REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product name: ASAHI MAX

Product code: ARY-0469-04

Chemical active substance:

0.9% w/w sodium p-nitrophenolate

0.6% w/w sodium o-nitrophenolate

0.3% w/w sodium 5-nitroguaiacolate

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Asahi Chemical Europe s.r.o.

Submission date: June 2022

MS Finalisation date: March 2023 (initial Core Assessment)

June 2023 (final Core Assessment)

Version history

When	What
June 2022	Initial version of dRR for submission to zRMS
March 2023	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
June 2023	Final report (National Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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8 Fate and behaviour in the environment (KCP 9)

This document reviews the environmental fate studies and modelling for the product ASAHI MAX containing the active substances sodium 5-nitroguaiacolate (Na 5-NG), sodium *ortho*-nitrophenolate (Na *o*-NP) and sodium *para*-nitrophenolate (Na *p*-NP) which were included into Annex I of Directive 91/414/EEC (Commission Directive 2009/11/EC). All active substances included into Annex I of Directive 91/414 have been approved under Regulation 1107/2009 by Commission Implementing Regulation (EU) No. 540/2011 of 25 May 2011. A full risk assessment according to Uniform Principles is provided which demonstrates that the product is safe for the environment.

The SANCO report for the active substances sodium 5-nitroguaiacolate, sodium *ortho*-nitrophenolate and sodium *para*-nitrophenolate (SANCO/210/08 – 02 December 2008) and the EFSA Conclusion on the peer review of sodium 5-nitroguaiacolate, sodium *ortho*-nitrophenolate and sodium *para*-nitrophenolate (EFSA Journal 2008; 191, 1-130) are considered to provide the relevant review information or a reference to where such information can be found. Each section will begin with a table providing the EU endpoints to be used in this evaluation.

Properties considered relevant in assessing the fate of sodium 5-nitroguaiacolate, sodium *ortho*-nitrophenolate and sodium *para*-nitrophenolate are shown in Table 9-2. A complete list of the active substances with their chemical names and structures are included in Appendix 3.

Table 8-1 Agreed EU Physical chemical properties used in the Evaluation (EFSA Scientific Report (2008) 191, 1-130)

Property	**Na 5-NG**	**Na *o*-NP**	**Na *p*-NP**
Molar mass [g/mol]	191.1	161.1	161.1
Molecular formula	$C_7H_6NNaO_4$	$C_6H_4NNaO_3$	$C_6H_4NNaO_3$
Solubility in water (at 20°C) [g/L]	pH 4: 1.29 pH 7: 1.83 pH 10: 86.8	pH 4: 0.78 pH 7: 2.76 pH 10: 181.6	pH 4: 14.7 pH 7: 13.9 pH 10: 57.4
Vapour pressure (at 25°C) [Pa]	$<1.33 \times 10^{-5}$	7.75×10^{-5}	$<1.33 \times 10^{-5}$
log P_{OW} (at 20°C) (n-Octanol/water partition coefficient)	pH 4: 1.491 pH 7: 1.62 pH 10: -0.25	pH 4: 1.70 pH 7: 1.12 pH 10: -1.03	pH 4: 1.82 pH 7: 1.28 pH 10: -0.93
Henry's Law Constant (at 25°C) [Pa m^3/mol]	4.51×10^{-4}	5.55×10^{-4}	5.55×10^{-4}
Photolytic stability	3 days	60-88 days	6 days
Hydrolytic stability	Stable	Stable	Stable

8.1 Critical GAP and overall conclusions

Table 8.1.1: Critical use pattern of the formulated product ASAHI MAX

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** Groundwater
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter oilseed rape	F	Plant growth regulator, number of pods per plant, number of seeds per plant, higher lignification of pods	Spray	BBCH 29-69 (spring)	2	7	0.2	0.6 1.2 1.8	200-500	28		A
2	PL	Winter wheat	F	Plant growth regulator, number of tillers and ears, portion above the sieves, germination energy	Spray	BBCH 21-49 (spring)	1	-	0.2	0.6 1.2 1.8	200-300	28		A
3	PL	Sugar beet	F	Plant growth regulator, effect on higher yield of sugar, lower content of unwanted Sodium	Spray	BBCH 12-49 (spring-summer)	2	7	0.2	0.6 1.2 1.8	200-500	15		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)														
None.														
Minor uses according to Article 51 (zonal uses)														
4	PL	Mustard, spring rape, turnip rape, camelina, ~~garden radish~~, poppy, linseed, hemp, ~~sunflower~~, borage	F	Plant growth regulator, number of pods per plant, number of seeds per plant, higher lignification of pods	Spray	BBCH 29-69 (spring)	2	7	0.2	0.6 1.2 1.8	200-500	28	Extrapolation from winter osr	A
5	PL	Spring rye, spelt, emmer wheat, small spelt, durum wheat	F	Plant growth regulator, number of tillers and ears, portion above the sieves, germination energy	Spray	BBCH 21-49 (spring)	1	-	0.2	0.6 1.2 1.8	200-300	28	Extrapolation from winter wheat.	A
6	PL	Fodder beet, red beet, swede, turnip	F	Plant growth regulator, effect on higher yield.	Spray	BBCH 12-49 (spring-summer)	2	7	0.2	0.6 1.2 1.8	200-500	15	Extrapolation from sugar beet	A

7	PL	Garden radish	F	Plant growth regulator, number of pods per plant, number of seeds per plant, higher lignification of pods	Spray	BBCH 29-69 (spring)	2	7	0.2	0.6 1.2 1.8	200-500	28	Extrapolation from main crops not possible, exposure assessment performed with consideration of cabbage/leafy vegetables as a surrogate crop.	A
8	PL	Sunflower	F	Plant growth regulator, number of pods per plant, number of seeds per plant, higher lignification of pods	Spray	BBCH 29-69 (spring)	2	7	0.2	0.6 1.2 1.8	200-500	28	Extrapolation from main crops not possible, exposure assessment performed with consideration of maize as a surrogate crop.	A

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

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

Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Table 8.1.2: Assessed (critical) uses during approval of Na 5-NG, Na *o*-NP and Na *p*-NP concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
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
					Method / Kind	Timing / Growth stage of crop & season	Max. number	Min. interval between applications (days)	g a.s/hL	g as/ha	Water L/ha min/max		
1	NEU	Sugar beet	F	Plant growth stimulator	Spraying	BBCH 12-49	4	7-30	0.25 - 0.5 0.5 - 1.0 0.5 - 0.75	1.0 2.0 3.0	200-400	15	
2	SEU	Sugar beet	F	Plant growth stimulator	Spraying	BBCH 12-49	4	7-30	0.25 - 0.5 0.5 - 1.0 0.5 - 0.75	1.0 2.0 3.0	200-400	15	
3	NEU	Oilseed rape	F	Plant growth stimulator	Spraying	BBCH 31-69	2	30-60	0.25 - 0.5 0.5 - 1.0 0.5 - 0.75	1.0 2.0 3.0	200-400	30	
4	SEU	Oilseed rape	F	Plant growth stimulator	Spraying	BBCH 31-69	2	30-60	0.25 - 0.5 0.5 - 1.0 0.5 - 0.75	1.0 2.0 3.0	200-400	30	
5	NEU	Tomato	F/G	Plant growth stimulator	Spraying	BBCH 59 BBCH 69 BBCH 71 BBCH 79 BBCH 81	5	14	0.1 - 0.25 0.2 - 0.5 0.3 - 0.75	1.0 2.0 3.0	400-1000	3	
6	SEU	Tomato	F/G	Plant growth stimulator	Spraying	BBCH 59 BBCH 69 BBCH 71 BBCH 79 BBCH 81	5	14	0.1 - 0.25 0.2 - 0.5 0.3 - 0.75	1.0 2.0 3.0	400-1000	3	

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

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

8.2 Metabolites considered in the assessment

Table 8.2.1 Metabolites of Na 5-NG, Na *o*-NP and Na *p*-NP potentially relevant for exposure assessment

Metabolite	Molar mass	Maximum observed occurence in compartements	Exposue assessment required due to
M5	191.1	3.1% in soil	PEC_{gw}: leaching potential to groundwater
M6	161.1	Not formed in soil 48.7% in aquatic systems	$PEC_{sw/sed}$: potential exposure
M12	191.1	Not formed in soil 25% in aquatic systems	$PEC_{sw/sed}$: potential exposure

Groundwater

There are no metabolites that are considered to be of relevance for groundwater assessment. A data gap for identification and further assessment of the unknown soil metabolite M5 in groundwater was identified during the EU review. This issue has been addressed in a separate confirmatory data submission in accordance with current EU regulatory guidance (SANCO/5634/2009 rev. 6.1) and an assessment has been accordingly performed for metabolite M5 in the present dRR (refer to Point 8.8)

Surface water

A data gap to assess the potential impact to the environment of the unidentified photodegradation products M3, M5, M8 and M13 formed from Na 5-NG and M3, M5 and M6 formed from Na *p*-NP, was identified during the EU review. This issue was addressed in a confirmatory data addendum (cited by UK (central zRMS) as being addendum 3 vol3 of nov 2012) which does not seem to be available on ciracabc. However, according to UK, the surface water residue definition remained unchanged after review of this addendum, and photolytic metabolites need to be addressed in the preparation assessment.

Predicted environmental concentrations in surface water and sediment for the unidentified photodegradation products M12, formed from Na 5-NG and M6, formed from Na *p*-NP, were calculated at FOCUS Steps 1 and 2 using the STEPS 1-2 in FOCUS calculator. The simulations were based on applications of the ASAHI MAX formulation (refer to Point 8.9). M12 and M6 present the maximum occurrences and thus cover all other photodegradation metabolites.

zRMS comments:

Information regarding metabolite M5 formed from Na 5-NG is in line with information presented in EFSA Scientific Report (2008) 191, 1-130. It has been noted that metabolites M6 (formed from Na *p*-NP) and M12 (formed from Na 5-NG) were found at >10% in aqueous photolysis study according to Sodium nitrocompounds_amended Addendum 3 Vol3 B8_Nov.2012.

8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Agreed EU Endpoints used in the Evaluation (EFSA Scientific Report (2008) 191, 1-130)

Endpoint	Na 5-NG	Na *o*-NP	Na *p*-NP
DT_{50} (lab) (20°C, pF2/10 kPa)	0.6 days (worst-case DT_{50}, n=4)	1.5 days (worst-case DT_{50}, n=4)	2.2 days (worst-case DT_{50}, n=4)

The rate of degradation in soil of Na 5-NG, Na *o*-NP and Na *p*-NP was evaluated during the Annex I Inclusion. No additional studies have been performed.

The degradation of ^{14}C- labelled ATONIK, consisting of sodium 5-nitroguaiacolate (Na 5-NG), sodium *ortho*-nitrophenolate (Na *o*-NP) and sodium *para*-nitrophenolate (Na *p*-NP) at a ratio of 1:2:3 (w/w/w), was investigated under laboratory conditions in four soils (OC 1.0-1.8%, pH 6.2-7.4) under aerobic conditions in the dark at 20°C and 40% maximum water holding capacity.

Bound residues ranged from 32.1-41.1% of applied radioactivity after 120 days and mineralisation to carbon dioxide was significant, reaching 54.9-60.8% of applied radioactivity after 120 days.

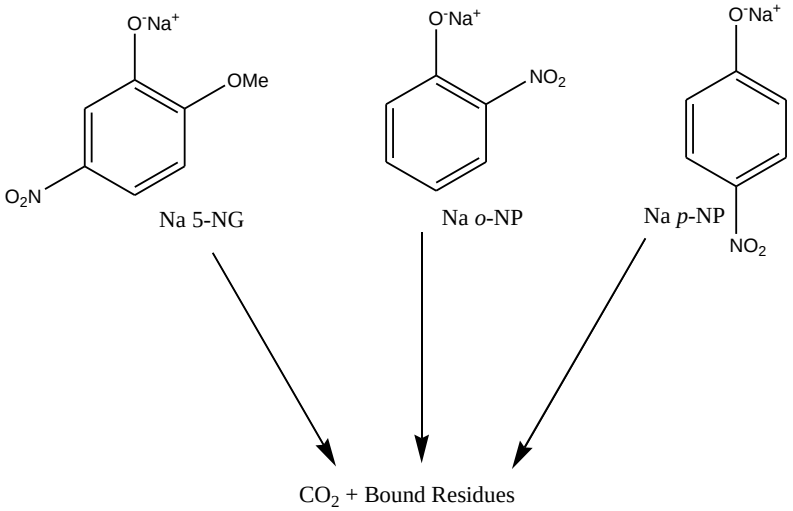
Significant amounts of volatile radioactivity (4.5-10.3% AR), containing Na *o*-NP were trapped in ethylene glycol traps.

The only extractable breakdown product was an unidentified metabolite M5, which reached a maximum of 3.1% of applied radioactivity at day 7, on the basis of the three active substances. A data gap was however included for identification of this metabolite M5 which could be considered as major with respect to Na 5-NG, the compound with the smallest ratio in the mix of the three compounds (equivalent of 20.5% AR at day 7). This metabolite is part of the residue definition for soil, ground water and surface water and PECs should be calculated for it. This issue is currently being addressed in a separate confirmatory data submission in accordance with current EU regulatory guidance (SANCO/5634/2009 rev. 6.1)[1].

The degradation of ^{14}C- labelled ATONIK was also investigated under laboratory conditions at 10°C in one soil. Under these conditions mineralisation to carbon dioxide reached 49.1% of applied radioactivity and the formation of non-extractable residues accounted for 45.7% of applied radioactivity after 120 days.
In a laboratory soil photolysis study, no photodegradation products were detected and soil photolysis was not regarded as a significant route of dissipation for the active substances.

A proposed pathway of degradation is shown in Figure 8.3-1 ~~Figure 9.1-1~~.

Figure 8.3-1: Proposed pathway of ATONIK in soil



zRMS comments:

Soil degradation data for Na 5-NG, Na *o*-NP and Na *p*-NP are in line with EU agreed endpoints reported in EFSA Scientific Report (2008) 191, 1-130.

For relevant endpoints considered in the exposure assessment, please refer to points 8.7 (soil), 8.8 (groundwater) and 8.9 (surface water) of this document.

[1] European Commission Guidance document on the procedures for submission and assessment of confirmatory information following approval of an active substance in accordance with Regulation (EC) No 1107/2009 SANCO/5634/2009 rev. 6.1, dated December 2013

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

The rate of degradation of Na 5-NG, Na *o*-NP and Na *p*-NP was estimated in four soils.

In the case of Na *o*-NP, some volatilisation was observed in the laboratory study and the meeting of experts PRAPeR 52 concluded that the calculated degradation rates for this compound should therefore be regarded as dissipation rates (degradation and volatilisation). However, application of SFO kinetics was eventually considered appropriate and a first-order $DisT_{50}$ are therefore presented in the summary table below.

Table 8.3.1-1 Summary of aerobic degradation rates of sodium 5-nitroguaiacolate (Na 5-NG) in laboratory soils (EFSA Scientific Report (2008) 191, 1-130)

Soil type	pH	Temperature (°C) / % MWHC	DT_{50} / DT_{90} (days)	DT_{50} (days) (20°C & pF2/10kPa)	r^2	Method of calculation
Silt loam	7.2	20°C / 40%	0.1 / 0.4	0.1	0.9871	SFO
Sandy loam	6.3	20°C / 40%	0.2 / 0.7	0.2	0.9906	SFO
Clay loam	6.2	20°C / 40%	0.1 / 0.4	0.1	0.9732	SFO
Loam	7.4	20°C / 40%	0.6 / 2.1	0.6	0.9624	SFO
Silt loam	7.2	10°C / 40%	0.3 / 0.9	-	0.9746	SFO

Table 8.3.1-2 Summary of aerobic degradation rates of sodium *ortho*-nitrophenolate (Na *o*-NP) in laboratory soils (EFSA Scientific Report (2008) 191, 1-130)

Soil type	pH	Temperature (°C) / % MWHC	$DisT_{50}$ / $DisT_{90}$ (days)	$DisT_{50}$ (days) (20°C & pF2/10kPa)	r^2	Method of calculation
Silt loam	7.2	20°C / 40%	0.4 ~~0.1~~/ 1.3	0.4	0.9924	SFO
Sandy loam	6.3	20°C / 40%	1.45 / 4.82*	1.45	0.9999	SFO
Clay loam	6.2	20°C / 40%	0.6 / 1.9	0.6	0.9858	SFO
Loam	7.4	20°C / 40%	1.5 / 5.0	1.5	0.9478	SFO
Silt loam	7.2	10°C / 40%	0.8 / 2.6	-	0.9045	SFO

Dissipation includes volatilisation observed in the study
* validity of the values was not confirmed by the peer review

Table 8.3.1-3 Summary of aerobic degradation rates of sodium *para*-nitrophenolate (Na *p*-NP) in laboratory soils (EFSA Scientific Report (2008) 191, 1-130)

Soil type	pH	Temperature (°C) / % MWHC	DT_{50} / DT_{90} (days)	DT_{50} (days) (20°C & pF2/10kPa)	r^2	Method of calculation
Silt loam	7.2	20°C / 40%	1.3 / 4.4	1.3	0.9318	SFO
Sandy loam	6.3	20°C / 40%	2.2 / 7.5	2.2	0.9931	SFO
Clay loam	6.2	20°C / 40%	0.6 / 1.9	0.6	0.9648	SFO
Loam	7.4	20°C / 40%	0.8 / 2.7	0.8	0.9672	SFO
Silt loam	7.2	10°C / 40%	3.3 / 11	-	0.9845	SFO

zRMS comments:

Soil degradation data for Na 5-NG, Na *o*-NP and Na *p*-NP are in line with EU agreed endpoints reported in EFSA Scientific Report (2008) 191, 1-130. Some typing errors were corrected by the zRMS in Table 8.3.1-2 above.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Degradation of ^{14}C-labelled ATONIK, consisting of sodium 5-nitroguaiacolate (Na 5-NG), sodium *ortho*-nitrophenolate (Na *o*-NP) and sodium *para*-nitrophenolate (Na *p*-NP) at a ratio of 1:2:3 (w/w/w) was investigated under anaerobic conditions in one soil (loam, OC 1.82%, pH 7.34) at 20°C.
The formation of non-extractable residues reached a maximum of 77.25% of applied radioactivity after 57 days and was a significant sink, accounting for 74.8% of applied radioactivity at the end of the study (120 days).

Mineralisation to carbon dioxide accounted for 9.4% of applied radioactivity at the end of the study. Unidentified metabolites M7 and M8 accounted for a maximum of 5.1% and 3.3%, of the applied radioactivity, respectively, on the basis of the three active substances.

A data gap for identification of metabolites M7 and M8 was identified during the EU review for uses where anaerobic conditions cannot be excluded. However, this was not considered as being essential to finalise the EU risk assessment and anaerobic conditions are neither considered to be relevant for the uses of the ATONIK preparation. This will not be considered further.

Table 8.3.2–1 Summary of anaerobic degradation rates of sodium 5-nitroguaiacolate (Na 5-NG) in laboratory soil (EFSA Scientific Report (2008) 191, 1-130)

Soil type	pH	Temperature (°C)	DT_{50} / DT_{90} (days)	DT_{50} (days) (20°C & pF2/10kPa)	r^2	Method of calculation
Loam	7.34	20°C	3.3 / 11	3.3	0.9993	SFO

Table 8.3.2–2 Summary of anaerobic degradation rates of sodium *ortho*-nitrophenolate (Na *o*-NP) in laboratory soil (EFSA Scientific Report (2008) 191, 1-130)

Soil type	pH	Temperature (°C)	DT_{50} / DT_{90} (days)	DT_{50} (days) (20°C & pF2/10kPa)	r^2	Method of calculation
Loam	7.34	20°C	3.3 / 10.8	3.3	0.9998	SFO

Table 8.3.2–3 Summary of anaerobic degradation rates of sodium *para*-nitrophenolate (Na *p*-NP) in laboratory soil (EFSA Scientific Report (2008) 191, 1-130)

Soil type	pH	Temperature (°C)	DT_{50} / DT_{90} (days)	DT_{50} (days) (20°C & pF2/10kPa)	r^2	Method of calculation
Loam	7.34	20°C	12.6 / 41.8	12.6	0.9607	SFO

zRMS comments:

Anaerobic soil degradation data for Na 5-NG, Na *o*-NP and Na *p*-NP are in line with EU agreed endpoints reported in EFSA Scientific Report (2008) 191, 1-130.

8.4 Field studies (KCP 9.1.1.2)

Each of the active substances contained in ATONIK (Na 5-NG, Na *o*-NP and Na *p*-NP) degrade very rapidly in soil under laboratory conditions, with DT_{50lab} <<60 days at 20°C and pF2. Therefore field dissipation, residues or accumulation studies are not required and have not been performed.

zRMS comments:

According to EFSA Scientific Report (2008) 191, 1-130, studies on field degradation of Na 5-NG, Na *o*-NP and Na *p*-NP were not required.

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

Not required. Please, refer to Point 8.4.

zRMS comments:

Please, refer to point 8.4 above.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Not required. Please, refer to Point 8.4.

zRMS comments:

Please, refer to point 8.4 above.

8.5 Mobility in soil (KCP 9.1.2)

Agreed EU Endpoints used in the Evaluation (EFSA Scientific Report (2008) 191, 1-130)

Endpoint	Na 5-NG	Na *o*-NP	Na *p*-NP
K_{FOC} (mL/g)	463.4 (geometric mean, n=4)	156.1 (geometric mean, n=4)	288.1 (geometric mean, n=4)

The adsorption / desorption of Na 5-NG, Na *o*-NP and Na *p*-NP was investigated in five soils, from which finally four were used (OC 1.16-2.98%, pH 5.7-7.5, clay content 7.5-34.2%) in a satisfactory batch adsorption experiment. There was no evidence of a correlation of adsorption with any soil parameter.

The detailed measured adsorption K_F, K_{FOC} and 1/n values for Na 5-NG, Na *o*-NP and Na *p*-NP are summarised in Tables 8.5-1 to 8.5-3.

Table 8.5-1 K_{FOC} and 1/n (Freundlich exponent) values for sodium 5-nitroguaiacolate (Na 5-NG) in different sets of soils (EFSA Scientific Report (2008) 191, 1-130)

Soil type	OC (%)	pH	Sand (%)	Clay (%)	CEC (mmol/kg)	K_F (mL/g)	K_{FOC} (mL/g)	1/n
Loamy sand	2.17	5.7	77.1	7.5	11	3.604	166	0.98
Silty clay loam	1.16	6.6	19.2	28.2	18	15.654	1350	1.00
Clay loam	2.98	7.5	21.5	34.2	36.2	19.156	643	0.84
Loam	1.22	7.3	50.9	14.4	9.6	3.905	320	0.85
						Geometric mean/median	463.4/482	
						pH dependence	No	

Table 8.5-2 K_{FOC} and 1/n (Freundlich exponent) values for sodium *ortho*-nitrophenolate (Na *o*-NP) in different sets of soils (EFSA Scientific Report (2008) 191, 1-130)

Soil type	OC (%)	pH	Sand (%)	Clay (%)	CEC (mmol/kg)	K_F (mL/g)	K_{FOC} (mL/g)	1/n
Loamy sand	2.17	5.7	77.1	7.5	11	1.937	89	0.98
Silty clay loam	1.16	6.6	19.2	28.2	18	6.053	522	1.00
Clay loam	2.98	7.5	21.5	34.2	36.2	2.812	94	0.82
Loam	1.22	7.3	50.9	14.4	9.6	1.657	136	0.82
						Geometric mean/median	156.1/115	
						pH dependence	No	

Table 8.5-3 K_{FOC} and 1/n (Freundlich exponent) values for sodium *para*-nitrophenolate (Na *p*-NP) in different sets of soils (EFSA Scientific Report (2008) 191, 1-130)

Soil type	OC (%)	pH	Sand (%)	Clay (%)	CEC (mmol/kg)	K_F (mL/g)	K_{FOC} (mL/g)	1/n
Loamy sand	2.17	5.7	77.1	7.5	11	2.676	123	0.98
Silty clay loam	1.16	6.6	19.2	28.2	18	6.979	602	1.00
Clay loam	2.98	7.5	21.5	34.2	36.2	8.031	269	0.84
Loam	1.22	7.3	50.9	14.4	9.6	4.224	346	0.85
						Geometric mean/median	288.1/308	
						pH dependence	No	

zRMS comments:

Soil mobility data for Na 5-NG, Na *o*-NP and Na *p*-NP presented in tables above are in line with EU agreed endpoints reported in EFSA Scientific Report (2008) 191, 1-130.

The mean Kfoc values provided in tables above are indicated as geometric mean, although in the EFSA conclusion is stated that they are arithmetic means. However, based on the individual Kfoc reported mean values correspond to the geometric means, so it seems that mistake was made in the EFSA conclusion.

8.5.1 Column leaching (KCP 9.1.2.1)

No studies submitted, not required.

zRMS comments:

According to EFSA Scientific Report (2008) 191, 1-130, column leaching studies with Na 5-NG, Na *o*-NP and Na *p*-NP were not required.

8.5.2 Lysimeter studies (KCP 9.1.2.2)

No studies submitted, not required.

zRMS comments:

According to EFSA Scientific Report (2008) 191, 1-130, lysimeter studies with Na 5-NG, Na *o*-NP and Na *p*-NP were not required.

8.5.3 Field leaching studies (KCP 9.1.2.3)

No studies submitted, not required.

zRMS comments:

According to EFSA Scientific Report (2008) 191, 1-130, field leaching studies with Na 5-NG, Na *o*-NP and Na *p*-NP were not required.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Na 5-NG, Na *o*-NP and Na *p*-NP were essentially stable under sterile hydrolysis conditions at 50°C at pH 4, pH 7 and pH 9.

The aqueous photolysis of Na 5-NG, Na *o*-NP and Na *p*-NP was investigated under sterile conditions in the laboratory at pH 7. The rate of degradation (first-order DT50) equated to summer sunlight at 30°N was determined as 2.8 days for Na 5-NG, 60.5 days for Na *o*-NP and 5.5 days for Na *p*-NP.

A ready biodegradability test (OECD 301A) indicated that Na 5-NG, Na *o*-NP and Na *p*-NP are 'not readily biodegradable' using the criteria defined by the test.

In water-sediment studies (two systems studied at 20°C in the laboratory, sediment pH 7.17 and 7.47) Na 5-NG, Na *o*-NP and Na *p*-NP dissipated rapidly from the water partitioning to sediment in both systems. First-order half-life of the active substances were: 2.4 and 3.4 days for Na 5-NG; 1.9 and 2.2 days for Na *o*-Np and 2.7 and 2.8 days for Na *p*-NP. The observed degradations of the active substances in the whole system were also rapid, resulting in the following SFO DT_{50} values: 3.0 and 5.4 days for Na 5-NG, 2.0 and 2.2 days for Na *o*-Np and 3.0 and 3.6 days for Na *p*-NP.

Agreed EU Endpoints (EFSA Scientific Report (2008) 191, 1-130)

Endpoint	Na 5-NG	Na *o*-NP	Na *p*-NP
DT_{50} total system	5.4 days (worst-case, n=2)	2.2 days (worst-case, n=2)	3.6 days (worst-case, n=2)

Endpoint	Na 5-NG	Na *o*-NP	Na *p*-NP
DT_{50} water	5.4 days (worst-case total system value, n=2)	2.2 days (worst-case total system value, n=2)	3.6 days (worst-case total system value, n=2)
DT_{50} sediment	5.4 days (worst-case total system value, n=2)	2.2 days (worst-case total system value, n=2)	3.6 days (worst-case total system value, n=2)

Major metabolites were not found in this study. Mineralisation to carbon dioxide was a significant sink that accounted for 66.1-63.5% AR at 122 days. Residues not extracted from sediment by acetonitrile/water were a sink representing 30.7% and 34.6% AR at study end (122 days).

zRMS comments:

Degradation data for Na 5-NG, Na *o*-NP and Na *p*-NP s in water/sediment systems provided in table above are in line with EU agreed endpoints reported in EFSA Scientific Report (2008) 191, 1-130 and are relevant for the surface water exposure assessment.

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

8.7.1 Justification for new endpoints

Not relevant, EU-agreed endpoints have been used in the risk assessment.

8.7.2 Active substance(s) and relevant metabolite(s)

Report:	KCP 9.1.3/01, Garitano, M., 2022
Title:	ASAHI MAX: Predicted Environmental Concentrations in soil (PECs)
Document No:	DR20221020
Guidelines:	FOCUS (2006) "Guidance Document on Estimating Persistence and Degradation Kinetics form Environmental Fate Studies on Pesticides in EU Registration", Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference SANCO/10058/2005, ver. 2.0. and its latest revision in Dec. 2014 (ver. 1.1) EFSA (2014). EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662
GLP	No (calculation)

Material and methods:
The predicted environmental concentrations in soil ($PEC_{initial,\ act,\ twa}$) were calculated for the active ingredients Na 5-NG, Na *o*-NP and Na *p*-NP according to recommendations by the "FOCUS" group (FOCUS 2006). Calculations were based on a simple first tier approach. The following formulae were used assuming degradation according to 1st order kinetics:

$PEC_{initial} = A * (1-f_{int}) / (100 * d * bd)$ [mg/kg] $\quad k = ln2/DT_{50}$
$PEC_{act}(t) = PEC_{initial} * e^{-k}$ [mg/kg]
$PEC_{twa}(t) = PEC_{initial} * (1-e^{-kt}) / (kt)$ [mg/kg]
$PEC_{initial,n}(t) = PEC_{initial,1} * (1-e^{-nkt}) / (1-e^{-ki})$ [mg/kg]

where A is the application rate of the active ingredient in g/ha, f_{int} the fraction intercepted by plant cover, d the soil depth (5 cm), bd the bulk density of soil (1.5 g/cm^3), n the number of application, i the application interval and DT_{50} the half-life (in days) of the active ingredient in soil.

Crop interception data which correspond to the intended growth stages were taken from the AppDate Tool.

The proposed application pattern for the formulated product ASAHI MAX is summarised below:

Table 8.7.1: Input parameters related to application for PEC_{soil} calculations

Crop	Oilseed rape	Winter wheat	Sugar beet
Application rate (g as/ha)	Na 5-NG: 0.6 Na *o*-NP: 1.2 Na *p*-NP: 1.8	Na 5-NG: 0.6 Na *o*-NP: 1.2 Na *p*-NP: 1.8	Na 5-NG: 0.6 Na *o*-NP: 1.2 Na *p*-NP: 1.8
Number of applications/interval	2 / 7	1 / -	2 / 7
Application moment	BBCH 29-69 (spring)	BBCH 21-49 (spring)	BBCH 12-49 (spring-summer)
Crop interception (%)	80	20	20

The following table provides the EU endpoints to be used for the PEC soil calculations.

Table 8.7-2: Input parameters related to the active ingredients for PEC_{soil} calculations

Endpoint	Na 5-NG	Na *o*-NP	Na *p*-NP	Reference
DT_{50} soil	0.6 days (worst-case DT_{50lab} at 20°C, n=4, SFO)	1.5 days (worst-case $DisT_{50lab}$ at 20°C, n=4, SFO)	2.2 days (worst-case DT_{50lab} at 20°C, n=4, SFO)	EFSA Scientific Report (2008) 191, 1-130
Molecular weight [g mol^{-1}]	191.1	161.1	161.1	EFSA Scientific Report (2008) 191, 1-130

Results:

Table 8.7.2 PEC_{soil} for Na 5-NG ~~on winter cereal~~

PEC_{soil} (mg/kg)		Oilseed rape				Winter wheat		Sugar beet			
		Single app.		Multiple app.		Single app.		Single app.		Multiple app.	
		Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial		**0.0002**	0.000	**0.0002**	0.000	**0.0006**	0.001	**0.0006**	0.001	**0.0006**	0.001
Short term	24h	0.0001	0.000	0.0001	0.000	0.0002	0.000	0.0002	0.000	0.0002	0.000
	2d	0.0000	0.000	0.0000	0.000	0.0001	0.000	0.0001	0.000	0.0001	0.000
	4d	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000
Long term	7d	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000
	14d	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000
	28d	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000
	50d	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000
	100d	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000
$PEC_{accumulation}$		-		-		-		-		-	

Table 8.7-4: PEC_{soil} for Na *o*-NG ~~on winter cereal~~

PEC_{soil} (mg/kg)		Oilseed rape				Winter wheat		Sugar beet			
		Single app.		Multiple app.		Single app.		Single app.		Multiple app.	
		Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial		**0.0003**	0.000	**0.0003**	0.000	**0.0013**	0.001	**0.0013**	0.001	**0.0013**	0.001
Short term	24h	0.0002	0.000	0.0002	0.000	0.0008	0.001	0.0008	0.001	0.0008	0.001
	2d	0.0001	0.000	0.0001	0.000	0.0005	0.001	0.0005	0.001	0.0005	0.001
	4d	0.0001	0.000	0.0001	0.000	0.0002	0.001	0.0002	0.001	0.0002	0.001
Long term	7d	0.0000	0.000	0.0000	0.000	0.0001	0.000	0.0001	0.000	0.0001	0.000
	14d	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000
	28d	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000
	50d	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000
	100d	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000
$PEC_{accumulation}$		-		-		-		-		-	

Table 8.7-5: PEC_{soil} for Na *p*-NG ~~on winter cereal~~

PEC_{soil} (mg/kg)		Oilseed rape				Winter wheat		Sugar beet			
		Single app.		Multiple app.		Single app.		Single app.		Multiple app.	
		Actual	**TWA**	**Actual**	**TWA**	**Actual**	**TWA**	**Actual**	**TWA**	**Actual**	**TWA**
Initial		**0.0005**	0.000	**0.0005**	0.001	**0.0019**	0.002	0.0019	0.002	**0.0021**	0.002
Short term	24h	0.0004	0.000	0.0004	0.000	0.0014	0.002	0.0014	0.002	0.0016	0.002
	2d	0.0003	0.000	0.0003	0.000	0.0010	0.001	0.0010	0.001	0.0011	0.002
	4d	0.0001	0.000	0.0002	0.000	0.0005	0.001	0.0005	0.001	0.0006	0.001
Long term	7d	0.0001	0.000	0.0001	0.000	0.0002	0.001	0.0002	0.001	0.0002	0.001
	14d	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000
	28d	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000
	50d	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000
	100d	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000	0.0000	0.000
$PEC_{accumulation}$		-		-		-		-		-	

Conclusion:

The PECs to be used in the ecotoxicological risk assessment are:

	Na 5-NG	**Na *o*-NP**	**Na *p*-NP**
Max PECsoil	0.0006	0.0013	0.0021

zRMS comments:

The application pattern presented in Table 8.7-1 and assumed in the soil exposure assessment is in line with the critical Central Zone GAP presented in Table 8.1-1.

Input parameters presented in Table 8.7-2 for Na 5-NG, Na *o*-NP and Na *p*-NP are in line with EU agreed parameters reported in EFSA Scientific Report (2008) 191, 1-130. Relevant crop interception of 80% for oilseed rape and 20% for winter wheat and sugar beet in line with FOCUS groundwater guidance (2021) has been selected.

The soil exposure for Na 5-NG, Na *o*-NP and Na *p*-NP has been independently validated by the zRMS using FOCUS methods and EU agreed endpoints. The calculated PEC_{SOIL} values were in good agreement with these obtained by the Applicant. Therefore, results reported in tables above may be used for the soil risk assessment purposes.

8.7.2.1 PEC_{soil} of ASAHI MAX

The initial PECs of the formulated product is calculated for ASAHI MAX, considering the total annual rate and the interception:

Table 8.7.3: PEC_{soil} for formulation on crop

Preparation	**Crop**	**Application rate (g/ha)**	**Interception**	**$PEC_{s\ act}$ (mg/kg)**
ASAHI MAX	Oilseed rape	2 x 0.2 L/ha (2 x 200 g/ha)	80%	0.1067
ASAHI MAX	Winter wheat	0.2 L/ha (200 g/ha)	20%	0.2133
ASAHI MAX	Sugar beet	2 x 0.2 L/ha (2 x 200 g/ha)	20%	0.4267

zRMS comments:

Soil exposure calculated by the Applicant for the formulated product is agreed by the zRMS and may be used in the risk assessment for soil organisms.

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

8.8.1 Justification for new endpoints

Not relevant, EU-agreed endpoints have been used in the risk assessment.

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

Report:	KCP 9.2.4/01, Garitano, M., 2022
Title:	ASAHI MAX: Predicted Environmental Concentrations in groundwater (PECgw)
Document No:	DR20221021
Guidelines:	European Commission (2014): "Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU". The Final Report of the Ground Water Work Group of FOCUS. EC Document Reference SANCO/13144/2010, v.3. FOCUS (2014) "Generic Guidance for Tier 1 FOCUS Ground Water Assessments", v. 2.2.
GLP	No (calculation)

Materials and Methods:

The predicted environmental concentrations in groundwater (PECgw) for the active ingredients Na 5-NG, Na *o*-NP and Na *p*-NP were calculated using the simulation models FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5 for all FOCUS groundwater scenarios.

From the discussion under Annex points CP 9.1 - CP 9.3, there are no metabolites that are considered to be of relevance for groundwater assessment. A data gap for identification and further assessment of the unknown soil metabolite M5 in groundwater was identified during the EU review. This issue has been addressed in a separate confirmatory data submission in accordance with current EU regulatory guidance (SANCO/5634/2009 rev. 6.1) and an assessment has been accordingly performed for metabolite M5 in the present dRR.

Predictions were calculated at the maximum number and highest rate of application for which authorisation is sought (critical GAP uses) applied for the envisaged uses of ASAHI MAX.

In line with the approach presented in the EFSA Conclusion Report, metabolite M5 was simulated as parent using pseudo application rates based on the combined mass of the three active substances in ASAHI MAX (Na 5-NG, Na *o*-NP and Na *p*-NP, 3.6 g/ha), corrected to account for the maximum amount of the metabolite formed in soil (3.1%) and assuming the same molecular weight as Na 5-NG.

Absolute application dates and interception values were set according to the AppDate Tool and the lowest intended BBCH as worst case.

The proposed application pattern for the formulated product ASAHI MAX is summarised below:

Table 8.8-1: Application data for the calculation of PECS values

Crop		**Oilseed rape**	**Oilseed rape**	**Winter wheat**	**Sugar beet**
Surrogate crop		Winter OSR	Summer OSR	Winter cereals ~~wheat~~	Sugar beet
Max. application rate (g/ha)		Na 5-NG: 0.6 Na *o*-NP: 1.2 Na *p*-NP: 1.8 M5: 0.1116	Na 5-NG: 0.6 Na *o*-NP: 1.2 Na *p*-NP: 1.8 M5: 0.1116	Na 5-NG: 0.6 Na *o*-NP: 1.2 Na *p*-NP: 1.8 M5: 0.1116	Na 5-NG: 0.6 Na *o*-NP: 1.2 Na *p*-NP: 1.8 M5: 0.1116
Application number / Interval (days)		2 / 7	2 / 7	1 / -	2 / 7
Application moment		BBCH 29-69 (spring)	BBCH 29-69 (spring)	BBCH 21-49 (spring)	BBCH 12-49 (spring-summer)
Interception by plants (%)		80	80	20	20
Rate reaching soil (g/ha)		Na 5-NG: 0.12 Na *o*-NP: 0.24 Na *p*-NP: 0.36 M5: 0.02	Na 5-NG: 0.12 Na *o*-NP: 0.24 Na *p*-NP: 0.36 M5: 0.02	Na 5-NG: 0.48 Na *o*-NP: 0.96 Na *p*-NP: 1.44 M5: 0.09	Na 5-NG: 0.48 Na *o*-NP: 0.96 Na *p*-NP: 1.44 M5: 0.09
Application date (absolute)	Châteaudun	10/03 – 17/03	-	06/04	26/04 – 03/05
	Hamburg	17/04 – 24/04	-	25/04	30/04 – 07/05
	Jokioinen	-	11/06 – 18/06	05/05	03/06 – 10/06
	Kremsmünster	14/04 – 21/04	-	15/04	30/04 – 07/05
	Okehampton	08/04 – 15/04	21/04 – 26/04	12/04	09/05 – 16/05
	Piacenza	06/03 – 13/03	-	10/03	02/04 – 09/04
	Porto	23/12 – 30/12	25/04 – 02/05	03/01	21/03 – 28/03
	Sevilla	-	-	21/12	27/11 – 04/12
	Thiva	-	-	27/12	08/05 – 15/05

Table 8.8-2: Input parameters related to active ingredients for PEC_{gw} calculations

Compound	**Na 5-NG**	**Na *o*-NP**	**Na *p*-NP**	**Value in accordance with EU endpoint y/n/Reference**
Molecular weight (g/mol)	191.1	161.1	161.1	Yes, EFSA Scientific Report (2008) 191, 1-130
Water solubility (mg/L):	1830 (pH 7, 20°C)	2760 (pH 7, 20°C)	13900 (pH 7, 20°C)	Yes, EFSA Scientific Report (2008) 191, 1-130
Saturated vapour pressure (Pa):	0	0	0	Yes, EFSA Scientific Report (2008) 191, 1-130
DT_{50} in soil (d)	0.6 days (worst-case DT_{50lab}, n=4) Na 5-NG	5.5 days (worst-case pseudo DT_{50} back-calculated from worst-case DFOP DT_{90lab} value of 18.4 days)	3.3 days (worst-case DT_{50lab} at 10°C)	Yes, EFSA Scientific Report (2008) 191, 1-130
K_{foc} (mL/g)	463.4 mL/g (geometric mean, n=4)	156.1 mL/g (geometric mean, n=4)	288.1 mL/g (geometric mean, n=4)	Yes, EFSA Scientific Report (2008) 191, 1-130
K_{fom} (mL/g)	268.8	90.5	167.1	Yes, EFSA Scientific Report (2008) 191, 1-130
1/n	1.0 (worst-case)	1.0 (worst-case)	1.0 (worst-case)	Yes, EFSA Scientific Report (2008) 191, 1-130
Plant uptake factor	0	0	0	Yes, EFSA Scientific Report (2008) 191, 1-130

Table 8.8-3 Summary of chemical input parameters for metabolite M5

Parameter	Value	Remarks
Molecular weight (g/mol)	191.1	Based on Na 5-NG
Water solubility (mg/L)	1000 (20°C)	Conservative assumption
Vapour pressure (Pa)	0 (20°C)	Conservative assumption
Degradation in soil		
DT_{50} soil (d)	120	Worst-case estimate. M5 was not detected at the 120 day time point in the aerobic soil metabolism, therefore it is assumed that the DT_{50} in soil is <120 days.
Sorption to soil		
K_{FOC} (mL/g)	1.0 (20°C)	Conservative assumption
K_{FOM} (mL/g)	0.58	Conservative assumption
Freundlich exponent 1/n (-)	1.0 (20°C)	Conservative assumption
Crop/management related parameters		
Crop uptake factor (-)	0	FOCUS default

Results:

The resulting 80th percentiles at 1 m soil depth (µg/L) are summarised in the following table:

Table 8.8-4: PEC_{gw} for ASAHI MAX (FOCUS PELMO 6.6.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		Na 5-NG	Na *o*-NP	Na *p*-NP	M5
Winter OSR	Châteaudun	<0.001	<0.001	<0.001	0.016
	Hamburg	<0.001	<0.001	<0.001	0.012
	Kremsmünster	<0.001	<0.001	<0.001	0.010
	Okehampton	<0.001	<0.001	<0.001	0.007
	Piacenza	<0.001	<0.001	<0.001	0.008
	Porto	<0.001	<0.001	<0.001	0.008
Summer OSR	Jokioinen	<0.001	<0.001	<0.001	0.018
	Okehampton	<0.001	<0.001	<0.001	0.007
	Porto	<0.001	<0.001	<0.001	0.006
Winter wheat	Châteaudun	<0.001	<0.001	<0.001	0.027
	Hamburg	<0.001	<0.001	<0.001	0.029
	Jokioinen	<0.001	<0.001	<0.001	0.042
	Kremsmünster	<0.001	<0.001	<0.001	0.023
	Okehampton	<0.001	<0.001	<0.001	0.017
	Piacenza	<0.001	<0.001	<0.001	0.023
	Porto	<0.001	<0.001	<0.001	0.017
	Sevilla	<0.001	<0.001	<0.001	0.014
	Thiva	<0.001	<0.001	<0.001	0.026
Sugar beet	Châteaudun	<0.001	<0.001	<0.001	0.058
	Hamburg	<0.001	<0.001	<0.001	0.056
	Jokioinen	<0.001	<0.001	<0.001	0.082
	Kremsmünster	<0.001	<0.001	<0.001	0.042
	Okehampton	<0.001	<0.001	<0.001	0.031
	Piacenza	<0.001	<0.001	<0.001	0.041
	Porto	<0.001	<0.001	<0.001	0.032
	Sevilla	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	0.056

Table 8.8-5: PEC_{gw} for ASAHI MAX (FOCUS PEARL 5.5.5)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		Na 5-NG	Na *o*-NP	Na *p*-NP	M5
Winter OSR	Châteaudun	<0.001	<0.001	<0.001	0.020338
	Hamburg	<0.001	<0.001	<0.001	0.014687
	Kremsmünster	<0.001	<0.001	<0.001	0.008540
	Okehampton	<0.001	<0.001	<0.001	0.007588
	Piacenza	<0.001	<0.001	<0.001	0.006930
	Porto	<0.001	<0.001	<0.001	0.008397
Summer OSR	Jokioinen	<0.001	<0.001	<0.001	0.021066
	Okehampton	<0.001	<0.001	<0.001	0.007836
	Porto	<0.001	<0.001	<0.001	0.006150
Winter wheat	Châteaudun	<0.001	<0.001	<0.001	0.031741
	Hamburg	<0.001	<0.001	<0.001	0.033756
	Jokioinen	<0.001	<0.001	<0.001	0.053088
	Kremsmünster	<0.001	<0.001	<0.001	0.019929
	Okehampton	<0.001	<0.001	<0.001	0.018174
	Piacenza	<0.001	<0.001	<0.001	0.021026
	Porto	<0.001	<0.001	<0.001	0.016281
	Sevilla	<0.001	<0.001	<0.001	0.016570
	Thiva	<0.001	<0.001	<0.001	0.036905
Sugar beet	Châteaudun	<0.001	<0.001	<0.001	0.051978
	Hamburg	<0.001	<0.001	<0.001	0.072013
	Jokioinen	<0.001	<0.001	<0.001	0.092737
	Kremsmünster	<0.001	<0.001	<0.001	0.040406
	Okehampton	<0.001	<0.001	<0.001	0.032579
	Piacenza	<0.001	<0.001	<0.001	0.048397
	Porto	<0.001	<0.001	<0.001	0.032392
	Sevilla	<0.001	<0.001	<0.001	0.048549
	Thiva	<0.001	<0.001	<0.001	0.091283

Conclusion:

All 80th percentiles at 1 m soil depth (µg/L) are estimated to be lower than 0.1 µg/L for the active ingredients Na 5-NG, Na *o*-NP and Na *p*-NP and their metabolite M5. Therefore, no leaching to groundwater is expected for Asahi Max due to the intended uses.

zRMS comments:

The application pattern assumed in simulations is in line with the critical Central Zone GAP presented in Table 8.1-1. Absolute application dates used for groundwater exposure assessment were checked by the zRMS using AppDate ver. 3.06 and are confirmed to be correct for the earliest BBCH stages of the respective crops intended in the Central Zone. Assumed crop interception corresponds with BBCH stages at which the product is intended to be applied.

Input parameters presented in Table 8.8-2 and used in the modelling are in line with the EU agreed endpoints reported in EFSA Scientific Report (2008) 191, 1-130.

Metabolite M5 was included in the groundwater exposure assessment in line with decisions taken during the EU review. Input parameters presented in Table 8.8-3 and used in the groundwater modelling are in line with information reported in EFSA Scientific Report (2008) 191, 1-130 and with data presented in Sodium nitrocompounds, Addendum 3 Vol3 B8 (2012).

In simulations PUF value of 0 was assumed for all compounds, which is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance (2021).

The Applicants' modelling was independently validated by the zRMS in additional simulations and resulted with the same PEC_{GW} values as these obtained by the Applicant.

It is noted that the Central Zone GAP presented in Table 8.1-1 includes several minor crops. The following surrogate crops were considered by the Applicant in simulations:

1. Winter wheat (major crop) for spring rye, spelt, emmer wheat, small spelt and durum wheat. This is agreed by the zRMS, as all minor crops in this group belong to cereals.
2. Sugar beet (major crop) for fodder beet, red beet, swede and turnip. Although some Member States consider root or leafy vegetables as relevant surrogate crops for this group, the zRMS is of the opinion that sugar beet is much more relevant for fodder beet and red beet as all these crops are just various cultivars of the same species, *Beta vulgaris* and their morphology and physiology are comparable. Swede and turnip are leafy vegetables and, in general, cabbage seems to be the relevant surrogate crop. Nevertheless, the morphology of these crops as well as their cultivation are much more comparable with sugar beet than with cabbage and for this reason the zRMS agrees that the groundwater exposure following application to swede and turnip is covered by simulations performed for sugar beet.
3. Winter oilseed rape (major crop) for mustard, spring rape, turnip rape, camelina, garden radish, poppy, linseed, hemp, sunflower and borage. The zRMS agrees that winter OSR is most suitable surrogate crop for mustard, spring rape, turnip rape, camelina, poppy, linseed, hemp and borage. However, it is not relevant for garden radish and sunflower for which, based on FOCUS crop scenarios and crop morphology, leafy vegetables (cabbage) and maize, respectively, are in opinion of the zRMS more relevant.

Since the surrogate crops selected by the Applicant for garden radish and sunflower were not agreed, additional groundwater modelling was performed by the zRMS for the following assumptions:

- For sunflower simulations were run using maize as surrogate crop with application periods selected using the AppDate v. 3.06 based on application timing (BBCH 29-69) and 7 days application interval. Crop interception at 50% was assumed.
- For garden radish simulations were run using cabbage as surrogate crop with application periods selected using the AppDate v. 3.06 based on application timing (BBCH 41-50, covering BBCH 29-69) and 7 days application interval. Crop interception at 70% was assumed. Please note that for modelling purposes BBCH 41-50 was selected for this crop, as AppDate and PELMO assume applications to cabbage at either BBCH 09-19 or 41-50. Taking into account the intended application timing in garden radish, consideration of application at BBCH 41-50 in modelling programs is more appropriate as it is included in intended BBCH range (29-69).

The assumed application dates and application rates are presented in table below.

Crop		**Sunflower**	**Garden radish**
Surrogate crop		**Maize**	**Cabbage**
Application timing		BBCH 29-69	BBCH 41-50 (covering BBCH 29-69)
Interception by plants (%)		50	70
Application number / Interval (days)		2/7	2/7
Max. application rate (g/ha)		Na 5-NG: 0.6 Na *o*-NP: 1.2 Na *p*-NP: 1.8 M5: 0.1116	Na 5-NG: 0.6 Na *o*-NP: 1.2 Na *p*-NP: 1.8 M5: 0.1116
Rate reaching soil (g/ha)		Na 5-NG: 0.3 Na *o*-NP: 0.6 Na *p*-NP: 0.9 M5: 0.0558	Na 5-NG: 0.18 Na *o*-NP: 0.36 Na *p*-NP: 0.54 M5: 0.0335
Absolute application date	Châteaudun	06/06 – 13/06	05/06-12/06
	Hamburg	03/06 – 10/06	05/06-12/06
	Jokioinen	-	07/09-14/09
	Kremsmünster	03/06 – 10/06	05/06-12/06
	Okehampton	12/06-19/06	-
	Piacenza	10/06-17/06	-
	Porto	06/06-13/06	20/05-27/05
	Sevilla	10/04-17/04	04/05-11/05

	Thiva	9/05-16/05	06/10-13/10

Additional groundwater modelling was performed by the zRMS for Na 5-NG, Na *o*-NP and Na *p*-NP and their metabolite M5 using FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5. Results are presented in the table below:

PEC_{gw} for ASAHI MAX (FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5)

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)							
		Na 5-NG		Na *o*-NP		Na *p*-NP		M5	
		PELMO 6.6.4	PEARL 5.5.5	PELMO 6.6.4	PEARL 5.5.5	PELMO 6.6.4	PEARL 5.5.5	PELMO 6.6.4	PEARL 5.5.5
maize	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.031	0.032
	Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.037	0.045
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.026	0.024
	Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.020	0.022
	Piacenza	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.021	0.027
	Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.011	0.012
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.017	0.018
	Thiva	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.031	0.044
cabbage	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.016	0.016
	Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.019	0.023
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.030	0.036
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.014	0.014
	Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.006	0.007
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.011	0.010
	Thiva	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.016	0.017

Overall, based on Applicants' and zRMS modelling, no unacceptable leaching of Na 5-NG, Na *o*-NP and Na *p*-NP and their metabolite M5 is expected following application of ASAHI MAX according to the intended use pattern.

Please note that in case of mutual recognition process additional groundwater modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations or prefer other surrogate crops (this issue is not harmonised at the Central Zone level).

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

8.9.1 Justification for new endpoints

Not relevant, EU-agreed endpoints have been used in the risk assessment.

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

Report:	KCP 9.2.5/01, Garitano, M., 2022
Title:	ASAHI MAX: Predicted Environmental Concentrations in surface water (PECsw) and sediment (PECsed)
Document No:	DR20221022
Guidelines:	FOCUS (2001) "FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EC". Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev2 FOCUS (2015) "Generic guidance for FOCUS surface water Scenarios" (version 1.4, May 2015) EFSA (2013) Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290
GLP	No (calculation)

Materials and Methods

The predicted environmental concentrations in surface water (PECsw) and sediment (PECsed) for the active ingredients Na 5-NG, Na *o*-NP and Na *p*-NP were calculated using the simulation models STEP 1-2 (v.3.2) in the EU FOCUS scenarios.

Predictions were calculated at the highest rate of application for which authorisation is sought (critical GAP uses) applied for the envisaged uses of ASAHI MAX.

Application windows were set according to the AppDate Tool and the lowest intended BBCH as worst case. The proposed application pattern for the formulated product Asahi is summarised below:

Table 8.9.1 Input parameters related to application for $PEC_{SW/SED}$ calculations

Crop		**Winter OSR**	**Summer OSR**	**Winter wheat**	**Sugar beet**
Application rate (g as/ha)		Na 5-NG: 0.6 Na *o*-NP: 1.2 Na *p*-NP: 1.8	Na 5-NG: 0.6 Na *o*-NP: 1.2 Na *p*-NP: 1.8	Na 5-NG: 0.6 Na *o*-NP: 1.2 Na *p*-NP: 1.8	Na 5-NG: 0.6 Na *o*-NP: 1.2 Na *p*-NP: 1.8
Number of applications/interval (d)		2 / 7	2 / 7	1 / -	2 / 7
Application moment		BBCH 29-69 (spring)	BBCH 29-69 (spring)	BBCH 21-49 (spring)	BBCH 12-49 (spring-summer)
Step 1-2	Application window	Mar-May Jun-Sep	Mar-May Jun-Sep	Mar-May Jun-Sep	Mar-May Jun-Sep
	Crop interception	Full canopy	Full canopy	Average crop cover	Minimal crop cover
	Models	STEPS 1-2 v 3.2	STEPS 1-2 v 3.2	STEPS 1-2 v 3.2	STEPS 1-2 v 3.2

The input parameters related to the active substance are summarised in the following table:

Table 8.9.2 Input parameters related to active substances for PECsw calculations

	Na 5-NG	Na *o*-NP	Na *p*-NP	Value in accordance with EU endpoint y/n/ Reference
Physico-chemical				
Molecular mass (g/mol)	191.1	161.1	161.1	Yes, EFSA Scientific Report (2008) 191, 1-130
Aqueous solubility (mg/L)	1830 (pH 7, 20°C)	2760 (pH 7, 20°C)	13900 (pH 7, 20°C)	Yes, EFSA Scientific Report (2008) 191, 1-130
K_{FOC} (mL/g)	463.4	156.1	288.1	Yes, EFSA Scientific Report (2008) 191, 1-130
Degradation in soil				
Soil DT_{50} (days) (normalised to 20°C & pF2)	0.6	5.5	3.3	Yes, EFSA Scientific Report (2008) 191, 1-130
Degradation in aquatic systems				
DT_{50} water (days)	5.4	2.2	3.6	Yes, EFSA Scientific Report (2008) 191, 1-130
DT_{50} sediment (days)	5.4	2.2	3.6	Yes, EFSA Scientific Report (2008) 191, 1-130
DT_{50} total system (days)	5.4	2.2	3.6	Yes, EFSA Scientific Report (2008) 191, 1-130

Metabolites

A data gap to assess the potential impact to the environment of the unidentified photodegradation products M3, M5, M8, M12 and M13 formed from Na 5-NG and M3, M5 and M6 formed from Na *p*-NP, was identified during the EU review. This issue was addressed in a confirmatory data addendum (cited by UK (central zRMS) as being addendum 3 vol3 of nov 2012) which does not seem to be available on ciracabc. However, according to UK, the surface water residue definition remained unchanged after review of this addendum, and photolytic metabolites need to be addressed in the preparation assessment.

Predicted environmental concentrations in surface water and sediment for the unidentified photodegradation products M12, formed from Na 5-NG and M6, formed from Na *p*-NP, were calculated at FOCUS Steps 1 and 2 using the STEPS 1-2 in FOCUS. ~~These metabolites present the maximum occurrences and thus cover all other metabolites~~. M12 and M6 present the maximum occurrences and thus cover all other photodegradation metabolites.

Table 8.9.3 Summary of input parameters for the photodegradation products M12 and M6 for PEC_{SW} and $PECS_{ED}$ calculations according to the FOCUS Surface Water models

Parameter	M12	M6	Remarks
Molecular weight [g mol^{-1}]	191.1	161.1	In the absence of data for the metabolites, parent values were assumed to give a molar correction of 1.0 (Sodium nitrocompounds_amended Addendum 3 Vol3 B8_Nov.2012)
Water solubility [mg/L^{-1}]	13900 (pH 7, 20°C)	13900 (pH 7, 20°C)	As the metabolites are expected to be more soluble than the active substances, the highest measured value for the active substances (13900 mg/L for Na *p*-NP) was assumed in the calculations to provide a conservative assessment (Sodium nitrocompounds_amended Addendum 3 Vol3 B8_Nov.2012)
Degradation in soil			
Maximum observed in soil [%]	Not formed	Not formed	(Sodium nitrocompounds_amended Addendum 3 Vol3 B8_Nov.2012)
DT_{50} soil [d] (Step 1, Step 2)	1000	1000	Conservative assumption (Sodium nitrocompounds_amended Addendum 3 Vol3 B8_Nov.2012)
Sorption to soil			
K_{FOC} [mL g^{-1}]	1	1	Conservative assumption (Sodium nitrocompounds_amended Addendum 3 Vol3 B8_Nov.2012)
Degradation in aquatic systems			

Parameter	M12	M6	Remarks
Maximum observed in aquatic systems [%]	25	48.7	(Sodium nitrocompounds_amended Addendum 3 Vol3 B8_Nov.2012)
DT_{50} total system [d] (Step 1)	1000	1000	Conservative assumption (Sodium nitrocompounds_amended Addendum 3 Vol3 B8_Nov.2012)
DT_{50} water [d] (Step 2)	1000	1000	
DT_{50} sediment [d] (Step 2)	1000	1000	

Results:

The results of PECsw and PECsed calculations are summarised in the following tables:

Table 8.9.4 FOCUS Step 1-2 PEC_{sw} and PEC_{sed} in Winter OSR

	Focus scenario			Single application		Multiple application	
				Max PEC_{sw} (µg/L)	**Max PEC_{sed} (µg/kg)**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sed} (µg/kg)**
Na 5-NG	**Step 1**			-	-	0.26	1.15
	Step 2	Mar-May	SEU	0.01	0.01	0.01	0.01
			NEU	0.01	0.01	0.01	0.01
		Jun-Sep	SEU	0.01	0.01	0.01	0.01
			NEU	0.01	0.01	0.01	0.01
Na *o*-NP	**Step 1**			-	-	0.34	0.52
	Step 2	Mar-May	SEU	0.02	0.03	0.03	0.05
			NEU	0.01	0.02	0.02	0.02
		Jun-Sep	SEU	0.02	0.03	0.02	0.04
			NEU	0.01	0.02	0.02	0.02
Na *p*-NP	**Step 1**			-	-	0.90	2.50
	Step 2	Mar-May	SEU	0.02	0.07	0.03	0.08
			NEU	0.02	0.04	0.02	0.05
		Jun-Sep	SEU	0.02	0.05	0.02	0.06
			NEU	0.02	0.04	0.02	0.05
M12	**Step 1**			-	-	0.10	0.00
	Step 2	Mar-May	SEU	0.00	0.00	0.00	0.00
			NEU	0.00	0.00	0.00	0.00
		Jun-Sep	SEU	0.00	0.00	0.00	0.00
			NEU	0.00	0.00	0.00	0.00
M6	**Step 1**			-	-	0.60	0.01
	Step 2	Mar-May	SEU	0.02	0.00	0.03	0.00
			NEU	0.01	0.00	0.02	0.00
		Jun-Sep	SEU	0.02	0.00	0.03	0.00
			NEU	0.01	0.00	0.02	0.00

Table 8.9.5 FOCUS Step 1-2 PEC_{sw} and PEC_{sed} in Summer OSR

	Focus scenario			Single application		Multiple application	
				Max PEC_{sw} (µg/L)	Max PEC_{sed} (µg/kg)	Max PEC_{sw} (µg/L)	Max PEC_{sed} (µg/kg)
Na 5-NG	**Step 1**					0.26	1.15
	Step 2	Mar-May	SEU	0.01	0.01	0.01	0.01
			NEU	0.01	0.01	0.01	0.01
		Jun-Sep	SEU	0.01	0.01	0.01	0.01
			NEU	0.01	0.01	0.01	0.01
Na *o*-NP	**Step 1**			-	-	0.34	0.52
	Step 2	Mar-May	SEU	0.02	0.03	0.03	0.05
			NEU	0.01	0.02	0.02	0.02
		Jun-Sep	SEU	0.02	0.03	0.02	0.04
			NEU	0.01	0.02	0.02	0.02
Na *p*-NP	**Step 1**			-	-	0.90	2.50
	Step 2	Mar-May	SEU	0.02	0.07	0.03	0.08
			NEU	0.02	0.04	0.02	0.05
		Jun-Sep	SEU	0.02	0.05	0.02	0.06
			NEU	0.02	0.04	0.02	0.05
M12	**Step 1**					0.10	0.00
	Step 2	Mar-May	SEU	0.00	0.00	0.00	0.00
			NEU	0.00	0.00	0.00	0.00
		Jun-Sep	SEU	0.00	0.00	0.00	0.00
			NEU	0.00	0.00	0.00	0.00
M6	**Step 1**			-	-	0.60	0.01
	Step 2	Mar-May	SEU	0.02	0.00	0.03	0.00
			NEU	0.01	0.00	0.02	0.00
		Jun-Sep	SEU	0.02	0.00	0.03	0.00
			NEU	0.01	0.00	0.02	0.00

Table 8.9.6 FOCUS Step 1-2 PEC_{sw} and PEC_{sed} in Winter wheat

	Focus scenario			Single application	
				Max PEC_{sw} (µg/L)	Max PEC_{sed} (µg/kg)
Na 5-NG	**Step 1**			0.13	0.57
	Step **2**	Mar-May	SEU	0.01	0.01
			NEU	0.01	0.01
		Jun-Sep	SEU	0.01	0.01
			NEU	0.01	0.01
Na *o*-NP	**Step 1**			0.34	0.52
	Step 2	Mar-May	SEU	0.07	0.10
			NEU	0.03	0.05
		Jun-Sep	SEU	0.05	0.08
			NEU	0.03	0.05
Na *p*-NP	**Step 1**			0.45	1.25
	Step 2	Mar-May	SEU	0.07	0.18
			NEU	0.04	0.10
		Jun-Sep	SEU	0.05	0.14
			NEU	0.04	0.10
M12	**Step 1**			0.05	0.00
	Step 2	Mar-May	SEU	0.00	0.00
			NEU	0.00	0.00
		Jun-Sep	SEU	0.00	0.00
			NEU	0.00	0.00
M6	**Step 1**			0.30	0.00
	Step 2	Mar-May	SEU	0.05	0.00
			NEU	0.03	0.00
		Jun-Sep	SEU	0.04	0.00
			NEU	0.03	0.00

Table 8.9.7 FOCUS Step 1-2 PEC_{sw} and PEC_{sed} in sugar beet

	Focus scenario			Single application		Multiple application	
				Max PEC_{sw} (µg/L)	Max PEC_{sed} (µg/kg)	Max PEC_{sw} (µg/L)	Max PEC_{sed} (µg/kg)
Na 5-NG	**Step 1**					0.26	1.15
	Step 2	Mar-May	SEU	0.01	0.01	0.01	0.01
			NEU	0.01	0.01	0.01	0.01
		Jun-Sep	SEU	0.01	0.01	0.01	0.01
			NEU	0.01	0.01	0.01	0.01
Na *o*-NP	**Step 1**			-	-	0.34	0.52
	Step 2	Mar-May	SEU	0.07	0.10	0.09	0.14
			NEU	0.03	0.05	0.05	0.07
		Jun-Sep	SEU	0.05	0.08	0.07	0.11
			NEU	0.03	0.05	0.05	0.07
Na *p*-NP	**Step 1**			-	-	0.90	2.50
	Step 2	Mar-May	SEU	0.07	0.18	0.08	0.23
			NEU	0.04	0.10	0.04	0.12
		Jun-Sep	SEU	0.05	0.14	0.06	0.17
			NEU	0.04	0.10	0.04	0.12
M12	**Step 1**			-	-	0.10	0.00
	Step 2	Mar-May	SEU	0.00	0.00	0.00	0.00
			NEU	0.00	0.00	0.00	0.00
		Jun-Sep	SEU	0.00	0.00	0.00	0.00
			NEU	0.00	0.00	0.00	0.00
M6	**Step 1**			-	-	0.60	0.01
	Step 2	Mar-May	SEU	0.05	0.00	0.06	0.00
			NEU	0.03	0.00	0.04	0.00
		Jun-Sep	SEU	0.04	0.00	0.05	0.00
			NEU	0.03	0.00	0.04	0.00

Conclusion:

The PECsw values at Step 1-2 are below the RAC values. All Step 1-2 PECsw and PECsed values are valid for the aquatic ecotoxicological risk assessment.

zRMS comments:

The input parameters considered by the Applicant in surface water modelling for Na 5-NG, Na *o*-NP and Na *p*-NP presented in Table 8.9-2 are in line with EU agreed endpoints reported in EFSA Scientific Report (2008) 191, 1-130.

According to EFSA Scientific Report (2008) 191, 1-130, metabolites: M3, M5, M8, M12, and M13 are formed via photolysis from Na 5-NG, while metabolites M3, M5, M6 are formed via photolysis from Na *p*-NP. Respective changes were introduced in the text above.

The input parameters presented in Table 8.9-3 for metabolites M12 and M6 as the photodegradation products of Na 5-NG and Na *p*-NP, respectively, are in line with data presented in Sodium nitrocompounds, Addendum 3 Vol3 B8 (2012).

The surface water modelling was independently validated by the zRMS using the same application pattern and the same input parameters for the active substances. Obtained PEC_{SW} and PEC_{SED} were in good agreement with values calculated by the Applicant. Surface water exposure of Na 5-NG, Na *o*-N and Na *p*-NP, and metabolites M12 and M6 presented in Tables 8.9-3 to 8.9-6 may be thus used in the aquatic risk assessment.

It is noted that the Central Zone GAP presented in Table 8.1-1 includes several minor crops. The following surrogate crops were considered by the Applicant in simulations:

1. Winter wheat (major crop) for spring rye, spelt, emmer wheat, small spelt and durum wheat. This is agreed by the zRMS, as all minor crops in this group belong to cereals.
2. Sugar beet (major crop) for fodder beet, red beet, swede and turnip. Although some Member States consider root or leafy vegetables as relevant surrogate crops for this group, the zRMS is of the opinion that sugar beet is much more relevant for fodder beet and red beet as all these crops are just various cultivars of the same species, *Beta vulgaris* and their morphology and physiology are comparable. Swede and turnip are leafy vegetables which seem thus to be the relevant surrogate crop. Nevertheless, the morphology of these crops as well as their cultivation are much more comparable with sugar beet than with leafy vegetables and

for this reason the zRMS agrees that the surface water exposure following application to swede and turnip is covered by simulations performed for sugar beet.

3. Winter oilseed rape (major crop) for mustard, spring rape, turnip rape, camelina, garden radish, poppy, linseed, hemp, sunflower and borage. The zRMS agrees that winter OSR is most suitable surrogate crop for mustard, spring rape, turnip rape, camelina, poppy, linseed, hemp and borage. However, it is not relevant for garden radish and sunflower. Based on FOCUS crop scenarios and crop morphology, leafy vegetables, are in opinion of the zRMS more relevant for garden radish, while for sunflower there is no need to consider surrogate crop as sunflower is available as crop scenario in FOCUS.

Since the surrogate crops selected by the Applicant for garden radish and sunflower were not agreed, additional surface water modelling was performed with consideration of application to sunflower and leafy vegetables at BBCH 29-69, with assumption of two applications with 7 days interval. Crop interception was set as an average crop cover as representing a worst case for the intended application period. The calculated $PEC_{SW/SED}$ are presented in table below.

	Focus scenario		Crop	Single application		Multiple application	
				Max PEC_{sw} (µg/L)	**Max PEC_{sed} (µg/kg)**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sed} (µg/kg)**
Na 5-NG	**Step 1**					0.26	1.15
	Step 2	Mar-May	Sunflower	0.01	0.01	0.01	0.01
			Leafy vegetables	0.01	0.01	0.01	0.01
		Jun-Sep	Sunflower	0.01	0.01	0.01	0.01
			Leafy vegetables	0.01	0.01	0.01	0.01
Na *o*-NP	**Step 1**			-	-	0.34	0.52
	Step 2	Mar-May	Sunflower	0.02	0.03	0.03	0.05
			Leafy vegetables	0.02	0.03	0.03	0.05
		Jun-Sep	Sunflower	0.02	0.03	0.03	0.05
			Leafy vegetables	0.02	0.03	0.03	0.05
Na *p*-NP	**Step 1**			-	-	0.90	2.50
	Step 2	Mar-May	Sunflower	0.02	0.07	0.03	0.08
			Leafy vegetables	0.02	0.07	0.03	0.08
		Jun-Sep	Sunflower	0.02	0.07	0.03	0.08
			Leafy vegetables	0.02	0.07	0.03	0.08
M12	**Step 1**			-	-	0.10	0.00
	Step 2	Mar-May	Sunflower	0.00	0.00	0.00	0.00
			Leafy vegetables	0.00	0.00	0.00	0.00
		Jun-Sep	Sunflower	0.00	0.00	0.00	0.00
			Leafy vegetables	0.00	0.00	0.00	0.00
M6	**Step 1**			-	-	0.60	0.01
	Step 2	Mar-May	Sunflower	0.02	0.00	0.03	0.00
			Leafy vegetables	0.02	0.00	0.03	0.00
		Jun-Sep	Sunflower	0.02	0.00	0.03	0.00
			Leafy vegetables	0.02	0.00	0.03	0.00

Please note that additional surface water modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

8.9.2.1 $PEC_{sw/sed}$ of ASAHI MAX

The initial PECsw and PECsed due to spray drift of the formulated product has been calculated considering the total annual rate. 30 cm of water height, 1 cm of sediment layer for water/sediment distribution and 0.8 g/cm^3 sediment density according to EFSA GD on tiered RA for edge-of-field surface water (2013) have been assumed for the calculation. The Rautmann Spray Drift values have been used. A maximum occurrence in sediment of 100% has been considered as worst case.

Table 8.9.8: PECsw and PECsed for ASAHI MAX

Formulated product	Crop	Application rate (g/ha)	Drift	PECsw (µg/L)	PECsed (µg/kg)
Asahi Max	Oilseed rape	2 x 0.2 L FP/ha	2.77%	3.693	138.500

Formulated product	Crop	Application rate (g/ha)	Drift	PECsw (µg/L)	PECsed (µg/kg)
	Sugar beet	(2 x 200 g a.s./ha)			
Asahi Max	Winter wheat	0.2 L FP/ha (200 g a.s./ha)	2.77%	1.847	69.250

Density of the product: 1 g/mL

zRMS comments:

The surface water exposure to formulation was validated by the zRMS using Spray Drift Calculator. Obtained PEC_{SW} were in agreement with these reported in Table 8.9.8 and may be used in the aquatic risk assessment.

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Table 8.10.1 Summary of atmospheric degradation and behaviour

Compound	Na 5-NG	Na *o*-NP	Na *p*-NP
Direct photolysis in air	Not available, not required	Not available, not required	Not available, not required
Quantum yield of direct phototransformation	1.56×10^{-5} molecules degraded photon-1 in water	6.52×10^{-7} molecules degraded photon-1 in water	3.77×10^{-6} molecules degraded photon-1 in water
Photochemical oxidative degradation in air	DT_{50} = 2.2 days (derived using the Atkinson method)	DT_{50} = 2.3 days (derived using the Atkinson method)	DT_{50} = 2.3 days (derived using the Atkinson method)
Volatilisation	No	No	No

Due to the relatively low vapour pressure of each of the active substances in the ASAHI MAX mixture (<1.33×10^{-5} Pa at 25°C for Na 5-NG and Na *p*-NP and 7.75×10^{-5} Pa at 25°C for Na *o*-NP), the substances are not expected to undergo significant volatilisation in the environment.

In addition, the atmospheric half-lives for the active substances calculated using the Atkinson method (2.2 days for Na 5-NG and 2.3 days for Na *o*-NP and Na *p*-NP) indicate that the substances are not persistent in the atmosphere. Therefore, should Na 5-NG, Na *o*-NP and Na *p*-NP reach air they will not persist and will be rapidly degraded.

Further volatility studies are therefore not required.

zRMS comments:

Information regarding fate and behaviour of Na 5-NG, Na *o*-NP and Na *p*-NP in the air presented in Table 8.10-1 is in line with EU agreed data reported in EFSA Scientific Report (2008) 191, 1-130.

In line with the EFSA conclusion, based on the vapour pressure all compounds are classified as very slightly volatile with losses due to volatilisation not expected. However, it should be noted that under acidic conditions some volatilisation of the phenolic form of Na *o*-NP may occur.

The DT_{50} of Na 5-NG, Na *o*-NP and Na *p*-NP in air is higher than 2 days, which indicate some potential for long range transport of these active substances. Nevertheless, due to low vapour pressure no significant volatilisation is expected and with DT50 slightly above, but still close to 2 days no unacceptable contamination of the atmosphere is expected following application of ASAHI MAX.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	Owner
Kcp 9.1.3/01	Garitano, M.	2022	ASAHI MAX: Predicted Environmental Concentrations in soil (PECs) Devreg Consulta SLU, Report No. DR20221020 Non GLP / Non GEP (modelling calculation) Unpublished	N	Asahi Chemical Europe s.r.o.
Kcp 9.2.4/01	Garitano, M.	2022	ASAHI MAX: Predicted Environmental Concentrations in groundwater (PECgw) Devreg Consulta SLU, Report No. DR20221021 Non GLP / Non GEP (modelling calculation) Unpublished	N	Asahi Chemical Europe s.r.o.
Kcp 9.2.5/01	Garitano, M.	2022	ASAHI MAX: Predicted Environmental Concentrations in surface water (PECsw) and sediment (PECsed) Devreg Consulta SLU, Report No. DR20221022 Non GLP / Non GEP (modelling calculation) Unpublished	N	Asahi Chemical Europe s.r.o.

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
As most of endpoints for Na 5-NG, Na *o*-NP and Na *p*-NP and its relevant metabolites was taken from the EU review, for the list of respective studies please refer to Volume 2 of the monograph.					

List of data submitted by the applicant and not 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
There were no data submitted by the Applicant and not relied on.					

List of data relied on not submitted by the applicant but necessary for evaluation

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
There were no data relied on and not submitted by the Applicant.					

Appendix 2 Detailed evaluation of the new Annex II studies

zRMS comments:

No new Annex II studies were submitted in support of the evaluation of ASAHI MAX.

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

zRMS comments:

No additional data were provided by the Applicant and the evaluation was performed by the zRMS based on information included in respective points of this document above as well as the modelling reports.