FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: CHR/H/IMA 40 SL

Product name(s):

Mazzam 40 SL

Zemax 40 SL

Chemical active substance:

Imazamox, 40 g/L

Central Zone

Zonal Rapporteur Member State: Poland

Co-Rapporteur Member State: Hungary, Romania, Slovakia

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: 09.2022

Update: 08.2023

MS Finalisation date: 12/07/2024

Version history

When	What
January 2023	Dossier sent for evaluation
August 2023	Applicant update
March 2024	Additional information provided by the Applicant (change in GAP)
April 2024	zRMS evaluation of dRR
July 2024	Final version prepared by zRMS after Commenting period

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New, not previously evaluated information and studies are highlighted in yellow.

zRMS comments:
This report has been completed by the Applicant.
The text highlighted in grey was provided by the zRMS.
The changes indicated in green were made by the Applicant in March 2024.

7 Metabolism and residue data (KCA section 6)

Considering winter oilseed rape magnitude of residue studies we are obliged to relied upon following studies taking account that according to Regulation (EC) No 1107/2009 Article 59 Data protection: The period of data protection is 30 months starting at the date of renewal in accordance to art. 43 in that Member State. Renewal of the product in Poland was in 20.11.2017 (R-45/2017), therefore data protection is over, and other applicants can refer to studies performed during inclusion and extensions of uses of the product Clentiga 262.5 SC.

7.1 Summary and zRMS Conclusion

Stability
According to the EFSA Journal 2016;14(4):4432 imazamox and CL 263284 are stable in high water and high starch content commodity for 48 months and 44 months in high oil content commodities. CL 189215 is stable in high water-and and in high oil content commodities for 18 and 24 months respectively.CL 312622 is stable in high water content commodity for 18 months. According to the study provided by the Applicant imazamox, CL 263284 and CL 189215 are stable in dry commodities (peas) for 200 days.
The data presented cover the uses accepted in the GAP for CHR/H/IMA 40 SL.
Additional studies are not required.

Nature of residue in plants
The Applicant did not provide new studies. Data on metabolism in crops evaluated at EU level are sufficient for CHR/H/IMA 40 SL authorization.
Imazamox, its hydroxymethyl metabolite (CL 263284) and its glucose conjugate (CL 189215) are relevant plant metabolites. In rotational crops–spinach, radish and wheat–grown in the soil treated at a rate of 75 g/ha, the TRRs were low, except in wheat hay, straw and grains. Only parent imazamox and its hydroxymethyl metabolite were identified and thus the peer review concluded that metabolism in rotational crops proceeds in a similar pathway as in primary crops (EFSA, 2016).
Imazamox is stable under conditions representing pasteurisation, boiling and sterilisation. Due to similarity of structure between imazamox and CL 263284 it can be assumed that metabolite CL 263284 will be stable under standard hydrolysis conditions. The residues definition proposed for plants is also applicable to processed commodities.
Residue definition is limited to the pulses, oilseeds and cereals/grass crop groups.
Plan reside definition for monitoring (Reg. (EU) 2021/2202): imazamox (sum of imazamox and its salts, expressed as imazamox)
Plant residue definition for risk assessment (EFSA Journal 2016;14(4):4432): sum of imazamox, CL 263284, and CL 189215, expressed as imazamox – Provisional pending the conclusions on the toxicological properties of metabolite CL 263284 and its glucose conjugate CL 189215.
Conversion factors (monitoring to risk assessment):
1.9 for sunflower seeds (derived from residue trials)
2 for alfalfa (derived from metabolism study).

Nature of residue in livestock
The Applicant did not provide new studies. Data on metabolism in crops evaluated at EU level are sufficient for CHR/H/IMA 40 SL authorization. However, it should be noted that the Applicant is obliged

to refer to appropriate studies (even if they have already been evaluated at EU level) and not only EFSA opinions.
According to the EFSA Journal 2016;14(4):4432: Different livestock studies on goat and hens were submitted where animals were dosed over 7 consecutive days either with 14C-imazamox or with the hydroxymethyl-14C-metabolite at low (2 mg/kg feed) and high (10 mg/kg feed) dose rates. Studies with the diacid-14C-metabolite were also provided where poultries were dosed at 0.2 and 10 mg/kg feed and goats at 3 and 33 mg/kg feed over 5 consecutive days. In all animal matrices, TRRs were all below the LOQ of 0.01 mg eq/kg, except at the highest feeding levels in the goat study where TRRs of 0.06, 0.03 and 0.025 mg eq/kg were measured in kidney in the imazamox, hydroxymethyl and diacid metabolites studies respectively. The component identified in kidney in the different studies refers to the component used to dose animals. The RMS proposed to set the residue definition for monitoring and risk assessment as sum of imazamox and its hydroxymethyl metabolite (CL 263284) expressed as imazamox. However since animal metabolism studies clearly indicate that residues are not expected to be present in animal matrices, EFSA proposes for monitoring and risk assessment to set the residue definition by default as imazamox only. Based on the representative uses, no residues are expected in animal matrices and MRLs for products of animal origin were therefore proposed at the LOQ of 0.01* mg/kg.

Magnitude of residues in plants

Peas
Comparison of intended and critical EU GAPs

Type of GAP	Crop	Number of applications	Method of application	Growth stage at last application	Max appl. rate per treatment (g a.s./ha)	PHI (days)
critical NEU GAP (EFSA Journal 2013;11(6):3282)	Peas dry - 0300030 without pods - 0260040	1	Soil treatment-spraying	BBCH 0-7	75	63
Intended GAP	Peas dry – 0300030 without pods - 0260040 with pods – 0260030	1	Spray	BBCH 12-16	36	-
Intended GAP	Beans dry – 0300010	1	Spray	BBCH 10-16	36	-

The data submitted for dry peas show that no exceedance of the MRL will occur.
According to the SANTE/2019/12752 Rev. 01 the residue values for dry peas (0300030) may be extrapolated to whole category Pulses (0300000), extrapolation on dry beans (0300010) and lupins (0300040) is accepted. Extrapolation from peas (pulses, 0300030) on whole group Legume vegetables (0260000) may be accepted only for seed treatment which does not apply to the proposed GAPs. Therefore, **extrapolation from dry peas (pulses) to beans with/without pods (0260010/0260020), broad bean (0260020) and lentils (0260050) is not acceptable.**

Oilseed rape
Comparison of intended and critical EU GAPs

Type of GAP	Crop	Number of applications	Method of application	Growth stage at last application	Max appl. rate per treatment (g a.s./ha)	PHI (days)	Remarks
critical NEU GAP EFSA Journal	Winter and Spring oilseed rape	1	Spray	BBCH 10-18	35	-	One application every three years only based on the

Type of GAP	Crop	Number of applications	Method of application	Growth stage at last application	Max appl. rate per treatment (g a.s./ha)	PHI (days)	Remarks
2016;14(4):4432							groundwater assessment submitted by the applicant To be used in Clearfield Oilseed rape hybrids only
	Sunflower	1	Spray	BBCH 12-18	50	-	-
	Soybean	1	Spray	BBCH 12-14	50	-	-
Intended GAP	Spring oilseed rape, Linseeds, Poppy, Sesam, Mustard, Sunflower, Soy, Safflower, Borage, Pumpkin, Hemp, Castor beans, Cotton	1	Spray	BBCH 10-18	36	-	-

According to the SANTE/2019/12752 Rev. 01 the residue values for rapeseeds may be extrapolated to Whole group Oilseeds (0401000) before forming of the edible part, therefore the extrapolation can cover all proposed in the GAP uses in oilseeds i.e. linseeds, poppy seeds, sesame seeds, mustard seeds, sunflower seeds, soyabeans, safflower seeds, borage seeds, pumpkin seeds, hemp seeds, castor beans and cotton seeds.
The data submitted for rape seeds show that no exceedance of the MRL will occur.
The proposed in the GAP uses on oilseeds are considered acceptable.

Tabacco, forest nurseries, ornamental plants, wicker
These plants have not got edible parts therefore studies on the magnitude of residues are not required.
Authorisation can be granted.

Honey
The residue levels of imazamox in treated honey samples were in the range < 0.003 mg/kg – 0.0160 mg/kg. No residues of imazamox metabolites CL 312622, CL 189215 and CL 263284 were detected at or above the limit of detection (0.003 mg/kg) in any of the treated honey samples. The applicable MRL value for honey is 0.05 mg/kg (Reg. (EU) 2021/2202). Therefore, the MRL is not expected to be exceeded when CHR/H/IMA 40 SL is used in accordance with the proposed GAP.

Succeeding crops
According to the EFSA Journal 2016;14(4):4432: A confined rotational crop study was submitted, conducted with a single application of ^{14}C-pyridine-imazamox at 70 g/ha (1.4 N rate) on soya bean plants at the four to six trifoliate growth stage as primary crop. Soya bean was harvested at maturity 100 days after application and winter wheat sowed immediately. Maize was sowed next year, 9 months after application and lettuce and radish 9 and 14 months after application. Total radioactive residues were all below the limit of quantification of 0.01 mg/kg in all plant matrices. A new

study was submitted in the framework of the renewal process, using $^{14}C/^{15}N$-imidazoline-imazamox and ^{14}C-pyridine-imazamox applied at a rate of 75 g/ha (1.5 N rate) on bare soil and conducted according to the current guidance recommendations. Spinach, radish and wheat were sowed at plant back intervals (PBI) of 31, 119 and 364 days. In all plant matrices at all plant back intervals, TRRs were low, mostly at or below 0.01 mg/kg except in wheat hay, straw and grains where maximum levels of 0.08, 0.13 and 0.05 mg/kg level were observed respectively at 31 or 119 days PBI. Only parent imazamox and its hydroxymethyl metabolite were identified at maximum level of 0.07 and 0.002 mg/kg. Based on these studies, it was concluded that residues are not expected to be present in rotational crops, providing that imazamox is applied according to the representative uses.
The GAP evaluated at EU level covers the intended uses in the GAP for CHR/H/IMA 40 SL. Additional studies are not required.

Magnitude of residues in livestock
No residues are expected in animal matrices.

Consumer risk assessment
In addition consumer risk assessment was performed using EFSA PRIMo Rev. 3.1 and all applicable MRLs (Reg. (EU) 2021/2202) as input values.
The proposed and accepted uses of imazamox in the formulation CHR/H/IMA 40 SL do not represent unacceptable acute and chronic risks for the consumer.

Change provided by the applicant in March 2024
After completing the assessment, the Applicant provided the following information with a revised GAP table:
During the documentation review, we noticed an error in the GAP table in section B7 (residues) of CHR/H/IMA 40 SL (ZEMAX/MAZZAM). The table was missing code names from the SANTE/2019/12752 guide for broad beans, field beans and lentils grown for dry seeds. Therefore, we are attaching the GAP table with the correct code names for the Pulses pant group.

The Applicant added lentils (dry, code 0300020) and "other" from the Pulses (code 0300990) group in the GAP table. The codes indicated in the GAP are given in accordance with Regulation 396/2005. It appears that the Applicant identified the guidelines (SANTE/2019/12752) as the source of the codes by mistake.
According to the SANTE/2019/12752 Rev. 01 the residue values for dry peas (0300030) may be extrapolated to whole category Pulses (0300000), extrapolation on dry beans (0300010), lupins (0300040), lentils (0300020) and others from Pulses group (0300990) is accepted.
The data submitted for dry peas show that no exceedance of the MRL will occur.
The risk assessment performed previously took into account all applicable MRL values (Reg. (EU) 2021/2202), which means that it was significantly overestimated. Additional calculations are not required.
The proposed and accepted uses of imazamox in the formulation CHR/H/IMA 40 SL do not represent unacceptable acute and chronic risks for the consumer.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation CHR/H/IMA 40 SL are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central Zone for legume vegetables, oilseeds, cotton tobacco and ornamentals. A list of all intended uses within the Central Zone is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of

0.05 mg/kg (according to Reg. (EU) 2021/2202) for imazamox as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of imazamox residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, Ministry of Agriculture, Poland agrees with the authorization of the intended uses **except, beans with/without pods (0260010/0260020), broad bean (0260020) and lentils (0260050).**

According to available data, no specific mitigation measures should apply.

Data gaps

Noticed data gaps are: None

Issues that could not be finalised at EU level (EFSA Journal 2016;14(4):4432):

1. The residue definition for enforcement and risk assessment in plants were set provisionally pending the submission of additional data to address the genotoxic potential of the metabolite CL 263284 and its glucose conjugate (CL 189215).

2. The consumer risk assessment from consumption of drinking water could not be finalised whilst the nature of residues in drinking water following water treatment had not been addressed

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					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			Residues
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Pea *Pisum sativum* (0260030, ~~0260040~~, 0300030)	F	Mono and dicots weeds	Spray	BBCH 12-16	1	N/A	a) 0,9 b) 0,9	a) 0,036 b) 0,036	200-400	N/A		Accepted for peas (pulses) Not accepted for legume vegetables
2	HU, RO, SK	Soy *Glycine max* (0401070)	F	Mono and dicots weeds	Spray	Early postemergence BBCH 12-16	1	N/A	a) 1,0 - 1,2 b) 1,0 - 1,2	a) 0,040 - 0,048 b) 0,040 - 0,048	200-300	N/A		A
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
Minor uses according to Article 51 (zonal uses)														
3	PL, HU, RO, SK	Beans ~~*Phaseolus L*~~ (0260010, ~~0260020~~, 0300010)	F	Mono and dicots weeds	Spray	Spring BBCH 10-16, weeds BBCH 10-13	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200-400			Accepted for beans (pulses) Not accepted for legume vegetables
~~4~~	~~PL, HU, RO, SK~~	~~Broad bean Vicia faba (260020)~~	~~F~~	~~Mono and dicots weeds~~	~~Spray~~	~~Spring BBCH 10-16, weeds BBCH 10-13~~	~~1~~	~~N/A~~	~~a) 0,6 - 0,9 b) 0,6 - 0,9~~	~~a) 0,024 - 0,036 b) 0,024 - 0,036~~	~~200-400~~			Not accepted, appropriate studies were not provided
~~5~~	~~PL, HU,~~	~~Lentils *Lens culinaris* (260050)~~	~~F~~	~~M8ono and dicots weeds~~	~~Spray~~	~~Spring BBCH 10-16, weeds~~	~~1~~	~~N/A~~	~~a) 0,6 - 0,9 b) 0,6 - 0,9~~	~~a) 0,024 - 0,036 b) 0,024 - 0,036~~	~~200-400~~			Not accepted, appropriate

	~~RO, SK~~					~~BBCH 10-13~~								studies were not provided
6	PL, HU, RO, SK	Lupine *Lupinus sp.* ~~(300000)~~ 300040	F	Mono and dicots weeds	Spray	Spring BBCH 10-16, weeds BBCH 10-13	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200-400			A
7	PL, HU, RO, SK	Linseeds *Linum usitatissimum* (401010)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200-400			A
8	PL, HU, RO, SK	Spring oilseed rape *Brassica napus* (401060)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200-400			A
9	PL, HU, RO, SK	Poppy *Papaver rhoeas* (401030)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200-400			A
10	PL, HU, RO, SK	Sesame *Sesamum indicum* (401040)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200-400			A
11	PL, HU, RO, SK	Mustard *Sinapis arvensis* (401080)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200-400			A
12	PL, HU, RO, SK	Sunflower *Helianthus annuus* (401050	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200-400			A
13	PL, HU, RO, SK	Soy *Glycine max* (0401070)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200-400			A
14	PL, HU, RO, SK	Safflower *Carthamus tinctorius* (401110)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200-400			A

15	PL, HU, RO, SK	Borage *Borago sp.* (401120)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200-400			A
16	PL, HU, RO, SK	Pumpkin *Cucurbita sp.* (401100)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200-400			A Only for seeds
17	PL, HU, RO, SK	Hemp *Cannabis sp.* (401140)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200-400			A
28	PL, HU, RO, SK	Castor beans *Ricinus communis* (401150)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200-400			A
19	PL, HU, RO, SK	Cotton *Gossypium* (401090)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200-400			A
20	PL, HU, RO, SK	Tobacco *Nicotiana tabacum*	F	Mono and dicots weeds	Spray	Spring BBCH 10-89	1	N/A	a) 0,38 - 0,9 b) 0,38 - 0,9	a) 0,015 - 0,036 b) 0,015 - 0,036	200-300			A
21	PL, HU, RO, SK	Coniferous / deciduous forest nurseries, Ornamental shrubs, Ornamental plants	F	Mono and dicots weeds	Spray	Spring BBCH 10-89, the risk of infection, warning	1	N/A	a) 0,38 - 0,9 b) 0,38 - 0,9	a) 0,015 - 0,036 b) 0,015 - 0,036	200-300			A
22	PL, HU, RO, SK	*Salix viminalis* Wicker *Salix sp.*	F	Mono and dicots weeds	Spray	BBCH 10-89, the risk of infection, warning	1	N/A	a) 0,38 - 0,9 b) 0,38 - 0,9	a) 0,015 - 0,036 b) 0,015 - 0,036	200-300			A

Minor uses according to Article 51 (interzonal uses)														

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005
*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for Column 11 “Conclusion”

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

The changes indicated in green were made by the Applicant.

Changes included in 03.2024 were highlighted in green.

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, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					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			~~Groundwater~~ Residues
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Pea *Pisum sativum* ~~(0260030, 0260040,~~	F	Mono and dicots weeds	Spray	BBCH 12-16	1	N/A	c) 0,9 d) 0,9	a) 0,036 b) 0,036	200- 400	N/A		Accepted for peas (pulses) Not accepted for legume vegetables

		0300030)												
2	HU, RO, SK	Soy *Glycine max* (0401070)	F	Mono and dicots weeds	Spray	Early postemergence BBCH 12-16	1	N/A	c) 1,0 - 1,2 d) 1,0 - 1,2	a) 0,040 - 0,048 b) 0,040 - 0,048	200- 300	N/A		A
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
Minor uses according to Article 51 (zonal uses)														
3	PL, HU, RO, SK	Beans *Phaseolus L* (~~0260010, 0260020,~~ 0300010)	F	Mono and dicots weeds	Spray	Spring BBCH 10-16, weeds BBCH 10-13	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200- 400			Accepted for beans (pulses) Not accepted for legume vegetables
4	PL, HU, RO, SK	~~Broad bean *Vicia faba* (260020);~~ (0300990)	F	Mono and dicots weeds	Spray	Spring BBCH 10-16, weeds BBCH 10-13	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200- 400		(0300990) Pulses (dry seeds)	Accepted for pulses Not accepted for legume vegetables
5	PL, HU, RO, SK	Lentils *Lens culinaris* ~~(260050);~~ (0300020)	F	M8ono and dicots weeds	Spray	Spring BBCH 10-16, weeds BBCH 10-13	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200- 400		(0300020) Pulses (dry seeds)	Accepted for pulses Not accepted for legume vegetables
6	PL, HU, RO, SK	Lupine *Lupinus sp.* ~~(300000)~~ 0300040	F	Mono and dicots weeds	Spray	Spring BBCH 10-16, weeds BBCH 10-13	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200- 400			A
7	PL, HU, RO, SK	Linseeds *Linum usitatissimum* (401010)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200- 400			A
8	PL, HU,	Spring oilseed	F	Mono and	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9	a) 0,024 -	200- 400			A

	RO, SK	rape *Brassica napus* (401060)		dicots weeds					b) 0,6 - 0,9	0,036 b) 0,024 - 0,036				
9	PL, HU, RO, SK	Poppy *Papaver rhoeas* (401030)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200- 400			A
10	PL, HU, RO, SK	Sesame *Sesamum indicum* (401040)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200- 400			A
11	PL, HU, RO, SK	Mustard *Sinapis arvensis* (401080)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200- 400			A
12	PL, HU, RO, SK	Sunflower *Helianthus annuus* (401050	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200- 400			A
13	PL, HU, RO, SK	Soy *Glycine max* (0401070)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200- 400			A
14	PL, HU, RO, SK	Safflower *Carthamus tinctorius* (401110)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200- 400			A
15	PL, HU, RO, SK	Borage *Borago sp.* (401120)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200- 400			A

16	PL, HU, RO, SK	Pumpkin *Cucurbita sp.* (401100)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200- 400			A Only for seeds
17	PL, HU, RO, SK	Hemp *Cannabis sp.* (401140)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200- 400			A
18	PL, HU, RO, SK	Castor beans *Ricinus communis* (401150)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200- 400			A
19	PL, HU, RO, SK	Cotton *Gossypium* (401090)	F	Mono and dicots weeds	Spray	BBCH 10-18	1	N/A	a) 0,6 - 0,9 b) 0,6 - 0,9	a) 0,024 - 0,036 b) 0,024 - 0,036	200- 400			A
20	PL, HU, RO, SK	Tobacco *Nicotiana tabacum*	F	Mono and dicots weeds	Spray	Spring BBCH 10-89	1	N/A	a) 0,38 - 0,9 b) 0,38 - 0,9	a) 0,015 - 0,036 b) 0,015 - 0,036	200-300			A
21	PL, HU, RO, SK	Coniferous / deciduous forest nurseries, Ornamental shrubs, Ornamental plants	F	Mono and dicots weeds	Spray	Spring BBCH 10-89, the risk of infection, warning	1	N/A	a) 0,38 - 0,9 b) 0,38 - 0,9	a) 0,015 - 0,036 b) 0,015 - 0,036	200-300			A
22	PL, HU, RO, SK	*Salix viminalis* Wicker *Salix sp.*	F	Mono and dicots weeds	Spray	BBCH 10-89, the risk of infection, warning	1	N/A	a) 0,38 - 0,9 b) 0,38 - 0,9	a) 0,015 - 0,036 b) 0,015 - 0,036	200-300			A
Minor uses according to Article 51 (interzonal uses)														

7.1.2 Summary of the evaluation

The preparation CHR/H/IMA 40 SL is composed of imazamox.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of imazamox

Reference value	Source	Year	Value	Study relied upon	Safety factor
Imazamox – parent compound					
ADI	Reg. (EU) 2017/1531	2017	3 mg/kg bw/day	Rabbit developmental study	100
ARfD	Reg. (EU) 2017/1531	2017	3 mg/kg bw	Rabbit developmental study	100
AOEL	Reg. (EU) 2017/1531	2017	2.25 mg/kg bw/day	Rabbit developmental study	100

7.1.2.1 Summary for imazamox

Table 7.1-3: Summary for imazamox

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
Major crops								
1	Peas (0300030)	Yes	Yes	Yes	Yes	Yes	No	No
2	Soybean	Yes	Yes	Yes	Yes	Yes		No
Minor crops								
3	Beans (030010)	Yes	Yes for dry beans	Yes	Yes	Yes	No	No
4	Broad bean	Yes	~~Yes~~ No	Yes	Yes	Yes	No	No
5	Lentils	Yes	~~Yes~~ No	Yes	Yes	Yes	No	No
6	Lupine	Yes	Yes	Yes	Yes	Yes	No	No
7	Linseeds	Yes	Yes	Yes	Yes	Yes	No	No
8	Spring oilseed rape	Yes	Yes	Yes	Yes	Yes	No	No
9	Breadseed poppy	Yes	Yes	Yes	Yes	Yes	No	No
10	Sesame	Yes	Yes	Yes	Yes	Yes	No	No
11	Mustard	Yes	Yes	Yes	Yes	Yes	No	No
12	Sunflower	Yes	Yes	Yes	Yes	Yes	No	No

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
13	Soy	Yes	Yes	Yes	Yes	Yes	No	No
14	Safflower	Yes	Yes	Yes	Yes	Yes	No	No
15	Borage	Yes	Yes	Yes	Yes	Yes	No	No
16	Pumpkin only for seeds	Yes	Yes	Yes	Yes	Yes	No	No
17	Hemp	Yes	Yes	Yes	Yes	Yes	No	No
18	Castor beans	Yes	Yes	Yes	Yes	Yes	No	No
19	Cotton	Yes	Yes	Yes	Yes	Yes	No	No
20	Tobacco *Nicotiana tabacum*	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~No~~ Not required	~~No~~ Not required
21	Coniferous / deciduous forest nurseries, Ornamental shrubs, Ornamental plants	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~No~~ Not required	~~No~~ Not required
22	*Salix viminalis* Wicker	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~Yes~~ Not required	~~No~~ Not required	~~No~~ Not required

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

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

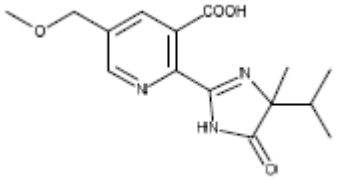
Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.
According to Reg. (EU) 2021/2202, MRLs in following crops/ following mitigation measures have been proposed: 0.05 mg/kg for pulses/legumes (e.g. peas, beans, soybean) and 0.05 mg/kg for oilseeds (e.g. oilseed rape, linseed, pumpkin), excluding sunflower which have proposed MRL 0.3 mg/kg.

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

7.2 Imazamox

General data on imazamox are summarized in the table below (last updated 20)

Table 7.2-1: General information on imazamox

Active substance (ISO Common Name)	Imazamox
IUPAC	(+/-)-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-5-(methoxymethyl) nicotinic acid
Chemical structure	
Molecular formula	$C_{15}H_{19}N_3O_4$
Molar mass	305.3
Chemical group	Imidazoline
Mode of action (if available)	Inhibition of enzyme acetohydroxyacid synthase (AHAS), which is involved in the synthesis of branched-chain aliphatic amino-acids; it disrupts protein synthesis
Systemic	Yes
Company (ies)	BASF
Rapporteur Member State (RMS)	Greece
co-Rapporteur Member State (cRMS)	Italy
Approval status	Approved Date of approval (01/11/2017) and reference to decision (Commission Directive (EC) No. 1107/2009 of 21 October 2009 - Commission Implementing Regulation (EU) No 2019/717 of 8 May 2019)
Restriction	see Commission Directive No 1107/2009 of 21 October 2009 Reg. (EU) 2017/1531 The Commission considers that imazamox is a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009. Imazamox is a persistent and toxic substance in accordance with points 3.7.2.1 and 3.7.2.3 respectively, of Annex II to Regulation (EC) No 1107/2009, given that the half-life in fresh water and sediment is higher than 120 days and the long term no-observed effect concentration for aquatic plants is 0,0045 mg/l. Imazamox therefore fulfils the condition set in the second indent of point 4 of Annex II to Regulation (EC) No 1107/2009.
Review Report	SANTE/10499/2017 – rev. 4 20/7/2017
Current MRL regulation	Regulation (EC) No 2021/2202
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	EFSA Journal 2013;11(6):3282
EFSA Journal : Conclusion on the peer review	EFSA Journal 2016;14(4):4432
EFSA Journal: conclusion on article 12	EFSA Journal 2019;17(2):5584

Current MRL applications on intended uses	~~EFSA Journal 2020;18(1):5952~~ None

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

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Wheat forage	High water content	Imazamox: 48 months CL 263284: 48 months	Bibo X., 2002a, 2002/5004279
Maize plant	High water content	Imazamox: 24 months CL 263284: 24 months	Rawle N. A., 2003a, report no. 2003/1030079
Soybean (forage)	High water content	Imazamox: 24 months	Witkonton S., 1995, report no. RES 95-060
Alfalfa (forage)	High water content	Imazamox: 18 months CL 263284: 18 months CL 189215: 18 months CL 312622: 18 months	Fletcher J.S., 2001a, report no. ID-326-024
Soybean (seeds)	High lipid content	Imazamox: 24 months	Witkonton S., 1995, report no. RES 95-060
Soybean (seeds)	High lipid content	Imazamox: 44 months CL 263284: 44 months	Bixler T.A., Safarpour H., 2000a, Report no. ID-720-070
Soybean (seeds)	High lipid content	CL 263284: 10 months CL 189215: 10 months	Leite R.,Alves M., 2011a, report no. 2011/1207286
Peanut	High lipid content	CL 263284: 24 months CL 189215: 24 months	Leite R., Nejad H., Xu B., 2000c, report no. IA-740-023
Wheat (grain)	High starch content	Imazamox: 48 months CL 263284: 48 months	Bibo X., 2002a, 2002/5004279
Maize (grain)	High starch content	Imazamox: 24 months CL 263284: 24 months	Rawle N. A., 2003a, report no. 2003/1030079
Soybean defatted meal	Processed commodity	CL 263284: 3 months CL 189215: 3 months	Leite R.,Alves M., 2011a, report no. 2011/1207286
Wheat straw (hay)	Other	Imazamox: 48 months CL 263284: 48 months	Bibo X., 2002a, 2002/5004279
Alfalfa (hay)	Other	Imazamox: 18 months CL 263284: 18 months	Fletcher J.S., 2001a, ID-326-024

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
		CL 189215: 18 months CL 312622: 18 months	
New data			
Pea (dry)	Dry commodities	Imazamox: 200 days CL 263284: 200 days CL 189215: 200 days	Sowik, I., 2022, BA-13/21-04
Pea (whole plants)	High water content	Imazamox: 200 days CL 263284: 200 days CL 189215: 200 days	Sowik, I., 2022, BA-13/21-04
Animal Products			
No data provided and not required as no residue expected in foods of animal origin			

Conclusion on stability of residues during storage

Based on the results of the study it is possible to conclude that residues of imazamox and metabolite CL 263284 are stable up to 44 months in high lipid content matrices and up to 48 months in high water- and high starch content matrices.

Conclusion

Residues of imazamox are stable in soybean seed for at least 24 months at the level of 0.5 mg/kg when stored frozen at approximately -10ºC.

Conclusion on stability of residues in sample extracts

The stability of fortification solutions of imazamox was tested and concucted that they were stable up to one year in methanol. Calibration solutions of imazamox and its metabolites CL 263284, CL 189215 and CL 312622 in methanol or water were found to be stable under refrigeration for at least 1 month. Procedural recoveries that were conducted along with every analytical measurements series also demonstrated the stability of imazamox residues in the sample extracts.

zRMS comments:
According to the EFSA Journal 2016;14(4):4432 imazamox and CL 263284 are stable in high water and high starch content commodity for 48 months and 44 months in high oil content commodities. CL 189215 is stable in high water and in high oil content commodities for 18 and 24 months respectively.CL 312622 is stable in high water content commodity for 18 months. According to the study provided by the Applicant imazamox, CL 263284 and CL 189215 are stable in dry commodities (peas) for 200 days.
The data presented cover the uses accepted in the GAP for CHR/H/IMA 40 SL.
Additional studies are not required.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.
Considering metabolism studies we are obliged to relied upon following studies taking account that according to Regulation (EC) No 1107/2009 Article 59 Data protection: The period of data protection is 30 months starting at the date of renewal in accordance to art. 43 in that Member State. Renewal of the product in Poland was in 20.11.2017 (R-45/2017), therefore data protection is over, and other applicants can refer to studies performed during inclusion and extensions of uses of the product Clentiga 262.5 SC.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Pulses and oilseeds	Soybean	6-pyridine-^{14}C	Incorporation in soil, G	PPI: 146 g as/ha	1	28,58,91, 151, 162	BASF Study	Mallipuldi, N. M., 1994, Cyanamid Report No.: MET 94-003 (DAR, FR 1999)
				POST-low rate: 76 g as/ha	2	0, 30, 63, 123, 134		
				POST-high-rate: 150 g as/ha	3			
	Peas	6-pyridine-^{14}C	Post-emergence foliar spray, F	N/D	1	0, 61, 84	BASF Study	Chiu, T., 1995, Cyanamid Report No.: MET 95-011 (DAR, FR 1999)
					2	20, 84		
					3	61		
	Canola	6-pyridine-^{14}C	Post-emergence foliar spray, F	20 g ai/ha	1	-1, 0, 75, 82	BASF Study	McDonnel, R., 1995, Cyanamid Report No.: MET 95-004 (DAR, FR 1999)
Unprotected studies presented in Clentiga 262.5 SC								
Pulses and	Soybean	6-^{14}C-	Soil, pre-	0.146	1	25, 58,	-	EFSA, 2016

oilseeds		pyridine	planting , F			91, 151		
		6-^{14}C-pyridine	Foliar, post emergence, F	0.076	1	0, 30, 123	-	EFSA, 2016
				0.150				
	Pea	6-^{14}C-pyridine	Foliar, BBCH 33-35, F	0.040	1	20, 61, 84	-	EFSA, 2016
	Rapeseed (Tolerant variety)	6-^{14}C-pyridine	Foliar, BBCH 13-14, F	0.020	1	0, 84	-	EFSA, 2016
				0.051	1	0, 22, 78	-	EFSA, 2016
				0.004				
				0.089				
		^{14}C, ^{15}N-imidazolinone	Foliar, BBCH 10-18, F	0.075 + adjuvant	1	22, 90	-	EFSA, 2016
	Alfalfa (Tolerant variety)	6-^{14}C-pyridine	Foliar, post emergence, F	0.135	1	0-157	-	EFSA, 2016
Cereals (Tolerant Varieties)	Maize	6-^{14}C-pyridine	Soil, pre-emergence, F	0.141	1	14, 30, 62, 112	-	EFSA, 2016
		6-^{14}C-pyridine	Foliar, BBCH 14-18, F	0.130	1	0, 14, 62, 100	-	EFSA, 2016
	Wheat	6-^{14}C-pyridine	Foilar, post emergence, F	0.140	1	28, 45, 70	-	EFSA, 2016
		5-^{14}C,3-^{15}N-imidazolinone	Foliar, BBCH 13-24, F	0.076 + adjuvant	1	8, 62	-	EFSA, 2016
	Rice	3-^{14}C,3-^{15}N-imidazolinone	Foliar, BBCH 13-25, F	0.076 + adjuvant	1	42, 182	-	EFSA, 2016

Summary of plant metabolism studies reported in the EU

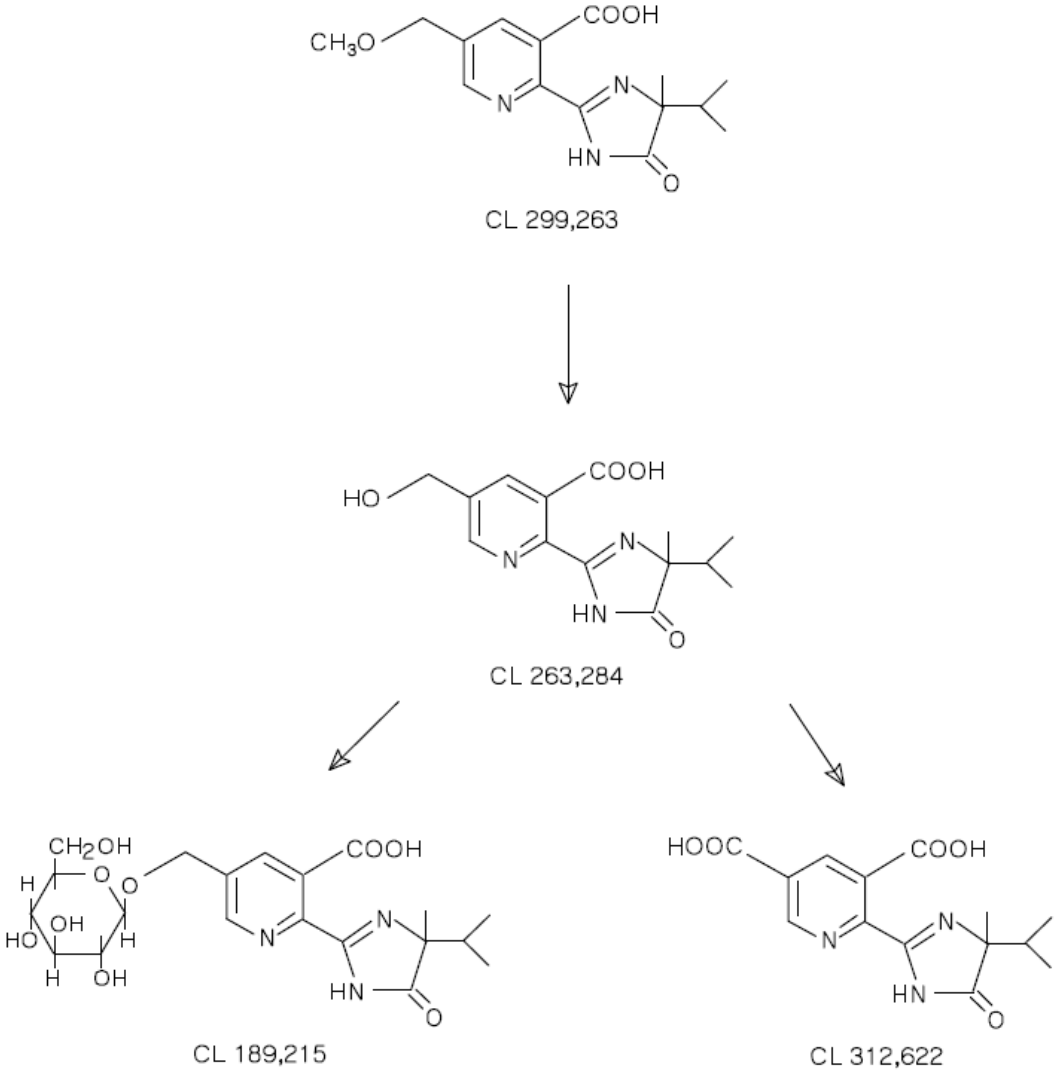
Metabolism in soybean

- PPI (Plot A) received a single pre-plant incorporated (PPI) application at 146g ai/ha of [6-pyridine-14C] -
labeled CL 299263/A
- POST-low rate (Plot C) received a single postemergence (POST) broadcast application at 76 g ai/ha [6-pyridine-14C]-labeled CL 299263/A
- POST-high rate (Plot B) received a single postemergence (POST) broadcast application at 150 g a i /ha [6-pyridine-14C]-labeled CL 299263/A

The total radioactive residues indicated that 14C-CL 299263-derived residues do not translocate or accumulate significantly in the immature soybean plant, or the harvest soybean seed and straw. Generally, the significant TRR appeared in the early vegetative stages of soybean plant growth. The soybean plant residue consisted of three (3) predominant metabolites--CL 312622; CL 263284; and CL 189215. With the exception of immediately following treatment, only trace amounts of the unaltered parent were found. There were other minor degradates; however, each accounted for less than 0.01 ppm 14C-CL 299263 equivalents. A similar metabolic profile was observed in both the pre-plant incorporation- and post-emergent-treated soybeans.

Based on the data presented, soybean plants metabolize CL 299263 very rapidly via O-dealkylation of the 5-methoxymethyl position to form the 5-hydroxymethyl analog [CL 263284]. This metabolite is subsequently either oxidized to form the dicarboxylic acid metabolite [CL 312622] or rapidly conjugated to form the largest metabolite component [CL 189215]. CL 299263-derived residues were detected only in the plant samples but not in the soybeans, even at an exaggerated treatment rate of 0.130 lb ae/A (146 g as/ha) that produced transient phytotoxicity. Isolation of soybean oil failed to produce positive CL 299263-derived residues. The proposed metabolic pathway is shown in figure below.

Proposed metabolic pathway of imazamox in soybean:



Metabolism in peas

Field peas received a 40 g a.i/ha application of 14C-CL 299263 thirty days after planting. Very low but detectable carbon-14 residues (<0.01 ppm) were found in the immature field pea and immature whole field pea plants two months following treatment. At harvest (84 DAT), total radioactive residue levels were observed in the dry field pea (0.01 ppm) and the dry field pea hay (0.05 ppm). Characterization and identification of carbon-14 residues in the various substrates indicates that CL 299263 metabolism begins at the 5-methoxymethyl position to form the 5-hydroxymethyl metabolite [CL 263284]. This metabolite is subsequently either oxidized to form the either the di-acid metabolite [CL 312622] or conjugated to form the glycoside [CL 189215]. The proposed metabolic pathway is the same as for soybean shown above.

Metabolism in canola

The study shows that CL 299263 (imazamox) when used as a post-emergence herbicide on field canola at a rate of 20 g a.s./ha does not lead to the appearance of CL 299263-derived residues in harvest canola seeds. No residues above 0.004 ppm CL 299263 (the minimum quantifiable limit) were found. Furthermore, based on the ^{14}C-CL 299263 residue levelsin the laboratory processing study, concentration of ^{14}C-CL 299263 residues in canola oil were not observed. The unaltered CL 299263 is the most significant residue component in the immature canola foliage (0-DAT).

Summary of studies presented in EFSA Peer review 2016

At harvest in mature plants and seeds, imazamox was present in low proportions (< 10% TRR), except in wheat grains where the active substance accounted for 40% to 76% TRR (0.03 to 1.05 mg/kg). Two, three weeks after application, the hydroxymethyl metabolite (CL 263284) and its glucose conjugate (CL 189215) were usually identified as the most abundant components, accounting together for more than 20% TRR, up to 50–70% in maize forage and wheat forage and straw. In addition, the di-acid metabolite (CL 312622) was also identified in alfalfa at ca. 20% TRR representing up to 0.12 mg eq/kg in forage and 0.19 mg eq/kg in hay. The metabolism of imazamox in primary crops proceeds mainly by O-demethylation of the methoxymethyl group to form the hydroxymethyl metabolite which undergoes further metabolism via oxidation and glucose conjugation to form the di-acid and glucose conjugate metabolites respectively. Enantiomer specific analyses were performed in plant matrices with significant TRR levels. A shift of the enantiomeric ratio was not observed for imazamox and its hydroxymethyl metabolite in wheat forage, straw, grain and in rice straw. However, in rapeseed and rice forage the enantiomeric ratio was found to be about 30:70.

Summary of new plant metabolism studies

No new plant metabolism studies were performed – not required.

Conclusion on metabolism in primary crops

EFSA Peer review, 2016:
Metabolic pathway similar following foliar or soil application. Metabolism involves the O-demethylation of the methoxymethyl group to form the hydroxymethyl metabolite (CL 263284) which undergoes further metabolism via oxidation and glucose conjugation to form the di-acid metabolite (CL 312622) and the glucose conjugate (CL 189215) respectively.
Sufficient data were provided to propose plant residue definitions for monitoring and risk assessment.

zRMS comments:
The Applicant did not provide new studies. Data on metabolism in primary crops evaluated at EU level are sufficient for CHR/H/IMA 40 SL authorization.
According to the EFSA Journal 2019;17(2):5584: The results of all available studies indicate that at harvest in mature plants and seeds, imazamox was present in low proportions (<10% total radioactive residue (TRR)), except in wheat grain. Two to three weeks after application, the hydroxymethyl metabolite (CL 263284) and its glucose conjugate (CL 189215) were identified as the most abundant components. The *d*-acid metabolite (CL 312622) was present at high proportions in alfalfa forage and hay, but since alfalfa is only used for animal feed, the peer review did not include this metabolite in the residue definitions, taking also into account the fact that animal metabolism studies showed that this metabolite is to a large extent excreted with no residues expected in animal matrices. The metabolism of imazamox in primary crops proceeds mainly by O-demethylation of the methoxymethyl group to form the hydroxymethyl metabolite (CL 263284) which undergoes further metabolism via oxidation and glucose conjugation to form the diacid and glucose conjugate metabolites respectively. A shift of the enantiomeric ratio was not observed for imazamox and its hydroxymethyl metabolite in wheat forage, straw, grain and in rice straw (EFSA, 2016). The peer review concluded that imazamox, its hydroxymethyl metabolite (CL 263284) and its glucose conjugate (CL 189215) are relevant plant metabolites.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Root and tuber vegetables	Radish	6-pyridine-14C	F	0.070 kg as/ha	268	311	No	Gatterdam, P., 1994, Cyanamid Report No.: MET 94-007
Leafy vegetables	Lettuce	6-pyridine-14C	F	0.070 kg as/ha	268	355	No	Gatterdam, P., 1994, Cyanamid Report No.: MET 94-007
Cereals	Maize	6-pyridine-14C	F	0.070 kg as/ha	268	420	No	Gatterdam, P., 1994, Cyanamid Report No.: MET 94-007
	Wheat (grain and straw)	6-pyridine-14C	F	0.070 kg as/ha	100	331	No	Gatterdam, P., 1994, Cyanamid Report No.: MET 94-007

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

Summary of plant metabolism studies reported in the EU

Rotational crops were grown following soybeans which received a 70 g a.s./ha application of CL 299263. Rotational crops were planted 100-DAT (wheat) and 268-DAT (corn, radish and lettuce) after treatment. Total carbon-14 residues in all rotational crops at both intervals were less than the 0.01 ppm ^{14}C-CL 299263 nominal limit of detection. These data clearly demonstrate that CL 299263 residues from a previous application do not accumulate in cereal crops planted 100 days after application or in root, leafy vegetable or oil seed grain crops planted 268 days after application.

Table B 7.6.1-1: Validation of Radioassay Method PPM CL 299263 EQUIVALENTS

	fortification	residue found		planting	sampl.	residue found
Soybean Plant	0.01	0.010			0	1.7
Wheat Mid-Maturity	0.01	0.011		100	238	< 0.01
Wheat Grain	0.01	0.009		100	331	< 0.01
Wheat Straw	0.01	0.011		100	331	< 0.01
Corn Mid-Maturity	0.01	0.010		268	357	< 0.01
Corn Grain	0.01	0.010		268	420	< 0.01
Corn Fodder	0.01	0.008		268	420	< 0.01
Radish Tops	0.01	0.010		268	311	< 0.01
Radish Root	0.01	0.009		268	311	< 0.01
Radish Mid-Maturity				268	302	<0.01
Radish Mid-Maturity				420	455	<0.01
Lettuce Mid-Maturity				268	311	<0.01
Lettuce	0.01	0.010		268	335	< 0.01
Soil	0.01	0.009				< 0.01

Radish Tops (Mature), Radish Root (Mature), Lettuce Mid-Maturity and Lettuce (Mature) 420 days were not analyzed, the study was terminated.

Summary of new plant metabolism studies

No new studies were performed – it is not required.

Conclusion on metabolism in rotational crops

Results from this rotational crop study using radiolabelled imazamox (CL 299263) show no accumulation in following crops. Furthermore DT_{90} of AC 299263 in field soil dissipation study is typically less than 100 days indicating that at the time following crops are planted there will be no significant residues of CL 299263 remaining in soil.

Based on the fact that no residues were observed in following crops in the confined rotational crop study and the consistent lack of residues above LOQ in field residue trials following direct application it is not anticipated that residues of AC 299263 will be found in following crops.

zRMS comments:
The Applicant did not provide new studies. Data on metabolism in rotational crops evaluated at EU level are sufficient for CHR/H/IMA 40 SL authorization. According to the EFSA Journal 2019;17(2):5584 in rotational crops–spinach, radish and wheat grown in the soil treated at a rate of 75 g/ha, the TRRs were

low, except in wheat hay, straw and grains. Only parent imazamox and its hydroxymethyl metabolite were identified and thus the peer review concluded that metabolism in rotational crops proceeds in a similar pathway as in primary crops (EFSA, 2016).

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

No new data submitted in the framework of this application.

Processed commodities (standard hydrolysis study)	**Conditions**	TAR*	**Imazamox**	**Unknown**
	20 min, 90°C, pH 4	102.2	102.2	-
	60 min, 100°C, pH 5	103.5	103.5	-
	20 min, 120°C, pH 6	99.9	95.2*	4.7
	*TAR: Total Applied Radioactivity Imazamox stable under conditions representing pasteurisation, boiling and sterilisation. Due to similarity of structure between imazamox and CL 263284 it can be assumed that metabolite CL 263284 will be stable under standard hydrolysis conditions.			
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Residue pattern is expected to be qualitatively similar. The residues definitions proposed for plants are also applicable to processed commodities			

zRMS comments:
The Applicant did not provide new studies. Relevant studies were evaluated at EU level.

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

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

Endpoints	
Plant groups covered	~~Pulses/Legumes (Peas)~~ ~~Oilseeds (Canola, soybean)~~ Cereals/grass (maize, wheat, rice) Pulses/Oilseeds (soybean, pea, rapeseed, alfalfa)
Rotational crops covered	Root/tuber crops (Radish) Leafy vegetables (Lettuce, spinach) Cereals (Maize, Wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	~~Not stable under standard hydrolytic conditions~~ Imazamox stable under conditions representing pasteurisation, boiling and sterilisation. Due to similarity of structure between imazamox and CL 263284 it can be assumed that metabolite CL 263284 will be stable under standard hydrolysis conditions (EFSA Journal 2016;14(4):4432).
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes

Plant residue definition for monitoring	Current: Imazamox (sum of imazamox and its salts, expressed as imazamox) ~~(Regulation(EU) 2016/567)~~ Reg. (EU) 2021/2202 New: Sum of imazamox and CL 263284, expressed as imazamox (EFSA Journal 2016;14(4):4432)
Plant residue definition for risk assessment	~~Current: Imazamox (sum of imazamox and its salts, expressed as imazamox) (Regulation(EU) 2016/567)~~ ~~New:~~ Sum of imazamox, CL 263284, and CL 189215, expressed as imazamox. Provisional pending the conclusions on the toxicological properties of metabolite CL 263284 and its glucose conjugate CL 189215 (EFSA Journal 2016;14(4):4432)
Conversion factor from enforcement to RA	For sunflower seeds: 1.9 For other crops listed in GAP: 1 Alfalfa: 2

* If residue pattern in processed commodities is not similar to that in raw commodities
** A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).
*** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

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

Available data

No new data submitted in the framework of this application.

Table 7.2-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants (imazamox)	Goats	6-pyridine-^{14}C labelled imazamox	2	0.065 0.391 (one animal at each dose rate)	7 days	Milk	Twice daily	EFSA Peer review, 2016
						Urine and faeces	Daily	
						Tissues	At sacrifice	
Laying poultry (imazamox)	Hens	6-pyridine-^{14}C labelled imazamox	16	0.16 0.792 (eight animals at each dose rate)	7 days	Eggs	Twice daily	EFSA Peer review, 2016
						Excreta	Daily	
						Tissues	At sacrifice	
Lactating ruminants (CL 263284)	Goats	6-pyridine-^{14}C labelled CL 263284	2	0.0846 0.308 (one animal at each dose rate)	7 days	Milk	Twice daily	EFSA Peer review, 2016
						Urine and faeces	Daily	
						Tissues	At sacrifice	

Laying poultry (CL 263284)	Hens	6-pyridine-^{14}C labelled CL 263284	16	0.148 0.786 (eight animals at each dose rate)	7 days	Eggs	Twice daily	EFSA Peer review, 2016
						Excreta	Daily	
						Tissues	At sacrifice	
Lactating ruminants (CL 312622)	Goats	6-pyridine-^{14}C labelled CL 312622	2	0.753 6.77 (one animal at each dose rate)	5 days	Milk	Twice daily	EFSA Peer review, 2016
						Urine and faeces	Daily	
						Tissues	At sacrifice	
Laying poultry (CL 312622)	Hens	6-pyridine-^{14}C labelled CL 312622	16	0.0087 0.733 (eight animals at each dose rate)	7 days	Eggs	Twice daily	EFSA Peer review, 2016
						Excreta	Daily	
						Tissues	At sacrifice	
New data								
No new data submitted, not required								

Summary of animal metabolism studies reported in the EU

In all animal matrices, TRRs were all below the LOQ of 0.01 mg eq/kg, except at the highest feeding levels in the goat study where TRRs of 0.06, 0.03 and 0.025 mg eq/kg were measured in kidney in the imazamox, hydroxymethyl and diacid metabolites studies respectively. The component identified in kidney in the different studies refers to the component used to dose animals.

The RMS proposed to set the residue definition for monitoring and risk assessment as sum of imazamox and its hydroxymethyl metabolite (CL 263284) expressed as imazamox. However since animal metabolism studies cleary indicate that residues are not expected to be present in animal matrices. EFSA proposes for monitoring and risk assessment to set the residue definition by default as imazamox only.

zRMS comments:
The Applicant did not provide new studies. Data on metabolism in crops evaluated at EU level are sufficient for CHR/H/IMA 40 SL authorization.
According to the EFSA Journal 2016;14(4):4432: Different livestock studies on goat and hens were submitted where animals were dosed over 7 consecutive days either with ^{14}C-imazamox or with the hydroxymethyl-^{14}C-metabolite at low (2 mg/kg feed) and high (10 mg/kg feed) dose rates. Studies with the diacid-^{14}C-metabolite were also provided where poultries were dosed at 0.2 and 10 mg/kg feed and goats at 3 and 33 mg/kg feed over 5 consecutive days. In all animal matrices, TRRs were all below the LOQ of 0.01 mg eq/kg, except at the highest feeding levels in the goat study where TRRs of 0.06, 0.03 and 0.025 mg eq/kg were measured in kidney in the imazamox, hydroxymethyl and diacid metabolites studies respectively. The component identified in kidney in the different studies refers to the component used to dose animals. The RMS proposed to set the residue definition for monitoring and risk assessment as sum of imazamox and its hydroxymethyl metabolite (CL 263284) expressed as imazamox. However since animal metabolism studies clearly indicate that residues are not expected to be present in animal matrices, EFSA proposes for monitoring and risk assessment to set the residue definition by default as imazamox only. Based on the representative uses, no residues are expected in animal matrices and MRLs for products of animal origin were therefore proposed at the LOQ of 0.01* mg/kg.

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

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

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	N/A – concentration below LOD (0.01 mg/kg)
	N/A – concentration below LOD (0.01 mg/kg)
Animal residue definition for monitoring	Imazamox
Animal residue definition for risk assessment	Imazamox
Conversion factor	Not determined, not required
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	~~Not relevant as no residue definition is set.~~ No (EFSA Journal 2016;14(4):4432)

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)
** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.
*** If metabolism in rat and ruminant are not similar

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Considering winter oilseed rape magnitude of residue studies we are obliged to relied upon following studies taking account that according to Regulation (EC) No 1107/2009 Article 59 Data protection: The period of data protection is 30 months starting at the date of renewal in accordance to art. 43 in that Member State. Renewal of the product in Poland was in 20.11.2017 (R-45/2017), therefore data protection is over, and other applicants can refer to studies performed during inclusion and extensions of uses of the product Clentiga 262.5 SC.

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of CHR/H/IMA 40 SL and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Peas – dry pea Extrapolated on whole category PULSES	13/21-01 – Poland 13/21-02 – Hungary 13/21-03 - Germany BA-29/22 - France	N-EU	Based on: 1 x 0.048 kg as/ha, BBCH 16 E: 4 × < 0.0096 mg/kg RA: 4 × < 0.0137 mg/kg	N/A				
	Overall supporting data for cGAP	N-EU	E: 4 × < 0.0096 mg/kg RA: 4 × < 0.0137 mg/kg	E: 0.0096 RA: 0.0137	E: 0.0096 RA: 0.0137	N/R	0.05 for dry peas dry beans lupins and	Yes

							others from pulses group 0.2 for lentils	
Peas – whole plant w/o roots	13/21-01 – Germany BA-29/22 - France	N-EU	E: 2 × < 0.0096 mg/kg RA: 2 × < 0.0137 mg/kg	E: 0.0096 RA: 0.0137	E: 0.0096 RA: 0.0137	N/R	~~0.05~~	~~Yes~~
Oilseed rape	EFSA, 2016, France 2016, Trials with BAS 798 00H and BAS 83100H	N-EU	Based on: 1 x 0.035 kg as/ha, BBCH 16-50 E: 4 x <0.02 RA: 4 x <0.03	N/A				
	~~EFSA, 2016, France 2016, (additional information, trials with BAS 798 KAH)~~	~~N-EU~~	~~Trial GAP: 1 x 0.050 kg as/ha, BBCH 51~~ ~~E: 2 x <0.10~~ ~~RA:~~	~~N/A~~				
	Overall supporting data for cGAP	N-EU	E: 4 x <0.02 RA: 4 x <0.03	E: 0.02 RA: 0.03	E: 0.02 RA: 0.03	~~N/R~~ 0.02	0.05 for linseeds, poppy seeds, sesam seeds, mustard seeds, soyabeans, safflower seeds, borage seeds, pumpkin	Yes

							seeds, hemp seeds, castor beans and cotton seeds 0.3 for sunflower seeds	
Honey (oilseed rape)	S22-01627	EU	Based on: 1 x 0.048 kg as/ha, BBCH 61-64 E: 0.006, 0.009, 0.010, 0.019 RA: 0.012, 0.015, 0.16, 0.025	N/A				
	Overall supporting data for cGAP	EU	E: 0.006, 0.009, 0.010, 0.019 RA: 0.012, 0.015, 0.016, 0.025	E: 0.0010 RA: 0.016	E: 0.019 RA: 0.025	0.05	0.05	Yes
Other pulses/legumes (e.g. beans, lentils)	According to SANTE 2019/12752 Document the residue values for peas may be extrapolated to all crops in this group. According to the SANTE/2019/12752 Rev. 01 the residue values for dry peas (0300030) may be extrapolated to whole category Pulses (0300000). Extrapolation from peas (pulses, 0300030) may be extrapolated on whole group Legume vegetables (0260000) only for seed treatment which does not apply to the proposed GAPs.							
Other oilseeds (e.g. sunflower, hemp, pumpkin)	According to SANTE 2019/12752 Document the residue values for oilseed rape may be extrapolated to all crops in this group. According to the SANTE/2019/12752 Rev. 01 the residue values for rapeseeds may be extrapolated to Whole group Oilseeds (0401000) before forming of the edible part, therefore the extrapolation can cover all proposed in the GAP uses in oilseeds i.e. linseeds, poppy seeds, sesam seeds, mustard seeds, sunflower seeds, soyabeans, safflower seeds, borage seeds, pumpkin seeds, hemp seeds, castor beans and cotton seeds.							
Cotton, tobacco and ornamentals	These plants have not got edible parts therefore studies on the magnitude of residues are not required.							

* Source of EU MRL: respective Regulation

7.2.3.2 Conclusion on the magnitude of residues in plants

~~The data submitted show that no exceedance of the MRL will occur.~~
~~The uses are considered acceptable.~~

zRMS comments

Peas

Comparison of intended and critical EU GAPs

Type of GAP	Crop	Number of applications	Method of application	Growth stage at last application	Max appl. rate per treatment (g a.s./ha)	PHI (days)
critical NEU GAP (EFSA Journal 2013;11(6):3282)	Peas dry - 0300030 without pods - 0260040	1	Soil treatment-spraying	BBCH 0-7	75	63
Intended GAP	Peas dry – 0300030 without pods - 0260040 with pods – 0260030	1	Spray	BBCH 12-16	36	-
Intended GAP	Beans dry – 0300010	1	Spray	BBCH 10-16	36	-

According to the SANTE/2019/12752 Rev. 01 the residue values for dry peas (0300030) may be extrapolated to whole category Pulses (0300000), extrapolation on dry beans (0300010) and lupins (0300040) is accepted. Extrapolation from peas (pulses, 0300030) on whole group Legume vegetables (0260000) may be accepted only for seed treatment which does not apply to the proposed GAPs. Therefore, **extrapolation from dry peas (pulses) to beans with/without pods (0260010/0260020), broad bean (0260020) and lentils (0260050) is not acceptable.**
The data submitted for dry pea show that no exceedance of the MRL will occur.
The proposed in the GAP uses on dry pea are considered acceptable.

Oilseed rape

Comparison of intended and critical EU GAPs

Type of GAP	Crop	Number of applications	Method of application	Growth stage at last application	Max appl. rate per treatment (g a.s./ha)	PHI (days)	Remarks
critical NEU GAP EFSA Journal 2016;14(4):4432	Winter and Spring oilseed rape	1	Spray	BBCH 10-18	35	-	One application every three years only based on the groundwater assessment submitted by the applicant To be used in Clearfield Oilseed rape hybrids only
	Sunflower	1	Spray	BBCH 12-18	50	-	-

Type of GAP	Crop	Number of applications	Method of application	Growth stage at last application	Max appl. rate per treatment (g a.s./ha)	PHI (days)	Remarks
	Soybean	1	Spray	BBCH 12-14	50	-	-
Intended GAP	Spring oilseed rape, Linseeds, Poppy, Sesam, Mustard, Sunflower, Soy, Safflower, Borage, Pumpkin, Hemp, Castor beans, Cotton	1	Spray	BBCH 10-18	36	-	-

According to the SANTE/2019/12752 Rev. 01 the residue values for rapeseeds may be extrapolated to Whole group Oilseeds (0401000) before forming of the edible part, therefore the extrapolation can cover all proposed in the GAP uses in oilseeds i.e. linseeds, poppy seeds, sesam seeds, mustard seeds, sunflower seeds, soyabeans, safflower seeds, borage seeds, pumpkin seeds, hemp seeds, castor beans and cotton seeds.
The data submitted for rape seeds show that no exceedance of the MRL will occur.
The proposed in the GAP uses on oilseeds are considered acceptable.

Tabacco, forest nurseries, ornamental plants, wicker
These plants have not got edible parts therefore studies on the magnitude of residues are not required.
Authorisation can be granted.

Honey
The residue levels of imazamox in treated honey samples were in the range < 0.003 mg/kg – 0.0160 mg/kg. No residues of imazamox metabolites CL 312622, CL 189215 and CL 263284 were detected at or above the limit of detection (0.003 mg/kg) in any of the treated honey samples. The applicable MRL value for honey is 0.05 mg/kg (Reg. (EU) 2021/2202). Therefore, the MRL is not expected to be exceeded when CHR/H/IMA 40 SL is used in accordance with the proposed GAP.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Residue levels for all analytes and matrices were below LOQ levels, therefore dietary burden calculations are not required.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Based on residue levels in plant matrices, no livestock feeding studies are necessary.

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

Processing studies are not triggered since residue levels are lower than 0.1 mg/kg.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.
Data dealing with magnitude of residues in succeeding crops are available/have been submitted and are summarized hereafter.

zRMS comments:
According to the EFSA Journal 2016;14(4):4432: A confined rotational crop study was submitted, conducted with a single application of ^{14}C-pyridine-imazamox at 70 g/ha (1.4 N rate) on soya bean plants at the four to six trifoliate growth stage as primary crop. Soya bean was harvested at maturity 100 days after application and winter wheat sowed immediately. Maize was sowed next year, 9 months after application and lettuce and radish 9 and 14 months after application. Total radioactive residues were all below the limit of quantification of 0.01 mg/kg in all plant matrices. A new study was submitted in the framework of the renewal process, using ^{14}C/^{15}N-imidazoline-imazamox and ^{14}C-pyridine-imazamox applied at a rate of 75 g/ha (1.5 N rate) on bare soil and conducted according to the current guidance recommendations. Spinach, radish and wheat were sowed at plant back intervals (PBI) of 31, 119 and 364 days. In all plant matrices at all plant back intervals, TRRs were low, mostly at or below 0.01 mg/kg except in wheat hay, straw and grains where maximum levels of 0.08, 0.13 and 0.05 mg/kg level were observed respectively at 31 or 119 days PBI. Only parent imazamox and its hydroxymethyl metabolite were identified at maximum level of 0.07 and 0.002 mg/kg. Based on these studies, it was concluded that residues are not expected to be present in rotational crops, providing that imazamox is applied according to the representative uses.
The GAP evaluated at EU level covers the intended uses in the GAP for CHR/H/IMA 40 SL. Additional studies are not required.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

According to confined rotational crop study, no residue of imazamox and its metabolite CL 263284 above 0.01 mg/kg are expected in succeeding crops and no other single component are expected in amounts above 0.01 mg/kg.
Therefore field rotational crop study is not considered necessary when crops are treated according to the intended GAP.

7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of CHR/H/IMA 40 SL. Therefore, other special studies are not required.

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

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

7.2.8.1 Input values for the consumer risk assessment

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Unprocessed commodities				
Legumes				
Beans (with pods)	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Beans (without pods)	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Peas (with pods)	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Peas (without pods)	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Lentils (fresh)	0.2	MRL ((EU) 2021/2202)	0.2	MRL ((EU) 2021/2202)
Other legume vegetables (fresh)	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Pulses				
Beans	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Lentils	0.2	MRL ((EU) 2021/2202)	0.2	MRL ((EU) 2021/2202)
Peas	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Lupins/lupini beans	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Other pulses	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Oilseeds				
Linseeds	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Poppy seeds	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Sesame seeds	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Sunflower seeds	0.3	MRL ((EU) 2021/2202)	0.57	MRL*CF ((EU) 2021/2202)
Rapeseeds/canola seeds	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Soyabeans	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Mustard seeds	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Cotton seeds	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Pumpkin seeds	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Hemp seeds	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)
Other oilseeds	0.05	MRL ((EU) 2021/2202)	0.05	MRL ((EU) 2021/2202)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Processed commodities				
Beans (with pods) / boiled	-	-	0.05	MRL ((EU) 2021/2202)
Beans (without pods) / boiled	-	-	0.05	MRL ((EU) 2021/2202)
Peas (with pods) / boiled	-	-	0.05	MRL ((EU) 2021/2202)
Peas (without pods) / boiled	-	-	0.05	MRL ((EU) 2021/2202)
Peas (without pods) / canned	-	-	0.05	MRL ((EU) 2021/2202)
Beans / canned	-	-	0.05	MRL ((EU) 2021/2202)
Lentils / boiled	-	-	0.2	MRL ((EU) 2021/2202)
Peas / canned	-	-	0.05	MRL ((EU) 2021/2202)
Sunflower seeds / oils	-	-	0.3	MRL ((EU) 2021/2202)
Rapeseeds / oils	-	-	0.05	MRL ((EU) 2021/2202)
Soyabeans / soya drink	-	-	0.05	MRL ((EU) 2021/2202)
Soyabeans / boiled	-	-	0.05	MRL ((EU) 2021/2202)

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-10: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	<0.1% (based on GEMS food G08)
IEDI (% ADI) according to EFSA PRIMo	<0.1% (based on GEMS food G11 and STMR from studies)
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities - children: 0.01% - beans (with pods) Unprocessed commodities - adults: 0.01% - soyabeans Processed commodities - children: <0.01% - beans (with pods)/boiled Processed commodities - adults: <0.01% - beans/ canned

* include raw and processed commodities if both values are required for PRIMo

The proposed uses of imazamox in the formulation CHR/H/IMA 40 SL do not represent unacceptable acute and chronic risks for the consumer.

zRMS comments:
In addition consumer risk assessment was performed using EFSA PRIMo Rev. 3.1 and all applicable MRLs (Reg. (EU) 2021/2202) as input values.

TMDI (% ADI)	0.1% (based on NL toddler)
IEDI (% ADI)	Not necessary
IESTI (% ARfD)	Unprocessed commodities Potatoes: 0.3% (based in UK infant) Melons: 0.3% (based on BE toddlers) Processed commodities Sugar beet (root (sugar): 0.2% (based on NL child) Potatoes/fried: 0.2% (based on NL toddler)

The proposed uses of imazamox in the formulation CHR/H/IMA 40 SL do not represent unacceptable acute and chronic risks for the consumer.

7.3 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised "scientific methods accepted by the Authority to assess such effects are available."
Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

The following paragraphs are to be considered as proposals, based on "standard" criteria.

Combined exposure is not relevant because the product contains only one active substance.

7.4 References

EFSA, 2016. Peer review of the pesticide risk assessment of the active substance imazamox, EFSA Journal 2016;14(4):4432

European Commission, 2015, Draft Renewal Assessment Report of the of Inclusion of Active Substances in Annex I of Council Directive 91/414/EEC, Volume 3 – Annex CA – B.7

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1	Sowik, I.	2022	CHR/H/IMA 40 SL Storage stability of the residues of Imazamox and its salts in dry pea and whole plants w/o roots. Insitute of Industrial Oranic Chemistry, Warsaw, Poland BA-13/21-04 GLP Unpublished	N	Chemirol
KCA 6.3/01	Wołoszynowska, M., Wańczyk, K.	2022	Magnitude of the residue of Imazamox and its salts in dry pea (Raw Agricultural Commodity) after one application of CHR/H/IMA 40 SL – one single harvest trial in Poland – 2021 SGS Polska, Warsaw, Insitute of Industrial Oranic Chemistry, Warsaw, Poland 21SGS96, BA-13/21-01 GLP Unpublished	N	Chemirol
KCA 6.3/02	Wołoszynowska, M., Wańczyk, K.	2022	Magnitude of the residue of Imazamox and its salts in dry pea (Raw Agricultural Commodity) after one application of CHR/H/IMA 40 SL – one single harvest trial in Hungary – 2021 SGS Polska, Warsaw, Insitute of Industrial Oranic Chemistry, Warsaw, Poland 21SGS94, BA-13/21-02 GLP Unpublished	N	Chemirol
KCA 6.3/03	Wołoszynowska, M., Wańczyk, K.	2022	Magnitude of the residue of Imazamox and its salts in dry pea (Raw Agricultural Commodity) after one application of CHR/H/IMA 40 SL – one single decline curve study in Germany – 2021 SGS Polska, Warsaw, Insitute of Industrial Oranic Chemistry, Warsaw, Poland 21SGS95, BA-13/21-03 GLP Unpublished	N	Chemirol
KCA 6.3/04	Sowik, I. Peda, T.	2022	Magnitude of the residue of Imazamox and its salts in dry pea (Raw Agricultural Commodity) after one application of CHR/H/IMA 40 SL – one decline curve study in Northern France – 2022 SGS Polska, Warsaw, Insitute of Industrial Oranic Chemistry, Warsaw, Poland 22SGS09, BA-29/22 GLP Unpublished	N	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3/05	Appeltauer, A.	2022	Determination of Residues of Imazamox in Honey after One Application of CHR/H/IMA 40 SL in Spring Oilseed Rape at Four Sites in Central and Southern Europe in 2022 Eurofins Agroscience Services Ecotox GmbH, Niefern-Öschelbronn, Germany S22-01627 GLP Unpublished	N	Chemirol

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1/01	Bibo, X.	2002	Freezer storage stability of CL 299236 and CL 263284 in wheat forage, Hay, straw, and grain BASF Corp. Agro Research, Princeton NJ, United States of America 2002/5004279 GLP Unpublished	N	BASF
KCA 6.1/02	Rawle, N. W.	2003	Freezer stability of AC 299263 and CL 263284 in maize grain, ear and immature whole plant samples CEMAS - CEM Analytical Services Ltd.; North Ascot Berkshire SL5 8JB; United Kingdom 2003/1030079 GLP Unpublished	N	BASF
KCA 6.1/03	Fletcher J. S.	2001	CL 299263 (Imazamox): Freezer storage stability of CL 299263, CL 263284 , CL 189215 and CL 312622 residues in alfalfa seed, forage and hay BASF Corp. Agro Research, Princeton NJ, United States of America ID-326-024 GLP Unpublished	N	BASF
KCA 6.1/04	Fletcher J. S.	2001	CL 299263 (Imazamox): Freezer storage stability of CL 299263, (and its metabolites) CL 263284, CL 189215 and CL 312622 residues in alfalfa seed, forage and hay - Report amendment No. 01 BASF Corp. Agro Research, Princeton NJ, United States of America ID-790-014 GLP Unpublished	N	BASF
KCA 6.1/05	Witkonton, S.	1995	CL 299, 263: Twenty-four month freezer storage stability of CL 299, 263 residues in soybean seed American Cyanamid Co.; Princeton NJ; United States of America ID-326-004 GLP Unpublished	N	BASF
KCA 6.1/06	Bixler, T. A., Safarpour, H.	2000	Freezer stability of residues of CL 299, 263 and CL 263, 284 in soybean commodities (seed, forage and hay) American Cyanamid Co., Princeton NJ, United States of America ID-720-070 GLP Unpublished	N	BASF
KCA	Leite, R.,	2011	Investigation study of the storage stability of Imazapyr (BAS	N	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
6.1/07	Alves, M		693 H), Imazapic (BAS 715 H) and its metabolites CL 263,284 and CL 189,215 in soybean and processed fractions BASF SA, Guaratingueta, Brazil 2011/1207286 GLP Unpublished		
KCA 6.1/08	Leite, R., Nejad, H.	2000	CL 263,222 (Imazapic): Freezer stability of residues of CL 263,222, CL 263,284 and CL 189,215 in peanut hull and nutmeat Centre Analytical Laboratories Inc., State College PA, United States of America IA-740-023 GLP Unpublished	N	BASF
KCA 6.2.1/01	Mallipuldi, N. M.	1994	CL 299, 263: Metabolism of carbon-14 labeled CL 299, 263 in soybean under field conditions American Cyanamid Co.; Princeton NJ; United States of America ID-640-001 GLP Unpublished	N	BASF
KCA 6.2.1/02	Chiu, T.	1995	CL 299, 263: Metabolism of carbon-14 labeled CL 299, 263 in peas under field conditions American Cyanamid Co.; Princeton NJ; United States of America ID-640-004 GLP Unpublished	N	BASF
KCA 6.2.1/03	McDonnell, R. J.	1995	CL 299, 263: Metabolism of carbon-14 labeled CL 299, 263 in field grown canola American Cyanamid Co.; Princeton NJ; United States of America ID-640-003 GLP Unpublished	N	BASF
KCA 6.3.1/01	North, I.	2007	Study on the residue behaviour of Imazamox, Metazachlor and Quinmerac in oilseed rape following foliar applications under field conditions in Northern and Southern Europe during 2005-2006 Agrisearch UK Ltd., Melbourne Derbyshire DE73 8AG, United Kingdom 2007/1007939 GLP Unpublished	N	BASF
KCA 6.3.1/02	North, I.	2007	Study on the residue behaviour of Imazamox, Metazachlor and Quinmerac in oilseed rape following foliar applications under field conditions in Northern and Southern Europe during 2005-2006 Agrisearch UK Ltd., Melbourne Derbyshire DE73 8AG, United Kingdom	N	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			2007/1007963 GLP Unpublished		
KCA 6.3.1/03	Gabriel, E. J.	2013	Study on the residue behaviour of Metazachlor, Quinmerac and Imazamox in oilseed rape after treatment with BAS 798 00 H and BAS 160 00 S under field conditions in Germany and the United Kingdom, 2011 SGS Institut Fresenius GmbH, Taunusstein, Germany Fed. Rep. 2012/1084182 GLP Unpublished	N	BASF
KCA 6.3.1/04	Martin, T.	2013	Study on the residue behavior of Quinmerac (BAS 518 H) and Imazamox (BAS 720 H) on oilseed rape after the application of BAS 831 00 H under field conditions in Germany, United Kingdom, Italy and Spain, 2012 Agrologia SL, Utrera, Spain 2013/1044540 GLP Unpublished	N	BASF
KCA 6.6.1	Gatterdam, P.	1994	CL 299, 263: Confined accumulation study of carbon-14 labeld CL 299, 263 using radishes, corn, lettuce and wheat as rotational crops American Cyanamid Co.; Princeton NJ; United States of America ID-640-002 GLP Unpublished	N	BASF

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Imazamox

A 2.1.1 Stability of residues

Not performed, not required

Comments of zRMS	The study is accepted. However, the results of the study should be provided in accordance with Annex 2 to OECD 506.

A 2.1.1.1.1 Study 1

Reference:	KCA 6.1
Report	Wańczyk K., Wołoszynowska, M., CHR/H/IMA 40 SL Storage stability of the residues of Imazamox and its salts in dry pea and whole plants w/o roots; Testing faculties: Łukasiewicz Research Network, study code: BA-13/21-04
Guideline(s):	Yes (OECD 506 Stability of Pesticide residues in Stored Commodities)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Objective of the study

The study was carried out in accordance with a framework agreement no. UBK/BA/2021/016 signed by both the Sponsor, Chemirol Sp. z o.o. and the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry. The objective of the study was to generate data about the stability of residues of Imazamox and its salts in dry pea and whole plants w/o roots upon deep freezing storage conditions (at range of ≥ -18 °C ≤ - 12 °C.).

Methods and results

Imazamox and its salts residues content in the test system was determined by Ultra High-Performance Liquid Chromatography (ExionLC AC) coupled with mass spectrometer (SCIEX Triple Quad™ 4500) equipped with electrospray source and Analyst software using reversed phase column according to the SPO/BA/141/b 1st edition and validated method MT/BA-47/21. The method was developed and validated in Analytical Research Laboratory of Łukasiewicz Research Network – Institute of Industrial Organic Chemistry.
The stability of solutions of imazamox and its salts was demonstrated by analyzing solutions of known concentrations at 0 and 200 days of freezer storage. For each determination, a standard curve was made for each analyte separately, 2 control samples and 2 blanks. Also, 3 control samples were prepared and fortified with standards of Imazamox and its salts for determination after 0 days of storage. They were then wrapped with parafilm and placed in a suitable container and frozen for 200 days. After those days, the contents of imazamox and its salts were again determined in them. For comparison, three additional

fortified control samples with identical concentrations to those stored for 200 days were prepared and their contents of imazamox and its salts were also determined.

Table 1. Summary results

Matrix	Analysed substance	Recovery Acceptance criteria [%]	Recovery [%]		
			Samples analyzis at day 0	Analysis after 200 days of storage	
				Stored fortified samples	Freshly fortified samples
Dry pea	Imazamox	70 - 120	80.77	105.16	102.05
	CL189215		112.72	79.62	74.18
	CL263284		74.23	115.49	72.85
Whole plants w/o roots	Imazamox		73.78	100.50	99.51
	CL189215		114.56	106.43	101.51
	CL263284		106.52	92.00	96.91

Conclusion

The obtained results are acceptable. Imazamox, CL189215 and CL263284 are stable over period of 200 days in dry peas and whole plants.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

Not performed, not required

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Peas

zRMS comments:
Comparison of intended and critical EU GAPs.

Type of GAP	Crop	Number of applications	Method of application	Growth stage at last application	Max application rate per treatment (g a.s./ha)	PHI (days)
critical NEU GAP (EFSA Journal 2013;11(6):3282)	Peas dry - 0300030 without pods - 0260040	1	Soil treatment-spraying	BBCH 0-7	75	63
Intended GAP	Peas dry - 0300030 without pods - 0260040 with pods - 0260030	1	Spray	BBCH 12-16	36	-

A 2.1.3.1.1 Study 1

Comments of zRMS	The objective of the study (n=1, Poland) was to determine the residue level of imazamox and its salts in dry pea after one application in BBCH 16 with formulated product CHR/H/IMA 40 SL, the target dose rate was 48 g a.s./ha. The validation of the analytical method used in the study has been reviewed and accepted in Part B5 (KCP 5.2/01). Residues of imazamox and its salts in dry pea were below LOQ. LOQ for imazamox 0.0056 mg/kg, for CL189215 0.0041 mg/kg and for CL263284 0.0079 mg/kg. The sum of LOQ values is 0.0176 mg/kg, which is below current MRL value for imazamox in dry pea. The study is accepted.

Reference:	KCA 6.3/01
Report	Wańczyk K., Wołoszynowska, M., Magnitude of the residue of Imazamox and its salts in dry pea (Raw Agricultural Commodity) after one application of CHR/H/IMA 40 SL – one single harvest trial in Poland – 2021; Testing faculties: SGS, Poland, Łukasiewicz Research Network, study codes: 21SGS96, BA-13/21-01
Guideline(s):	Yes (OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009))
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Objective of the study

The objective of the study was to determine the residue level of imazamox and its salts in dry pea (Raw Agricultural Commodity) after one application with formulated product CHR/H/IMA 40 SL under cultural practice typical for dry pea production.
Materials and methods

Test item

Name:	CHR/H/IMA 40 SL
Trade names:	Mazzam, Zemax
Batch No.:	2018.08.21
Nominal density (from MSDS):	1,075 g/l
Formulation Name:	SL
Formulation Type:	Water-soluble concentrat
Main uses:	Herbicide
Expiry date:	08/2022
Active substance (a. s.):	Imazamox

CAS Number:		114311-32-9
Content of a. s.	nominal:	3,7 % w/w
	analysed:	3,77±0,31 % w/w
Certificate of Analysis dated:		18/03/2021

Test system

Crop	Dry pea (*Pisum sativum* L.)
Variety, planting date	See Table A2 – Test system information
Crop Group classification	Codex alimentarius: VD 0072
RACs harvested	Dry seeds

Field phase description

One harvest study (HS) was established in Poland. Trial consisted of one untreated plot U and one treated plot T.
Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negative impact on the integrity and validity of this study.
One typical for herbicide application was performed in trial with boom sprayer on the treated plots at the target dose rate of 1,2 l/ha (CHR/H/IMA 40 SL). For the test item CHR/H/IMA 40 SL reported dose rate was 1,181 l/ha
The target spray volume was 300 litres per hectare according to Good Agricultural Practices. The reported spray volume was actually 295,3 l/ha.
The spray mixture volumes remaining after applications were measured and the volumes applied to the treated plot were calculated to verify delivery rates. The calculations and the delivery rates were verified by the Study Director.
Deviations to the target rates were all between ± 5% as requested in the study plan (actually it was -1,6 %).
In harvest study (HS), RAC specimens for analyses (seeds) were collected at:
S1 - Commercial Harvest.
Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site.
Samplings dates and weights of collected specimens are presented in Table 15 – Sampling procedures and shipment of RAC specimens.
RAC specimens were put in deep freezing conditions at a target temperature
of ≤ -18° C on the day of sampling, within 12 hours after sampling.
All specimens remained deep frozen during storage at the test site, during shipment to the laboratory.

Matrix

The matrix used in this study was dried peas. All samples used in this study have been characterized and described with appropriate codes by SGS Polska Sp. z o.o. and delivered to Łukasiewicz-IPO where they were given the sample code 72/21-01. The sample delivery protocol is presented in Appendix no. 15 and their characteristics are presented below.

Country	Treatment	Specimen ID	Sampling occasion	Harvest date
Poland	U	21SGS96-01 **1**	S1=BBCH 89/CH*	21.07.2021
	T	21SGS96-01 **2**		21.07.2021

*BBCH –grown stage, CH-commercial Harvest, U-untreated, T-treated

Extraction and clean-up

The QuEChERS method (EN 15562 method with following modifications) was employed for extraction and clean-up process.

Homogenized dry pea powder (5 g) was weighed into a 50ml centrifuge tube. The sample was moistened with cold water acidified with formic acid (0.1%) to the level of about 90% (10 ml of solution) and left to soak for 15 minutes. Next 10 ml of acetonitrile and 100 µl of the internal standard solution (**A2, Table 3**) were added, the centrifuge tube was capped and shaken vigorously for 1 min. Next a mixture of salts QuEChERS MIX I containing 4 g of anhydrous magnesium sulphate, 0.5 g of di-Sodium hydrogen citrate 1,5-hydrate, 1 g of sodium chloride and 1 g of tri-Sodium citrate dihydrate was added and again shaken vigorously for 1 min to mix the sample thoroughly. The sample was centrifuged for 5 min at 5000 rpm. 6 ml of supernatant was transferred into a dSPE tube and purified by adding the mixture of salts QuEChERS Mix II. The sample was mixed thoroughly by shaken vigorously for 1 min and centrifuged for 5 min at 5000 rpm. Finally, the sample extract was transferred into a 1.5 ml glass autosampler vial for LC/MS-MS and analyzed within 24 hours. Each determination set included a reagent blank, two control samples (dry pea) five calibration solutions in matrix and three weights of the samples for each specimen.

Results and discussion

The content of Imazamox and its salt residues was determined by analyzing of three samples of **dry pea and** two samples of **control sample.** Results are presented in **Tables 13 - 18**.

Table 13. Determination of Imazamox content – dry pea control sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – Imazamox	Average peak area – Imazapic	Result [mg/kg]
21SGS96-01 1	1	5.0053	-	1216852	< LOQ
	2	5.0019	-	1258722	< LOQ

Table 14. Determination of CL189215 content – dry pea control sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL189215	Average peak area – Imazapic	Result [mg/kg]
21SGS96-01 1	1	5.0053	-	985181.3	< LOQ
	2	5.0019	-	960639.8	< LOQ

Table 15. Determination of CL263284 content – dry pea control sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL263284	Average peak area – Imazapic	Result [mg/kg]
21SGS96-01 1	1	5.0053	-	1014013	< LOQ
	2	5.0019	-	957555.1	< LOQ

Table 16. Determination of Imazamox content – dry pea sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – Imazamox	Average peak area – Imazapic	Result [mg/kg]
21SGS96-01 2	1	5.0102	-	1486302	< LOQ
	2	5.0043	-	718182	< LOQ
	3	5.0049	-	948397	< LOQ

Table 17. Determination of CL189215 content – dry pea sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL189215	Average peak area – Imazapic	Result [mg/kg]
21SGS96-01 2	1	5.0102	-	1473871	< LOQ
	2	5.0043	-	1057420	< LOQ
	3	5.0049	-	1007723	< LOQ

Table 18. Determination of CL263284 content – dry pea sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL263284	Average peak area – Imazapic	Result [mg/kg]
21SGS96-01 2	1	5.0102	-	1252977	< LOQ
	2	5.0043	-	730692	< LOQ
	3	5.0049	-	722891	< LOQ

The content of Imazamox and its salts in dry pea is < LOQ it means below 0.0056 mg/kg for Imazamox, 0.0041 mg/kg for CL189215 and for CL263284 is 0.0079 mg/kg. The sum of LOQ values is 0.0176 mg/kg, which is below MRL value 0.05 mg/kg of dry pea.

Conclusion

The residual content of imazamox and its salts is lower than the LOQ, and which in turn is lower than MRL, 0.05 mg/kg, therefore the risk is acceptable.

Comments of zRMS	The objective of the study (n=1, Hungary) was to determine the residue level of imazamox and its salts in dry pea after one application in BBCH 16 with formulated product CHR/H/IMA 40 SL, the target dose rate was 48 g a.s./ha. The validation of the analytical method used in the study has been reviewed and accepted in Part B5 (KCP 5.2/01). Residues of imazamox and its salts in dry pea were below LOQ. LOQ for imazamox 0.0056 mg/kg, for CL189215 0.0041 mg/kg and for CL263284 0.0079 mg/kg. The sum of LOQ values is 0.0176 mg/kg, which is below current MRL value for imazamox in dry pea. The study is accepted.

A 2.1.3.1.2 Study 2

Reference:	KCA 6.3/02
Report	Wańczyk K., Wołoszynowska, M., Magnitude of the residue of Imazamox and its salts in dry pea (Raw Agricultural Commodity) after one application of CHR/H/IMA 40 SL – one single harvest trial in Hungary – 2021; Testing faculties: SGS, Poland, Łukasiewicz Research Network, study codes: 21SGS94, BA-13/21-02
Guideline(s):	Yes (OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009))
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Objective of the study

The objective of the study was to determine the residue level of imazamox and its salts in dry pea (Raw Agricultural Commodity) after one application with formulated product CHR/H/IMA 40 SL under cultural practice typical for dry pea production.
Materials and methods

Test item

Name:	CHR/H/IMA 40 SL
Trade names:	Mazzam, Zemax
Batch No.:	2018.08.21
Nominal density (from MSDS):	1,075 g/l
Formulation Name:	SL
Formulation Type:	Water-soluble concentrat
Main uses:	Herbicide
Expiry date:	08/2022
Active substance (a. s.):	Imazamox

CAS Number:		114311-32-9
Content of a. s.	**nominal:**	3,7 % w/w
	analysed:	3,77±0,31 % w/w
Certificate of Analysis dated:		18/03/2021

Test system

Crop	Dry pea (*Pisum sativum* L.)
Variety, planting date	See Table A2 – Test system information
Crop Group classification	Codex alimentarius: VD 0072
RACs harvested	Dry seeds

Field phase description

One harvest study (HS) was established in Hungary. Trial consisted of one untreated plot U and one treated plot T.
Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negative impact on the integrity and validity of this study.
One typical for herbicide application was performed in trial with boom sprayer on the treated plots at the target dose rate of 1,2 l/ha (CHR/H/IMA 40 SL). For the test item CHR/H/IMA 40 SL reported dose rate was 1,173 l/ha
The target spray volume was 300 litres per hectare according to Good Agricultural Practices. The reported spray volume was actually 293,3 l/ha.
The spray mixture volumes remaining after applications were measured and the volumes applied to the treated plot were calculated to verify delivery rates. The calculations and the delivery rates were verified by the Study Director.
Deviations to the target rates were all between ± 5% as requested in the study plan (actually it was -2,3 %).
In harvest study (HS), RAC specimens for analyses (seeds) were collected at:
S1 - Commercial Harvest.
Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site.
Samplings dates and weights of collected specimens are presented in Table 15 – Sampling procedures and shipment of RAC specimens.
RAC specimens were put in deep freezing conditions at a target temperature of ≤ -18°C on the day of sampling, within 12 hours after sampling.
All specimens remained deep frozen during storage at the test site, during shipment to the laboratory.

Matrix

The matrix used in this study was dried peas. All samples used in this study have been characterized and described with appropriate codes by SGS Polska Sp. z o.o. and delivered to Łukasiewicz-IPO where they were given the sample code 72/21-02. The sample delivery protocol is presented in Appendix no. 15 and their characteristics are presented below.

Country	Treatment	Specimen ID	Sampling occasion	Harvest date
Hungary	U	21SGS94-01 **1**	S1=BBCH 89/CH*	21.07.2021
	T	21SGS94-01 **2**		21.07.2021

*BBCH –grown stage, CH-commercial Harvest, U-untreated, T-treated

Extraction and clean up

The QuEChERS method (EN 15562 method with following modifications) was employed for extraction and clean-up process.

Homogenized dry pea powder (5 g) was weighed into a 50ml centrifuge tube. The sample was moistened with cold water acidified with formic acid (0.1%) to the level of about 90% (10 ml of solution) and left to soak for 15 minutes. Next 10 ml of acetonitrile and 100 µl of the internal standard solution (**A2, Table 3**) were added, the centrifuge tube was capped and shaken vigorously for 1 min. Next a mixture of salts QuEChERS MIX I containing 4 g of anhydrous magnesium sulphate, 0.5 g of di-Sodium hydrogen citrate 1,5-hydrate, 1 g of sodium chloride and 1 g of tri-Sodium citrate dihydrate was added and again shaken vigorously for 1 min to mix the sample thoroughly. The sample was centrifuged for 5 min at 5000 rpm. 6 ml of supernatant was transferred into a dSPE tube and purified by adding the mixture of salts QuEChERS Mix II. The sample was mixed thoroughly by shaken vigorously for 1 min and centrifuged for 5 min at 5000 rpm. Finally, the sample extract was transferred into a 1.5 ml glass autosampler vial for LC/MS-MS and analyzed within 24 hours. Each determination set included a reagent blank, two control samples (dry pea) five calibration solutions in matrix and three weights of the samples for each specimen.

Results

The content of Imazamox and its salt residues was determined by analyzing of three samples of **dry pea and** two samples of **control sample.** Results are presented in **Tables 13 - 18**.

Table 13. Determination of Imazamox content – dry pea control sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – Imazamox	Average peak area – Imazapic	Result [mg/kg]
21SGS94-01 1	1	5.0002	-	1028304	< LOQ
	2	5.0034	-	1062323	< LOQ

Table 14. Determination of CL189215 content – dry pea control sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL189215	Average peak area – Imazapic	Result [mg/kg]
21SGS94-01 1	1	5.0002	-	1214774	< LOQ
	2	5.0034	-	1195427	< LOQ

Table 15. Determination of CL263284 content – dry pea control sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL263284	Average peak area – Imazapic	Result [mg/kg]
21SGS94-01 1	1	5.0002	-	810441.5	< LOQ
	2	5.0034	-	838000.4	< LOQ

Table 16. Determination of Imazamox content – dry pea sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – Imazamox	Average peak area – Imazapic	Result [mg/kg]
21SGS94-01 2	1	5.0023	-	1055305	< LOQ
	2	5.0071	-	527236,6	< LOQ
	3	5.0014	-	1172013	< LOQ

Table 17. Determination of CL189215 content – dry pea sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL189215	Average peak area – Imazapic	Result [mg/kg]
21SGS94-01 2	1	5.0023	-	1245535	< LOQ
	2	5.0071	-	619599.0	< LOQ
	3	5.0014	-	1363208	< LOQ

Table 18. Determination of CL263284 content – dry pea sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL263284	Average peak area – Imazapic	Result [mg/kg]
21SGS94-01 2	1	5.0023	-	816487	< LOQ
	2	5.0071	-	684756	< LOQ
	3	5.0014	-	605597	< LOQ

The content of Imazamox and its salts in dry pea is < LOQ it means below 0.0056 mg/kg for Imazamox, 0.0041 mg/kg for CL189215 and for CL263284 is 0.0079 mg/kg. The sum of LOQ values is 0.0176 mg/kg, which is below MRL value 0.05 mg/kg of dry pea.

Conclusion

The residual content of imazamox and its salts is lower than the LOQ, and which in turn is lower than MRL, 0.05 mg/kg, therefore the risk is acceptable.

Comments of zRMS	The objective of the study (n=1, Germany) was to determine the residue level of imazamox and its salts in dry pea and whole plants of pea w/o roots after one application in BBCH 16 with formulated product CHR/H/IMA 40 SL, the target dose rate was 48 g a.s./ha. The validation of the analytical method used in the study has been reviewed and accepted in Part B5 (KCP 5.2/01). Residues of imazamox and its salts in dry pea were below LOQ. LOQ for imazamox 0.0056 mg/kg, for CL189215 0.0041 mg/kg and for CL263284 0.0079 mg/kg. The sum of LOQ values is 0.0176 mg/kg, which is below current MRL value for imazamox in dry pea. Residues o in the whole plants were in the range: < LOQ – 0.0185 mg/kg for imazamox < LOQ – 0.0388 mg/kg for CL263284. Residues of CL18921 in the whole plants were below LOQ. LOQ for imazamox in whole plants was 0.0056 mg/kg, for CL189215 0.0041 mg/kg and for CL263284 0.0079 mg/kg. The study is accepted.

A 2.1.3.1.3 Study 3

Reference:	KCA 6.3/03
Report	Wańczyk K., Bajdor K., Magnitude of the residue of Imazamox and its salts in dry pea and whole plant w/o roots (Raw Agricultural Commodity) after one application of CHR/H/IMA 40 SL – one single harvest trial in Germany – 2021; Testing faculties: SGS, Poland, Łukasiewicz Research Network, study codes: 21SGS95, BA-13/21-03
Guideline(s):	Yes (OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009))
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Objective of the study

The objective of the study was to determine the residue level of imazamox and its salts in dry pea (Raw Agricultural Commodity) after one application with formulated product CHR/H/IMA 40 SL under cultural practice typical for dry pea production.

Materials and methods

Test item

Name:	CHR/H/IMA 40 SL

Trade names:		Mazzam, Zemax
Batch No.:		2018.08.21
Nominal density (from MSDS):		1,075 g/l
Formulation Name:		SL
Formulation Type:		Water-soluble concentrat
Main uses:		Herbicide
Expiry date:		08/2022
Active substance (a. s.):		Imazamox
CAS Number:		114311-32-9
Content of a. s.	nominal:	3,7 % w/w
	analysed:	3,77±0,31 % w/w
Certificate of Analysis dated:		18/03/2021

Test system

Crop	Dry pea (*Pisum sativum* L.)
Variety, planting date	See Table A2 – Test system information
Crop Group classification	Codex alimentarius: VD 0072
RACs harvested	Dry seeds

One decline curve study (DCS) was established in Germany. Trial consisted of one untreated plot U and one treated plot T.
Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negative impact on the integrity and validity of this study.
One typical for herbicide application was performed in trial with boom sprayer on the treated plots at the target dose rate of 1,2 l/ha (CHR/H/IMA 40 SL). For the test item CHR/H/IMA 40 SL reported dose rate was 1,208 l/ha
The target spray volume was 250 litres per hectare according to Good Agricultural Practices. The reported spray volume was actually 251,7 l/ha.
The spray mixture volumes remaining after applications were measured and the volumes applied to the treated plot were calculated to verify delivery rates. The calculations and the delivery rates were verified by the Study Director.
Deviations to the target rates were all between ± 5% as requested in the study plan (actually it was +0,7 %).
In decline curve study (DCS), RAC specimens for analyses (whole plants w/o roots, seeds) were collected at:
S1 - 0 DBA/0 DAA
S2 - BBCH 39

S3 - BBCH 59
S4 - BBCH 75
S5 - Commercial Harvest.

Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial site.
Samplings dates and weights of collected specimens are presented in Table 15 – Sampling procedures and shipment of RAC specimens.
RAC specimens were put in deep freezing conditions at a target temperature of ≤ -18°C on the day of sampling, within 12 hours after sampling.
All specimens remained deep frozen during storage at the test site, during shipment to the laboratory.

Matrix

The matrix used in this study was dried peas. All samples used in this study have been characterized and described with appropriate codes by SGS Polska Sp. z o.o. and delivered to Łukasiewicz-IPO where they were given the sample code 72/21-03. The sample delivery protocol is presented in Appendix no. 15 and their characteristics are presented below.

Country	Treatment	Specimen ID	Sampling occasion	Harvest date
Germany	Whole plants w/o roots			
	U	21SGS95-01 1	S1= 0 DBA	01.06.2021
	T	21SGS95-01 2R	S1= 0 DAA	09.06.2021
	T	21SGS95-01 3R	S2 = BBCH 39	14.06.2021
	T	21SGS95-01 4R	S3 = BBCH 59	13.07.2021
	T	21SGS95-01 5R	S4= BBCH 79	01.06.2021
	Dry seeds			
	U	21SGS95-01 **6**	S5= BBCH 89/ CH	12.08.2021
	T	21SGS95-01 **7**		12.08.2021

*BBCH –grown stage, CH-commercial Harvest, U-untreated, T-treated

Specimen and control samples were sent from SGS on 14 September 2021 and received at Analytical Research Laboratory on 16 September 2021. Upon receipt, samples were logged in and stored in freezer, then allowed to defrost prior to analysis in refrigerator. Temperature ranges during the storage were -15±2 °C and the temperature range during the course of this study for refrigerator was 7±3°C. Prior to analysis, the samples were sub-sampled and described by the code assigned by SGS. Sample extracts were stored in refrigerator while awaiting LC-MS/MS analysis. The control samples were checked for contamination prior to use in this determination study by employing the same extraction and detection method as described in method MT/BA-47/21.

Extraction and clean up

The QuEChERS method (EN 15562 method with following modifications) was employed for extraction and clean-up process.

Homogenized dry pea powder (5 g) was weighed into a 50ml centrifuge tube. The sample was moistened with cold water acidified with formic acid (0.1%) to the level of about 90% (10 ml of solution) and left to soak for 15 minutes. Next 10 ml of acetonitrile and 100 µl of the internal standard solution (**A2, Table 4**) were added, the centrifuge tube was capped and shaken vigorously for 1 min. Next a mixture of salts QuEChERS MIX I containing 4 g of anhydrous magnesium sulphate, 0.5 g of di-Sodium hydrogen citrate 1,5-hydrate, 1 g of sodium chloride and 1 g of tri-Sodium citrate dihydrate was added and again shaken vigorously for 1 min to mix the sample thoroughly. The sample was centrifuged for 5 min at 5000 rpm. 6 ml of supernatant was transferred into a dSPE tube and purified by adding the mixture of salts QuEChERS Mix II. The sample was mixed thoroughly by shaken vigorously for 1 min and centrifuged for 5 min at 5000 rpm. Finally, the sample extract was transferred into a 1.5 ml glass autosampler vial for LC/MS-MS and analyzed within 24 hours. Each determination set included a reagent blank, two control samples (dry pea) five calibration solutions in matrix and three weights of the samples for each specimen.

For the analysis of whole plants samples without roots 5 g was taken into a 50 ml centrifuge tube. 5 ml of cold acidified water was added to the sample and left to soak for 15 minutes. Next 10 ml of acetonitrile and 100 µl of the internal standard solution (**A2, Table 12**) were added, the centrifuge tube was capped and shaken vigorously for 1 min. Mixture of salts QuEChERS MIX I containing 4 g of anhydrous magnesium sulphate, 0.5 g of di-Sodium hydrogen citrate 1,5-hydrate, 1 g of sodium chloride and 1 g of tri-Sodium citrate dihydrate was added and again shaken vigorously for 1 min to mix the sample thoroughly. The sample was centrifuged for 5 min at 5000 rpm. 6 ml of supernatant was transferred into a dSPE tube and purified by adding the mixture of salts QuEChERS Mix II, while in the case of samples containing chlorophyll, the mixture QuEChERS Mix III was additionally added, and the tube was shaken again for 1 min and then centrifuged for 5 min (5000 rpm). The sample was mixed thoroughly by shaken vigorously for 1 min and centrifuged for 5 min at 5000 rpm. Finally, the sample extract was transferred into a 1.5 ml glass autosampler vial for LC/MS-MS and analyzed within 24 hours.

Results – dry pea

The content of Imazamox and its salt residues was determined by analyzing of three samples of **dry pea** and **control sample.** Results are presented in **Tables 22 - 27.**

Table 22. Determination of Imazamox content – dry pea control sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – Imazamox	Average peak area – Imazapic	Result [mg/kg]
21SGS95-01 6	1	5.0102	-	913241.1	< LOQ
	2	5.0052	-	965875.0	< LOQ

Table 23. Determination of CL189215 content – dry pea control sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL189215	Average peak area – Imazapic	Result [mg/kg]
21SGS95-01 6	1	5.0102	-	1171706	< LOQ
	2	5.0052	-	1202386	< LOQ

Table 24. Determination of CL263284 content – dry pea control sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL263284	Average peak area – Imazapic	Result [mg/kg]
21SGS95-01 6	1	5.0102	-	729324.9	< LOQ
	2	5.0052	-	711888.2	< LOQ

Table 25. Determination of Imazamox content – dry pea sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – Imazamox	Average peak area – Imazapic	Result [mg/kg]
21SGS95-01 7	1	5.0057	-	1307620	< LOQ
	2	5.0022	-	1214857	< LOQ
	3	5.0098	-	1312718	< LOQ

Table 26. Determination of CL189215 content – dry pea sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL189215	Average peak area – Imazapic	Result [mg/kg]
21SGS95-01 7	1	5.0057	-	1378622	< LOQ
	2	5.0022	-	1303549	< LOQ
	3	5.0098	-	1285109	< LOQ

Table 27. Determination of CL263284 content – dry pea sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL263284	Average peak area – Imazapic	Result [mg/kg]
21SGS95-017	1	5.0057	-	1143519	< LOQ
	2	5.0022	-	915071	< LOQ
	3	5.0098	-	1057234	< LOQ

Results – whole plants w/o roots

The content of Imazamox and its salt residues was determined by analyzing of three samples of **whole plants w/o roots and control sample.** Results are presented in **Tables 31 – 45.**

Table 31. Determination of Imazamox content – whole plants w/o roots sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – Imazamox	Average peak area – Imazapic	Result [mg/kg]
21SGS95-012R	1	5.0050	122283	1086015	0.0180
	2	5.0029	118119	1043436	0.0181
	3	5.0071	122665	1024436	0.0193
				Mean	0.0185
				SD	0.0007
				RSD [%]	3.69

Table 32. Determination of CL189215 content – whole plants w/o roots sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL189215	Average peak area – Imazapic	Result [mg/kg]
21SGS95-012R	1	5.0050	-	1266388	< LOQ
	2	5.0029	-	1099845	< LOQ
	3	5.0071	-	1030010	< LOQ

Table 33. Determination of CL263284 content – whole plants w/o roots sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL263284	Average peak area – Imazapic	Result [mg/kg]
21SGS95-01 2R	1	5.0050	190825	722413	0.0384
	2	5.0029	216915	796018	0.0396
	3	5.0071	199120	754748	0.0384
				Mean	0.0388
				SD	0.0007
				RSD [%]	1.78

Table 34. Determination of Imazamox content – whole plants w/o roots sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – Imazamox	Average peak area – Imazapic	Result [mg/kg]
21SGS95-01 3R	1	5.0008	60213.5	988600.0	0.0091
	2	5.0121	60154.2	978306.8	0.0092
	3	5.0056	62324.8	992751.40	0.0092
				Mean	0.0093
				SD	0.0002
				RSD [%]	1.78

Table 35. Determination of CL189215 content – whole plants w/o roots sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL189215	Average peak area – Imazapic	Result [mg/kg]
21SGS95-01 3R	1	5.0008	-	1047588	< LOQ
	2	5.0121	-	1009224	< LOQ
	3	5.0056	-	874662.9	< LOQ

Table 36. Determination of CL263284 content – whole plants w/o roots sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL263284	Average peak area – Imazapic	Result [mg/kg]
21SGS95-01 3R	1	5.0008	36396	704087	0.0087
	2	5.0121	36240	779219	0.0079
	3	5.0056	32256	700904	0.0079
				Mean	0.0082
				SD	0.0004
				RSD [%]	5.39

Table 37. Determination of Imazamox content – whole plants w/o roots sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL189215	Average peak area – Imazapic	Result [mg/kg]
21SGS95-01 4R	1	5.0037	-	974996.4	< LOQ
	2	5.0045	-	1312620	< LOQ
	3	5.0050	-	1135005	< LOQ

Table 38. Determination of CL189215 content – whole plants w/o roots sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL189215	Average peak area – Imazapic	Result [mg/kg]
21SGS95-01 4R	1	5.0037	-	974996.4	< LOQ
	2	5.0045	-	1312620	< LOQ
	3	5.0050	-	1135005	< LOQ

Table 39. Determination of CL263284 content – whole plants w/o roots sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL263284	Average peak area – Imazapic	Result [mg/kg]
21SGS95-01 4R	1	5.0037	-	780262.5	< LOQ
	2	5.0045	-	715533.9	< LOQ
	3	5.0050	-	989944.8	< LOQ

Table 40. Determination of Imazamox content – whole plants w/o roots sample

Sample ID	Sample No	Sample mass [mg]	Peak area – Imazamox	Peak area – Imazapic	Result [mg/kg]
21SGS95-01 5R	1	5.0010	-	1050018	< LOQ
	2	5.0046	-	1091411	< LOQ
	3	5.0088	-	1088215	< LOQ

Table 41. Determination of CL189215 content – whole plants w/o roots sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL189215	Average peak area – Imazapic	Result [mg/kg]
21SGS95-01 5R	1	5.0010	-	1114185	< LOQ
	2	5.0046	-	1037137	< LOQ
	3	5.0088	-	1017902	< LOQ

Table 42. Determination of CL263284 content – whole plants w/o roots sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL263284	Average peak area – Imazapic	Result [mg/kg]
21SGS95-01 5R	1	5.0010	-	732716.1	< LOQ
	2	5.0046	-	768637.4	< LOQ
	3	5.0088	-	757171.1	< LOQ

Table 43. Determination of Imazamox content – whole plants w/o roots control sample

Sample ID	Sample No	Sample mass [mg]	Peak area – Imazamox	Peak area – Imazapic	Result [mg/kg]
21SGS95-01 1	1	5.0028	-	1080509	< LOQ
	2	5.0087	-	1016320	< LOQ

Table 44. Determination of CL189215 content – whole plants w/o roots control sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL189215	Average peak area – Imazapic	Result [mg/kg]
21SGS95-01 1	1	5.0028	-	621941.3	< LOQ
	2	5.0087	-	936356.0	< LOQ

Table 45. Determination of CL263284 content – whole plants w/o roots control sample

Sample ID	Sample No	Sample mass [mg]	Average peak area – CL263284	Average peak area – Imazapic	Result [mg/kg]
21SGS95-01 1	1	5.0028	-	952643	< LOQ
	2	5.0087	-	995056	< LOQ

The content of Imazamox and its salts in **dry pea** is < LOQ it means below 0.0056 mg/kg for Imazamox, 0.0041 mg/kg for CL189215 and for CL263284 is 0.0079 mg/kg. The sum of LOQ values is 0.0176 mg/kg, which is below actual MRL value 0.05 mg/kg.

The content of Imazamox and its salts in **whole plant w/o roots** was respectively:

- **sample ID 21SGS95-01 2R – 0.0185 mg/kg** of imazamox and **0.0388 mg/kg** of CL263284**, so the sum of residues according to the definition is 0.0573 mg/kg**
- **sample ID 21SGS95-01 3R – 0.00093 mg/kg** of imazamox and **0.0082 mg/kg** of CL263284**, so the sum of residues according to the definition is 0.0175 mg/kg.** The obtained result is below actual MRL – 0.05 mg/kg

- **sample ID 21SGS95-01 4R** – is < LOQ it means below 0.0052 mg/kg, for CL189215 is 0.0030 mg/kg and for CL263284 is 0.0079 mg/kg. The sum of LOQ values is 0.0161 mg/kg, which is below actual MRL value 0.05 mg/kg.
- **sample ID 21SGS95-01 5R** – is < LOQ it means below 0.0052 mg/kg, for CL189215 is 0.0030 mg/kg and for CL263284 is 0.0079 mg/kg. The sum of LOQ values is 0.0161 mg/kg, which is below actual MRL value 0.05 mg/kg.
- **sample ID 21SGS95-01 1 (control sample)** – is < LOQ it means below 0.0052 mg/kg, for CL189215 is 0.0030 mg/kg and for CL263284 is 0.0079 mg/kg. The sum of LOQ values is 0.0161 mg/kg, which is below actual MRL value 0.05 mg/kg.

Conclusion

The results for the dry pea samples were below the LOQ. On the other hand, for samples ID 21SGS95-01 2R and ID 21SGS95-01 2R from whole plants without roots, the results ranged from 0.0093 to 0.0185 mg/kg of imazamox, ~~which are still lower than the MRL, 0.05 mg/kg~~, while for the others they are lower than the LOQ. Therefore the risk is acceptable.

Comments of zRMS	The objective of the study (n=1, Northern France) was to determine the residue level of imazamox and its salts in dry pea and whole plants of pea w/o roots after one application in BBCH 16 with formulated product CHR/H/IMA 40 SL, the target dose rate was 48 g a.s./ha. The validation of the analytical method used in the study has been reviewed and accepted in Part B5 (KCP 5.2/01). Residues of imazamox and its salts in dry pea were below LOQ. LOQ for imazamox 0.0056 mg/kg, for CL189215 0.0041 mg/kg and for CL263284 0.0079 mg/kg. The sum of LOQ values is 0.0176 mg/kg, which is below current MRL value for imazamox in dry pea. Residues o in the whole plants were in the range: < LOQ – 0.0023 mg/kg for imazamox Residues of CL18921 and CL263284 in the whole plants were below LOQ. LOQ for imazamox in whole plants was 0.0052 mg/kg, for CL189215 0.003 mg/kg and for CL263284 0.0079 mg/kg. The study is accepted.

A 2.1.3.1.4 Study 4

Reference:	KCA 6.3/04
Report	Peda, T., Sowik, I., Magnitude of the residue of Imazamox and its salts in dry pea (Raw Agricultural Commodity) after one application of CHR/H/IMA 40 SL – one decline curve study in Northern France – 2022; Testing faculties: SGS, Poland, Łukasiewicz Research Network, study codes: 22SGS09, BA-29/22
Guideline(s):	Yes (OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009))
Deviations:	No

GLP: Yes

Acceptability: Yes

Objective of the study

The aim of the study was to determine content of Imazamox and its salts: 2-(4-isopropyl-4-methyl-5-oxo-4,5-dihydro-1H-imidazol-2-yl)-5-((((2R,3R,4S,5S,6R)-3,4,5-trihydroxy-6-(hydroxymethyl)tetrahydro-2H-pyran-2-yl)oxy)methyl)nicotinic acid **(CL189215)** and 5-(hydroxymethyl)-2-(4-isopropyl-4-methyl-5-oxo-4,5-dihydro-1H-imidazol-2-yl)nicotinic acid **(CL263284)** in dry pea and whole plants w/o roots following one application of the CHR/H/IMA 40 SL preparation according to present EU requirements.

Materials and methods

Test item

Name:		CHR/H/IMA 40 SL
Trade names:		Mazzam, Zemax
Batch No.:		2018.08.21
Nominal density (from MSDS):		1,075 g/l
Formulation Name:		SL
Formulation Type:		Water-soluble concentrat
Main uses:		Herbicide
Expiry date:		08/2022
Active substance (a. s.):		Imazamox
CAS Number:		114311-32-9
Content of a. s.	nominal:	3,7 % w/w
	analysed:	3,77±0,31 % w/w
Certificate of Analysis dated:		18/03/2021

Test system

Decline Curve Study trial (DCS) was established in Northern France. Trial consisted of one untreated plot U and one treated plot T.
Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial site to such a degree as to have negative impact on the integrity and validity of this study.
One typical for herbicide application of CHR/H/IMA 40 SL was performed with boom sprayer on the treated plot at the target dose rate of 1,2 l/ha, equivalent to 0,048 kg/ha of imazamox. Spray volume was 200-400 l/ha according to Good Agricultural Practice.
The reported dose rate of test item was actually 1,211 l/ha and 302,8 l/ha water.
Application was performed at BBCH 16.
Remaining spray mixture volume after the application was measured and the volume applied to the treated plot was calculated to verify delivery rates. The calculations and the delivery rates were verified by the Study Director.
Deviation to the target rate was between ± 5% as requested in the study plan. Actually it was +0,9%

RAC specimens for analyses were collected:
- S1 (Whole plants without root) – 0 DALA
- S2 (Whole plants without root) – BBCH 39
- S3 (Whole plants without root) – BBCH 59
- S4 (Whole plants without root) – BBCH 79
- S5 (Dry seeds) - BBCH 89/Commercial Harvest

RAC specimens were put in deep freezing conditions at a target temperature of ≤ -18°C on the day of sampling, within 12 hours after sampling.
All specimens remained deep frozen during storage at the test site, during shipment to the laboratory.

Matrix

The matrix used in this study were dry pea and whole plants w/o roots. The control sample used in this study was characterized by SGS Polska Sp. z o.o. and reported to Łukasiewicz-IPO under sample code 66/22.

Country	Treatment	Specimen ID	Sampling occasion	Harvest date
France	Whole plants w/o roots			
	U	22SGS09-01 1	S1	04.05.2022
	T	22SGS09-01 2	S1	04.05.2022
	T	22SGS09-01 3	S2	16.05.2022
	T	22SGS09-01 4	S3	21.05.2022
	T	22SGS09-01 5	S4	13.06.2022
	Dry pea			
	U	22SGS09-01 6	S5	04.07.2022
	T	22SGS09-01 7	S5	04.07.2022

Specimen and control samples were received on 03 August 2022 at Analytical Research Laboratory Łukasiewicz Research Network – Institute of Industrial Organic Chemistry from SGS. Upon receipt, samples were logged in and stored in freezer, then allowed to defrost prior to analysis in refrigerator. Temperature ranges during the storage were -15±4 °C. Prior to analysis, the samples were sub-sampled and unique laboratory codes were assigned to each sub-sample and they are associated with the numbers assigned to those given by SGS. Sample extracts were stored in refrigerator while awaiting LC-MS/MS analysis.

Extraction and clean up

The QuEChERS method ((buffered EN 15562 method with following modifications) was employed for extraction and clean-up process.

For the analysis of whole plant samples without roots (5 g) was taken into a 50 ml centrifuge tube. 5 ml of cold acidified water was added to the sample and left to soak for 15 minutes. Next 10 ml of acetonitrile, 0.10 ml of the internal standard solution (A2) were added. In case of preparing standard curves, appropriate volumes of B2/C2/D2 solutions were also added. The centrifuge tube was capped and shaken vigorously for 1 min. Next a mixture of salts QuEChERS MIX I containing 4 g anhydrous magnesium sulphate, 0.5 g of di-sodium hydrogen citrate 1,5-hydrate, 1 g of sodium chloride and 1 g of tri-sodium citrate dihydrate was added and again shaken vigorously for 1 min to mix the sample. The sample was

centrifuged for 5 min at 5000 rpm. The obtained extract was purified by adding the mixture of salts QuEChERS Mix II, while in the case of sample containing chlorophyll, the mixture QuEChERS Mix III was additionally added, and the tube was shaken again for 1 min and then centrifuged for 5 min (5000 rpm). The extract prepared in this manner was transferred to the autosampler vial and subjected to chromatographic analysis.
Homogenized dry pea powder (5 g) was weighed out into a 50-ml centrifuge tube. The sample was moistened with water acidified with formic acid (0.1%) to the level of water about 90%

(10 ml of solution) and left to soak for 15 minutes. Next 10 ml of acetonitrile, 0.10 ml of the internal standard solution (A2) were added. In case of preparing standard curves, appropriate volumes of B2/C2/D2 solutions were also added. The centrifuge tube was capped and shaken vigorously for 1 min. Next a mixture of salts QuEChERS MIX I containing 4 g anhydrous magnesium sulphate, 0.5 g of di-sodium hydrogen citrate 1,5-hydrate, 1 g of sodium chloride and 1 g of tri-sodium citrate dihydrate was added and again shaken vigorously for 1 min to mix the sample thoroughly. The sample was centrifuged for 5 min at 5000 rpm. The obtained extract was purified by adding the mixture of salts QuEChERS Mix II. The sample was mixed by shaken vigorously for 1 min and centrifuged for 5 min at 5000 rpm. Finally, the sample solution was transferred into a 1.5 ml glass auto sampler vial for LC/MS-MS.

Results

The residue analytical method is suitable for the determination of Imazamox and its salts in dry pea and whole plant w/o roots. Specimen samples were analyzed directly upon QuEChERS extraction with acetonitrile using liquid chromatography tandem mass spectrometry (LC-MS/MS) and internal standard method.

Table 1. Summary of the results for Imazamox and its salts - **dry pea**

Sample ID	Treatment	Imazamox	CL189215	CL263284
22SGS09-01 6	U	< LOQ	< LOQ	< LOQ
22SGS09-01 7	T	0.0021	< LOQ	< LOQ

U – untreated, T – treated

Table 2. Summary of the results for Imazamox and its salts - **whole plants w/o roots**

Sample ID	Treatment	Imazamox	CL189215	CL263284
22SGS09-01 1	U	< LOQ	< LOQ	< LOQ
22SGS09-01 2	T	0.0022	< LOQ	< LOQ
22SGS09-01 3	T	0.0023	< LOQ	< LOQ
22SGS09-01 4	T	< LOQ	< LOQ	< LOQ
22SGS09-01 5	T	< LOQ	< LOQ	< LOQ

U – untreated, T – treated

Conclusion

The content of Imazamox in dry pea sample 22SGS09-01 7 is 0.0021 mg/kg. No imazamox content was detected in the sample 22SGS09-01 6. The content of Imazamox and its salts in dry pea samples are <LOQ, it means below 0.0056 mg/kg for Imazamox, 0.0041 mg/kg for for CL189215 and 0.0079 mg/kg for CL263584. The sum of LOQ values is 0.0176 mg/kg, which is below actual MRL value 0.05 mg/kg.

The content of Imazamox in whole plant w/o roots samples 22SGS09-01 2 and 22SGS09-01 3 are 0.0022 mg/kg and 0.0023 mg/kg. Imazamox was not detected in the samples 22SGS09-01 1, 22SGS09-01 4 and 22SGS09-01 5. The content of Imazamox and its salts in whole plant w/o roots samples are <LOQ, it means below 0.0052 mg/kg for Imazamox, 0.0030 mg/kg for for CL189215 and 0.0079 mg/kg for CL263584. The sum of LOQ values is 0.0161 mg/kg, which is below actual MRL value 0.05 mg/kg.

Summary of magnitude of residues in peas

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./ha				Imazamox	CL 263284	CL 189215		
	(a)	(b)				(c)						(d)	(e)
Trial 1. Murczyn, kujawsko-pomorskie, Poland	Dry pea (*Pisum sativum*)/Model	1 27.03.2021 2 10.06.2021 20.06.2021 3 14.07.2021	47	295.3	47	One treatment 20.05.21	BBCH 16	Dry seeds	< LOQ	< LOQ	<LOQ	62	N/A
Trial 2. Tiszavasvári, (Szabolcs-Szatmár-Bereg County), Hungary	Dry pea (*Pisum sativum*)/Hanka	1- 22/03/2021 2- 24/05/2021-10/06/2021 3 - 14/07/21-24/07/2021	47	293.3	47	One treatment 03.05.32	BBCH 16	Dry seeds	< LOQ	< LOQ	<LOQ	72	N/A
Trial 3. Wallsbüll (Schleswig Holstein), Germany	Dry pea (*Pisum sativum*)/Ostinato	1- 06/04/2021 2- 14/06/2021-02/07/2021 3- 12/08/2021	48.32	251.7	48.32	One treatment 01.06.21	BBCH 16	Dry seeds Whole plants	< LOQ 0.0185 0.0093 < LOQ < LOQ	< LOQ < LOQ < LOQ < LOQ < LOQ	<LOQ 0.0388 0.0082 < LOQ < LOQ	0 8 13 42 72	N/A

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./ha				Imazamox	CL 263284	CL 189215		
Trial 4. Northern France, Aumenancourt	Dry pea (*Pisum sativum*)/Kagnotte	1- 07/03/2022 2- 25/05/2022-05/06/2022 3-01/07/2022-15/07/2022	~~0.048~~ 48	302.8	48	04/05/2022	BBCH 16	Dry seeds Whole plants	~~0.0021~~ <LOQ ~~0.0022~~ <LOQ ~~0.0023~~ <LOQ < LOQ < LOQ	< LOQ < LOQ < LOQ < LOQ < LOQ	<LOQ < LOQ < LOQ < LOQ < LOQ	0 12 17 40 61	N/A

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS	The study is accepted. The residue levels of imazamox in treated honey samples were in the range < 0.003 mg/kg – 0.0160 mg/kg. No residues of imazamox metabolites CL 312622, CL 189215 and CL 263284 were detected at or above the limit of detection (0.003 mg/kg) in any of the treated honey samples. The applicable MRL value for honey is 0.05 mg/kg (Reg. (EU) 2021/2202). Therefore, the MRL is not expected to be exceeded when CHR/H/IMA 40 SL is used in accordance with the proposed GAP.

A 2.1.3.1.5 Study 5

Reference:	KCA 6.3/05
Report	Appeltauer, A., Determination of Residues of Imazamox in Honey after One Application of CHR/H/IMA 40 SL in Spring Oilseed Rape at Four Sites in Central and Southern Europe in 2022; Testing faculties: Eurofins Agroscience Services Ecotox GmbH, Niefern, Oschelbronn, Germany study codes: S22-01627
Guideline(s):	OECD Guideline for the testing of chemicals on Crop Field Trial (TG 509 published in September 2009 SANTE/11956/2016 rev. 9 (2018) Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey. SANTE/2020/12830, Rev. 1 (2021): Guidance document on pesticide analytical methods for risk assessment and post-approval control and monitoring purposes.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Objective of the study

The objective of this study was the determination of residues of Imazamox and its metabolites CL263284, CL189215 and CL312622 in honey from spring oilseed rape collected by honey bees under semi-field conditions after one application of CHR/H/IMA 40 SL.

Summary

Four residue trials were conducted on spring oilseed rape during 2022, two in Northern Europe – Germany (S22-01627-01 and -02), and two in Southern Europe - Bulgaria (S22-01627-03 and -04). Field trial sites were at least 20 km apart. One application of CHR/H/IMA 40 SL was applied at a target rate of 1200 mL product/ha (47.7 g imazamox/ha) at an application spray volume of 200-400 L/ha. Application was conducted at BBCH 61-64, 4 days before sampling S1 (T) and 7 days before sampling S1 (C) for trial -01, 7 days before sampling S1 for trial -02, 8 days before sampling S1 for trial -03 and 7 days before sampling S1 for trial -04. Empty combs were inserted to the bee hive before application for later honey collection. In trial -02 the A sample (control) was sampled from combs which were formerly brood combs, since no honey was available in the provided empty combs. According to a water content check, which was conducted two days before sampling, no nectar was available in these brood combs at this point of time. Therefore, it is proofed that the sampled honey was foraged inside the tunnel.

The samples of honey from the untreated and treated plots were taken by hand using a spoon or a one-way syringe and a funnel (trial -01 and trial -02).
A method validation with procedural recoveries was not performed within the analytical phase because the analytical method was previously validated in accordance to SANTE/2020/12830, rev.1 for the determination of Imazamox and its metabolies CL312622, CL189215 and CL263284 in honey with an LOQ of 0.01 mg/kg in GLP study S22-02937 (SAHVOROST N. 2022).
The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for all analytes with a limit of detection (LOD) set at 0.003 mg/kg (defined as the lowest calibration standard, which is 30 % of the LOQ).
The metabolites were expressed as parent equivalents.
No residues of analytes at or above 30 % of the LOQ were detected in any of the untreated honey samples.
The residue levels of the treated honey samples are summarised in the table below.

Summary of Imazamox and its Metabolites CL263284, CL189215 and CL312622 Residues in Honey Samples

Sampling code	Trial No.	Sample timing	Treatment	Sample	Residues			
					Imazamox	CL263284	CL189215	CL312622
					mg/kg	mg/kg*	mg/kg*	mg/kg*
S1	-01	7DAA	C	A1	n.d.	n.d.	n.d.	n.d.
		4DAA	T	A1	n.d.	n.d.	n.d.	n.d.
	-02	7DAA	C	A1	n.d.	n.d.	n.d.	n.d.
			T	A1	0.0160	n.d.	n.d.	n.d.
	-03	8DAA	C	A1	n.d.	n.d.	n.d.	n.d.
			T	A1	< LOQ (0.00604)	n.d.	n.d.	n.d.
	-04	7DAA	C	A1	n.d.	n.d.	n.d.	n.d.
			T	A1	< LOQ (0.00698)	n.d.	n.d.	n.d.

C: control sample; T: treated sample, DAA = days after application
LOQ = Limit of quantification (0.01 mg/kg), LOD = Limit of detection (0.003 mg/kg)
Residues are not corrected for concurrent recoveries
*Residues are expressed as parent equivalents

Conclusion
The objective of this study was the determination of residues of imazamox and its metabolites CL263284, CL189215 and CL312622 in honey from spring oilseed rape collected by honey bees under semi-field conditions after one application of CHR/H/IMA 40 SL. The study was conducted as four separate field trials in Germany and Bulgaria in 2022. One application of CHR/H/IMA 40 SL was applied at a target rate of 1200 mL product/ha (47.7 g imazamox/ha) at an application spray volume of 200-400 L/ha.
No residues of of Imazamox and its metabolies CL312622, CL189215 and CL263284 in were detected at or above the limit of detection (0.003 mg/kg) in any of the untreated honey samples of all trials.
The residue levels of Imazamox in the treated honey samples were below LOD (0.003 mg/kg) in trial 01, 0.0160 mg/kg in the treated sample of trial 02, and below LOQ (0.01 mg/kg) in trial 03 and trial 04.

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

Studies not required.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

Studies not required.

A 2.1.6 Magnitude of residues in representative succeeding crops

Studies not required.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

Chronic risk assessment:TMDI calculation

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

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	commodities not under assessment (in % of ADI)
0.0%	GEMS/Food G08	0.09	0.0%	Soyabeans	0.0%	Sunflower seeds	0.0%	Rapeseeds/canola seeds	
0.0%	GEMS/Food G15	0.08	0.0%	Soyabeans	0.0%	Sunflower seeds	0.0%	Rapeseeds/canola seeds	
0.0%	GEMS/Food G10	0.12	0.0%	Soyabeans	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds	
0.0%	GEMS/Food G07	0.09	0.0%	Soyabeans	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds	
0.0%	GEMS/Food G11	0.12	0.0%	Soyabeans	0.0%	Beans (without pods)	0.0%	Sunflower seeds	
0.0%	RO general	0.02	0.0%	Sunflower seeds	0.0%	Beans (with pods)	0.0%	Beans (with pods)	
0.0%	NL toddler	0.06	0.0%	Rapeseeds/canola seeds	0.0%	Beans (with pods)	0.0%	Sunflower seeds	
0.0%	GEMS/Food G06	0.06	0.0%	Soyabeans	0.0%	Cotton seeds	0.0%	Sunflower seeds	
0.0%	FR child 3 15 yr	0.03	0.0%	Other oilseeds	0.0%	Sunflower seeds	0.0%	Beans (with pods)	
0.0%	NL child	0.04	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds	0.0%	Soyabeans	
0.0%	IE adult	0.03	0.0%	Sunflower seeds	0.0%	Linseeds	0.0%	Peas	
0.0%	PT general	0.03	0.0%	Soyabeans	0.0%	Sunflower seeds	0.0%	Beans (without pods)	
0.0%	FR toddler 2 3 yr	0.03	0.0%	Beans (with pods)	0.0%	Other oilseeds	0.0%	Sunflower seeds	
0.0%	ES child	0.01	0.0%	Sunflower seeds	0.0%	Beans (with pods)	0.0%	Lentils	
0.0%	NL general	0.02	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds	0.0%	Soyabeans	
0.0%	FR adult	0.02	0.0%	Sunflower seeds	0.0%	Beans (with pods)	0.0%	Other oilseeds	
0.0%	ES adult	0.01	0.0%	Beans (with pods)	0.0%	Sunflower seeds	0.0%	Lentils	
0.0%	UK toddler	0.02	0.0%	Beans	0.0%	Peas (without pods)	0.0%	Peas	
0.0%	UK infant	0.02	0.0%	Peas (without pods)	0.0%	Beans	0.0%	Beans (with pods)	
0.0%	DE child	0.01	0.0%	Sunflower seeds	0.0%	Peas (without pods)	0.0%	Soyabeans	
0.0%	FR infant	0.01	0.0%	Beans (with pods)	0.0%	Other oilseeds	0.0%	Peas (without pods)	
0.0%	UK vegetarian	0.01	0.0%	Beans	0.0%	Peas (without pods)	0.0%	Lentils	
0.0%	DE women 14-50 yr	0.01	0.0%	Sunflower seeds	0.0%	Soyabeans	0.0%	Peas (without pods)	
0.0%	IT toddler	0.01	0.0%	Peas (without pods)	0.0%	Beans (with pods)	0.0%	Other oilseeds	
0.0%	DE general	0.01	0.0%	Sunflower seeds	0.0%	Soyabeans	0.0%	Peas (without pods)	
0.0%	IT adult	0.01	0.0%	Beans (with pods)	0.0%	Other oilseeds	0.0%	Peas (without pods)	
0.0%	UK adult	0.01	0.0%	Beans	0.0%	Peas (without pods)	0.0%	Beans (with pods)	
0.0%	FI 6 yr	0.01	0.0%	Other oilseeds	0.0%	Rapeseeds/canola seeds	0.0%	Beans	
0.0%	FI 3 yr	0.01	0.0%	Rapeseeds/canola seeds	0.0%	Other oilseeds	0.0%	Peas (without pods)	
0.0%	SE general	0.00	0.0%	Beans (with pods)	0.0%	Beans (with pods)	0.0%	Beans (with pods)	
0.0%	LT adult	0.00	0.0%	Sunflower seeds	0.0%	Peas (without pods)	0.0%	Beans (without pods)	
0.0%	FI adult	0.00	0.0%	Other oilseeds	0.0%	Soyabeans	0.0%	Peas	
0.0%	PL general	0.00	0.0%	Beans (without pods)	0.0%	Beans	0.0%	Peas	
0.0%	DK adult	0.00	0.0%	Peas (without pods)	0.0%	Beans (with pods)	0.0%	Beans	
0.0%	IE child	0.00	0.0%	Beans (without pods)	0.0%	Peas (without pods)	0.0%	Beans (with pods)	
0.0%	DK child	0.00	0.0%	Beans (with pods)	0.0%	Rapeseeds/canola seeds	0.0%	Peas (with pods)	

The TMDI calculations are for information purpose only.
The results of the more refined intake calculations are presented in the spreadsheet "Results".

A 3.2 IEDI calculations

Chronic risk assessment: JMPR methodology (IEDI/TMDI)												
				No of diets exceeding the ADI :	---						Exposure resulting from	
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities		MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	0.0%	GEMS/Food G11	0.12	0.0%	Soyabeans	0.0%	Beans (without pods)	0.0%	Sunflower seeds			
	0.0%	GEMS/Food G10	0.12	0.0%	Soyabeans	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds			
	0.0%	GEMS/Food G07	0.09	0.0%	Soyabeans	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds			
	0.0%	GEMS/Food G08	0.09	0.0%	Soyabeans	0.0%	Sunflower seeds	0.0%	Rapeseeds/canola seeds			
	0.0%	GEMS/Food G15	0.08	0.0%	Soyabeans	0.0%	Sunflower seeds	0.0%	Rapeseeds/canola seeds			
	0.0%	GEMS/Food G06	0.06	0.0%	Soyabeans	0.0%	Cotton seeds	0.0%	Sunflower seeds			
	0.0%	NL toddler	0.06	0.0%	Rapeseeds/canola seeds	0.0%	Beans (with pods)	0.0%	Sunflower seeds			
	0.0%	NL child	0.04	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds	0.0%	Soyabeans			
	0.0%	FR child 3 15 yr	0.03	0.0%	Other oilseeds	0.0%	Sunflower seeds	0.0%	Beans (with pods)			
	0.0%	FR toddler 2 3 yr	0.03	0.0%	Beans (with pods)	0.0%	Other oilseeds	0.0%	Sunflower seeds			
	0.0%	IE adult	0.03	0.0%	Sunflower seeds	0.0%	Linseeds	0.0%	Peas			
	0.0%	PT general	0.03	0.0%	Soyabeans	0.0%	Sunflower seeds	0.0%	Beans (without pods)			
	0.0%	NL general	0.02	0.0%	Rapeseeds/canola seeds	0.0%	Sunflower seeds	0.0%	Soyabeans			
	0.0%	RO general	0.02	0.0%	Sunflower seeds	0.0%	Beans (with pods)	0.0%	Beans (with pods)			
	0.0%	UK toddler	0.02	0.0%	Beans	0.0%	Peas (without pods)	0.0%	Peas			
	0.0%	FR adult	0.02	0.0%	Sunflower seeds	0.0%	Beans (with pods)	0.0%	Other oilseeds			
	0.0%	UK infant	0.02	0.0%	Peas (without pods)	0.0%	Beans	0.0%	Beans (with pods)			
	0.0%	ES child	0.01	0.0%	Sunflower seeds	0.0%	Beans (with pods)	0.0%	Lentils			
	0.0%	FR infant	0.01	0.0%	Beans (with pods)	0.0%	Other oilseeds	0.0%	Peas (without pods)			
	0.0%	ES adult	0.01	0.0%	Beans (with pods)	0.0%	Sunflower seeds	0.0%	Lentils			
	0.0%	DE child	0.01	0.0%	Sunflower seeds	0.0%	Peas (without pods)	0.0%	Soyabeans			
	0.0%	UK vegetarian	0.01	0.0%	Beans	0.0%	Peas (without pods)	0.0%	Lentils			
	0.0%	FI 6 yr	0.01	0.0%	Other oilseeds	0.0%	Rapeseeds/canola seeds	0.0%	Beans			
	0.0%	FI 3 yr	0.01	0.0%	Rapeseeds/canola seeds	0.0%	Other oilseeds	0.0%	Peas (without pods)			
	0.0%	IT toddler	0.01	0.0%	Peas (without pods)	0.0%	Beans (with pods)	0.0%	Other oilseeds			
	0.0%	IT adult	0.01	0.0%	Beans (with pods)	0.0%	Other oilseeds	0.0%	Peas (without pods)			
	0.0%	UK adult	0.01	0.0%	Beans	0.0%	Peas (without pods)	0.0%	Beans (with pods)			
	0.0%	DE general	0.01	0.0%	Sunflower seeds	0.0%	Soyabeans	0.0%	Peas (without pods)			
	0.0%	DE women 14-50 yr	0.01	0.0%	Sunflower seeds	0.0%	Soyabeans	0.0%	Peas (without pods)			
	0.0%	FI adult	0.00	0.0%	Other oilseeds	0.0%	Soyabeans	0.0%	Peas			
	0.0%	SE general	0.00	0.0%	Beans (with pods)	0.0%	Beans (with pods)	0.0%	Beans (with pods)			
	0.0%	LT adult	0.00	0.0%	Sunflower seeds	0.0%	Peas (without pods)	0.0%	Beans (without pods)			
	0.0%	DK adult	0.00	0.0%	Peas (without pods)	0.0%	Beans (with pods)	0.0%	Beans			
	0.0%	PL general	0.00	0.0%	Beans (without pods)	0.0%	Beans	0.0%	Peas			
	0.0%	IE child	0.00	0.0%	Beans (without pods)	0.0%	Peas (without pods)	0.0%	Beans (with pods)			
	0.0%	DK child	0.00	0.0%	Beans (with pods)	0.0%	Rapeseeds/canola seeds	0.0%	Peas (with pods)			
	Conclusion: The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Imazamox 40 SL (F) is unlikely to present a public health concern.											

A 3.3 IESTI calculations

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

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

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

Show results for all crops

Unprocessed commodities

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.01%	Beans	0.05 / 0.01	0.25
0.01%	Beans (with pods)	0.05 / 0.01	0.16
0.00%	Peas (without pods)	0.05 / 0.01	0.11
0.00%	Peas (with pods)	0.05 / 0.01	0.11
0.00%	Beans (without pods)	0.05 / 0.01	0.11
0.00%	Sunflower seeds	0.3 / 0.03	0.10
0.00%	Lentils	0.2 / 0.01	0.09
0.00%	Peas	0.05 / 0.01	0.09
0.00%	Lentils (fresh)	0.05 / 0.01	0.08
0.00%	Soyabeans	0.05 / 0.03	0.07
0.00%	Sesame seeds	0.05 / 0.03	0.04
0.00%	Pumpkin seeds	0.05 / 0.03	0.04
0.00%	Rapeseeds/canola seeds	0.05 / 0.03	0.04
0.00%	Linseeds	0.05 / 0.03	0.03
0.00%	Mustard seeds	0.05 / 0.03	0.03

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.01%	Soyabeans	0.05 / 0.03	0.17
0.00%	Beans (with pods)	0.05 / 0.01	0.11
0.00%	Beans	0.05 / 0.01	0.09
0.00%	Lentils	0.2 / 0.01	0.08
0.00%	Peas (without pods)	0.05 / 0.01	0.07
0.00%	Beans (without pods)	0.05 / 0.01	0.05
0.00%	Pumpkin seeds	0.05 / 0.03	0.05
0.00%	Peas (with pods)	0.05 / 0.01	0.05
0.00%	Peas	0.05 / 0.01	0.05
0.00%	Lentils (fresh)	0.05 / 0.01	0.05
0.00%	Sunflower seeds	0.3 / 0.03	0.03
0.00%	Poppy seeds	0.05 / 0.03	0.02
0.00%	Poppy seeds	0.05 / 0.03	0.02
0.00%	Poppy seeds	0.05 / 0.03	0.02
0.00%	Rapeseeds/canola seeds	0.05 / 0.03	0.02

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.04%	Lentils	0.2 / 0.2	1.3
0.03%	Sunflower seeds	0.3 / 0.3	0.96
0.03%	Beans	0.05 / 0.05	0.91
0.02%	Beans (with pods)	0.05 / 0.05	0.57
0.01%	Peas (without pods)	0.05 / 0.05	0.41
0.01%	Peas (with pods)	0.05 / 0.05	0.41
0.01%	Beans (without pods)	0.05 / 0.05	0.39
0.01%	Peas	0.05 / 0.05	0.33
0.01%	Lentils (fresh)	0.05 / 0.05	0.29
0.00%	Soyabeans	0.05 / 0.05	0.12
0.00%	Sesame seeds	0.05 / 0.05	0.07
0.00%	Pumpkin seeds	0.05 / 0.05	0.07
0.00%	Rapeseeds/canola seeds	0.05 / 0.05	0.07
0.00%	Linseeds	0.05 / 0.05	0.05
0.00%	Mustard seeds	0.05 / 0.05	0.05

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

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.04%	Lentils	0.2 / 0.2	1.2
0.01%	Beans (with pods)	0.05 / 0.05	0.39
0.01%	Beans	0.05 / 0.05	0.33
0.01%	Sunflower seeds	0.3 / 0.3	0.30
0.01%	Soyabeans	0.05 / 0.05	0.28
0.01%	Peas (without pods)	0.05 / 0.05	0.27
0.01%	Beans (without pods)	0.05 / 0.05	0.20
0.01%	Peas (with pods)	0.05 / 0.05	0.17
0.01%	Peas	0.05 / 0.05	0.17
0.01%	Lentils (fresh)	0.05 / 0.05	0.17
0.00%	Pumpkin seeds	0.05 / 0.05	0.08
0.00%	Poppy seeds	0.05 / 0.05	0.04
0.00%	Poppy seeds	0.05 / 0.05	0.04
0.00%	Sesame seeds	0.05 / 0.05	0.04
0.00%	Rapeseeds/canola seeds	0.05 / 0.05	0.03

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

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

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.0%	Beans (with pods) / boiled	0.05 / 0.01	0.17
0.0%	Soyabeans / soya drink	0.05 / 0.03	0.13
0.0%	Lentils / boiled	0.2 / 0.01	0.11
0.0%	Peas (without pods) / cannec	0.05 / 0.01	0.11
0.0%	Peas / canned	0.05 / 0.01	0.10
0.0%	Sunflower seeds / oils	0.3 / 0.06	0.07
0.0%	Soyabeans / boiled	0.05 / 0.01	0.04
0.0%	Rapeseeds / oils	0.05 / 0.06	0.02
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.0%	Beans / canned	0.05 / 0.01	0.10
0.00%	Beans (without pods) /	0.05 / 0.01	0.07
0.00%	Peas (with pods) / boiled	0.05 / 0.01	0.05
0.00%	Peas (without pods) / boiled	0.05 / 0.01	0.04
0.00%	Peas / canned	0.05 / 0.01	0.04
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.05%	Lentils / boiled	0.2 / 0.2	1.6
0.02%	Sunflower seeds / oils	0.3 / 0.6	0.70
0.02%	Beans (with pods) / boiled	0.05 / 0.05	0.63
0.01%	Peas (without pods) /	0.05 / 0.05	0.40
0.01%	Peas / canned	0.05 / 0.02	0.36
0.01%	Soyabeans / soya drink	0.05 / 0.05	0.21
0.00%	Soyabeans / boiled	0.05 / 0.02	0.07
0.00%	Rapeseeds / oils	0.05 / 0.1	0.03
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

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

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.01%	Beans / canned	0.05 / 0.05	0.36
0.01%	Beans (without pods) / boiled	0.05 / 0.05	0.26
0.01%	Peas (with pods) / boiled	0.05 / 0.05	0.17
0.01%	Peas (without pods) / boiled	0.05 / 0.05	0.16
0.00%	Peas / canned	0.05 / 0.02	0.13
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
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Appendix 4 Additional information provided by the applicant

Not required