects, compared to untreated check. No significant differences between test and reference products have been observed in the efficacy trials.

3.4.3.3 Quality of the harvested grain in winter wheat

Evaluations of quality parameters of the harvested grain have been carried out following single application of Asahi Max on a 8 5 of the 14 11 efficacy trials conducted between 2010 and 2021. Of these trials, 6 3 were carried out in the Maritime EPPO climatic zone (3 in Germany, 3 in France) and 2 were carried out in the North-East climatic zone (Poland).

Across these 8 5 trials, single application of Asahi Max was made when the crop growth stages were within the range of 29-30 to 31 (BBCH).

Across trials, the potential impact of Asahi Max on quality of the seeds has been tested under a wide range of climatic and agronomic conditions that are considered to be fully representative of those under which winter wheat is grown in Poland. Trials were carried out on a range of different commercially representative and commonly grown cultivars of winter wheat.

Single application of Asahi Max applied at the proposed label rate of 0.2 L product/ha and at twice this rate (0.4 L product/ha) caused no phytotoxic symptoms or pronounced adverse effects or pronounced adverse effects on various quality of the harvested seeds, on any of the 8 5 efficacy trials carried out in winter wheat.

Based on the absence of effects across trials, it is reasonable to conclude that single application of Asahi Max at the proposed label rate of 0.2 L product/ha, and applied according to label recommendations, has no adverse impact on the quality of plants or plant products in winter wheat.

Comments of zRMS:

Based on the trial results presented in chapter *Efficacy tests*, it can be concluded that Asahi Max at dose rate of 0,2 l/ha used once per growing season is safe for winter wheat yield. No negative impact on quality parameters of harvested grains has been noted in the submitted trials. Higher protein, starch and gluten content were visible for treated objects, compared to untreated check. Also positive effect in case of TGW and HLW was presented for Asahi Max. No significant differences between test and reference products have been observed in the efficacy trials.

3.4.4 Effects on transformation processes (KCP 6.4.4)

Products containing sodium *p*-nitrophenolate, sodium *o*-nitrophenolate and sodium 5-nitroguaiacolate have been approved and used for a number of years in various EU countries as a plant growth regulators in many crops such as: oilseed rape, sugar beet, tobacco, fruit plants, vegetable and ornamental plants.

Furthermore, Asahi Max is a new formulation providing the same amount of the three active substances as Asahi SL, currently registered for use as a plant growth regulator in various crops and EU countries, when applied at 0.2 L and 0.6 L product/ha respectively. Asahi SL has been used for many years in various crops and EU countries, including those relevant for this application for the approval of Asahi Max in the EU Central Registration zone, and no cases of negative effects on the plant processing have been reported.

It is therefore reasonable to conclude that Asahi Max applied at the proposed label rate of 0.6 L product/ha and applied according to label recommendations, has no effects on relevant processing procedures and causes no taints on sugar beet, oilseed rape and winter wheat crops.

Comments of zRMS:

Accepted.

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

Germination testing has been carried out on seed sampled at commercial harvest following a single application of Asahi Max at the proposed label rate of 0.2 L product/ha from 3 of the efficacy trials carried out between 2010 and 2021 in Czech Republic on winter wheat.

Single applications of Asahi Max were made in the early spring on all trials, when crop growth stages were in the range of 28-32 (BBCH).

A single application of Asahi Max at the proposed label rate of 0.2 L product/ha, had no consistent or significant adverse effects on the germination of progeny seed, compared to the untreated control, for progeny seed sampled at commercial harvest from 3 trials on winter wheat.

Based on the absence of effects adverse effects on germination of progeny seed sampled from trials, it is therefore reasonable to conclude that a single application of Asahi Max at the proposed label rate of 0.2 L product/ha, and applied according to other label recommendations, has no adverse impact on progeny seed in winter wheat and no restrictions are necessary regarding use on crops grown for seed production.

Comments of zRMS:

In 3 out of 11 efficacy trials in winter wheat, Asahi Max at 0,2 l/ha showed positive impact on germination energy and germination test increase with results of 128,8% and 128,5% respectively. No reference products were used in these trials. Taking into account the submitted results, it can be considered that Asahi Max is safe for plant parts used for propagation.

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

3.5.1 Impact on succeeding crops (KCP 6.5.1)

As the active substances in Asahi Max, sodium *p*-nitrophenolate, sodium *o*-nitrophenolate and sodium 5-nitroguaiacolate, are known to have no significant herbicidal activity. Products containing sodium *p*-nitrophenolate, sodium *o*-nitrophenolate and sodium 5-nitroguaiacolate have been authorised in a number of EU countries and worldwide for a number of years and are proven through widespread commercial use to have no adverse impact on succeeding crops.

Furthermore, Asahi Max is a new formulation providing the same amount of the three active substances as Asahi SL, currently registered for use as a plant growth regulator in various crops and EU countries, when applied at 0.2 L and 0.6 L product/ha respectively. Asahi SL has been used for many years in various crops and EU countries, including those relevant for this application for the approval of Asahi Max in the EU Central Registration zone, and no adverse impact on succeeding crops has been reported.

Comments of zRMS:

Accepted. The EPPO guideline PP 1/207(2) is standard describing methods used to examine whether the active substance of a plant protection product, in particular a herbicide, causes negative effects on crops grown as rotational or replacement crops after a crop treated with that product. Furthermore, no negative symptoms on intended crops have been observed in the submitted trials. Based on the previous report appropriate for Asahi SL, it can be considered that Asahi Max is safe also for other plants and no negative impact on succeeding crops is expected.

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

As the active substances in Asahi Max, sodium *p*-nitrophenolate, sodium *o*-nitrophenolate and sodium 5-nitroguaiacolate, are known to have no significant herbicidal activity. Products containing sodium *p*-nitrophenolate, sodium *o*-nitrophenolate and sodium 5-nitroguaiacolate have been authorised in a number of EU countries and worldwide for a number of years and are proven through widespread commercial use to have no significant risk with regard to adverse impact on other plants, including adjacent crops.

Furthermore, Asahi Max is a new formulation providing the same amount of the three active substances as Asahi SL, currently registered for use as a plant growth regulator in various crops and EU countries, when applied at 0.2 L and 0.6 L product/ha respectively. Asahi SL has been used for many years in various crops and EU countries, including those relevant for this application for the approval of Asahi Max in the EU Central Registration zone, and no significant risk with regard to adverse impact on other plants, including adjacent crops, has been reported.

Comments of zRMS:

Accepted.

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

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

Comments of zRMS:

Accepted.

Compatibility with current management practices including IPM


Asahi Max is a plant growth regulator and no use towards pest is performed, therefore compatibility with current management practices, including IPM practices, is not a relevant consideration.

3.6 Other/special studies

No additional studies are summarised.

3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

Organisation	Country	Trial numbers						GEP certification		
		2008	2009	2010	2011	2021	Total	Valid From	Valid To	Link
ANADIAG S.A. Oddział w Polsce	Poland	-	1	-	-	-	1	28/05/2007	27/05/2012	1d69156c05c
AGROSTAT SP. zo.o., Zalesie 12, Jaraczewo, Poland	Poland	1	-	-	-	-	1	11/12/2006	11/12/2011	1d69156c070
UP Poznań	Poland	1	1	-	-	-	2	14/04/2008	14/04/2013	1d691f0dc46
AGROSTAT GmbH, In den Gruben 6, Herrentierbach	Germany	4	-	-	-	-	4	28/10/2005	n/d	 GEP_certificate_AGR OSTAT GmbH, Germa
BIOTEK AGRICULTURE POLSKA SP. Z O.O.	Poland	5	5	-	2	-	12	01/01/2009	01/01/2014	1d69156c062
Research and Education Center Gorzyń	Poland	1	1	-	-	-	2	14/04/2008	14/04/2013	1d691c7a966
AGRECO Sp. z o.o.	Poland	-	-	-	-	2	2	16/04/2018	15/04/2023	1d6c9dfbc75
A&W FieldScreen GmbH	Germany	-	-	-	3	-	3	7-Jul-2008	7-Jul-2013	1d6c9dfb97c
		-	-	-	-	1	1	05/06/2018	06/06/2023	1d6c9dfbc0c
PHYLIAE	France	-	-	-	3	-	3	30/04/2010	30/04/2015	1d6c9dfb802
Zsusebni stanice Rymarov s.r.o.	Czech Republic	-	-	1	-	-	1	27/04/2009	30/09/2016	1d6c9dfb9e8
INF, v.o.s., Uhersky Ostroh	Czech Republic	-	-	1	-	-	1	02/06/2009	31/12/2020	1d6c9dfb667
Zkusebni stanice Kluky, spol. S r.o.	Czech Republic	-	-	1	-	-	1	08/03/2006	31/03/2011	1d6c9dfb39b
Total	-	12	8	3	8	3	34			

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

List of data submitted and relied on

Annex point	Author(s)	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 6.1/001 KCP 6.2/001 KCP 6.4.1/001	B. Tiggemann	2008	Selectivity&efficacy/CAL97R01/Anti-stress bioagent/BEAVA/ Germany 2008 AGROSTAT GmbH, In den Gruben 6, Herrentierbach EUR_MNN_BEAVA_DE_2771 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/002 KCP 6.2/002 KCP 6.4.1/002 KCP 6.4.2/001 KCP 6.4.3/001	Agnieszka Kukuła-Młynarczyk	2008	The influence of biostimulator ASAHI SL (CAL97R01) on sugar beet quantity and quality BIOTEK AGRICULTURE POLSKA SP. Z O.O. EUR_MNN_BEAVA_PL_2997 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/003 KCP 6.2/003 KCP 6.4.1/003 KCP 6.4.2/002 KCP 6.4.3/002	Agnieszka Kukuła-Młynarczyk	2008	The influence of biostimulator ASAHI SL (CAL97R01) and ALS08R369 on sugar beet quantity and quality BIOTEK AGRICULTURE POLSKA SP. Z O.O. EUR_MNN_BEAVA_PL_2998 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/004 KCP 6.2/004 KCP 6.4.1/004 KCP 6.4.2/003 KCP 6.4.3/003	Wojciech Cieśliski	2008	The influence of Asahi SL (CAL97R01) and ALS08R369 on quality and quantity of sugar beet yielding Uniwersytet Przyrodniczy Poznań EUR_MNN_BEAVA_PL_2999 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/005 KCP 6.2/005 KCP 6.4.1/005 KCP 6.4.2/004 KCP 6.4.3/004	Magdalena Zaremba	2008	Influence of ASAHI SL (CAL97R01), ALS08R369 o yield parameters in BEAVA, Poland 2008 AGROSTAT SP. zo.o., Zalesie 12, Jaraczewo, Poland EUR_MNN_BEAVA_PL_3000 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.

Annex point	Author(s)	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 6.1/006 KCP 6.2/006 KCP 6.4.1/006	Agnieszka Kukuła- Młynarczyk	2009	The influence of Asahi SL (CAL97R01) and ALS08R369 on sugar beet quantity and quality BIOTEK AGRICULTURE POLSKA SP. Z O.O. EUR_MNN_BEAVA_PL_3290 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/007 KCP 6.2/007 KCP 6.4.1/007	Agnieszka Kukuła- Młynarczyk	2009	The influence of Asahi SL (CAL97R01) and ALS08R369 on sugar beet quantity and quality BIOTEK AGRICULTURE POLSKA SP. Z O.O. EUR_MNN_BEAVA_PL_3291 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/008 KCP 6.2/008 KCP 6.4.1/008	Robert Idziak	2009	The influence of biostimulator ASAHI SL (CAL97R01) and ALS08R369 on yield and quality of sugar beet Uniwersytet Przyrodniczy Poznań EUR_MNN_BEAVA_PL_3292 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/009 KCP 6.2/009 KCP 6.4.1/009	Jacek Jatzak	2009	Evaluation of the effect biostimulators Asahi SL (CAL97R01) and ALS08R369 on development, increase of yield and yield quality of sugar beet ANADIAG S.A. Oddział w Polsce EUR_MNN_BEAVA_PL_3293 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/010 KCP 6.2/010 KCP 6.4.1/010	Bernd Tiggemann	2008	Selectivity&efficacy/CAL97R01/Anti-stress bioagent/BRSNW/ Germany 2008 (EUR_MNN_BRSNW_DE_2780_ALS08R02-01_R7371541) AGROSTAT GmbH, In den Gruben 6, Herrentierbach EUR_MNN_BRSNW_DE_2780 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/011 KCP 6.2/011 KCP 6.4.1/011	Bernd Tiggemann	2008	Selectivity&efficacy/CAL97R01/Anti-stress bioagent/BRSNW/ Germany 2008 (EUR_MNN_BRSNW_DE_2781_ALS08R02-02_R7321541) AGROSTAT GmbH, In den Gruben 6, Herrentierbach EUR_MNN_BRSNW_DE_2781 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.

Annex point	Author(s)	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 6.1/012 KCP 6.2/012 KCP 6.4.1/012	Bernd Tiggemann	2008	Selectivity&efficacy/CAL97R01/Anti-stress bioagent/BRSNW/ Germany 2008 (EUR_MNN_BRSNW_DE_2782_ALS08R02-03_R7311541) AGROSTAT GmbH, In den Gruben 6, Herrentierbach EUR_MNN_BRSNW_DE_2782 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/013 KCP 6.2/013 KCP 6.4.1/013 KCP 6.4.2/005 KCP 6.4.3/005	Wojciech Cieřlicki	2008	The influence of Asahi SL (CAL97R01) and ALS08R369 on quality and quantity of winter rape yielding Research and Education Center Gorzyń EUR_MNN_BRSNW_PL_3038 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/014 KCP 6.2/014 KCP 6.4.1/014 KCP 6.4.2/006 KCP 6.4.3/006	Agnieszka Kukula- Młynarczyk	2008	The influence of biostimulator ASAHI SL (CAL97R01) and ALS08R369 on Oilseed Rape quantity and quality BIOTEK AGRICULTURE POLSKA SP. Z O.O. EUR_MNN_BRSNW_PL_3039 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/015 KCP 6.2/015 KCP 6.4.1/015 KCP 6.4.2/007 KCP 6.4.3/007	Agnieszka Kukula- Młynarczyk	2008	The influence of biostimulator ASAHI SL (CAL97R01) ALS08R369 on Oilseed Rape quantity and quality BIOTEK AGRICULTURE POLSKA SP. Z O.O. EUR_MNN_BRSNW_PL_3040 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/016 KCP 6.2/016 KCP 6.4.1/016 KCP 6.4.2/008 KCP 6.4.3/008	Agnieszka Kukula- Młynarczyk	2008	The influence of biostimulator ASAHI SL (CAL97R01) and ALS08R369 on Oilseed Rape quantity and quality BIOTEK AGRICULTURE POLSKA SP. Z O.O. (EUR_MNN_BRSNW_PL_3041 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/017 KCP 6.2/017 KCP 6.4.1/017	Wojciech Cieřlicki	2009	The influence of ASAHI SL (CAL97R01) and ALS08R369 on quantity and quality of winter rape yielding Research and Education Center Gorzyń EUR_MNN_BRSNW_PL_3286 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.

Annex point	Author(s)	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 6.1/018 KCP 6.2/018 KCP 6.4.1/0118	Agnieszka Kukuła- Młynarczyk	2009	The influence of biostimulator ASAHI SL (CAL97R01) and ALS08R369 on winter Oilseed Rape quantity and quality BIOTEK AGRICULTURE POLSKA SP. Z O.O. EUR_MNN_BRSNW_PL_3287 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/019 KCP 6.2/019 KCP 6.4.1/019	Agnieszka Kukuła- Młynarczyk	2009	The influence of biostimulator ASAHI SL (CAL97R01) and ALS08R369 on Winter Oilseed Rape quantity and quality BIOTEK AGRICULTURE POLSKA SP. Z O.O. EUR_MNN_BRSNW_PL_3288 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/020 KCP 6.2/020 KCP 6.4.1/020	Agnieszka Kukuła- Młynarczyk	2009	The influence of biostimulator ASAHI SL (CAL97R01) and ALS08R369 on Winter Oilseed Rape quantity and quality BIOTEK AGRICULTURE POLSKA SP. Z O.O. EUR_MNN_BRSNW_PL_3289 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/021 KCP 6.2/021 KCP 6.4.1/021	Katarzyna Furman- Fratczak	2021	Efficacy of ARY-0469-01 and ARY-0469-01 in winter wheat, 2021 AGRECO Sp. z o.o. AE21-WHEAT-01 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/022 KCP 6.2/022 KCP 6.4.1/022	Katarzyna Furman- Fratczak	2021	Efficacy of ARY-0469-01 and ARY-0469-01 in winter wheat, 2021 AGRECO Sp. z o.o. AE21-WHEAT-02 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/023 KCP 6.2/023 KCP 6.4.1/023	Birgit Veckenstedt	2021	Effect of ARY-0469-01 and ARY-0469-04 on the spring crop regeneration, tillering and supporting effect against lodging and on yield and quality in winter wheat A&W FieldScreen GmbH AE21-WHEAT-03 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.

Annex point	Author(s)	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 6.1/024 KCP 6.2/024 KCP 6.4.1/024 KCP 6.4.5/001	Jan Ksiazkiewicz	2010	Growth regulator / Quality of harvested product / winter wheat / GEP INF, v.o.s., zkusebni pracoviiste Uhersky Ostroh EUR_MNN_TRZAW_CZ_4103 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/025 KCP 6.2/025 KCP 6.4.1/025 KCP 6.4.5/002	Milena Bernardova	2010	Growth regulator / efficacy, growth regulation effect / winter wheat / GEP Zkusebni stanice Kluky EUR_MNN_TRZAW_CZ_4104 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/026 KCP 6.2/026 KCP 6.4.1/026 KCP 6.4.5/003	Antonin Ruzicka	2010	Growth regulator, winter wheat, GEP Zkusebni stanice Rymarov s.r.o. EUR_MNN_TRZAW_CZ_4105 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/027 KCP 6.2/027 KCP 6.4.1/027 KCP 3.4.2/009 KCP 3.4.3/009	Birgit Veckenstedt	2020	REGULATOR/WINTER WHEAT/ANTI- LODGING/EFFICACY/REGISTRATION A&W FieldScreen GmbH EUR_MNN_TRZAW_DE_4351 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/028 KCP 6.2/028 KCP 6.4.1/028 KCP 6.4.2/010 KCP 6.4.3/010	Birgit Veckenstedt	2020	REGULATOR/WINTER WHEAT/ANTI- LODGING/EFFICACY/REGISTRATION A&W FieldScreen GmbH EUR_MNN_TRZAW_DE_4352 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/029 KCP 6.2/029 KCP 6.4.1/029 KCP 6.4.2/011 KCP 6.4.3/011	Birgit Veckenstedt	2020	REGULATOR/WINTER WHEAT/ANTI- LODGING/EFFICACY/REGISTRATION A&W FieldScreen GmbH EUR_MNN_TRZAW_DE_4353 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.

Annex point	Author(s)	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 6.1/030 KCP 6.2/030 KCP 6.4.1/030 KCP 6.4.2/012 KCP 6.4.3/012	Yannis TALLOT	2011	Essai efficacité contre la verse en culture de blé tendre Produit testé : ARY-0469-04 SARL PHYLIAE EUR_MNN_TRZAW_FR_4266 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/031 KCP 6.2/031 KCP 6.4.1/031 KCP 6.4.2/013 KCP 6.4.3/013	Yannis TALLOT	2011	GROWTH REGULATOR / LODGING OF CEREALS, WINTER WHEAT, 2011 SARL PHYLIAE EUR_MNN_TRZAW_FR_4267 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/032 KCP 6.2/032 KCP 6.4.1/032 KCP 6.4.2/014 KCP 6.4.3/014	Jean-Pierre Rivet	2011	Essai efficacité contre la verse en culture de blé tendre Produit testé : ARY-0469-04 SARL PHYLIAE EUR_MNN_TRZAW_FR_4268 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/033 KCP 6.2/033 KCP 6.4.1/033 KCP 6.4.2/015 KCP 6.4.3/015	KATARZYNA FURMAN-FRATCZAK	2011	ARY-0469-04/REGULATOR/WINTER WHEAT/ANTI- LODGING/EFFICACY/REGISTRATION BIOTEK AGRICULTURE POLSKA Sp. z o.o. POL_MNN_TRZAW_4608 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/034 KCP 6.2/034 KCP 6.4.1/034 KCP 6.4.2/016 KCP 6.4.3/016	Krzysztof Wozniak	2011	The evaluation of efficacy and selectivity of ARY-0469-04 on winter wheat Biotek Agriculture Sp. z o.o. POL_MNN_TRZAW_4609 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Source Company Report No. GLP or GEP status Published or Unpublished Syngenta File No.	Vertebrate study Y/N	Owner
KCP 6.1/030 KCP 6.2/030 KCP 6.4.1/030 KCP 6.4.2/012 KCP 6.4.3/012	Yannis TALLOT	2011	Essai efficacité contre la verse en culture de blé tendre Produit testé : ARY-0469-04 SARL PHYLIAE EUR_MNN_TRZAW_FR_4266 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/031 KCP 6.2/031 KCP 6.4.1/031 KCP 6.4.2/013 KCP 6.4.3/013	Yannis TALLOT	2011	GROWTH REGULATOR / LODGING OF CEREALS, WINTER WHEAT, 2011 SARL PHYLIAE EUR_MNN_TRZAW_FR_4267 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.
KCP 6.1/032 KCP 6.2/032 KCP 6.4.1/032 KCP 6.4.2/014 KCP 6.4.3/014	Jean-Pierre Rivet	2011	Essai efficacité contre la verse en culture de blé tendre Produit testé : ARY-0469-04 SARL PHYLIAE EUR_MNN_TRZAW_FR_4268 GEP Unpublished	Y	Asahi Chemical Europe s.r.o.