Annex to: Conclusion on the peer review of the pesticide risk assessment of the active substance s-metolachlor. doi:10.2903/j.efsa.2023.7852

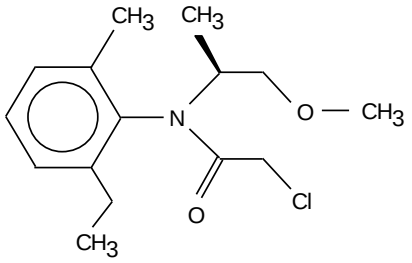
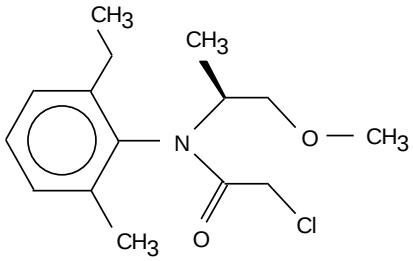
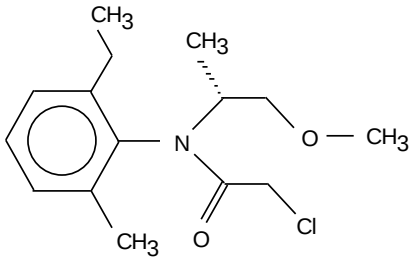
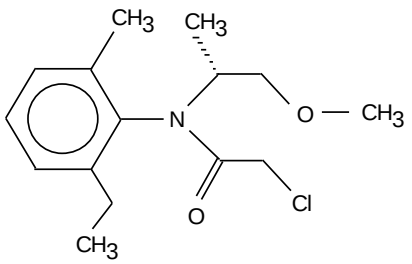
Appendix B – List of end points for the active substance and the representative formulation

Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

Active substance (ISO Common Name)	S-metolachlor
Function (*e.g.* fungicide)	herbicide
Rapporteur Member State	Germany
Co-rapporteur Member State	France

Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

Chemical name (IUPAC)	A reaction mixture of 80–100% 2-chloro-2′-ethyl-*N*-[(1*S*)-2-methoxy-1-methylethyl]-6′-methylacetanilide and 20–0% 2-chloro-2′-ethyl-*N*-[(1*R*)-2-methoxy-1-methylethyl]-6′-methylacetanilide
Chemical name (CA)	Mixture of 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(1 *S*)-2-methoxy-1-methylethyl)] acetamide (80-100 %) and 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(1 *R*)-2-methoxy-1-methylethyl)] acetamide (20-0 %)
CIPAC No	607
CAS No	87392-12-9 (S-isomer) 178961-20-1 (R-isomer)
EC No (EINECS or ELINCS)	618-004-1 (S-isomer)
FAO Specification (including year of publication)	-
Minimum purity of the active substance as manufactured	960 g/kg (total content) *S*-metolachlor min 840 g/kg *R*-metolachlor max 130 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Impurity 3 (CGA13656): max. 0.08 g/kg Impurity 6 (CGA50259): max. 0.08 g/kg
Location of the (proposed) reference specification (for significant impurities)	RAR confidential Volume 4
Molecular formula	$C_{15}H_{22}ClNO_2$
Molar mass	283.8 g/mol

Structural formula	S-metolachlor is a mixture of the 1*S* and 1*R* isomers each of which is a racemic mixture of rotamers as demonstrated by the structural formulas: CGA 77102 (S-isomers):  aS, 1S  aR, 1S CGA 77101 (R-isomers):  aR, 1R  aS, 1R

Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

Melting point (state purity)	-61.1 °C (99.8 % (S+R), 88.4 % (S))
Boiling point (state purity)	approx. 334 °C (99.8 % (S+R), 88.4 % (S))
Temperature of decomposition (state purity)	approx. 290 °C (99.8 % (S+R), 88.4 % (S))
Appearance (state purity)	Clear extremely pale-yellow liquid with a weak odour (99.8 % (S+R), 88.4 % (S))
Vapour pressure (state temperature, state purity)	3.7 x 10^{-3} Pa at 25 °C (99.8 % (S+R), 88.4 % (S))
Henry's law constant (state temperature)	2.2 x 10^{-3} Pa m^3 mol^{-1} (25 °C)
Solubility in water (state temperature, state purity and pH)	480 mg/L at 25 °C (pH 7.3) (99.8 % (S+R) 88.4 % (S))
Solubility in organic solvents (state temperature, state purity)	solubility at 25 °C (98.5% (S+R) 87.4 (S)) n-hexane: completely miscible toluene: completely miscible dichloromethane: completely miscible methanol: completely miscible n-octanol: completely miscible acetone: completely miscible ethyl acetate: completely miscible
Surface tension (state concentration and temperature, state purity)	54.3 mN/m - 54.5 mN/m at 22 °C (90 % saturated solution) (99.6 % (S+R) 89.3 % (S))
Partition coefficient (state temperature, pH and purity)	log P_{OW} = 3.05 ± 0.02 25 at °C (pH 7) (99.8 % (S+R) 88.4 % (S))
Dissociation constant (state purity)	No dissociation constant (pKa) in an accessible pH-range
UV/VIS absorption (max.) incl. ε (state purity, pH)	Maxima (99.8 % (S+R), 88.4 % (S)) 266.4 nm : ε = 534 $L.mol^{-1}.cm^{-1}$ 274.4 nm : ε = 443 $L.mol^{-1}.cm^{-1}$ above 290 nm (99.8 % (S+R), 88.4 % (S)) (data from original DAR for S-metolachlor): ε = 27.1 $L.mol^{-1}.cm^{-1}$ at pH 5 ε = 38.1 $L.mol^{-1}.cm^{-1}$ at pH 7 ε = 14.7 $L.mol^{-1}.cm^{-1}$ at pH 9 Data gap: spectral data for the relevant impurities
Flammability (state purity)	Not applicable
Explosive properties (state purity)	Not explosive (98.5 % (S+R) 87.4% (S))
Oxidising properties (state purity)	Not oxidising (98.5 %(S+R) 87.4% (S))

Summary of representative uses evaluated, for which all risk assessments needed to be completed (S-metolachlor**)**
(Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

Crop and/or situation (a)	Member State or Country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	g a.s / hL min-max (l)	Water L/ha min-max	g a.s. / ha min-max (l)		
1 - Maize	EU	A9396G	F	*Annual grasses,*	EC	960 g/L	Foliar spray	Pre-emergence crop BBCH 00-10	1	-	360-720	200-400	1440	not relevant	-
2 - Maize	EU	A9396G	F	*Annual grasses,*	EC	960 g/L	Foliar spray	Pre-emergence crop BBCH 00-10	1	-	312-624	200-400	1248	not relevant	-
3 - Maize	EU	A9396G	F	*Annual grasses,*	EC	960 g/L	Foliar spray	Post-emergence crop BBCH 11-18	1	-	360-720	200-400	1440	not relevant	-
4 - Maize	EU	A9396G	F	*Annual grasses,*	EC	960 g/L	Foliar spray	Post-emergence crop BBCH 11-18	1	-	312-624	200-400	1248	not relevant	-
5 - Sunflower	EU	A9396G	F	*Annual grasses,*	EC	960 g/L	Foliar spray	Pre-emergence crop BBCH 00-09	1	-	360-720	200-400	1440	not relevant	-
6 - Sunflower	EU	A9396G	F	*Annual grasses,*	EC	960 g/L	Foliar spray	Pre-emergence crop BBCH 00-09	1	-	312-624	200-400	1248	not relevant	-

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**

(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide (f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application (k) Indicate the minimum and maximum number of applications possible under practical conditions of use (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha (m) PHI - minimum pre-harvest interval

Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment
Regulation (EC) N° 1107/2009 Article 8.1(g))

Important note: efficacy, environmental risk and risk to humans by exposure other than via their diet have not been assessed for these uses

Crop and/or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Preparation**		**Application**				**Application rate per treatment**			**PHI (days)** (m)	**Remarks**
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															
Not applicable															

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

Representative uses of 'A9396G',= Dual Gold EC960, to control annual grasses and annual broadleaf weeds in several arable crops, such as maize and sunflower are supported.

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

The formulation for representative uses ('A9396G', Dual Gold EC960) is registered in several arable crops. When the product is applied correctly, according to the label recommendations it has no adverse effect either on yield or quality of the final produce.

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

The formulation for representative uses ('A9396G', Dual Gold EC960) does not pose any risk to adjacent or succeeding crops when it is used according to directions for use.

Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

Activity against target organism	SYN547977	CGA377735	SYN542488	SYN542492	SYN542491	SYN542489
	yes	no	no	no	no	no
	SYN542607	CGA50267	CGA40172	CGA50720	NOA436611	CGA368208
	no	no	no	no	no	no
	NOA413173	CGA357704	CGA51202 (OXA)	CGA354743 (ESA)	SYN542490	SYN545027
	no	no	no	no	no	Data gap
	SYN547969	SYN545026				
	no	Data gap				

Methods of Analysis

Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)	metolachlor (total content S- and R- isomers): GC-FID S-isomer (CGA77102) and R-isomer (CGA77101): HPLC-UV, chiral method
Impurities in technical a.s. (analytical technique)	GC-FID Data gap: method (s) for impurity 3 and impurity 6 in the technical material with a LOQ at least 20% less than the specification limit of 0.08 g/kg
Plant protection product (analytical technique)	metolachlor (total content S and R isomers): HPLC-UV S-isomer (CGA77102) and R-isomer (CGA77101): HPLC-UV, chiral method Data gap: method for relevant impurities imp. 3 and imp. 6 in the formulation

Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

Residue definitions for monitoring purposes

Food of plant origin		Metolachlor including other mixtures of constituent isomers including S-metolachlor (sum of isomers)
Food of animal origin		Metolachlor including other mixtures of constituent isomers including S-metolachlor (sum of isomers) Provisional – Pending outcome of the identified data gap[(1)] in Residues section and potential carry-over of CGA 133275, free and conjugated from feed items in rotational crops to animal matrices.
Soil		metolachlor (mixture of constituent isomers)
Sediment		metolachlor (mixture of constituent isomers)
Water	surface	metolachlor (mixture of constituent isomers)
	drinking/ground	metolachlor, CGA354743 (ESA), CGA51202 (OXA), CGA357704, CGA368208, CGA37735, CGA40172, CGA50720, NOA413173, NOA436611, SYN542488, SYN542489, SYN542490, SYN542491, SYN542492, SYN542607, SYN545026, SYN545027, SYN547969, SYN547977 all mixtures of constituent isomers
Air		metolachlor (mixture of constituent isomers)
Body fluids and tissues		Metolachlor (mixture of constituent isomers) and CGA46129 Open for (S-) metolachlor mercapturate

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	QuEChERS multiresidue method (EN 15662:2008): LC-MS/MS, LOQ = 0.01 mg/kg for metolachlor in high water content, high acid content, dry and fatty matrix. Confirmatory method is available. ILV is available. Extraction efficiency not verified (not required, since residues above LOQ in all matrix groups, as a result of the representative uses, were not found)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	QuEChERS multiresidue method (EN 15662:2008): LC-MS/MS, LOQ = 0.01 mg/kg for metolachlor in milk, egg, meat, liver, fat. Confirmatory method is available. ILV is available. Extraction efficiency not verified. Whether the extraction efficiency needs to be addressed is pending upon the finalisation of the livestock exposure assessment and whether residues above the LOQ are expected in animal matrices
Soil (analytical technique and LOQ)	Method GRM016.03A LC-MS/MS; LOQ = 0.01 mg/kg for metolachlor, CGA-51202, CGA-354743. Confirmatory method is available.
Water (analytical technique and LOQ)	Method GRM016.02A LC-MS/MS, LOQ = 0.01 µg/L for metolachlor, LOQ = 0.05 µg/L for CGA-51202, CGA-354743, each in drinking water, ground water and surface water. Confirmatory method is available. ILV for drinking water is available. Method GRM016.08A LC-MS/MS, LOQ = 0.05 µg/L for SYN542492, SYN547977, CGA-40172, CGA-41507 each in ground water and surface water. Confirmatory method is available. ILV for drinking water. Method GRM016.07A LC-MS/MS, LOQ = 0.05 µg/L for CGA357704, CGA368208, CGA50720, NOA413173 and NOA436611 each in ground water and surface water. Confirmatory method is available. Data gap for ILV Data gap for a method for other compounds in the ground/drinking water residue definition.
Air (analytical technique and LOQ)	Method RAM 456/01 LC-MS/MS, LOQ = 4.5 µg/m³ for metolachlor Method REM 186.04 GC-ECD, LOQ = 5 µg/m³ for metolachlor
Body fluids and tissues (analytical technique and LOQ)	QuEChERS multiresidue method (EN 15662:2008): LC-MS/MS, LOQ = 0.01 mg/kg for metolachlor in body fluid (blood) and tissues. Confirmatory method is available. Data gap for gap for monitoring method for the metabolite CGA46129 Open for (S-) metolachlor mercapturate

Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

Substance	S-metolachlor
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][1]:	No classification
According to the Peer review, the criteria for classification may be met for:	No proposal

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

Impact on Human and Animal Health

It is noted that the toxicity of S-metolachlor can be bridged from metolachlor; the studies reported under this chapter are performed with S-metolachlor unless otherwise reported (metolachlor).

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability	≥ 85 % within 48h based on urinary and biliary excretion
Toxicokinetics	For 0.5 mg/kg bw dose level: Cmax approx. 0.03 mg/kg; Tmax approx. 8 h; T1/2 approx. 24-31 h AUC 0.8 mg.h/kg
Distribution	Widely distributed: quite uniformly, primarily in well-perfused organs and red blood cells
Potential for bioaccumulation	No evidence for accumulation: decrease to very low levels at d7 (max 0.22% of dose in liver)
Rate and extent of excretion	Rapidly excreted (mostly within 48 h), mainly via faeces (53%, major biliary excretion) and urine (42 %) at high dose
Metabolism in animals	Extensive metabolisation; *oxidative reactions (80 %): (i) cleavage of the methyl ether, (ii) oxidation of the resultant alcohol to the corresponding acid, (iii) oxidation of the aryl methyl and/or ethyl groups, and (iv) substitution of the chlorine atom * glutathione conjugations (20 %)
In vitro metabolism	Metabolite M4 identified in human micrososmes only (4% radioactivity), metabolite M9 major metabolite in humans but not in rats (39% vs 11%). Identity or toxicological profile of M4 and M9 not available (data gap). No information on metabolism in other key species available (data gap).
Toxicologically relevant compounds (animals and plants)	S-metolachlor
Toxicologically relevant compounds (environment)	S-metolachlor and groundwater metabolites >0.1 µg/L

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

Rat LD_{50} oral	> 2000 mg/kg bw (rat, mouse)	
Rat LD_{50} dermal	> 2000 mg/kg bw (rabbit)	
Rat LC_{50} inhalation	> 2.91 mg/L air /4h (nose only)	
Skin irritation	Non-irritant	
Eye irritation	Non-irritant	
Skin sensitisation	Sensitising (*M&K, Buehler*)	**H317**

Phototoxicity	No phototoxicity > 315 nm but test material absorbs mainly at wavelengths <315nm (data gap)	

Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

Target organ / critical effect	**Rat**: liver (increased weight, changes in clinical chemistry parameters, centrilobular hypertrophy, eosinophilic inclusions), kidney (increased weight, changes in clinical chemistry parameters and urine analysis), decreased body weight (gain) **Dog**: liver (increased weight, increased alkaline phosphatase, acute perivascular inflammation), blood (changes in red blood cell parameters), decreased body weight (gain) **Rabbit**: liver (increased weight)	
Relevant oral NOAEL	28-day rat (2 studies, 1 with metolachlor): 24.5 mg/kg bw per day 90-day rat (3 studies, 1 with metolachlor): 20 mg/kg bw per day 6-month, dog (metolachlor): 2.92 mg/kg bw per day	
Relevant dermal NOAEL	21-day, rabbit (metolachlor): systemic effects (increased liver weight): 100 mg/kg bw per day local effects: LOAEL 10 mg/kg bw per day (erythema and hyperkeratosis)	
Relevant inhalation NOAEL	No study submitted – not required	

Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

In vitro studies	Mutagenicity tests: - in bacterial cells (Ames tests) (3): negative - in mammalian cells (HGPRT & MLA): negative Clastogenicity tests: - in human lymphocytes: equivocal (non-reproducible structural chromosome aberration in one test) - micronucleus test: equivocal (positive but not reproducible result)	
In vivo studies	Micronucleus tests (2): negative (bone marrow exposure sufficiently demonstrated, albeit only for a short time period)	
Photomutagenicity	No study submitted – not required	
Potential for genotoxicity	S-metolachlor is unlikely to be genotoxic	

Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

Long-term effects (target organ/critical effect)	Rat (metolachlor): liver, body weight (gain) (bw) Mouse: unacceptable study with many deviations (data gap)	
Relevant long-term NOAEL	2-year, rat: 15 mg/kg bw per day	
Carcinogenicity (target organ, tumour type)	Rat: - liver: hepatocellular focal alterations and "foci + carcinoma" (m & f); - pituitary: adenoma and carcinoma (f); - thyroid: adenoma (f); - nasal turbinates: adenocarcinoma (m)	Cat. 2 H351
Relevant NOAEL for carcinogenicity	2-year, rat: 15 mg/kg bw per day	

Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	Rat 2-generation study (metolachlor): Parental toxicity: ↑ relative liver and thyroid weights, ↓ food intake Reproductive toxicity: no adverse effect Offspring's toxicity: decreased body weight in pups	
Relevant parental NOAEL	17.7 mg/kg bw per day	
Relevant reproductive NOAEL	54.9 mg/kg bw per day (highest dose tested)	
Relevant offspring NOAEL	17.7 mg/kg bw per day	

Developmental toxicity

Developmental target / critical effect	Rat: Maternal toxicity: clinical signs, decreased bw(gain) and food consumption (after initial few doses) Developmental toxicity: decreased foetal weight, skeletal variations (study with S-metolachlor), ossification delay (study with metolachlor) Rabbit: Maternal toxicity: clinical signs, decreased bw(gain) and food consumption Developmental toxicity: decreased foetal weight, increase in skeletal variations (fully formed ribs) and malformations (e.g. hydrocephalus)	
Relevant maternal NOAEL	Rat: 50 mg/kg bw per day Rabbit: 100 mg/kg bw per day	

Relevant developmental NOAEL	Rat: 300 mg/kg bw per day Rabbit: 100 mg/kg bw per day	

Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity	No study submitted (data gap)	
Repeated neurotoxicity	No study submitted (data gap)	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	No study submitted (data gap)	

Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance	Enzyme induction and proliverative changes in rat liver caused by a mode of action only to some extend similar to phenobarbital. Other possible mechanisms responsible for tumor formation cannot be excluded. Immunotoxicity: adverse effects observed on immune-related parameters in rats, dogs and mice (data gap)		
Endocrine disrupting properties	Data gap, further data (level 5) needed to conclude on ED potential (EAS-modalities) The peer review conclusion will be finalised without the ED assessment following the receipt of the mandate in September 2022.		
Studies performed on metabolites or impurities	Metabolite	Genotoxicity	General toxicity (doses in mg/kg bw (per day))
	OXA **CGA 51202**	Ames: negative (-ve) *In vitro* gene mutation (GM): -ve *In vivo* micronucleus (MN): -ve Unlikely to be genotoxic	Oral absorption >75%, excreted unchanged (dog) Rat oral LD_{50} > 2000 Rat dermal LD_{50} > 1333 Eye irritant, Skin sensitiser 90-d rat NOAEL 62 90-d dog NOAEL 50 Rat dev: no teratogenic effect - maternal NOAEL 100 - dev NOAEL 1000
	ESA **CGA354743*** **and ESA S-enantiomer (CGA376944)**	Ames: -ve *In vitro* GM: equivocal *In vivo* MN: equivocal (data gap)	Oral absorption 2-4%, eliminated unchanged (ESA S-enantiomer) Rat oral LD_{50} > 2000 Rat dermal LD_{50} > 1333 Non irritant (eye/skin) Skin sensitisation: equivocal 90-d rat NOAEL 461 90-d dog NOAEL 200 Rat dev: no teratogenic effect, maternal/dev NOAEL 1000
	NOA413173*	Ames: -ve *In vitro* GM: -ve *In vitro* CA: equivocal Aneugenicity not investigated (data gap)	Rat oral LD_{50} > 2000 28-day rat NOAEL 1370 90-day rat NOAEL 444
	CGA368208	Ames: -ve *In vitro* GM: -ve	Rat oral LD_{50} > 2000

	In vitro CA: -ve Aneugenicity not investigated (data gap)	28-d rat NOAEL 1261 (CGA369873)
CGA50720	Ames: -ve *In vitro* GM: -ve *In vitro* CA: positive (+ve) *In vivo* MN: -ve Unlikely to be genotoxic	Rat oral LD_{50} > 2000 Insufficient data/information
CGA357704	Ames: -ve *In vitro* GM: -ve *In vitro* CA: equivocal *In vivo* MN: -ve Unlikely to be genotoxic	Rat oral LD_{50} > 2000 Read-across from CGA51202 not accepted
SYN548164 (ammonium salt of SYN542491)	Ames: -ve (164) *In vitro* GM: -ve (164) *In vitro* CA: +ve (164) *In vivo* MN: -ve (164) Unlikely to be genotoxic	Read-across from CGA51202 not accepted
CGA50267	Ames: -ve *In vitro* GM: -ve *In vitro* CA: +ve *In vivo* MN: -ve Unlikely to be genotoxic	Rat oral LD_{50} > 2000 Insufficient data/information
NOA436611 **SYN546829**	Ames: -ve (NOA) *In vitro* GM: -ve (SYN) *In vitro* CA: -ve (SYN) Aneugenicity not investigated (data gap)	Rat oral LD_{50} > 2000 (NOA) Read-across from CGA51202 not accepted
SYN548163 (SYN542489)	Ames: -ve (163) *In vitro* GM: -ve (163) *In vitro* CA: -ve (163) Aneugenicity not investigated (data gap)	Read-across from CGA51202 not accepted Structural alert for carcinogenicity
SYN542492	Ames: -ve *In vitro* GM: -ve *In vitro* CA: +ve *In vivo* MN: -ve Unlikely to be genotoxic	Read-across from CGA51202 not accepted
SYN542488	Ames: -ve *In vitro* GM: equivocal *In vitro* CA: +ve *In vivo* MN: -ve (data gap mutagenicity)	Read-across from CGA51202 not accepted
SYN548165 (SYN542607)	Ames: -ve (165) *In vitro* GM: -ve (165) *In vitro* CA: -ve (165) Aneugenicity not investigated (data gap)	Read-across from CGA354743 not accepted

SYN542490	Read-across from CGA542607 not accepted (data gap)	Read-across from CGA 542607 not accepted
SYN547969	Read-across from SYN542488 not accepted (data gap)	Read-across from CGA51202 not accepted
CGA37735	Read-across from CGA368208 not accepted (data gap)	Read-across from CGA368208 not accepted
CGA37913	No data (data gap)	Rat oral LD_{50} > 2000 Hydroxyl amines of toxicological concern
CGA41507	Ames: -ve *In vitro* GM: -ve *In vitro* CA: +ve *In vivo* MN: -ve Unlikely to be genotoxic	No data
CGA369873	Ames: -ve *In vitro* gene mutation: -ve *In vitro* CA: -ve Aneugenicity not investigated (data gap)	28-d rat NOAEL = 1261
Impurity 3 (CGA13656)	Clastogenicity: positive *in vitro*, equivocal *in vivo*	-
Impurity 6 (CGA50259)	Gene mutation: positive *in vitro*, equivocal *in vivo*	-

* It was noted during the MS written procedure on the draft conclusion that new genotoxicity studies are available and have been submitted for national assessment in France. Based on a national assessment of these additional studies, it was concluded that both metabolites are unlikely to be genotoxic (see EFSA, 2023).

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

no detrimental effects on health in manufacturing personnel reported; health incidences in occupational, accidental or intentional exposure cases (severity ranging from none/minor up to fatal outcome)

Summary (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	0.03	dog, 6-month	100
Acute Reference Dose (ARfD)	0.5	rat, developmental (maternal effects)	100
Acceptable Operator Exposure Level (AOEL)	0.03	dog, 6-month	100**
Acute Acceptable Operator Exposure Level (AAOEL)	0.5	rat, developmental (maternal effects)	100**

**correction for limited oral absorption/bioavailability not necessary.

From the first peer review for S-metolachlor (European Commission, 2004): ADI 0.1 mg/kg bw per day based on the 1-year dog study (UF 100), ARfD considered not necessary, AOEL 0.15 mg/kg bw per day based on the 90-day dog study (UF 100).

Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

S-Metolachlor EC (A9396G)

In vitro dermal absorption study (human skin)		
Tested concentration	Value (EFSA, 2012)*	Value (EFSA, 2017)
Concentrate	0.4%	0.3%
Spray dilution 1:100	12%	15%
Spray dilution 1:200	8%	12%
Spray dilution 1:400	13%	16%

*applicable at the time of the dossier submission

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Operators

Use: maize and sunflower, tractor mounted equipment, application rate 1x 1.44 kg a.s./ha				
Models:	German (%AOEL)	UK POEM (%AOEL)	EFSA 2014* (%AOEL)	EFSA 2014* (%AAOEL)
No PPE (workwear)	379	2217	112	31
Gloves (ML and A**) Coverall and sturdy footwear***	95	363	9	4
*not applicable at the time of the dossier submission **ML and A: during mixing/loading and application ***only in German model				
Use: maize and sunflower, tractor mounted equipment, application rate 1x 1.248 kg a.s./ha				
Models:	German (%AOEL)	UK POEM (%AOEL)	EFSA 2014* (%AOEL)	EFSA 2014* (%AAOEL)
No PPE (workwear)	329	1921	98	28
Gloves (ML and A**) Coverall and sturdy footwear***	82	314	8	4
*not applicable at the time of the dossier submission **ML and A: during mixing/loading and application ***only in German model				

Workers

Use: maize and sunflower, tractor mounted equipment, application rate 1x 1.44 kg a.s./ha Re-entry task: inspection (2 h/day) Model: EFSA, 2014		
Exposure estimates (%AOEL)	Default DFR (3 µg/cm²/kg a.s./ha)	Refined DFR (2.43 µg/cm²/kg a.s./ha)
Potential exposure	780	632

With workwear	88	71
Use: maize and sunflower, tractor mounted equipment, application rate 1x 1.248 kg a.s./ha Re-entry task: inspection (2 h/day) Model: EFSA, 2014		
Exposure estimates (%AOEL)	Default DFR (3 µg/cm²/kg a.s./ha)	Refined DFR (2.43 µg/cm²/kg a.s./ha)
Potential exposure	676	548
With workwear	76	61

Bystanders and residents

Use: maize and sunflower, tractor mounted equipment, application rate 1x 1.44 kg a.s./ha EFSA, 2014: **no risk mitigation measure** (buffer strip 2-3m)					
Exposure pathway:	Drift	Vapour	Deposits	Re-entry	Sum
Resident (%AOEL) - child - adult	 84.2 20.1	 3.6 <1	 13.0 4.3	 105.3 58.5	 143.5 60.1
Bystander (%AAOEL) - child - adult	 11.5 3.1	 <1 <1	 2.3 <1	 6.3 3.5	 - -
EFSA, 2014: **refined DFR** value of 2.43 µg/cm²/kg a.s./ha based on field study (Kennedy, 2019)					
Exposure pathway:	Drift	Vapour	Deposits	Re-entry	Sum
Resident (%AOEL) - child - adult	 84.2 20.1	 3.6 <1	 13.0 4.3	 85.3 47.4	 127.5 51.2
Bystander (%AAOEL) - child - adult	 11.5 3.1	 <1 <1	 2.3 <1	 5.1 2.8	 - -
EFSA, 2014: **refined DFR** value of 2.43 + **buffer strip 10m**					
Exposure pathway:	Drift	Vapour	Deposits	Re-entry	Sum
Resident (%AOEL) - child - adult	 46.3 8.7	 3.6 <1	 3.0 <1	 85.3 47.4	 99.7 44.0
Bystander (%AAOEL) - child - adult	 6.1 1.2	 <1 <1	 <1 <1	 5.1 2.8	 - -
EFSA, 2014: **refined DFR** value of 2.43 + **drift-reducing** nozzles					
Exposure pathway:	Drift	Vapour	Deposits	Re-entry	Sum
Resident (%AOEL) - child - adult	 42.1 10.0	 3.6 <1	 6.5 2.1	 85.3 47.4	 99.6 44.9

	Bystander (%AAOEL) - child - adult	 5.8 1.6	 <1 <1	 1.1 <1	 5.1 2.8	 - -
Bystanders and residents	Use: maize and sunflower, tractor mounted equipment, application rate 1x 1.248 kg a.s./ha EFSA, 2014: **no risk mitigation measure** (buffer strip 2-3m)					
	Exposure pathway:	Drift	Vapour	Deposits	Re-entry	Sum
	Resident (%AOEL) - child - adult	 73 17.4	 3.6 <1	 11.3 3.7	 91.3 50.7	 125 52.2
	Bystander (%AAOEL) - child - adult	 10.0 2.7	 <1 <1	 2.0 <1	 5.5 3.0	 - -
	EFSA, 2014: **refined DFR** value of 2.43 µg/cm^2/kg a.s./ha based on field study (Kennedy, 2019)					
	Exposure pathway:	Drift	Vapour	Deposits	Re-entry	Sum
	Resident (%AOEL) - child - adult	 73.0 17.4	 3.6 <1	 11.3 3.7	 73.9 41.1	 111 44.5
	Bystander (%AAOEL) - child - adult	 10.0 2.7	 <1 <1	 2.0 <1	 4.4 2.5	 - -
	EFSA, 2014: **refined DFR** value of 2.43 + **buffer strip 5m**					
	Exposure pathway:	Drift	Vapour	Deposits	Re-entry	Sum
	Resident (%AOEL) - child - adult	 48.6 8.8	 3.6 <1	 4.6 1.5	 73.9 41.1	 93.0 39.3
	Bystander (%AAOEL) - child - adult	 6.5 1.3	 <1 <1	 <1 <1	 4.4 2.5	 - -
	EFSA, 2014: **refined DFR** value of 2.43 + **buffer strip 10m**					
	Exposure pathway:	Drift	Vapour	Deposits	Re-entry	Sum
	Resident (%AOEL) - child - adult	 40.1 7.6	 3.6 <1	 2.6 1.5	 73.9 41.1	 86.9 38.2
	Bystander (%AAOEL) - child - adult	 5.3 1.1	 <1 <1	 <1 <1	 4.4 2.5	 - -
	EFSA, 2014: **refined DFR** value of 2.43 + **drift-reducing** nozzles					
	Exposure pathway:	Drift	Vapour	Deposits	Re-entry	Sum

Resident (%AOEL)					
- child	36.5	3.6	5.6	73.9	86.8
- adult	8.7	<1	1.8	41.1	39.0
Bystander (%AAOEL)					
- child	5.0	<1	1.0	4.4	-
- adult	1.4	<1	<1	2.5	-

Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance:	S-metolachlor
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][2] :	Warning, Skin Sens. 1, H317: May cause an allergic skin reaction Note: there is a RAC Opinion (adopted on 2/06/2022) proposing: Carc. 2; H351 Skin Sens. 1; H317
According to the Peer review, the criteria for classification may be met for:	As above

[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

Residues in or on treated products food and feed

Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

Primary crops (Plant groups covered) **OECD Guideline 501**	**Crop groups**	**Crop(s)**	**Application(s)**	**DAT** (days)
	Fruit crops	--	--	--
	Root crops	Potato	Soil (pre-emergence), F: 1x 2.24 kg as/ha (MOC) Soil (pre-emergence), G: 1x 3.36 kg as/ha (MOC) Foliar (pre-emergence), G: 1x 2.8 kg as/ha (MOC)	Soil appl.: 25, 50, 100% maturity Foliar appl.: 0, 7, 14, 21 and 74 (maturity) (Foliage, tubers)
			Soil (pre-emergence): 1x 2.26 kg as/ha + Foliar (post-emergence): 1.39 kg as/ha + partly soil (drenching 66d after planting): 1.59 kg as/ha, G (MOC)	Foliage and tubers: 66, 99 and 161 (maturity)
	Leafy crops	-	-	-
	Cereals/grass crops	Maize	Foliar (early post-emergence), F: 1x 1.44 kg as/ha – BBCH 13 (S-MOC or MOC)	Plant: 30, 82 Stalks/Cobs/ grains: 153
	Pulses/Oilseeds	Soya bean	Soil (pre-emergence), F: 1x 1.72 kg as/ha (S-MOC) Soil (pre-emergence), F: 1x 5.17 kg as/ha (S-MOC) Stem injection, F: 0.6 mg as/plant in 10µL dimethylsulfoxide (S-MOC)	Soil appl.: 19, 57, 75 (whole plant/dried hay) and 156 (stalk, beans) Stem inj.: 1, 75 (whole plant) and 99 (stalk, beans)
	Miscellaneous	--	--	--
	Metabolism in plants was investigated with S-metolachlor (S-MOC) and metolachlor (MOC) uniformly ^{14}C-labelled in the phenyl ring. Metabolic pathways in all studies were found to be similar. The parent compound undergoes a rapid and extensive metabolism into mainly polar aqueous metabolites and it is either metabolised by glutathione conjugation or by oxidative reactions. A supplementary study in lettuce was available.			

Rotational crops (metabolic pattern) **OECD Guideline 502**	**Crop groups**	**Crop(s)**	**PBI** (days)	**Comments**
	Root/tuber crops	Radish	30, 120, 364	Bare soil application of phenyl labelled ^{14}C-S-metolachlor at 1.63 kg as/ha
	Leafy crops	Lettuce	30,120, 364	
	Cereal (small grain)	Spring wheat (forage, grain, fodder)	30,120, 364	

		Winter wheat (forage, grain, fodder)	174
	Other	--	--

Rotational crop and primary crop metabolism similar?	Yes. Unchanged parent was only detected in minor amounts in lettuce (0.001 mg/kg) at 30d PBI. Residues mainly consisted of a large range of small fractions, none of them exceeding 0.01 mg/kg in any of the edible crop parts, except metabolite CGA133275, free and its glucose and malonyl-glucose conjugated forms that were predominant in the feed items (wheat forage, wheat fodder at maturity (straw and husks) and in radish tops). The rest of the residue was associated with natural components, with glucose conjugates being the most predominant ones. It was not demonstrated that all persistent soil metabolites were adequately addressed in the studies.

Processed commodities (standard hydrolysis study) **OECD Guideline 507**	**Conditions**				
	20 min, 90 °C, pH 4	--	--	--	--
	60 min, 100 °C, pH 5	--	--	--	--
	20 min, 120 °C, pH 6	--	--	--	--

Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable. No processing studies were available, and none are necessary since residues of S-metolachlor in treated maize grain and sunflower seeds are below the LOQ of 0.01 mg/kg.

Plant residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Primary crops: "Metolachlor including other mixtures of constituent isomers including S-metolachlor (sum of isomers)" for all crop groups Rotational crops: "Metolachlor including other mixtures of constituent isomers including S-metolachlor (sum of isomers)"

Plant residue definition for risk assessment (RD-RA)	Primary crops: "Metolachlor including other mixtures of constituent isomers including S-metolachlor (sum of isomers)" Rotational crops: "Metolachlor including other mixtures of constituent isomers including S-metolachlor (sum of isomers)" – **Provisional** **Data gap**: Sufficient[3] rotational crops field trials in NEU and SEU analysing for CGA133275, free and conjugated in food and feed edible parts of the rotational crops with a validated analytical method including a hydrolysis step to release the conjugates of CGA133275. In the absence of further evidence persistent soil metabolites are addressed by the rotational crops metabolism study, metabolites OXA [CGA51202], ESA [CGA354743], CGA40172, CGA 368208, NOA436611 and CGA 357704 will need also to be quantified in the rotational crops field trials. The genotoxicity potential of CGA133275, ESA [CGA354743], CGA 368208, NOA436611 may need to be addressed.
Conversion factor (monitoring to risk assessment)	Pending finalisation of RD-RA

Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

OECD Guideline 503 and **SANCO/11187/2013 rev. 3** (fish)	**Animal**	**Dose** (mg/kg bw/d)	**Duration** (days)	**N rate/comment**
Animals covered	Laying hen	7.2	4	The dietary burden was calculated considering only the S-metolachlor residue levels in maize and sunflower feed items and by-products. The poultry and ruminant metabolism studies were highly overdosed (>1000 N rate)
	Goat/Cow	3.85	4	
	Pig	--	--	Not necessary
	Fish	--	--	Not necessary
	The metabolism studies indicated an extensive degradation of the parent compound. A large number of metabolites were formed reflecting two main degradation pathways: glutathione conjugation with subsequent degradation of the glutathionyl moiety and/or oxidative reactions.			

Time needed to reach a plateau concentration in milk and eggs (days)	Eggs: no plateau reached (increasing residues over 4 study days) Milk: 2 days

[3] By "sufficient rotational crops field trials" it is understood limited field studies (at two sites in major growing areas on three representative crops, including a root crop) or extended field trials, as appropriate, in case the limited set of studies show residues above 0.01 mg/kg)

Animal residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	"Metolachlor including other mixtures of constituent isomers including S-metolachlor (sum of isomers)" – Provisional – Pending outcome of the identified data gap(1) and potential carry-over of CGA 133275, free and conjugated from feed items of rotational crops to animal matrices to be assessed.
Animal residue definition for risk assessment (RD-RA)	"Metolachlor including other mixtures of constituent isomers including S-metolachlor (sum of isomers)" - Provisional – Pending outcome of the identified data gap(1) and potential carry-over of CGA 133275, free and conjugated from feed items of rotational crops to animal matrices to be assessed.
Conversion factor (monitoring to risk assessment)	Pending finalisation of RD-RA
Metabolism in rat and ruminant similar (Yes/No)	Yes
Fat soluble residues (Yes/No) **(FAO, 2009)**	From the poultry and ruminant metabolism data, S-metolachlor residues were found in low levels in egg white and yolk (up to 2%TRR and 0.002 mg/kg). In fat, the residue levels accounted for up to 6% TRR and 0.02 mg/kg whilst these were not detected in fat free muscle. Also considering the log P_{OW} of 3.05, there is indication that S-metolachlor residues can be considered as fat soluble.

Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

Confined rotational crop study (Quantitative aspect) **OECD Guideline 502**	The uptake of radioactivity was most dominant at a PBI of 120d in wheat fodder and radish tops (0.78 and 0.23 mg/kg, respectively). S-metolachlor was only detected in lettuce (1% TRR; 0.001 mg/kg) at the 30d PBI. Residue levels of S-metolachlor above the LOQ (0.01 mg/kg) are therefore not expected in rotational crops. The residue mainly consisted of a large range of small fractions, none of them exceeding 0.01 mg/kg in edible crop parts, except for metabolite CGA133275, free and its glucose and malonyl-glucose conjugated forms that were predominant in wheat forage (up to 40% TRR), in wheat, fodder at maturity (straw and husks) (up to 32.7% TRR) and in radish tops (up to 19.3% TRR) at 120 and 365 day-PBIs.
Field rotational crop study **OECD Guideline 504**	See data gap(1)

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)
OECD Guideline 506

Plant products (Category)	Commodity	T (°C)	Stability (Month/Year)			
			S-Metolachlor	CGA133275		
High water content	Maize forage	-18	24	--		
	Maize whole plant	-18	13 (interim report)	--		
	Lettuce	-18	--	23		
High oil content	Soya bean	-18	24	--		
	Sunflower seeds	-18	— 13 (interim report)	23		
High protein content	Dry beans	-18	24	23		
High starch content	Potato	-18	24	--		
	Maize grain	-18	24	--		
	Maize grain	-18	13 (interim report)	--		
	Wheat grain	-18	--	23		
High acid content	Strawberries	-18	--	23		
	Oranges	-18	24	--		

Residues of S-metolachlor are stable at -18 °C for at least two years in commodities with high starch-, high water-, high oil-, high protein- and high acid- content.
Residues of CGA133275 are stable in high water-, high starch-, high oil-, high protein- and high acid- content commodities when stored at -18 °C for at least 23 months.

Animal	Animal commodity	T (°C)	Stability (Month/Year)			
--	Muscle	--	--	--	--	--
--	Liver	--	--	--	--	--
--	Kidney	--	--	--	--	--
--	Milk	--	--	--	--	--
--	Egg	--	--	--	--	--

No study available/not required pending upon the outcome of the identified data gap[(1)].

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator

Crop	**Region/ Indoor** (a)	**Residue levels** (mg/kg) **observed in the supervised residue trials relevant to the supported GAPs** (b)	**Recommendations/comments** (OECD calculations)	**MRL** proposals (mg/kg)	**HR** (mg/kg) (c)	**STMR** (mg/kg) (d)
Representative uses **RD-Mo/RD-RA:** "Metolachlor including other mixtures of constituent isomers including S-metolachlor (sum of isomers)"						
Sunflower seeds	NEU/outdoor	4x <0.01	Data set is sufficient for the intended uses.	0.01*	0.01	0.01
	SEU/outdoor	4x <0.01	Data set is sufficient for the intended uses.	0.01*	0.01	0.01
Maize	NEU/outdoor	Grain: 4x <0.01 Whole plant (forage): 4x <0.01 Whole plant (silage): 4x <0.01 Rest of plant (stover): 4x <0.01	Data set is sufficient for the intended uses.	0.01* n/a n/a n/a	0.01	0.01
	SEU/outdoor	Grain: 4x <0.01 Whole plant (forage): 4x <0.01 Whole plant (silage): 4x <0.01 Rest of plant (stover): 4x <0.01	Data set is sufficient for the intended uses.	0.01* n/a n/a n/a	0.01	0.01
Summary of the data on formulation equivalence OECD Guideline 509						
Crop	**Region**	**Residue data** (mg/kg)	**Recommendations/comments**			
Sunflower seeds	NEU/SEU outdoor	Not required.	Representative EC formulation.			
Maize						
Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)						
The data requirement to determine the residues in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom is not fulfilled pending upon the magnitude of residues of CGA133275 and its conjugates in rotational crops.						
–	–	–	–	–	–	–

(a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.
(b): Residue levels in trials conducted according to GAP reported in ascending order (*e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Mo**nitoring and **R**isk **A**ssessment.
(c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR_{Mo}).
(d): **STMR:** Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets ($STMR_{Mo}$).

Inputs for animal burden calculations – Provisional – Potential carry-over of the residues of CGA 133275, free and conjugated from the rotational crops to the animal commodities might need to be considered in the light of the outcome of the requested field trials analysing the magnitude of this compound in rotational crops and its toxicity. See also data gap(1)

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Representative uses Risk assessment residue definition: "**Metolachlor including other mixtures of constituent isomers including S-metolachlor (sum of isomers)" – Provisional – Data gap(1)**				
Corn field, Forage/silage	0.01	STMR (=LOQ)	0.01	HR (=LOQ)
Corn field, Stover	0.01	STMR (=LOQ)	0.01	HR (=LOQ)
Corn pop, Stover	0.01	STMR (=LOQ)	0.01	HR (=LOQ)
Corn field, Grain	0.01	STMR (=LOQ)	0.01	STMR (=LOQ)
Corn pop, Grain	0.01	STMR (=LOQ)	0.01	STMR (=LOQ)
Corn field, Milled by-products	0.01	STMR (=LOQ)	0.01	STMR (=LOQ)
Corn field, Hominy meal(2)	0.01	STMR (=LOQ) x default PF (~~6~~ 1)	0.01	STMR (=LOQ) x default PF (~~6~~ 1)
Corn field, Gluten feed(2)	0.01	STMR (=LOQ) x default PF (~~2.5~~ 1)	0.01	STMR (=LOQ) x default PF (~~2.5~~ 1)
Corn field, Gluten meal(2)	0.01	STMR (=LOQ)	0.01	STMR (=LOQ)
Distiller's grain, Dried(2)	0.01	STMR (=LOQ) x default PF (1)	0.01	STMR (=LOQ) x default PF (1)
Sunflower Meal(2)	0.01	STMR (=LOQ) x default PF (1)	~~0.012~~ 0.01	STMR (=LOQ) x default PF (1)
(2): In case residues in the RAC are below the LOQ, it is possible to waive the use of the default PF by the value of 1.				

Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4) – Provisional – See data gap[(1)]
OECD Guideline 505 and OECD Guidance, series on pesticides No 73

MRL calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Highest expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.0006	Ram/Ewe	0.0004	Breeding	0.0003	Broiler	0.001	Carp	--
	Dairy cattle	0.0009	Lamb	0.0005	Finishing	0.0003	Layer	0.001	Trout	--
							Turkey	0.001	Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	No		No		No		No		No	
Feeding study submitted	A feeding study with dairy cattle is available[(3)]									
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb: N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals
Muscle		Open		Open		Open		Open		Open
Fat		Open		Open		Open		Open		Open
Meat[(b)]										
Liver		Open		Open		Open		Open		
Kidney		Open		Open		Open		Open		
Milk[(a)]		Open		Open						
Eggs										
Method of calculation[(c)]		It								

[(a)]: Estimated HR calculated at 1N level (**estimated mean level for milk**).
[(b)]: HR in meat calculated for mammalian on the basis of 20 % fat + 80 % muscle and 10 % fat + 90 % muscle for poultry
[(c)]: The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.
[(3)]: Pending the outcome of the data gap[(1)] and potential carry-over of the residues of this compound from feed items to animal commodities, it cannot be concluded whether this feeding study can be representative of the actual exposure of the animals.

STMR calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Median expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.0006	Ram/Ewe	0.0004	Breeding	0.0003	Broiler	0.001	Carp	
	Dairy cattle	0.0009	Lamb	0.0005	Finishing	0.0003	Layer	0.001	Trout	
							Turkey	0.001		
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb: N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N
Muscle										
Fat										
Meat[(a)]										
Liver										
Kidney										
Milk										
Eggs										
Method of calculation[(c)]		It		It		It				

[(a)]: STMR in meat calculated for mammalian on the basis of 20 % fat + 80 % muscle and 10 % fat + 90 % muscle for poultry
[(b)]: When the mean level is set at the LOQ, the STMR is set at the LOQ.
[(c)]: The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

Conversion Factors (CF) for monitoring to risk assessment

Not relevant.

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

Not relevant

OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

Crop (RAC)/Edible part or Crop (RAC)/Processed product	Number of studies[a]	Processing Factor (PF)		Conversion Factor (CF_P) for RA[b]
		Individual values	Median PF	
Representative uses				
Sunflower seeds	--	--	--	--
Maize grain	--	--	--	--

[a]: Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)
[b]: When the residue definition for risk assessment differs from the residue definition for monitoring

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)

– Provisional - The residue definition for risk assessment for rotational crops cannot be finalised in view of the identified data gaps. In consequence, the livestock exposure assessment could also not be finalised.

Consumer risk assessment limited to the representative uses

ADI	0.03 mg/kg bw per day
TMDI (% ADI), according to EFSA PRIMo rev 3.1	Highest TMDI: 0.2 % ADI (NL toddlers)
IEDI (% ADI), according to EFSA PRIMo rev 3.1	Not calculated; not relevant
Factors included in the calculations	None
ARfD	0.5 mg/kg bw
IESTI (% ARfD, according to EFSA PRIMo rev 3.1	Highest IESTI: <1 % ARfD (sunflower seeds and maize grain)
Factors included in IESTI and NESTI	None

Additional contribution to the consumer intakes through drinking water resulting from groundwater metabolite(s) expected to be present above 0.75 µg/L

Metabolite(s)	The PECgw values calculated for numerous metabolites exceeded 0.75 µg/L (see Section 4 and Table 3).
ADI (mg/kg bw per day)	As these compounds were considered toxicologically relevant groundwater metabolites (see section 2), the consumer risk assessment through drinking water was not carried out.
Groundwater intake (% ADI)	Consumer risk assessment through drinking water was not carried out.
Assessment according consumption figures reported in **WHO guideline (WHO, 2009)**	

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

Code[a]	Commodity/Group	MRL/Import tolerance[b] (mg/kg) and Comments

Plant commodities			
Representative uses			
0401050	Sunflower seeds	0.01*	
0500030	Maize/ corn	0.01*	
Animal commodities			
1010000/ 1020000/ 1030000	Animal tissues Milk Birds eggs		Open – See data gap(1)

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005
(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.

Environmental fate and behaviour

Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

Mineralisation after 100 days	0.3 – 29.0 % after 3 month, (n[4]= 19)
Non-extractable residues after 100 days	4.6 – 44.5 % after 3 month d, (n= 19)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	ESA (CGA354743, CGACGA380168, CGA376944 (S-enantiomer), CGA380168 (S-enantiomer Sodium Salt) max. 21.3 % (20 °C) after 42 d, (n= 19); 23.6 % (10 °C) after 120 d (n=1) OXA (CGA51202/CGA351916) max. 21.1 % after 153 d, (n = 19) CGA40172 max. 6.5 % after 14 d CGA50720 max. 8.2 % after 3 month CGA368208 max. 7.6 % after 120 d CGA37735 max. 7.1 % after 181 d NOA436611 max. 9.1 % after 153 d CGA357704 max. 21.9 % after 28 d

Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation after 100 days	No mineralisation
Non-extractable residues after 100 days	36.6 % after 120 days
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	CGA41507 max. 44.2 % at 120 d (n= 1)

Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	CGA41638 max. 5.4 % (moist soil) and 5.6 % (dry soil) at day 40
Mineralisation at study end	1.4 – 1.5 % after 40 d
Non-extractable residues at study end	8.3 – 10.4 % after 40 d

Rate of degradation in soil (aerobic) laboratory studies substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.-1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Parent degradation rate values for trigger endpoints of S-metolachlor/metolachlor

[4] n corresponds to the number of soils.

Parent S-metolachlor (CGA77102, metolachor)	Dark aerobic conditions						
Soil type	Precursor	pH[a)]	t. °C / % MWHC	DT_{50} (d)	DT_{90} (d)	St. (χ^2)	Method of calculation
Sandy clay loam (18 Acres) (2013)	S-meto [c)]	5.7	20, pF2	44.6	4670[f)]	2.1	DFOP k_1 = 0.0225 k_2 =1.63e4 g =0.7862
Sandy clay loam (18 Acres) (2014)	S-meto [c)]	6.3	20, pF2	48.0	493[e)]	2.5	FOMC α = 0.90 β = 41.45
Loamy sand (Birkenheide)	S-meto [c)]	5.6 (KCl)	20, 40 % MWHC	18.1	128	4.2	FOMC α = 1.274 β = 25.09
Loamy sand (Borstel) (2013)	S-meto [c)]	5.3	20, pF2	175	583	1.0	SFO
Loamy sand (Borstel) (2014)	S-meto [c)]	6.1	20, pF2	257	16500 [e)]	1.8	FOMC α = 0.406 β = 56.8
Sandy loam (Buckeystown)	S-meto [c)]	8.0 [b)]	25, 75 % 1/3 bar	7.8	44.3	4.9	DFOP k_1 =0.1077 k_2 =0.00866 g = 0.8641
Sandy loam (Buckeystown)	Meto [d)]	8.0 [b)]	25, 75 % 1/3 bar	6.2	33.8	4.3	DFOP k_1 =0.134 k_2 =0.00914 g = 0.8767
Sandy loam (Collombey)	Meto [d)]	7.4 (KCl)	20, 40 % MWHC	11.2	37.1	3.6	SFO
Silt loam (Gardner)	S-meto [c)]	7.6	20, pF2	91.6	304	1.0	SFO
Sandy loam (Gardner)	S-meto [c)]	7.5	20, pF2	91.7	305	3.5	SFO
Loam (Gartenacker)	S-meto [c)]	7.3 (KCl)	20, 75 % 1/3 bar	13.2	43.9	10.3	SFO
Loam (Gartenacker)	Meto [d)]	7.3 (KCl)	20, 75 % 1/3 bar	15.2	50.6	4.6	SFO
Loam (Gartenacker)	S-meto [c)]	7.3	20, pF2	26.2	68.3	3.2	HS k_1 = 0.01137 k_2 = 0.0382 tb =11.44
Silt loam (Gartenacker)	S-meto [c)]	7.5	20, pF2	35.5	89.5	3.2	HS k_1 = 0.0255 k_2 = 0.02983 tb = 21.15
Silt loam (GartenackerA)	S-meto [c)]	7.3 (KCl)	20, 60 % FC	16.3	54.3	6.8	SFO
Loamy sand (Standard soil 2.2) (Neuhofen)	S-meto [c)]	5.7 [b)]	20, 40 % MWHC	32.4	45600[f]	5.3	DFOP k1 = 0.0252 k2 =7.15e7 g =0.8967
Loamy sand (Standard soil 2.2) (Speyer)	Meto [d)]	5.7 (KCl)	20, 40 % MWHC	17.8	75.5	2.5	DFOP k1 = 0.04349 k2 = 0.002754 g = 0.9195
Sandy loam (Lorsch)	S-meto [c)]	5.2 (KCl)	20, 40 % MWHC	49.9	166	6.9	SFO
Sandy loam (Pappelacker)	S-meto [c)]	7.6 [b)]	20, 40 % MWHC	17.5	78.5	4.5	DFOP k1 = 0.1538 k2 =0.0258 g =0.2416

Sandy loam (Weide)	Meto [d)]	7.6 (KCl)	20, 40 % MWHC	11.8	39.1	4.3	SFO
Sandy loam (Weide)	S-meto [c)]	7.6 [b)]	20, 40 % MWHC	11.9	54.5	4.5	FOMC $\alpha = 2.745$ $\beta = 41.44$
Maximum value				257			

[a)] Measured in H_2O unless otherwise stated
[b)] Medium not stated
[c)] S-metolachlor typically 99.4% CGA 77102
[d)] Meto mixture S- and R-isomer (R-isomer 0-50%)
[e)] DT_{90} not valid, (biphasic $DT_{50/90}$ extrapolated far beyond the duration of the experiemt should be interpreted with care (FOCUS 2006))
[f)] DT_{90} not valid, limited datapoints and k2 t-test not robust

Parent degradation rate values for modelling endpoints of S-metolachlor/metolachlor

Parent DT_{50} values for modelling endpoints of S-metolachlor							
Parent S-metolachlor (CGA77102, metolachlor)	Dark aerobic conditions						
Soil type	Precursor	pH[a)]	t. °C / % MWHC	DT_{50} (d)	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Sandy clay loam (18 Acres)	S-meto [d)]	5.7	20, pF2	97.2	91.2	1.4	slow phase HS k_{slow} = 0.007132
Sandy clay loam (18 Acres)	S-meto [d)]	6.3	20, pF2	84.8	84.8	1.9	slow phase HS k_{slow} = 0.008178
Geometric mean 18 Acres				90.8	87.9		
Loamy sand (Birkenheide)	S-meto [d)]	5.6 (KCl)	20, 40 % MWHC	38.6	24.5	4.2	FOMC DT_{90}/3.32 DT_{90} = 128
Loamy sand (Borstel)	S-meto [d)]	5.3	20, pF2	175	173	1.0	SFO
Loamy sand (Borstel)	S-meto [d)]	6.1	20, pF2	221	221	1.7	Slow phase HS k_{slow} = 0.003131
Geometric mean Borstel (n=2)				196.7	195.5		
Sandy loam (Buckeystown)	S-meto [d)]	8.0 [c)]	25, 75 % 1/3 bar	13.2	15.3	4.9	FOMC DT_{90}/3.32 DT_{90} = 43.9
Sandy loam (Buckeystown)	Meto [e)]	8.0 [c)]	25, 75 % 1/3 bar	10.1	11.7	4.3	FOMC DT_{90}/3.32 DT_{90} = 33.4
Geometric mean Buckeystown (n=2)				11.5	13.4		
Sandy loam (Collombey)	Meto [e)]	7.4 (KCl)	20, 40 % MWHC	11.2	11.2	3.6	SFO
Silt loam (Gardner)	S-meto [d)]	7.6	20, pF2	91.6	79.5	1.0	SFO
Sandy loam (Gardner)	S-meto [d)]	7.5	20, pF2	91.7	91.7	3.5	SFO
Geometric mean Gardner (n=2)				91.6	85.4		

Loam (Gartenacker)	S-meto [d)]	7.3 (KCl)	20, 75 % 1/3 bar	13.2	12.6	10.3	SFO
Loam (Gartenacker)	Meto [e)]	7.3 (KCl)	20, 75 % 1/3 bar	15.2	14.6	4.6	SFO
Loam (Gartenacker)	S-meto [d)]	7.3	20, pF2	26.2	24.7	3.2	Lag phase, overall DT_{50} HS
Silt loam (Gartenacker)	S-meto [d)]	7.5	20, pF2	35.5	30.8	3.2	Lag phase overall DT_{50} HS
Silt loam (GartenackerA)	S-meto [d)]	7.3 (KCl)	20, 60 % FC	16.3	12.5	6.8	SFO
Geometric mean Gartenacker (n=5)				19.8	17.7		
Loamy sand (Standard soil 2.2) (Neuhofen)	S-meto [d)]	5.7 [c)]	20, 40 % MWHC	48.8	48.8	5.5	FOMC DT_{90}/3.32 DT_{90} = 162
Loamy sand (Standard soil 2.2) (Speyer)	Meto [e)]	5.7 (KCl)	20, 40 % MWHC	24	24	3.4	FOMC DT_{90}/3.32 DT_{90} = 79.8
Geometric mean German standard soil 2.2 (n=2)				34.2	34.2		
Sandy loam (Lorsch)	S-meto [d)]	5.2 (KCl)	20, 40 % MWHC	49.9	32.9	6.9	SFO
Sandy loam (Pappelacker)	S-meto [d)]	7.6 [c)]	20, 40 % MWHC	25.3	15.3	4.5	FOMC DT_{90}/3.32 DT_{90} = 84
Sandy loam (Weide)	Meto [e)]	7.6 (KCl)	20, 40 % MWHC	11.8	11.8	4.3	SFO
Sandy loam (Weide)	S-meto [d)]	7.6 [c)]	20, 40 % MWHC	16.4	10.3	4.5	FOMC DT_{90}/3.32 DT_{90} = 54.5
Geometric mean Weide (n=2)				13.9	11.0		
Geometric mean (n = 11)					**30.1**		
pH dependence					**no**		

[a)] Measured in H_2O unless otherwise stated
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[c)] Medium not stated
[d)] S-meto typically 99.4% CGA77102
[e)] Meto: mixture S- and R-isomer (r-isomer 0-50%)

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

CGA354743/CGA380168 (S-enantiomer Sodium Salt) (ESA)	Dark aerobic conditions							
Soil type	Precursor	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Sandy clay loam (18 Acres)	S-meto [d)]	5.7	20, pF2	>1000 / >1000	0.08197	1000	10.1	SFO

Sandy clay loam (18 Acres)	S-meto [d)]	6.3	20, pF2	>1000 / >1000	0.08142	1000	9.3	SFO
Loamy sand (Birkenheide)	S-meto [d)]	5.6 (KCl)	20, 40 % MWHC	815 / >1000	0.1571	517	2.6	SFO
Sandy loam (Buckeystown)	S-meto [d)]	8.0[c)]	25, 75 % 1/3 bar	199 /660	0.1311	230	12.3	SFO
Sandy loam (Buckeystown)	Meto [e)]	8.0 [c)]	25, 75 % 1/3 bar	203 / 676	0.1115	235.3	10.9	SFO
Geometric mean Buckeystown (n=2)				-	-	233		
Arithmetic mean Buckeystown (n=2)				-	0.121	-		
Sandy loam (Collombey)	Meto [e)]	7.4 (KCl)	20, 40 % MWHC	65.7 / 218	0.1430	65.7	13.4	SFO
Sandy clay loam (Gardner)	S-meto [d)]	7.6	20, pF2	>1000 / >1000	0.1367	1000	11.5	SFO
Sandy clay loam (Gardner)	S-meto [d)]	7.5	20, pF2	>1000 / >1000	0.1174	1000	14.1	SFO
Loam (Gartenacker)	S-meto [d)]	7.3 (KCl)	20, 75 % 1/3bar	147 /488	0.2599	141	9.5	SFO
Loam (Gartenacker)	S-meto [d)]	7.3	20, pF2	28.8 / 95.5	0.1285	27.2	29.2	SFO
Silt loam (Gartenacker)	S-meto [d)]	7.5	20, pF2	168 / 557	0.2175	146	6.7	SFO
Silt loam (Gartenacker)	ESA	7.5	20, pF2	30.6 / 102	-	30.6	3.4	SFO
Silt loam (Gartenacker)	ESA	7.5	20, 75 % 1/3 bar	66.7 / 221	-	46.9	1.4	SFO
Silt loam (Gartenacker)	SYN546829	7.6	20, pF2 – pF	157 / 521	0.2319[f)]	145	9.6	SFO
Loam (GartenackerA)	S-meto [d)]	7.3 (KCl)	20, 60 % FC	65 /216	0.3020	49.9	9.8	SFO
Loamy sand (Standard soil 2.2. (Neuhofen)	S-meto [d)]	5.7 [c)]	20, 40 % MWHC	>1000 / >1000	0.1586	1000	21	SFO
Loamy sand (Standard soil 2.2, Speyer)	Meto [e)]	5.7 (KCl)	20, 40 % MWHC	>1000 / >1000	0.1597	1000	13.3	SFO
Geometric mean German standard soil 2.2 (n=2)				-	-	1000		
Arithmetic mean German standard soil 2.2 (n=2)				-	0.159	-		
Sandy loam (Lorsch)	S-meto [d)]	5.2 (KCl)	20, 40 % MWHC	>1000 / >1000	0.138	1000	12.4	SFO
Sandy loam (Lorsch)	ESA	5.2 (KCl)	20, 40 % MWHC	849 / >1000	-	560	1	SFO
Geometric mean Lorsch (n=2)				-	-	748.3		
Silty clay (Marsillargues)	SYN546829	8.0	pF2 – pF2.5	134 /444	-	113	13.4	SFO

Sandy loam (Pappelacker)	S-meto [d]	7.6 [c]	20, 40 % MWHC	149 / 496	0.1970	90	15.6	SFO
Loamy sand (Pappelacker)	ESA	7.5	20, pF2	33.7 / 112	-	33.7	2	SFO
Sandy loam (Weide)	Meto [e]	7.6 (KCl)	20, 40 % MWHC	53.1 / 176	0.2028	53.1	11.2	SFO
Sandy loam (Weide)	S-meto [d]	7.6 [c]	20, 40 % MWHC	109 / 362	0.1828	69	21.4	SFO
Loamy sand (Weide)	ESA	7.5	20, pF2	32.8 / 109	-	32.8	1.7	SFO
Geometric mean (n = 22)						**154.4**		
Arithmetic mean (n =16)					**0.164**			
pH dependence						**no**		

[a] Measured in H_2O unless otherwise stated
[b] Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7
[c] Medium not stated
[d] S-meto typically 99.4% CGA77102
[e] Meto mixture S- and R-isomer (r-isomer 0-50%)
[f] Not used to calculate the arithmetic mean as precursor is SYN546829

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

CGA51202/CGA 351916 (OXA)	Dark aerobic conditions							
Soil type	Precursor	pH[a]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa[b]	St. (χ^2)	Method of calculation
Sandy clay loam (18 Acres)	S-meto [d]	5.7	20, pF2	>1000 / >1000	0.1382	1000	16.6	SFO
Sandy clay loam (18 Acres)	S-meto [d]	6.3	20, pF2	>1000 / >1000	0.1717	1000	11.3	SFO
Loamy sand (Birkenheide)	S-meto [d]	5.6 (KCl)	20, 40 % MWHC	>1000 / >1000	0.186	1000	5.1	SFO
Borstel	S-meto [d]	5.3	20, pF2	>1000 / >1000	0.140	1000	19.3	SFO
Sandy loam (Buckeystown)	S-meto [d]	8.0 [c]	25, 75 % 1/3 bar	66.8 /222	0.1589	77.4	9.9	SFO
Sandy loam (Buckeystown)	Meto [e]	8.0 [c]	25, 75 % 1/3 bar	72.2 /240	0.1438	83.7	8.6	SFO
Geometric mean Buckeystown (n=2)				-	-	80.5		
Arithmetic mean Buckeystown (n=2)				-	0.151	-		
Sandy loam (Collombey)	Meto [e]	7.4 (KCl)	20, 40 % MWHC	21.3 / 70.3	0.1690	21.3	14.3	SFO
Sandy clay loam (Gardner)	S-meto [d]	7.6	20, pF2	>1000 / >1000	0.1709	1000	12	SFO

CGA51202/CGA 351916 (OXA)	Dark aerobic conditions							
Soil type	Precursor	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Sandy loam (Gardner)	S-meto [d)]	7.5	20, pF2	>1000 / >1000	0.2202	1000	18.1	SFO
Loam (Gartenacker)	S-meto [d)]	7.3 (KCl)	20, 75 % 1/3 bar	45.6 /151	0.1831	43.7	8.1	SFO
Loam (Gartenacker)	S-meto [d)]	7.3	20, pF2	90.7 / 301	0.2205	85.6	4.7	SFO
Silt loam (Gartenacker)	S-meto [d)]	7.5	20, pF2	36.8 / 122	0.2148	32	7	SFO
Silt loam (Gartenacker)	OXA	7.4 (KCl)	20, 40 % MWHC	38.9 / 129	-	24.2	3.1	SFO
Silt loam (Gartenacker)	OXA	7.4 (KCl)	20, 40 % MWHC	25.9 / 86.0	-	16.1	3.8	SFO
Loamy sand (Gartenacker)	OXA	7.5	20, pF2	12.2 / 40.6	-	12.2	12.9	SFO
Loamy sand (Standard soil 2.2 (Neuhofen)	S-meto [d)]	5.7[c)]	20, 40 % MWHC	307 / >1000	0.2001	307	12.2	SFO
Loamy sand (Standard soil 2.2 (Speyer)	Meto [e)]	5.7 (KCl)	20, 40 % MWHC	41.8	0.1577	41.8	33.8	SFO
Geometric mean German standard soil 2.2 (n=2)				113.4	-	113.4		
Arithmetic mean German standard soil 2.2 (n=2)				-	0.179	-		
Sandy loam (Lorsch)	S-meto [d)]	5.2 (KCl)	20, 40 % MWHC	876/ > 1000	0.272	1000	13.2	SFO
Silt loam (Lorsch)	OXA	5.7	pF2 – pF2.5	326 / > 1000	-	215	2.2	SFO
Sandy loam (Pappelacker)	S-meto [d)]	7.6 [c)]	20, 40 % MWHC	53.5 / 178	0.1407	32.5	21.7	SFO
Sandy loam (Pappelacker)	OXA	7.7	20, 40 % MWHC	16.6 7 55.1	-	16.6	12.5	SFO
Sandy loam (Weide)	Meto [e)]	7.6 (KCl)	20, 40 % MWHC	25.2 / 83.7	0.1380	25.2	22.8	SFO
Sandy loam (Weide)	S-meto [d)]	7.6 [c)]	20, 40 % MWHC	23.7 / 78.7	0.1181	14.9	23.9	SFO
Sandy loam (Weide)	OXA	7.6	20,75 % 1/3bar	13.6 / 45.0	-	13.6	10.8	SFO
Geometric mean (if not pH dependent) (n=22)						**98.1**		
Arithmetic mean (n=16)					**0.176**			
pH dependence				**no**				

[a)] Measured in H_2O unless otherwise stated

b) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7
c) Medium not stated
d) S-meto typically 99.4% CGA77102
e) Meto mixture S- and R-isomer (r-isomer 0-50%)

CGA368208	Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived is ESA.							
Soil type	Precursor	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10 kPa[b)]	St. (χ^2)	Method of calculation
Silt loam (Gartenacker)	ESA	7.7	20, 75 % 1/3bar	163 /543	0.4369 [c)]	115	12.4	SFO
Silt loam (Gartenacker)	ESA	7.5	20, pF2	20.4 / 67.7	0.3903 [d)]	20.4	25.4	SFO
Geometric mean Gartenacker (n=2)				-	-	48.5		
Arithmetic mean Gartenacker (n=2)				-	0.414	-		
Loamy sand (Pappelacker)	ESA	7.5	20, pF2	44.5 / 148	0.5014 [d)]	44.5	19.0	SFO
Loamy sand (Weide)	ESA	7.5	20, pF2	23.4 /77.8	0.5266 [d)]	23.4	25.4	SFO
Geometric mean (if not pH dependent) (n=3)						**36.9**		
Maximum non-normalized (n=3)				**163**	-	-	-	**SFO**
Arithmetic mean (n=3)					**0.481**			
pH dependence						**Not determined, only one soil pH tested**		

f) Measured in H_2O
g) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7
h) From ESA
i) via NOA413713

CGA37735	Dark aerobic conditions							
Soil type	Precursor	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10 kPa[b)]	St. (χ^2)	Method of calculation
Silt loam (Gartenacker)	CGA377 35	7.6	20, pF 2-2.5	0.5 /1.7	-	0.46	9.0	SFO
Sandy clay loam (18 Acres)	CGA377 35	6.5	20, pF 2-2.5	1.36 / 4.5	-	1.14	4.9	SFO
Silty clay loam (Marsillargues)	CGA377 35	8.0	20, pF 2-2.5	1.19 / 4.0	-	1.02	6.2	SFO
Geometric mean (if not pH dependent) (n=3)						**0.80**		
Maximum non-normalized (n=3)				**1.4**	-	-	-	**SFO**
Arithmetic mean					-			
pH dependence						**no**		

a) Measured in H_2O
b) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7

CGA40172	Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was S-metolachlor							
Soil type	Precursor	pH [a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10 kPa[b)]	St. (χ^2)	Method of calculation
Buckeystown	S-meto [c)]	8.0	25, 75 % 1/3 bar	115 / 380	0.0991	133.3	13.9	SFO
Single value (data gap identified for investigations from 3 field dissipation studies)						**133.3**		
Single value					**0.0991**			
pH dependence						**Not determined**		

a) Medium not stated
b) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7
c) S-meto typically 99.4% CGA 77102

CGA50720	Dark aerobic conditions							
Soil type	Precursor	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Sandy clay loam (18 Acres)	CGA377 35	6.5	20, pF2-pF 2.5	11.3 / 37.7	0.804 [c)]	9.5	8.6	SFO
Sandy loam (Collombey)	Meto[f)]	7.4 (KCl)	20, 40 % MWHC	17.3 / 57.6	1 [d)] 1 [e)]	17.3	14.3	SFO
Silt loam (Gartenacker)	CGA377 35	7.6	20, pF2–pF 2.5	4.74 / 15.8	1 [c)]	4.43	13.2	SFO
Silty clay (Marsillargues)	CGA377 35	8.0	20, pF2 – pF 2.5	8.5 / 28.2	0.707 [c)]	7.3	8.8	SFO
Sandy loam (Weide)	Meto[f)]	7.6 (KCl)	20, 40 % MWHC	23 / 76.3	0.528 [d)] 1 [e)]	23	3.9	SFO
Geometric mean (if not pH dependent) (n=5)						**10.4**		
Arithmetic mean from CGA37735 (n=3)					**0.837**			
Arithmetic mean from OXA (n=2)					**1**			
pH dependence						**no**		

a) Measured in H_2O unless otherwise stated
b) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7
c) From CGA37735
d) From ESA
e) From OXA
f) Meto mixture S- and R-isomer (r-isomer 0-50%)

NOA436611 (SYN546829)	Dark aerobic conditions							
Soil type	Precursor	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10 kPa[b)]	St. (χ^2)	Method of calculation
Sandy clay loam (18 Acres)	S-meto [c)]	5.7	20, pF2	171 /569	0.08502	160	15.9	SFO
Sandy clay loam (18 Acres)	SYN546 829	6.5	20, pF2-pF2.5	724 / > 1000	-	625	1.9	SFO
Geometric mean 18 Acres						316.2		
Loam (Gartenacker)	S-meto [c)]	7.5	20, pF2	89 / 296	0.06858	82.5	7.6	SFO
Silt loam (Gartenacker)	SYN546 829	7.6	20, pF2-pF2.5	47.9 / 159	-	44.4	3.5	SFO
Geometric mean Gartenacker						60.5		
Sandy loam (Lorsch)	S-meto [c)]	5.2 (KCl)	20, 40 % MWHC	345 />1000	0.1304	227	1.9	SFO
Silty clay (Marsillargues)	SYN546 829	8.0	20, pF2-pF2.5	202 / 670	-	170	2.7	SFO
Geometric mean (if not pH dependent) (n=4)						**164.9**		
Arithmetic mean (n=3)					**0.0947**			
pH dependence						**no**		

a) Measured in H_2O unless otherwise stated
b) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7
c) S-meto typically 99.4% CGA 77102

CGA357704	Dark aerobic conditions							
Soil type	Precursor	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10 kPa[b)]	St. (χ^2)	Method of calculation
Loamy sand (Neuhofen)	S-meto [c)]	5.65	20 /40%	1000	0.071	1000	13.0	SFO
Sandy loam (Weide)	S-meto [c)]	7.6	20 /40%	71.2	0.32	44.9	10.7	SFO
Sandy loam (Pappelacker)	S-meto [c)]	7.6	20 /40%	92.0	0.29	55.8	13.9	SFO
Geometric mean (if not pH dependent) (n=3)						**136**		
Arithmetic mean (n=3)					**0.22**			
pH dependence					no			

a) Measured in H_2O
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

c) S-meto typically 99.4% CGA 77102

SYN547977	Dark aerobic conditions							
Soil type	Precursor	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10 kPa[b)]	St. (χ^2)	Method of calculation
Silt loam (Gartenacker)	SYN547 977	7.53	20.7 / pF2	36.9 /123	-	39.4	3.96	SFO
Sandy clay loam (18 Acres)	SYN547 977	6.36	20.7 / pF2	65.6 /218	-	70.1	4.7	SFO
Silty clay loam (Marsillargues)	SYN547 977	8.14	20.7 / pF2	86 / 286	-	95.1	3.63	SFO
Geometric mean (if not pH dependent) (n=3)						**64.0**		
pH dependence						**no**		

a) Measured in H_2O
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

CGA41507 (anaerobic soil metabolite)	Dark aerobic conditions							
Soil type	Precursor	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10 kPa[b)]	St. (χ^2)	Method of calculation
Silt loam (Gartenacker)	CGA41507	7.3	20, 40 % MWHC	51.5 / 171	-	51.0	4.7	SFO
Single value						**51**		

a) Measured in KCl
b) Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7
c) S-meto typically 99.4% CGA77102

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

Parent (S-metolachlor, CGA77102)	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	Precursor	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	DT_{50} (d) Norm.	Method of calculation
Silt loam (bare)	Germany	S-metolachlor (80:20 S:R metolachlor)	6.5[a)]	0-30	24.1	183	6.28	NA	FOMC α: 1.171 β: 29.84
Sandy loam (bare)	Switzerland	S-metolachlor (80:20 S:R metolachlor)	7.4[a)]	0-30	3.55	50.4	4.77	NA	HS k1:0.1954 k2:0.0278 tb: 5.378

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

Parent (S-metolachlor, CGA77102)	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	Precursor	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	DT_{50} (d) Norm.	Method of calculation
Sandy loam (maize cover)	Switzerland	S-metolachlor (80:20 S:R metolachlor)	7.5[a)]	0-30	22.9	76.1	3.79	NA	SFO
Silt loam (bare)	Switzerland	S-metolachlor (80:20 S:R metolachlor)	7.9[a)]	0-30	18.6	61.9	1.65	NA	SFO
Sandy loam (maize cover)	Switzerland	S-metolachlor (80:20 S:R metolachlor)	7.8[a)]	0-30	11.4	37.9	1.96	NA	SFO
Loam (bare)	France	S-metolachlor (80:20 S:R metolachlor)	7.15[a)]	0-30	30.8	102	4.45	NA	SFO
Silt clay loam (bare)	France	S-metolachlor (80:20 S:R metolachlor)	7.45[a)]	0-30	12.8	256	21.7	NA	DFOP k1:0.07173 k2:0.00217 g: 0.8257
Silty sand (bare)	Germany	S-metolachlor (80:20 S:R metolachlor)	6.1[a)].	0-30	26.1	86.8	11.7	NA	SFO
Loamy silt (bare)	Germany	S-metolachlor (80:20 S:R metolachlor)	7.4[a)]	0-30	4.62	27.6	10.7	NA	FOMC α: 1.589 β: 8.458
Silt loam (bare)	Italy	S-metolachlor (80:20 S:R metolachlor)	7.6[b)]	0-20	43.9	146	13	NA	SFO
Clay loam (bare)	France	S-metolachlor (80:20 S:R metolachlor)	7.3 [b)]	0-30	21	69.9	15	NA	SFO
Sandy loam (bare)	Germany	Metolachlor (50:50 S:R metolachlor)	6.2 [a)]	0-20	17.2	244	5.29	NA	DFOP k1: p<0.01 k2: p=0.05
Clayey silt (bare)	Germany	Metolachlor (50:50 S:R metolachlor)	6.2 [a)]	0-20	7.95	55.6	8.10	NA	DFOP k1:p=0.5 k2:p<0.01
Loamy sand (bare)	Germany	Metolachlor (50:50 S:R metolachlor)	6.0 [a)]	0-20	38.2	127	6.0	NA	SFO

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

Parent (S-metolachlor, CGA77102)	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	Precursor	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	DT_{50} (d) Norm.	Method of calculation
Loamy silt (bare)	Germany	Metolachlor (50:50 S:R metolachlor)	6.0 [a)]	0-20	24.1	80.1	9.37	NA	SFO
Sandy silt loam (bare)	Germany	Metolachlor (50:50 S:R metolachlor)	5.7 [a)]	0-20	31.3	104	21.1	NA	SFO
Silty sand (bare)	Germany	Metolachlor (50:50 S:R metolachlor)	4.8 [a)]	0-20	55.7	185	7.37	NA	SFO
Maximum non-normalised field DT_{50}					**55.7**				**SFO**
Maximum non-normalised field DT_{90}					**-**	**256**	**-**	**-**	**DFOP**

[a)] Medium not stated
[b)] Measured in $CaCl_2$

Data gap: field dissipation studies providing kinetic endpoints for metabolites CGA 357704, CGA 368208, CGA 40172 and NOA 436611

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration	Studies with Sugar Beet crop: Application between 1.44 – 1.47 kg a.s./ha in field studies. No accumulation of S-metolachlor, CGA35196 or CGA51202 in the top soil at the end of the investigation periods.
	Studies with Sunflower crop: Application of 1.68 kg a.s./ha in field studies. No accumulation of S-metolachlor, CGA35196 or CGA51202 in the top soil at the end of the investigation periods.
	Studies with Maize crop: Application between 2.12 – 2.16 kg a.s./ha in field studies. No accumulation of S-metolachlor, CGA35196 or CGA51202 in the top soil at the end of the investigation periods.

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Studies with Soya bean crop: Application of 1.20 kg a.s./ha in field studies. No accumulation of S-metolachlor, CGA35196 or CGA51202 in the top soil at the end of the investigation periods.
Study with maize crop: Annual application between 1.5 – 3 kg a.s./ha in field studies. (combi-formulation metolachlor with atrazine, target crop maize rotational crop wheat) No accumulation of S-metolachlor, CGA35196 or CGA51202 in the top soil at the end of the 4 year period.
Study with maize crop: Annual application between 2 - 4 kg a.s./ha in field studies. (target crop maize, rotational crops sugar beets or winter wheat) No accumulation of S-metolachlor, CGA35196 or CGA51202 in the top soil at the end of the 4 year period.

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Parent	Dark anaerobic conditions
	DT_{90} < 120 days

Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Metabolite CGA41507	Dark anaerobic conditions
	DT90 < 120 days

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3

Parent	Soil photolysis				
Soil type	pH[a)]	t. ºC / % MWHC	DT_{50} / DT_{90} (d) calculated at 30-50 ºN	St. (χ^2)	Method of calculation
Loamy sand, dry soil	5.3	20 / not applicable	126 / 418	2.6	SFO
Loamy sand, moist soil	5.3	20 / pF2	78.5 / 261	1.1	SFO

[a)] Measured in water

Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Parent (S-metolachlor, CGA77102)					
Soil Type	OC %	Soil pH	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Leland Mississippi (clay)	1.276	7.2 a)	4.7	368	0.934
Lime Kiln Maryland (sandy loam)	1.160	8.0 a)	1.4	121	0.909
Middletown Maryland (silt loam)	0.986	7.0 a)	1.1	112	0.914
Collombey (loamy sand)	0.8	7.3 c)	1.4	175	0.909
Speyer 2.1 (sand)	0.3	6.8 c)	1.0	333	0.887
Gartenacker (silt loam)	2.0	7.1 c)	4.6	230	0.971
Vetroz (silt loam)	4.7	7.2 c)	11.5	245	1.002
Illarsaz (humic silt loam)	19.8	6.7 c)	44.8	226	0.926
Bahus 1 0-10cm (silt loam)	5.91	3.42 b)	10.82	183	0.927
Bahus 2 10-20cm (silt loam)	3.02	3.75 b)	7.63	253	0.925
Birkenheide, (loamy sand)	0.65	3.42 b)	1.09	168	0.952
Soil Lorsch Horizon I (sandy loam)	1.63	5.17 b)	2.37	145	0.9629
Geometric mean (n = 12)	**3.63**	**200.24**			
Arithmetic mean (n = 12)			**0.935**		
pH dependence			**no**		

a) Measured in $CaCl_2$
b) Measured in KCl
c) Medium in which the pH measurements were performed is not reported in study

Metabolite ESA (CGA376944, (CGA376943 S-enantiomer, CGA380168 ascribed to its sodium salt)					
Soil Type	OC %	Soil pH	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Vetroz (silt loam)	4.7	7.2 c)	0.5	11	0.91
Gartenacker (loam)	2.08	7.32 c)	0.21	10	0.9
Neunhofen (loamy sand)	2.2	5.65 c)	0.2	9	0.89
Lime Kiln (sandy loam)	1.276	7.7 c)	0.041	3	0.955
Burtonsville (loamy sand)	0.348	5.9 c)	0.007	2	0.785
Middletown (loam)	2.146	7.2 c)	0.1	5	0.909
Leland (clay)	1.392	6.5 c)	0.3	22	0.962
Geometric mean (n = 7)			**0.11**	**6.74**	
Arithmetic mean (n = 7)					**0.902**
pH dependence			**no**		

a) Measured in $CaCl_2$
b) Measured in KCl
c) Medium in which the pH measurements were performed is not reported in study.

Metabolite OXA (CGA51202)

Soil Type	OC %	Soil pH	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Maryland (clay)	2.8	5.9 c)	0.065	2	1.026
Mississippi (loam)	0.7	7.6 c)	0.083	12	0.715
Iowa (sand)	2.9	5.9 c)	0.169	6	0.895
Collombey (loamy sand)	0.76	7 c)	0.48	63	0.874
Les Evouettes (silt loam)	2.1	7.3 c)	0.48	23	0.758
Vetroz (silt loam)	4.4	7.1 c)	0.67	15	0.811
Geometric mean (n = 6)			**0.23**	**12.34**	
Arithmetic mean (n = 6)					**0.846**
pH dependence			**no**		

a) Measured in CaCl2
b) Measured in KCl
c) Medium in which the pH measurements were performed is not reported in study.

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Metabolite CGA40172					
Soil Type	OC %	Soil pH	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Collombey (loamy sand)	0.76	7.0 c)	1.39	182	0.7157
Les Evouettes (silt loam)	2.1	7.3 c)	4.29	204	0.6978
Vetroz (silt loam)	4.39	7.1 c)	6.30	143	0.8800
Geometric mean (n = 3)			**3.35**	**174.45**	
Arithmetic mean (n = 3)					**0.76**
pH dependence			**no**		

a) Measured in CaCl2
b) Measured in KCl
c) Medium in which the pH measurements were performed is not reported in study

Metabolite CGA41507					
Soil Type	OC %	Soil pH	KF (mL/g)	KFoc (mL/g)	1/n
Collombey (loamy sand)	2.00	7.60 b)	1.88	93.82	0.8703
Les Evouettes (silt loam)	2.40	7.20 b)	1.95	81.31	0.8424
Vetroz (silt loam)	4.70	7.20 b)	3.99	84.92	0.9128
Geometric mean (n = 3)			**2.45**	**86.53**	
Arithmetic mean (if not pH dependent)					**0.88**
pH dependence			**no**		

a) Measured in $CaCl_2$
b) Measured in KCl
c) Medium in which the pH measurements were performed is not reported in study

Metabolite CGA357704					
Soil Type	OC %	Soil pH	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Collombey (loam sand)	2.00	7.60	-	1*	1*
Les Evouttes (silt loam)	2.40	7.20	-	1*	1*
Vetroz (silt loam)	4.05	7.30	-	1*	1*
Geometric mean (n = 3)			**-**	**1**	
Arithmetic mean (n = 3)			**-**		**1**
pH dependence			**no**		

* No advanced adsorption study, therefore use of default values

Metabolite NOA436611 (SYN546829 test substance used is racemic NOA436611)					
Soil Type	OC %	Soil pH	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Seven Springs (loamy sand)	0.7	5.4[a)]	0.008	11	0.829
Marsillargues (silty clay)	1	7.7 [a)]	0.06	6	0.742
Louisville (silty clay loam)	1.7	6.2 [a)]	0.25	15	0.872
18 acres (sandy clay loam)	2.8	6.1 [a)]	0.14	5	0.853
Geometric mean (n = 4)			**0.11**	**8.43**	
Arithmetic mean (n = 4)					**0.824**
pH dependence			**no**		

[a)] Measured in $CaCl_2$
[b)] Measured in KCl
[c)] Medium in which the pH measurements were performed is not reported in study.

Metabolite CGA37735					
Soil Type	OC %	Soil pH	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Seven Springs (loamy sand)	0.7	5.4[a)]	0.15	21	0.948
Marsillargues (silty clay)	1	7.7 [a)]	0.12	12	0.948
Louisville (clay loam)	1.7	6.2 [a)]	0.25	15	0.934
18 acres (sandy clay loam)	2.8	6.1 [a)]	0.16	6	1.004
Gartenacker (silt loam)	2	7.3 [a)]	0.11	6	0.968
Geometric mean (n = 6)			**0.15**	**10.35**	
Arithmetic mean(n = 6)					**0.964**
pH dependence					

[a)] Measured in $CaCl_2$
[b)] Measured in KCl
[c)] Medium in which the pH measurements were performed is not reported in study.

Metabolite SYN542607					
Soil Type	OC %	Soil pH	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Seven Springs (loamy sand)	0.7	5.4[a)]	0.02	3	0.875
Louisville (clay loam)	1.7	6.5 [a)]	0.07	4	0.930
18 acres (sandy clay loam)	2.8	6.1 [a)]	0.02	1	0.829
Geometric mean (n = 3)			**0.03**	**1.9**	
Arithmetic mean (n = 3)					**0.878**
pH dependence					

[a)] Measured in $CaCl_2$
[b)] Measured in KCl
[c)] Medium in which the pH measurements were performed is not reported in study.

Metabolite SYN547977					
Soil Type	OC %	Soil pH	K_F (mL/g)	K_{Foc} (mL/g)	1/n
18 Ares	2.78	5.61[a]	1.78	64.2	0.931
Gartenacker	2.35	6.99[a]	1.03	43.9	0.918
Marsillargues	1.04	7.99[a]	0.83	80.2	0.926
Geometric mean (n = 3)			**1.15**	**60.9**	
Arithmetic mean (n = 3)					**0.93**
pH dependence, No					

a) Measured in $CaCl_2$

Metabolites without any advanced sorption studies			
	K_F (mL/g)	K_{Foc} (mL/g)	1/n
CGA368208	1*	1*	1*
CGA50720	1*	1*	1*

*default values, conservative assumption

Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching	(1) Aged leaching 7-33 days, 4 soils, elution (mm): 508 mm, Time period (d): 2 d (2) Aged leaching 19 days, 2 soils, elution (mm): 200 mm, Time period (d): 2 d (3) Aged leaching 28 days, 1 soil, elution (mm): 200 mm, Time period (d): 2 d
	Leachate (% applied radioactivity): (1) total residues: 7.5-16.5 % a.s.: 0.2-36.3 % (2) total residues: 19.1 % a.s.: < 0.01 % (3) total residues: 33.1-33.9 % a.s.: < 0.01 %

Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching	(1) Aged leaching 7-33 days, 4 soils, elution (mm): 508 mm, Time period (d): 2 d (2) Aged leaching 19 days, 2 soils, elution (mm): 200 mm, Time period (d): 2 d (3) Aged leaching 28 days, 1 soil, elution (mm): 200 mm, Time period (d): 2 d
	Leachate (% of applied radioactivity): (1) CGA51202: 5.5-11.0 % CGA 50720: 1.1-6.9 % (2) CGA51202: 8.3-11.3 % CGA 50720: 3.5-5.9 % (3) CGA51202: 6.3-6.9 % CGA 354743: 12.1-12.6 %

Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

Field leaching studies	*(1) Location: Lorsch, Hessen, Germany* Study type: Field leaching Soil properties: pH = ca. 5.2-8, OC= < 0.5-2.6 % Dates of application and application rate: 23.05.1995: 1454 g a.s./ha 03.06.1996: 1491 g a.s./ha 27/28.05.1997: 1499 g a.s./ha 26.05.1999: 1495 g a.s./ha 23.05.2000: 1499 g a.s./ha 24.05.2002: 1241 g a.s./ha 24.05.2003: 1250 g a.s./ha Crop: Maize Interception: 0 % (pre-emergence) Number of applications per year: 1 Duration: 10 years Average annual rainfall (mm): ca. 407-964 mm *(2) Location: Sherburne County, Minnesota, USA* Study type: Field leaching Soil properties: pH = ca. 6, OC= < 2 % Dates of application: 29.05.1996 Application rate: 3000 g/ha. Crop: Maize Interception: 0 % (pre-emergence) Number of applications: 1 Duration: 4 years Average annual rainfall (mm): ca. 500-600 mm For results of the field leaching studies please refer to the PEC_{GW}-section of this LoEP.
Lysimeter studies	(1) Location: Birkenheide, Rhineland Palatinate, Germany Study type: lysimeter Soil properties: loamy sand (pH = 6.4, OC = 1.3 %) Dates of application: 1st year (both lysimeter): 24/05/95; 2nd year (lysimeter 18): 04/06/96 Crop: maize, winter cereals, Interception estimated: 25 % Number of applications: 1 application per year Duration: 3 years Application rate: 1250 g/ha/year Average annual rainfall (mm): 807 - 923 Average annual leachate volume (mm): 114.5 – 223.9 Radioactivity in leachate - individual annual maximum concentrations expressed as µg a.s. equivalents /L:

S-metolachlor: < 0.01 - 0.08
CGA354743 (ESA): 1.1 - 28
CGA51202 (OXA): 0.3 - 16.3
CGA368208: 0.05 - 7.8
CGA50720: 0.03 - 4.7
CGA357704: 0.07 - 5.1
CGA37735: 0.16 - 0.98
unidentified radioactivity: 5.1 – 47.2

(2) Location: Stein/Argau, Switzerland

Study type: lysimeter

Soil properties: sandy soil (pH = 5.6, OC=1.7 %)
Dates of application: 06 May 2002 (all soil cores), 08 May 2003 (soil core 3 and 4)

Crop: maize
Interception estimated: 0 %
Number of applications: 1 application per year
Duration: 3 years
Application rate: 1500 g/ha/year
Average annual rainfall (mm): 759 - 884
Average annual leachate volume (mm): 328 – 502

Individual max. annual average concentrations in leachate expressed as µg a.s. equivalents /L:
S-metolachlor: not detected
CGA354743 (ESA): 2.0 - 32.5
CGA51202 (OXA): 1.1 - 26.5
CGA368208: 0.1 - 5.0
CGA50720: 0.1 – 1.1
CGA357704: 0.1 – 6.1
NOA436611: 0.1- 2.8
NOA413173: 0.3 – 4.2
SYN542489: 0.1 – 4.2
SYN542488: 0.1 – 1.7
SYN542490: 0.1 – 3.5
SYN542491: 0.5 – 3.2
SYN542492: 0.2 – 2.1
SYN542607: 0.1 – 1.2
SYN545026: 0.1 – 1.7
SYN545027: 0.5 – 2.4

Overall summary of definitively identified metabolites in the leachate of lysimeter 3, year 2 (lysimeter with highest annual mean ^{14}C- concentration) expressed as µg a.s. equivalents /L:

CGA354743 (ESA): 29.3
CGA51202 (OXA): 24.1
CGA368208: 2.4
CGA357704: 5.3
NOA436611: 1.8
NOA413173: 3.0
SYN542489: 5.1
SYN542488: 0.8
SYN542490: 3.1
SYN542491: 1.2
SYN542492: 1.7

SYN542607: 2.4 SYN547969: 2.0 SYN547977: 0.1 Total definitively identified metabolites: 82.2 (=76.6 % of total radioactivity in the leachate) minor metabolites: 9.3 (= 8.7 % of total radioactivity in the leachate) biogenic compounds: 15.8 (= 14.7 % of total radioactivity in the leachate) Overall total ^{14}C-radioactivity: 107.3

Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1

Hydrolytic degradation of the active substance and metabolites > 10 %	pH 5 at 25 °C: no degradation within 30 d
	pH 7 at 25 °C: no degradation within 30 d
	pH 9 at 25 °C: no degradation within 30 d

Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %	**pH 7, sterile buffer** S-metolachlor dosed DT_{50} : 146 days Natural light, 30° - 50 °N; DT_{50}:129 days **Sterile natural water** Metolachlor dosed DT_{50}: 12.1 d Natural summer sunlight, 30° - 50 °N, DT_{50}: 21.5d 45 degradates, none of them > 5.5% of applied ^{14}C
Quantum yield of direct phototransformation in water at Σ > 290 nm	Not relevant, molar absorptivity at wave lengths ≥ 290 nm: < 10 $L \cdot mol^{-1} \cdot cm^{-1}$

'Ready biodegradability' (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable (yes/no)	No

Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Parent S-metolachlor										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed [a]	t. °C[b]	DT_{50} /DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50} /DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to 12 °C[c]		At study temp	Normalised to x °C[c]		
Fresh water plus suspended sediment, 10 µg/L	8.6	7.6	20	74/245.1	158/ 523.32	2.41	NA	NA	--	SFO
Fresh water plus suspended sediment, 95 µg/L	8.6	7.6	20	97/321.7	207.12/ 686.87	1.23	NA	NA	--	SFO

a) Measured in calcium chloride solution
b) Temperature of incubation=temperature that the environmental media was collected or std temperature of 20 °C
c) Normalised based on ECHA R11 PBT guidance using a Q_{10} of 2.58 to the temperature of the environmental media at the point of sampling..

NA: not applicable

Metabolite CGA40172	Max in total system 9.1 % after 58 days									
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed [a]	t. °C[b]	DT_{50} /DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50} /DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to 12 °C[c]		At study temp	Normalised to x °C[c]		
Fresh water plus suspended sediment, 10 µg/L	8.6	7.6	20	NA	NA	--	NA	NA	--	--
Fresh water plus suspended sediment, 95 µg/L	8.6	7.6	20	NA	NA	--	NA	NA	--	--

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) Temperature of incubation=temperature that the environmental media was collected or std temperature of 20 °C
c) Normalised using a Q_{10} of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

NA: not applicable

Mineralisation and non extractable residues (for parent dosed experiments)					
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues. max *x* % after *n* d (suspended sediment test)	Non-extractable residues. max *x* % after *n* d (end of the study) (suspended sediment test)
Fresh water plus suspended sediment, 10 µg/L	8.6	7.6	4.5 % after 58 d	ND	ND
Fresh water plus suspended sediment, 95 µg/L	8.6	7.6	3.9 % after 58 d	ND	ND

ND: not detected

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

Parent S-metolachlor dosed Mamouni, metolachlor dosed Seyfried.	Distribution (max in water 8.9 % after 99 d, max. sed 21.2 % after 99 d)									
Water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
River (Rhine), sandy loam (study Mamouni)	7.7	8.3	20	54.8 / 182	1.9	NA	NA	NA	--	SFO
Pond (Ormalingen), silt loam (study Mamouni)	7.3	8.1	20	42.0 / 140	3.5	NA	NA	NA	--	SFO
River (Rhine), sandy loam (study Seyfried)	7.7	8.3	20	45.4 / 151	3.1	NA	NA	NA	--	SFO
Pond (Ormalingen), silt loam (study Seyfried)	7.3	8.1	20	33.6 / 112	3.8	NA	NA	NA	--	SFO
Geometric mean at 20 °C				43.3						

[a)] Measured in [medium to be stated, usually calcium chloride solution or water]

NA: not applicable

Metabolite CGA41507	Distribution (Max in water 8.2 % after 175 d, max. sed 12.1 % after 271 d). Max in total system 17.8 % after 175 days. Under anaerobic conditions: max. 54.7 % after 271 days in total system									
Water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
All systems	-	-	-	NA	NA	NA	NA	NA	NA	NA
$DegT_{50}$ used for modelling (days)				1000						

Metabolite CGA51202 (OXA)	Distribution (max in water 16.8 % after 362 d, max in total system 21.2 % after 362 days, max in sediment 5.1% after 271 d)									
Water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
All systems	-	-	-	NA	NA	NA	NA	NA	NA	NA
$DegT_{50}$ used for modelling (days)				1000						

Metabolite CGA354743 (ESA)	Distribution (Max in water 6.7 % after 362 d, max in total system 8.5 % after 362 days, max in sediment 2.7% after 362 d).									
Water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
All systems	-	-	-	NA	NA	NA	NA	NA	NA	NA
$DegT_{50}$ used for modelling (days)				1000						

Metabolite CGA217498	Distribution (Max in water 2.7% after 362 d., max in total system 5.6 % after 362 days, max in sediment 2.9% after 362 d)									
Water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
All systems	-	-	-	NA	NA	NA	NA	NA	NA	NA
$DegT_{50}$ used for modelling (days)				NA						

Mineralisation and non extractable residues (from parent dosed experiments)					
Water / sediment system	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
River (Rhine), sandy loam (study Mamouni)	7.7	8.3	4.5 % after 362 d	40.3 % after 175 d	39.7 % after 362 d
Pond (Ormalingen), silt loam (study Mamouni)	7.3	8.1	1.8 % after 362 d	58.8 % after 175 d	60.8 % after 362 d
River (Rhine), sandy loam (study Seyfried)	7.7	8.3	3.1 % after 180 d	35.8 % after 91 d	34.8 % after 180 d
Pond (Ormalingen), silt loam (study Seyfried)	7.3	8.1	2.0 % after 180 d	52.9 % after 91 d	56.5 % after 180 d

Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air	Not studied - no data requested
Photochemical oxidative degradation in air	DT_{50} of 2.3 hours derived by the Atkinson model (version 1.91). OH-radical concentration assumed = 1.5^6 (12 h).
Volatilisation	Experimental data demonstrates that S-metolachlor has a potential for volatilisation.
Metabolites	No information available

Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	Soil: S-metolachlor[a], metolachlor, OXA (CGA51202), ESA (CGA354743), CGA40172, CGA50720, CGA368208, CGA37735, NOA436611, CGA357704 Surface water and sediment: S-metolachlor[a], metolachlor, OXA (CGA51202), ESA (CGA354743), CGA40172, CGA50720, CGA368208, CGA37735, NOA436611, CGA41507, CGA357704 and (via bank filtration from groundwater) SYN542489, SYN542490, NOA413173, SYN542607, SYN547969, SYN542491, SYN542492, SYN542488, SYN547977 Groundwater: S-metolachlor[a], metolachlor, CGA354743 (ESA), CGA51202 (OXA), CGA357704, CGA368208, CGA37735, CGA40172, CGA50720, NOA413173. NOA436611, SYN542488, SYN542489, SYN542490, SYN542491, SYN542492, SYN542607, SYN545026, SYN545027, SYN547969, SYN547977 Air: S-metolachlor[a] (default)

[a] S-metolachlor (S-isomer 80-100%, R-isomer 20-0%)

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5

Soil (indicate location and type of study)	Not available
Surface water (indicate location and type of study)	Not available
Air (indicate location and type of study)	Not available
Ground water (indicate location and type of study)	Available (see below)

Summary of public groundwater monitoring data for S-metolachlor and its metabolites

Country	Reference	Substance	Number of samples	Number of wells	Number of residues >LOQ	Percentage of residues >LOQ	Percentage of residues >0.1 µg/L	Max. residue µg/L
Germany	**KCA 7.5/52 (2010-2013)**	S-Metolachlor	158	24	157	99	0	0.03
	KCA 7.5/52 (2002-2005)	S-Metolachlor	507	36	507	100	0	<LOQ
Belgium	**KCA 7.5/77 (2009-2014)**	S-Metolachlor	98-477	7-231	n.a.	n.a.	0.2-1.3	n.a.
Switzerland	**KCA 7.5/78 (1992-1993 2003-2004)**	S-Metolachlor	61	8	32	52	7	0.14
	KCA 7.5/79 (1990-1991)	Metolachlor	139	35	123	88	0	0.02
	KCA 7.5/80 (1988-2003)	Metolachlor	505	6	380	75	3	0.8
Portugal	**KCA 7.5/81 (1999-2007)**	Metolachlor	674	68	661	98	0.003	0.15
Spain	**KCA 7.5/82 (2000-2001)**	Metolachlor	242	47	192	79	6	>1.3
Italy	**KCA 7.5/83/84 (1997+2006)**	S-Metolachlor	199	100	149	75	5	3.085
France	**KCA 7.5/85 (2009)**	Metolachlor	568	21	507	89	0	0.24
	KCA 7.5/62 (2006-2013)	S-Metolachlor	768	21	679	88.4	0.65	0.58

Country	Reference	Substance	Number of samples	Number of wells	Number of residues >LOQ	Percentage of residues >LOQ	Percentage of residues >10µg/L	Max. residue µg/L
Germany	**KCA 7.5/52 (2010-2013)**	ESA	158	24	53	34	4	18.86

	KCA 7.5/61 (2009-2012)	ESA	3215	n.a.	2681	n.a.	n.a.	n.a.
	KCA 7.5/52 (2002-2005)	ESA	507	36	332	65	0	7.94
Switzerland	**KCA 7.5/80 (1988-2003)**	ESA	90	6	67	74	0	2.34
Portugal	**KCA 7.5/81 (1999-2007)**	ESA	187	68	140	75	0	1.79
Italy	**KCA 7.5/83/84 (1997+2006)**	ESA	100	100	42	42	0	4.35
France	**KCA 7.5/85 (2009)**	ESA	568	21	13	24	0	4.2
	KCA 7.5/62 (2006-2013)	ESA	770	21	170	22.08	0	4.2

Country	**Reference**	**Substance**	**Number of samples**	**Number of wells**	**Number of residues >LOQ**	**Percentage of residues >LOQ**	**Percentage of residues >10µg/L**	**Max. residue µg/L**
Germany	**KCA 7.5/52 (2010-2013)**	OXA	158	24	87	55	3	16.79
	KCA 7.5/61 (2009-2012)	OXA	3114		2824			
	KCA 7.5/52 (2002-2005)	OXA	507	36	426	84	0	2.47
Switzerland	**KCA 7.5/80 (1988-2003)**	OXA	90	6	79	88	0	0.81
Portugal	**KCA 7.5/81 (1999-2007)**	OXA	187	68	184	98	0	0.12
Italy	**KCA 7.5/83/84 (1997+2006)**	OXA	100	100	73	73	0	2.61
France	**KCA 7.5/85 (2009)**	OXA	568	21	492	87	0	0.75
	KCA 7.5/62 (2006-2013)	OXA	768	21	668	86.98	0	1.11

Summary of S-metolachlor and Metolachlor Groundwater Monitoring Results Obtained for the Selected Countries

Country	Parameter Name	Years	Sample Summary						Location Summary					
			Number of Samples	Number of Samples with Detections and percent of total number of samples					Number of Locations	Number of Locations with Maximum Detections and percent of total number of locations				
				ND	> RL	>0.1 µg/L	>1.0 µg/L	>10.0 µg/L		ND	> RL	>0.1 µg/L	>1.0 µg/L	>10.0 µg/L
Austria	SMOC/metolachlor	2008 - 2018	24,094	23,344 96.9%	750 3.1%	85 0.4%	10 0.0%	0 0%	1,675	1,430 85.4%	245 14.6%	40 2.4%	7 0.4%	0 0%
Bulgaria	Metolachlor	2012 - 2018	111	111 100%	0 0%	0 0%	0 0%	0 0%	52	52 100%	0 0%	0 0%	0 0%	0 0%
Czech Republic	Metolachlor	2008 - 2018	12,747	12,644 99.2%	103 0.8%	16 0%	0 0%	0 0%	797	763 95.7%	34 4.3%	9 1.1%	0 0%	0 0%
France	SMOC/metolachlor	2008 - 2018	151,574	146,565 96.7%	5,009 3.3%	1,026 0.7%	118 0.08%	18 0.01%	24,421	23,062 94.4%	1,359 5.6%	291 1.2%	40 0.2%	7 0.03%
Germany	SMOC/metolachlor	2008 - 2018	25,443	25,168 98.9%	275 1.1%	52 0.2%	2 0.01%	0 0%	6,117	6,001 98.1%	116 1.9%	31 0.5%	1 0.02%	0 0%
Italy	SMOC/metolachlor	2008 - 2018	33,013	31,629 95.8%	1,384 4.2%	242 0.7%	41 0.1%	2 0.01%	4,447	3,943 88.7%	504 11.3%	114 2.6%	25 0.6%	2 0.04%
Netherlands	SMOC/metolachlor	2008 - 2016	1,969	1,965 99.8%	4 0.2%	1 0.1%	0 0%	0 0%	1,417	1,413 99.7%	4 0.3%	1 0.1%	0 0%	0 0%
Portugal	Metolachlor	2010 - 2017	1,055	1,049 99.4%	6 0.6%	4 0.4%	4 0.4%	0 0%	422	417 98.8%	5 1.2%	3 0.7%	3 0.7%	0 0%
Slovakia	SMOC	2011 - 2014	801	793 99.0%	8 1.0%	3 0.4%	0 0%	0 0%	182	179 98.4%	3 1.6%	2 1.1%	0 0%	0 0%
Slovenia	Metolachlor	2008 - 2015	1,949	1,825 93.6%	124 6.4%	36 1.8%	6 0%	0 0%	261	224 85.8%	37 14.2%	18 6.9%	5 1.9%	0 0%
Spain	Metolachlor	2008 - 2018	3,821	3,639 95.2%	182 4.8%	54 1.4%	11 0.3%	2 0.1%	614	559 91.0%	55 9.0%	22 3.6%	6 1.0%	1 0.2%
Total	**SMOC/metolachlor**	**2008 - 2018**	**256,577**	**248,732** **96.9%**	**7,845** **3.1%**	**1,519** **0.6%**	**192** **0.1%**	**22** **0.01%**	**40,405**	**38,043** **94.2%**	**2,362** **5.8%**	**531** **1.3%**	**87** **0.2%**	**10** **0.02%**

Summary of groundwater monitoring data for S-metolachlor and its metabolites (performed by the applicant)[1]

Substance	Pan-European groundwater monitoring									
	Groundwater monitoring sites allocated to the FOCUS zone Hamburg (n=56), sites considered to represent triennial applications									
Dose rate covered at the sites	**1250 g/ha (n=13 sites)**					**1440 g/ha (n=10 sites)**				
	≥ LOQ[2] (in % of samples/wells)	≥ 0.1 µg/L (in % of samples/wells)	≥ 10 µg/L (in % of samples/wells)	Max. (µg/L)	90th perc. annual max. (µg/L)	≥ LOQ[2] (in % of samples/wells)	≥ 0.1 µg/L (in % of samples/wells)	≥ 10 µg/L (in % of samples/wells)	Max. (µg/L)	90th perc. annual max. (µg/L)
S-metolachlor	9 / 31	7 / 23	n.a.	1.3	0.078	6 / 25	4 / 13	n.a.	0.6	0.005
SYN547977	13 / 39	4.5 / 23	n.a.	0.304	0.09	3.6 / 25	0.7 / 13	n.a.	0.189	0.025
CGA354743 (ESA)	87 / 100	79 / 93	3 / 31	32.1	8.7	80 / 100	68 / 88	2 / 25	32.1	8.3
CGA51202 (OXA)	77 / 92	67 / 85	3 / 23	18.2	5.0	77 / 92	67 / 85	3 / 23	18.2	4.8

[1] It was clarified by EFSA during the Expert´s consultation on S-metolachlor (teleconference 28, 14-16 October 2020) that the representative uses with lower dose rates (500, 720 and

1000 g a.s./ha) introduced during the peer review process as “mitigation measures” cannot be formally accepted at this stage. EFSA is only able to conclude on the GAP included in the submitted dossier and the EFSA conclusion will be on the representative uses of 1250 and 1440 g a.s./ha. Therefore, the RMS crossed out the results for these uses in the RAR.

[2] Limit of quantification (LOQ) for S-metolachlor was 0.01 µg/L and 0.05 µg/L for OXA and ESA

n.a. Not available

PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent Method of calculation	DT_{50} (d): not required (only PECs, act is needed)
Application data	Crop: maize and sunflower (pre-emergence) and maize (post-emergence) Depth of soil layer: 5 cm Tillage depth: 20 cm Soil bulk density: 1.5g/cm^3 % plant interception: Pre-emergence 0 % Post-emergence 25 % Number of applications: 1 Interval (d): n.a. Application rate(s): 1440 and 1250 g as/ha

Metabolites
Method of calculation

Metabolite	**DT_{50}** Longest $DegT_{50}$ lab (FOCUS default)	**Molecular weight (g/mole)**	**Correction factor**	**Max. occurrence in soil (%)**
ESA (CGA354743)	1000	329.4	1.16	23.6
OXA (CGA51202)	1000	279.3	0.98	21.3
CGA368208	163	257.3	0.91	7.6
CGA40172	133	265.3	0.93	6.5
CGA50720	23	207.2	0.73	8.2
CGA37735	1 1.4	193.2	0.68	7.1
NOA436611	345	355.5	1.25	9.1
CGA357704	1000	279.3	0.984	21.9

Summary of initial and accumulated PEC_{soil} of A9396G, S-metolachlor and its soil metabolites to pre-emergent maize and sunflower crops (BBCH 00-10) at 1440 g a.s./ha

Formulation/ compound	Crop	Maximum use rate [g/ha]	No. of appl.	Crop interception [%]	Soil loading [g/ha]	PEC_{soil}, initial [mg/kg]	PEC_{soil}, peak accum* [mg/kg]
Formulation A9693G	Maize & sunflower	1665	1	0	1665	2.220	-
Active substance S-metolachlor	Maize & sunflower	1440	1	0	1440	1.920	NA
ESA (CGA354743)	Maize & sunflower	-	-	-	-	0.526	2.353
OXA (CGA51202)	Maize & sunflower	-	-	-	-	0.402	1.801
CGA368208	Maize & sunflower	-	-	-	-	0.132	0.168
CGA40172	Maize & sunflower	-	-	-	-	0.117	0.151
CGA50720	Maize & sunflower	-	-	-	-	0.115	NA
CGA37735	Maize & sunflower	-	-	-	-	0.093	NA
NOA436611	Maize & sunflower	-	-	-	-	0.219	0.421
CGA357704	Maize & sunflower	-	-	-	-	0.414	1.851

[1] A9396G is an EC formulation containing 960g a.s./L with a specific density of 1110 g/L, maximum use rate is based on applying 1.5L A9693G/ha; NA – not applicable

Summary of initial and accumulated PEC_{soil} of A9396G, S-metolachlor and its soil metabolites to post-emergent maize (BBCH 11-18) at 1440 g a.s./ha

Formulation/ compound	Crop	Maximum use rate [g/ha]	No. of appl.	Crop interception [%]	Soil loading [g/ha]	PEC_{soil}, initial [mg/kg]	PEC_{soil}, peak accum* [mg/kg]
Formulation A9693G[1]	Maize	1665	1	25	1249	1.67	-
Active substance S-metolachlor	Maize	1440	1	25	1080	1.44	-
ESA (CGA354743)	Maize	-	-	-	-	0.394	1.75
OXA (CGA51202)	Maize	-	-	-	-	0.301	1.34
CGA368208	Maize	-	-	-	-	0.100	0.126
CGA40172	Maize	-	-	-	-	0.087	0.113
CGA50720	Maize	-	-	-	-	0.086	-
CGA37735	Maize	-	-	-	-	0.070	-
NOA436611	Maize	-	-	-	-	0.164	0.316
CGA357704	Maize	-	-	-	-	0.310	1.388

[1] A9396G is an EC formulation containing 960g a.s./L with a specific density of 1110 g/L, maximum use rate is based on applying 1.5L A9693G/ha

Summary of initial and accumulated PEC_{soil} of A9396G, S-metolachlor and its soil metabolites to pre-emergent maize and sunflower crops (BBCH 00-10) at 1250 g a.s./ha

Formulation/ compound	Crop	Maximum use rate [g/ha]	No. of appl.	Crop interception [%]	Soil loading [g/ha]	PEC_{soil}, initial [mg/kg]	PEC_{soil}, peak accum* [mg/kg]
Formulation A9693G[1]	Maize & sunflower	1443	1	0	1443	1.92	-
Active substance S-metolachlor	Maize & sunflower	1250	1	0	1250	1.67	NA

ESA (CGA354743)	Maize & sunflower	-	-	-	-	0.457	2.03
OXA (CGA51202)	Maize & sunflower	-	-	-	-	0.349	1.55
CGA368208	Maize & sunflower	-	-	-	-	0.115	0.146
CGA40172	Maize & sunflower	-	-	-	-	0.101	0.131
CGA50720	Maize & sunflower	-	-	-	-	0.100	NA
CGA37735	Maize & sunflower	-	-	-	-	0.081	NA
NOA436611	Maize & sunflower	-	-	-	-	0.190	0.365
CGA357704	Maize & sunflower	-	-	-	-	0.359	1.607

[1] A9396G is an EC formulation containing 960g a.s./L with a specific density of 1110 g/L, maximum use rate is based on applying 1.3L A9693G/ha; NA – not applicable

Summary of initial and accumulated PEC_{soil} of A9396G, S-metolachlor and its soil metabolites to post-emergent maize (BBCH 11-18) at 1250 g a.s./ha

Formulation/ compound	Crop	Maximum use rate [g/ha]	No. of appl.	Crop interception [%]	Soil loading [g/ha]	PEC_{soil}, initial [mg/kg]	PEC_{soil}, peak accum* [mg/kg]
Formulation A9693G	Maize	1443	1	25	1082	1.44	-
Active substance S-metolachlor	Maize	1250	1	25	937.5	1.25	NA
ESA (CGA354743)	Maize	-	-	-	-	0.342	1.52
OXA (CGA51202)	Maize	-	-	-	-	0.261	1.17
CGA368208	Maize	-	-	-	-	0.086	0.109
CGA40172	Maize	-	-	-	-	0.076	0.098
CGA50720	Maize	-	-	-	-	0.075	NA
CGA37735	Maize	-	-	-	-	0.060	NA
NOA436611	Maize	-	-	-	-	0.142	0.274
CGA357704	Maize	-	-	-	-	0.270	1.205

1 A9396G is an EC formulation containing 960g a.s./L with a specific density of 1110 g/L, maximum use rate is based on applying 1.5L A9693G/ha; NA – not applicable

PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	**FOCUS gw modelling** Modelling using FOCUS model(s), with appropriate $FOCUS_{GW}$ scenarios, according to FOCUS guidance. Model(s) used: FOCUS-PEARL (v 4.4.4) and FOCUS-PELMO (v 5.5.3) Crop: Maize and sunflower TSCF: 0 and 0.17 (parent)* and 0 (metabolites) Water solubility (mg/L): 480 at pH 7 and 20 °C Vapour pressure : 3.7 x 10-3 Pa at 20 °C Geometric mean DT_{50} (d): S-metolachlor 30.1 lab., 20 °C pF2/10 kPa ESA (CGA354743) 235[a)] lab., 20 °C pF2/10 kPa OXA (CGA51202) 152.5[b)] lab., 20 °C pF2/10 kPa CGA368208 36.9 lab., 20 °C pF2/10 kPa CGA37735 0.8 lab., 20 °C pF2/10 kPa CGA40172 133.3 lab., 20 °C pF2/10 kPa CGA50720 10.4 lab., 20 °C pF2/10 kPa NOA436611 165.0 lab., 20 °C pF2/10 kPa CGA357704 136.0 lab., 20°C pF2/10 kPa SYN547977 64.0 lab., 20°C pF2/10kPa [a)]For future simulations 154.4 should be used. [b)]For future simulations 98.1 should be used. Formation fractions: S-metolachlor 0.154[a)] (to ESA) 0.175[b)] (to OXA) 0.0991 (to CGA40172) 0.0947 (to NOA436611) 0.22 (to CGA357704) 0.2572 / 0.1[#] (to SYN547977) ESA (CGA354743) 0.481 (to CGA368208) 0.519 (to CGA37735) OXA (CGA51202) 1.0 (to CGA50720) CGA37735 0.837 (to CGA50720) [a)]For future simulations 0.164 should be used. [b)]For future simulations 0.176 should be used. Geometric mean KFoc (mL/g) / Arihmetic mean 1/n: S-metolachlor 200.2 / 0.93 ESA (CGA354743) 6.7 / 0.9 OXA (CGA51202) 12.3 /0.84 CGA368208 1 /1 CGA37735 10.4 / 0.96 CGA40172 174.5 / 0.76 CGA50720 1 / 1 NOA436611 8.4 / 0.82 CGA357704 1/1 SYN547977 60.9 / 0.93 * During the expert's consultation (teleconference 28, 14-16 October 2020), the experts considered that in FOCUS simulation modelling for the active substance S-metolachlor a TSCF value of 0.3 would be appropriate for the crop maize and a value of 0.39 would be appropriate for other crops for which experimental data on those crops were not available. For future FOCUS simulations TSCF values of 0.3 (maize) and 0.39 (other

crops for which experimental data is not available) should be used.

calculated either as 1 minus the ff of the primary S-metolachlor metabolites ESA, OXA, CGA40172, NOA436611 and CGA357704 or ff of 0.1 estimated with a manually adjusting procedure that resulted in formation of 5% (as did not reach this level that triggers assessment in any of the soil lab incubations).

Lysimeter studies

(1) Location: Birkenheide, Rhineland Palatinate, Germany

Study type (e.g. lysimeter, field): Lysimeter

Soil properties: loamy sand (pH = 6.4, OC = 1.3 %)
Dates of application:
1st year (both lysimeter): 24/05/95;
2nd year (lysimeter 18): 04/06/96

Crop: maize, winter cereals,
Interception estimated: 25 %
Number of applications: 1 application per year
Duration: 3 years
Application rate: 1250 g/ha/year

Average annual rainfall (mm): 807 - 923
Average annual leachate volume (mm): 114.5 – 223.9

(2) Location: Stein/Argau, Switzerland

Study type (e.g. lysimeter, field): Lysimeter

Soil properties: sandy soil (pH = 5.6, OC=1.7 %)
Dates of application: 06 May 2002 (all soil cores), 08 May 2003 (soil core 3 and 4)

Crop: maize
Interception estimated: 0 %
Number of applications: 1 application per year
Duration: 3 years
Application rate: 1500 g/ha/year
Average annual rainfall (mm): 759 - 884
Average annual leachate volume (mm): 328 – 502

Field leaching studies

(1) Location: Lorsch, Hessen, Germany

Study type (e.g. lysimeter, field): Field leaching

Soil properties: pH = ca. 5.2-8, OC= < 0.5-2.6 %

Dates of application and application rate:

23.05.1995: 1454 g a.s./ha

03.06.1996: 1491 g a.s./ha

27/28.05.1997: 1499 g a.s./ha

26.05.1999: 1495 g a.s./ha

23.05.2000: 1499 g a.s./ha

24.05.2002: 1241 g a.s./ha

24.05.2003: 1250 g a.s./ha

Crop: Maize
Interception: 0 % (pre-emergence)

	Number of applications per year: 1 Duration: 10 years Average annual rainfall (mm): ca. 407-964 mm *(2) Location: Sherburne County, Minnesota, USA* Study type (e.g. lysimeter, field): Field leaching Soil properties: pH = ca. 6, OC= < 2 % Dates of application: 29.05.1996 Application rate: 3000 g/ha. Crop: Maize Interception: 0 % (pre-emergence) Number of applications: 1 Duration: 4 years Average annual rainfall (mm): ca. 500-600 mm
Application rate (modelling)	Gross application rates: 1440 and 1250 g/ha. Crop growth stage: Maize: BBCH 00-09 and BBCH 10-18 Sunflower: BBCH 00-09 Canopy interception %: 0 (BBCH 00-09) and 25 (BBCH 10-18) Application rate net of interception: BBCH 00-09: 1440 and 1250 g/ha BBCH 10-18: 1080 and 937.5g/ha No. of applications: 1 (annual, biennial, triennial) Time of application (absolute or relative application dates):

Maize

BBCH	00-09	10-18
Châteaudun	01-May	02-May
Hamburg	05-May	06-May
Kremsmünster	05-May	06-May
Okehampton	25-May	26-May
Piacenza	15-May	16-May
Porto	01-May	02-May
Seville	07-Mar	08-Mar
Thiva	20-Apr	21-Apr

Sunflower

BBCH	00-09
Piacenza	20-Apr
Seville	10-Mar

PEC_{GW} of S-metolachlor, NOA436611, CGA354743, CGA51202, CGA368208, CGA37735, CGA40172, CGA50720 and CGA357704 from FOCUS PELMO 5.5.3 for pre-emergent maize (TSCF = 0.17).

Use pattern	Compound	PEC_{GW} at 1 m soil depth [µg/L]							
		Chât	Ham	Kre	Oke	Pia	Por	Sev	Thi
Maize, pre-emergence, 1440 g/ha, annual	S-metolachlor	0.002	0.041	0.02	0.048	0.062	0.01	<0.001	0.001
	NOA436611	46.929	50.775	38.536	30.26	28.117	21.749	28.07	50.448
	CGA354743 (ESA)	90.225	87.966	68.657	54.277	51.108	38.169	65.89	106.516
	CGA51202 (OXA)	57.832	66.86	50.551	38.575	36.835	28.779	32.472	62.57
	CGA40172	0.001	0.038	0.02	0.084	0.095	0.006	<0.001	<0.001
	CGA368208	5.899	4.953	3.994	2.893	3.104	2.375	4.865	7.422
	CGA37735	0.086	0.085	0.065	0.051	0.05	0.033	0.06	0.102
	CGA50720	5.71	7.424	5.017	4.358	3.509	3.284	3.787	5.978
	CGA357704	93.935	109.719	79.095	64.893	59.889	37.731	53.661	95.211
Maize, pre-emergence, 1440 g/ha, biennial	S-metolachlor	0.001	0.015	0.009	0.023	0.035	0.004	<0.001	<0.001
	NOA436611	25.285	24.244	19.792	14.398	13.882	9.556	13.179	29.303
	CGA354743 (ESA)	49.627	41.648	34.68	25.311	24.644	17.726	33.116	63.398
	CGA51202 (OXA)	30.354	32.082	25.716	19.249	18.302	12.8	14.69	35.903
	CGA40172	<0.001	0.006	0.002	0.013	0.013	0.001	<0.001	<0.001
	CGA368208	3.167	2.474	1.931	1.287	1.461	1.111	2.665	4.541
	CGA37735	0.048	0.04	0.033	0.024	0.024	0.015	0.03	0.061
	CGA50720	3.101	3.629	2.567	1.997	1.685	1.449	1.96	3.497
	CGA357704	50.926	49.973	39.036	29.137	25.992	18.62	28.092	52.963
Maize, pre-emergence, 1440 g/ha, triennial	S-metolachlor	<0.001	0.008	0.006	0.012	0.017	0.002	<0.001	<0.001
	NOA436611	14.995	15.613	13.143	9.55	8.802	6.019	8.658	18.856
	CGA354743 (ESA)	29.506	28.348	25.364	16.249	15.756	10.674	21.897	43.696
	CGA51202 (OXA)	18.804	20.498	16.814	12.617	11.719	7.955	10.201	23.242
	CGA40172	<0.001	0.002	0.001	0.006	0.007	<0.001	<0.001	<0.001
	CGA368208	1.934	1.700	1.563	0.798	0.958	0.703	1.729	3.161
	CGA37735	0.028	0.028	0.024	0.016	0.016	0.009	0.02	0.042
	CGA50720	1.806	2.315	1.709	1.275	1.028	0.876	1.242	2.158
	CGA357704	31.014	32.455	27.815	18.413	16.376	11.071	17.995	34.561
	SYN547977[1] (ff = 0.1)	0.986	1.673	1.261	1.665	1.492	0.845	0.106	0.635
	SYN547977[1] (ff = 0.2572)	2.684	4.583	3.427	4.471	3.987	2.294	0.299	1.746
Maize, pre-emergence, 1250 g/ha, annual	S-metolachlor	0.001	0.033	0.016	0.038	0.051	0.008	<0.001	<0.001
	NOA436611	40.504	43.919	33.277	26.084	24.314	18.848	24.227	43.551
	CGA354743 (ESA)	78.239	76.327	59.54	47.027	44.287	33.157	57.18	92.372
	CGA51202 (OXA)	49.613	57.75	43.79	33.272	31.825	24.873	27.98	54.032
	CGA40172	0.001	0.023	0.011	0.057	0.065	0.004	<0.001	<0.001
	CGA368208	5.129	4.31	3.475	2.518	2.697	2.07	4.228	6.45
	CGA37735	0.075	0.074	0.057	0.044	0.043	0.028	0.052	0.089
	CGA50720	4.956	6.485	4.368	3.799	3.051	2.869	3.288	5.188
	CGA357704	81.56	95.238	68.678	56.325	52.013	32.761	46.6	82.662
Maize, pre-emergence, 1250 g/ha, biennial	S-metolachlor	0.001	0.012	0.007	0.018	0.029	0.003	<0.001	<0.001
	NOA436611	21.759	20.976	17.099	12.469	12.012	8.276	11.263	25.293
	CGA354743 (ESA)	43.036	36.145	30.073	21.938	21.381	15.371	28.664	55.012
	CGA51202 (OXA)	26.07	27.716	22.183	16.616	15.822	11.086	12.607	30.953
	CGA40172	<0.001	0.004	0.002	0.008	0.009	0.001	<0.001	<0.001
	CGA368208	2.755	2.151	1.681	1.12	1.271	0.967	2.315	3.942
	CGA37735	0.041	0.035	0.029	0.021	0.021	0.013	0.026	0.053
	CGA50720	2.687	3.173	2.235	1.74	1.467	1.263	1.702	3.034
	CGA357704	44.206	43.394	33.897	25.298	22.567	16.172	24.394	45.975
Maize, pre-emergence, 1250 g/ha, triennial	S-metolachlor	<0.001	0.006	0.005	0.01	0.014	0.001	<0.001	<0.001
	NOA436611	12.93	13.494	11.336	8.258	7.62	5.21	7.457	16.273
	CGA354743 (ESA)	25.571	24.56	21.979	14.096	13.669	9.262	18.981	37.893
	CGA51202 (OXA)	16.23	17.692	14.472	10.897	10.136	6.879	8.76	20.07
	CGA40172	<0.001	0.002	0.001	0.004	0.005	0	<0.001	<0.001
	CGA368208	1.683	1.481	1.359	0.695	0.833	0.612	1.502	2.746
	CGA37735	0.025	0.024	0.021	0.013	0.013	0.008	0.018	0.037
	CGA50720	1.567	2.021	1.486	1.113	0.895	0.766	1.08	1.871
	CGA357704	26.921	28.183	24.151	15.988	14.219	9.612	15.627	30.006
	SYN547977[1] (ff = 0.1)	0.840	1.422	1.074	1.423	1.279	0.721	0.089	0.539
	SYN547977[1] (ff = 0.2572)	2.287	3.898	2.918	3.825	3.419	1.958	0.252	1.482

[1] During the experts consultation (teleconference 28, 14-16 October 2020), the experts considered that in FOCUS

simulation modelling for the active substance S-metolachlor a TSCF value of 0.3 would be appropriate for the crop maize and a value of 0.39 would be appropriate for other crops for which experimental data on those crops were not available. The experts also considered the available PEC_{GW} values calculated with an TSCF value of 0.17 sufficient for a Tier 1 groundwater risk assessment. Therefore, only the PEC_{GW} values for the relevant me-tabolite SYN547977 were re-calculated by the RMS using the updated TSCF values and formation fractions.

PEC_{GW} of S-metolachlor, NOA436611, CGA354743, CGA51202, CGA368208, CGA37735, CGA40172, CGA50720 and CGA357704 from FOCUS PEARL 4.4.4 for pre-emergence maize (TSCF = 0.17).

Use pattern	Compound	PEC_{GW} at 1 m soil depth [µg/L]							
		Chât	Ham	Kre	Oke	Pia	Por	Sev	Thi
Maize, pre-emergence, 1440 g/ha, annual	S-metolachlor	0.005	0.051	0.020	0.062	0.035	0.006	0.000	0.001
	NOA436611	48.322	64.937	35.713	31.475	42.377	21.519	32.641	71.191
	CGA354743 (ESA)	89.775	118.328	64.340	55.960	81.372	37.798	82.545	148.387
	CGA51202 (OXA)	61.376	85.689	47.634	42.276	54.721	28.683	39.930	90.127
	CGA40172	0.007	0.094	0.034	0.111	0.064	0.004	0.000	0.000
	CGA368208	5.510	6.583	3.739	3.036	5.741	2.322	6.283	10.427
	CGA37735	0.087	0.119	0.063	0.055	0.084	0.034	0.078	0.147
	CGA50720	5.727	9.410	4.299	4.229	4.757	3.060	4.253	7.850
	CGA357704	94.448	134.311	73.172	67.660	81.521	38.057	60.957	137.912
Maize, pre-emergence, 1440 g/ha, biennial	S-metolachlor	0.001	0.020	0.010	0.026	0.010	0.001	0.000	0.000
	NOA436611	17.268	31.335	18.269	14.598	19.649	7.057	19.316	34.322
	CGA354743 (ESA)	31.436	57.515	33.423	25.974	38.935	13.484	50.015	74.653
	CGA51202 (OXA)	22.982	39.785	24.229	20.032	25.418	9.492	22.060	43.350
	CGA40172	0.000	0.011	0.003	0.017	0.006	0.000	0.000	0.000
	CGA368208	1.818	3.769	1.884	1.414	2.731	0.858	4.006	5.500
	CGA37735	0.031	0.057	0.033	0.026	0.039	0.012	0.047	0.074
	CGA50720	2.155	4.712	2.262	1.935	2.352	1.041	2.612	3.754
	CGA357704	32.601	76.103	37.067	30.233	39.022	14.348	43.327	65.541
Maize, pre-emergence, 1440 g/ha, triennial	S-metolachlor	0.001	0.013	0.007	0.015	0.008	0.001	0.000	0.000
	NOA436611	15.036	16.633	12.790	9.936	12.283	6.144	10.701	29.412
	CGA354743 (ESA)	28.699	32.031	24.156	17.513	24.708	11.098	32.606	68.297
	CGA51202 (OXA)	19.846	21.588	17.112	13.477	16.170	8.332	12.137	35.755
	CGA40172	0.000	0.004	0.001	0.007	0.003	0.000	0.000	0.000
	CGA368208	1.722	1.985	1.453	0.866	1.751	0.707	2.707	4.946
	CGA37735	0.028	0.032	0.024	0.017	0.025	0.010	0.031	0.068
	CGA50720	1.891	2.574	1.605	1.308	1.490	0.868	1.427	3.248
	CGA357704	30.097	38.367	27.631	19.611	24.246	11.660	22.691	56.185
	SYN547977[1] (ff = 0.1)	3.830	5.812	3.713	5.012	4.147	2.281	0.439	2.700
	SYN547977[1] (ff = 0.2572)	1.335	2.057	1.313	1.798	1.476	0.797	0.138	0.924
Maize, pre-emergence, 1250 g/ha, annual	S-metolachlor	0.004	0.042	0.016	0.051	0.029	0.005	0.000	0.001
	NOA436611	41.752	56.082	30.863	27.175	36.702	18.656	28.114	61.434
	CGA354743 (ESA)	77.861	102.565	55.777	48.505	70.595	32.825	71.608	128.632
	CGA51202 (OXA)	52.777	73.875	41.104	36.546	47.176	24.701	34.382	77.766
	CGA40172	0.004	0.061	0.020	0.076	0.042	0.002	0.000	0.000
	CGA368208	4.794	5.737	3.253	2.642	4.993	2.022	5.463	9.059
	CGA37735	0.076	0.103	0.055	0.048	0.073	0.029	0.067	0.127
	CGA50720	4.964	8.217	3.744	3.686	4.120	2.675	3.691	6.804
	CGA357704	81.983	116.595	63.516	58.732	70.763	33.037	52.937	119.710
Maize, pre-emergence, 1250 g/ha, biennial	S-metolachlor	0.001	0.016	0.008	0.021	0.008	0.001	0.000	0.000
	NOA436611	20.074	26.959	15.780	12.642	16.972	8.210	16.578	29.625
	CGA354743 (ESA)	36.405	49.896	28.983	22.522	33.769	15.614	43.309	64.705
	CGA51202 (OXA)	26.765	34.186	20.905	17.334	21.923	11.008	18.864	37.363
	CGA40172	0.000	0.007	0.002	0.011	0.004	0.000	0.000	0.000
	CGA368208	2.100	3.280	1.640	1.231	2.374	0.991	3.480	4.777

Use pattern	Compound	PEC_{GW} at 1 m soil depth [µg/L]							
		Chât	Ham	Kre	Oke	Pia	Por	Sev	Thi
	CGA37735	0.035	0.050	0.028	0.022	0.034	0.014	0.041	0.064
	CGA50720	2.487	4.118	1.969	1.688	2.044	1.196	2.264	3.255
	CGA357704	37.717	66.064	32.175	26.244	33.874	16.576	37.629	56.891
Maize, pre-emergence, 1250 g/ha, triennial	S-metolachlor	0.001	0.010	0.005	0.012	0.007	0.001	0.000	0.000
	NOA436611	12.952	14.316	11.056	8.592	10.605	5.318	9.182	25.354
	CGA354743 (ESA)	24.898	27.752	20.931	15.191	21.417	9.629	28.202	59.197
	CGA51202 (OXA)	17.122	18.602	14.773	11.642	13.969	7.205	10.421	30.747
	CGA40172	0.000	0.003	0.000	0.005	0.002	0.000	0.000	0.000
	CGA368208	1.500	1.730	1.264	0.755	1.522	0.615	2.351	4.293
	CGA37735	0.024	0.028	0.021	0.015	0.022	0.009	0.027	0.059
	CGA50720	1.647	2.243	1.398	1.141	1.295	0.758	1.237	2.813
	CGA357704	26.125	33.305	23.985	17.024	21.047	10.122	19.706	48.768
	SYN547977[1] (ff = 0.1)	1.137	1.758	1.121	1.539	1.259	0.680	0.116	0.784
	SYN547977[1] (ff = 0.2572)	3.267	4.972	3.174	4.293	3.552	1.948	0.369	2.296

[1] During the experts consultation (teleconference 28, 14-16 October 2020), the experts considered that in FOCUS simulation modelling for the active substance S-metolachlor a TSCF value of 0.3 would be appropriate for the crop maize and a value of 0.39 would be appropriate for other crops for which experimental data on those crops were not available. The experts also considered the available PEC_{GW} values calculated with an TSCF value of 0.17 sufficient for a Tier 1 groundwater risk assessment. Therefore, only the PEC_{GW} values for the relevant metabolite SYN547977 were re-calculated by the RMS using the updated TSCF values and formation fractions.

PEC_{GW} of S-metolachlor, NOA436611, CGA354743, CGA51202, CGA368208, CGA37735, CGA40172, CGA50720 and CGA357704 from FOCUS PELMO 5.5.3 for post-emergent maize (TSCF = 0.17).

Use pattern	Compound	PEC_{GW} at 1 m soil depth [µg/L]							
		Chât	Ham	Kre	Oke	Pia	Por	Sev	Thi
Maize, post-emergence, 1440 g/ha, annual	S-metolachlor	0.001	0.026	0.013	0.031	0.042	0.007	<0.001	<0.001
	NOA436611	34.792	37.824	28.592	22.369	20.957	16.262	20.808	37.447
	CGA354743 (ESA)	67.533	65.95	51.363	40.633	38.219	28.671	49.141	79.817
	CGA51202 (OXA)	42.349	49.688	37.726	28.564	27.388	21.395	24.074	46.475
	CGA40172	<0.001	0.013	0.006	0.037	0.044	0.003	<0.001	<0.001
	CGA368208	4.438	3.734	3.007	2.182	2.334	1.794	3.662	5.586
	CGA37735	0.065	0.064	0.049	0.039	0.038	0.025	0.045	0.077
	CGA50720	4.102	5.457	3.646	3.185	2.54	2.409	2.709	4.283
	CGA357704	70.557	82.371	59.348	48.773	45.03	28.306	40.142	71.508
Maize, post-emergence, 1440 g/ha, biennial	S-metolachlor	<0.001	0.008	0.005	0.012	0.019	0.002	<0.001	<0.001
	NOA436611	16.017	15.623	12.678	9.311	8.956	6.182	8.137	18.797
	CGA354743 (ESA)	32.197	27.099	22.518	16.417	16.033	11.5	21.209	41.251
	CGA51202 (OXA)	19.222	20.574	16.398	12.323	11.77	8.195	9.122	22.926
	CGA40172	<0.001	0.002	0.001	0.004	0.004	0	<0.001	<0.001
	CGA368208	2.077	1.618	1.268	0.845	0.959	0.728	1.728	2.953
	CGA37735	0.031	0.026	0.022	0.016	0.016	0.01	0.019	0.04
	CGA50720	1.916	2.338	1.627	1.274	1.067	0.923	1.205	2.171
	CGA357704	38.236	37.513	29.285	21.862	19.537	13.977	20.897	39.7
Maize, post-emergence, 1440 g/ha, triennial	S-metolachlor	<0.001	0.005	0.004	0.008	0.011	0.001	<0.001	<0.001
	NOA436611	11.097	11.607	9.725	7.115	6.567	4.49	6.39	13.999
	CGA354743 (ESA)	22.069	21.184	18.958	12.186	11.861	8	16.376	32.758
	CGA51202 (OXA)	13.941	15.197	12.387	9.376	8.728	5.922	7.492	17.249
	CGA40172	<0.001	0.001	0.001	0.003	0.003	<0.001	<0.001	<0.001
	CGA368208	1.459	1.285	1.176	0.602	0.723	0.53	1.297	2.378
	CGA37735	0.021	0.021	0.018	0.012	0.012	0.007	0.015	0.032
	CGA50720	1.355	1.757	1.288	0.969	0.777	0.667	0.935	1.618
	CGA357704	23.282	24.354	20.877	13.833	12.371	8.312	13.512	25.942
	SYN547977[1] (ff = 0.1)	0.711	1.203	0.911	1.211	1.093	0.613	0.092	0.454
	SYN547977[1] (ff = 0.2572)	2.050	3.519	2.613	3.396	3.026	1.756	0.285	1.343
Maize, post-	S-metolachlor	0.001	0.021	0.01	0.025	0.034	0.005	<0.001	<0.001

Use pattern	Compound	PECGW at 1 m soil depth [µg/L]							
		Chât	Ham	Kre	Oke	Pia	Por	Sev	Thi
emergence, 1250 g/ha, annual	NOA436611	30.019	32.708	24.692	19.27	18.111	14.082	17.952	32.325
	CGA354743 (ESA)	58.54	57.206	44.542	35.213	33.118	24.903	42.65	69.193
	CGA51202 (OXA)	36.312	42.923	32.665	24.627	23.651	18.478	20.784	40.154
	CGA40172	<0.001	0.008	0.004	0.024	0.03	0.002	<0.001	<0.001
	CGA368208	3.859	3.25	2.617	1.899	2.029	1.563	3.181	4.853
	CGA37735	0.056	0.056	0.043	0.033	0.033	0.021	0.039	0.067
	CGA50720	3.56	4.767	3.174	2.775	2.208	2.105	2.361	3.715
	CGA357704	61.242	71.518	51.506	42.34	39.094	24.58	34.86	62.103
Maize, post-emergence, 1250 g/ha, biennial	S-metolachlor	<0.001	0.01	0.006	0.015	0.024	0.003	<0.001	<0.001
	NOA436611	18.622	18.062	14.682	10.754	10.353	7.138	9.501	21.787
	CGA354743 (ESA)	37.135	31.221	25.959	18.941	18.481	13.268	24.502	47.549
	CGA51202 (OXA)	22.312	23.827	19.017	14.28	13.621	9.535	10.637	26.605
	CGA40172	<0.001	0.003	0.001	0.006	0.006	0.001	<0.001	<0.001
	CGA368208	2.387	1.86	1.456	0.97	1.102	0.837	1.99	3.403
	CGA37735	0.036	0.03	0.025	0.018	0.018	0.011	0.022	0.046
	CGA50720	2.212	2.674	1.868	1.459	1.225	1.058	1.388	2.502
	CGA357704	33.198	32.568	25.425	18.983	16.959	12.136	18.149	34.46
Maize, post-emergence, 1250 g/ha, triennial	S-metolachlor	<0.001	0.004	0.003	0.007	0.009	0.001	<0.001	<0.001
	NOA436611	9.566	10.029	8.383	6.15	5.684	3.886	5.499	12.078
	CGA354743 (ESA)	19.127	18.359	16.429	10.574	10.289	6.944	14.194	28.408
	CGA51202 (OXA)	12.029	13.112	10.657	8.102	7.547	5.12	6.441	14.888
	CGA40172	<0.001	0.001	0.001	0.002	0.003	<0.001	<0.001	<0.001
	CGA368208	1.269	1.119	1.022	0.524	0.629	0.461	1.127	2.065
	CGA37735	0.018	0.018	0.016	0.01	0.01	0.006	0.013	0.028
	CGA50720	1.176	1.534	1.121	0.846	0.677	0.583	0.813	1.403
	CGA357704	20.213	21.153	18.125	12.011	10.741	7.217	11.736	22.521
	SYN547977[1] (ff = 0.1)	0.605	1.022	0.777	1.035	0.936	0.522	0.078	0.385
	SYN547977[1] (ff = 0.2572)	1.747	2.994	2.226	2.905	2.595	1.499	0.241	1.140

[1] During the experts consultation (teleconference 28, 14-16 October 2020), the experts considered that in FOCUS simulation modelling for the active substance S-metolachlor a TSCF value of 0.3 would be appropriate for the crop maize and a value of 0.39 would be appropriate for other crops for which experimental data on those crops were not available. The experts also considered the available PEC_{GW} values calculated with an TSCF value of 0.17 sufficient for a Tier 1 groundwater risk assessment. Therefore, only the PEC_{GW} values for the relevant metabolite SYN547977 were re-calculated by the RMS using the updated TSCF values and formation fractions.

PEC_{GW} of S-metolachlor, NOA436611, CGA354743, CGA51202, CGA368208, CGA37735, CGA40172, CGA50720 and CGA357704 from FOCUS PEARL 4.4.4 for post-emergence maize (TSCF = 0.17).

Use pattern	Compound	PECGW at 1 m soil depth [µg/L]							
		Chât	Ham	Kre	Oke	Pia	Por	Sev	Thi
Maize,post-emergence, 1440 g/ha, annual	S-metolachlor	0.003	0.034	0.013	0.041	0.024	0.004	0.000	0.000
	NOA436611	36.109	48.187	26.540	23.346	31.619	16.119	24.085	52.733
	CGA354743 (ESA)	67.645	88.492	48.134	41.879	61.023	28.401	61.673	110.949
	CGA51202 (OXA)	45.434	63.359	35.288	31.467	40.465	21.175	29.310	66.756
	CGA40172	0.002	0.041	0.013	0.051	0.027	0.001	0.000	0.000
	CGA368208	4.149	4.974	2.814	2.285	4.322	1.752	4.717	7.831
	CGA37735	0.066	0.089	0.047	0.041	0.063	0.025	0.058	0.110
	CGA50720	4.307	7.144	3.250	3.199	3.552	2.330	3.188	5.869
	CGA357704	71.563	100.841	54.876	50.786	61.190	28.575	45.649	103.428
Maize, post-emergence, 1440 g/ha, biennial	S-metolachlor	0.001	0.017	0.006	0.018	0.009	0.002	0.000	0.000
	NOA436611	17.268	21.623	13.222	11.296	13.163	7.118	12.373	31.006
	CGA354743 (ESA)	31.704	41.204	24.241	19.858	27.062	13.301	33.937	70.154
	CGA51202 (OXA)	22.982	26.782	17.517	15.252	16.577	9.648	13.890	38.455
	CGA40172	0.000	0.006	0.001	0.008	0.002	0.000	0.000	0.000
	CGA368208	1.900	2.536	1.371	1.065	1.861	0.858	2.776	5.017

Use pattern	Compound	PEC_{GW} at 1 m soil depth [µg/L]							
		Chât	Ham	Kre	Oke	Pia	Por	Sev	Thi
	CGA37735	0.031	0.041	0.024	0.020	0.028	0.012	0.032	0.070
	CGA50720	2.165	3.456	1.681	1.493	1.606	1.041	1.742	3.412
	CGA357704	33.177	48.610	26.907	22.871	30.221	13.978	26.651	58.074
Maize, post-emergence, 1440 g/ha, triennial	S-metolachlor	0.001	0.010	0.005	0.010	0.005	0.001	0.000	0.000
	NOA436611	11.443	15.148	9.960	7.424	8.938	4.750	8.812	21.285
	CGA354743 (ESA)	21.620	28.671	17.899	13.369	17.948	8.621	23.344	49.411
	CGA51202 (OXA)	15.119	19.301	13.369	9.992	11.937	6.379	10.074	25.973
	CGA40172	0.000	0.002	0.000	0.003	0.001	0.000	0.000	0.000
	CGA368208	1.317	1.617	1.013	0.657	1.286	0.525	1.909	3.601
	CGA37735	0.021	0.029	0.018	0.013	0.018	0.008	0.022	0.049
	CGA50720	1.473	2.312	1.251	1.001	1.090	0.682	1.302	2.404
	CGA357704	22.909	32.930	19.317	14.809	17.540	9.090	21.290	42.257
	SYN547977[1] (ff = 0.1)	0.961	1.497	0.954	1.313	1.073	0.580	0.097	0.662
	SYN547977[1] (ff = 0.2572)	2.776	4.239	2.702	3.665	3.038	1.664	0.309	1.942
Maize, post-emergence, 1250 g/ha, annual	S-metolachlor	0.003	0.028	0.011	0.033	0.019	0.003	0.000	0.000
	NOA436611	30.869	41.600	22.928	20.139	27.268	13.969	20.734	45.490
	CGA354743 (ESA)	58.278	76.697	41.726	36.300	52.943	24.665	53.501	96.174
	CGA51202 (OXA)	38.803	54.602	30.439	27.198	34.879	18.225	25.225	57.580
	CGA40172	0.001	0.027	0.007	0.034	0.017	0.001	0.000	0.000
	CGA368208	3.611	4.335	2.449	1.989	3.759	1.526	4.101	6.803
	CGA37735	0.057	0.077	0.041	0.036	0.055	0.022	0.050	0.095
	CGA50720	3.712	6.239	2.836	2.788	3.076	2.037	2.767	5.086
	CGA357704	61.488	87.540	47.634	44.085	53.115	24.806	39.644	89.778
Maize, post-emergence, 1250 g/ha, biennial	S-metolachlor	0.001	0.014	0.005	0.015	0.007	0.001	0.000	0.000
	NOA436611	14.928	18.508	11.418	9.772	11.323	6.162	10.598	26.740
	CGA354743 (ESA)	27.504	35.716	21.021	17.222	23.433	11.534	29.375	60.818
	CGA51202 (OXA)	19.835	23.014	15.106	13.169	14.275	8.345	11.867	33.108
	CGA40172	0.000	0.004	0.000	0.005	0.001	0.000	0.000	0.000
	CGA368208	1.654	2.210	1.194	0.927	1.617	0.746	2.411	4.357
	CGA37735	0.027	0.036	0.021	0.017	0.024	0.010	0.028	0.060
	CGA50720	1.885	3.015	1.463	1.304	1.392	0.908	1.511	2.956
	CGA357704	28.799	42.198	23.356	19.853	26.231	12.134	23.144	50.409
Maize, post-emergence, 1250 g/ha, triennial	S-metolachlor	0.001	0.008	0.004	0.008	0.004	0.001	0.000	0.000
	NOA436611	9.884	13.037	8.614	6.415	7.723	4.108	7.553	18.327
	CGA354743 (ESA)	18.760	24.859	15.531	11.595	15.556	7.479	20.212	42.815
	CGA51202 (OXA)	13.042	16.583	11.550	8.617	10.306	5.511	8.612	22.332
	CGA40172	0.000	0.002	0.000	0.002	0.001	0.000	0.000	0.000
	CGA368208	1.147	1.410	0.882	0.573	1.117	0.457	1.658	3.126
	CGA37735	0.018	0.025	0.015	0.011	0.016	0.007	0.019	0.042
	CGA50720	1.283	2.015	1.090	0.873	0.948	0.596	1.129	2.081
	CGA357704	19.886	28.587	16.768	12.856	15.226	7.891	18.488	36.679
	SYN547977[1] (ff = 0.1)	0.817	1.279	0.814	1.123	0.917	0.495	0.081	0.562
	SYN547977[1] (ff = 0.2572)	2.367	3.625	2.309	3.139	2.602	1.421	0.259	1.651

[1] During the experts consultation (teleconference 28, 14-16 October 2020), the experts considered that in FOCUS simulation modelling for the active substance S-metolachlor a TSCF value of 0.3 would be appropriate for the crop maize and a value of 0.39 would be appropriate for other crops for which experimental data on those crops were not available. The experts also considered the available PEC_{GW} values calculated with an TSCF value of 0.17 sufficient for a Tier 1 groundwater risk assessment. Therefore, only the PEC_{GW} values for the relevant metabolite SYN547977 were re-calculated by the RMS using the updated TSCF values and formation fractions.

PEC_{GW} of S-metolachlor, NOA436611, CGA354743, CGA51202, CGA368208, CGA37735, CGA40172, CGA50720 and CGA357704 from FOCUS PELMO 5.5.3 for pre-emergent sunflower (TSCF = 0.17).

Use pattern	Compound	PEC_{GW} at 1 m soil depth [µg/L]	
		Piacenza	Sevilla
Sunflower, pre-emergence, 1440 g/ha, annual	S-metolachlor	0.093	<0.001
	NOA436611	30.825	35.418
	CGA354743 (ESA)	56.92	81.004
	CGA51202 (OXA)	39.89	42.157
	CGA40172	0.133	<0.001
	CGA368208	3.438	6.034
	CGA37735	0.056	0.074
	CGA50720	3.611	4.482
	CGA357704	67.08	67.977
Sunflower, pre-emergence, 1440 g/ha, biennial	S-metolachlor	0.038	<0.001
	NOA436611	15.6	16.905
	CGA354743 (ESA)	27.925	42.7
	CGA51202 (OXA)	20.439	19.184
	CGA40172	0.019	<0.001
	CGA368208	1.678	3.317
	CGA37735	0.027	0.039
	CGA50720	1.81	2.333
	CGA357704	29.721	35.414
Sunflower, pre-emergence, 1440 g/ha, triennial	S-metolachlor	0.033	<0.001
	NOA436611	9.626	10.872
	CGA354743 (ESA)	17.624	28.593
	CGA51202 (OXA)	12.748	12.664
	CGA40172	0.01	<0.001
	CGA368208	1.072	2.229
	CGA37735	0.017	0.026
	CGA50720	1.108	1.444
	CGA357704	18.481	21.629
	SYN547977[1] (ff = 0.1)	1.521	0.159
	SYN547977[1] (ff = 0.2572)	4.215	0.479
Sunflower, pre-emergence, 1250 g/ha, annual	S-metolachlor	0.076	<0.001
	NOA436611	26.595	30.675
	CGA354743 (ESA)	49.32	70.306
	CGA51202 (OXA)	34.461	36.146
	CGA40172	0.092	<0.001
	CGA368208	2.988	5.242
	CGA37735	0.049	0.064
	CGA50720	3.136	3.891
	CGA357704	58.215	59.007
Sunflower, pre-emergence, 1250 g/ha, biennial	S-metolachlor	0.031	<0.001
	NOA436611	13.49	14.538
	CGA354743 (ESA)	24.231	36.962
	CGA51202 (OXA)	17.658	16.407
	CGA40172	0.012	<0.001
	CGA368208	1.459	2.884
	CGA37735	0.024	0.034
	CGA50720	1.575	2.026
	CGA357704	25.799	30.751
Sunflower, pre-emergence, 1250 g/ha, triennial	S-metolachlor	0.027	<0.001
	NOA436611	8.32	9.364
	CGA354743 (ESA)	15.292	24.763
	CGA51202 (OXA)	11.023	10.877
	CGA40172	0.007	<0.001
	CGA368208	0.932	1.936
	CGA37735	0.015	0.023
	CGA50720	0.964	1.254
	CGA357704	16.045	18.781
	SYN547977[1] (ff = 0.1)	1.303	0.134
	SYN547977[1] (ff = 0.2572)	3.613	0.406

[1] During the experts consultation (teleconference 28, 14-16 October 2020), the experts considered that in FOCUS simulation modelling for the active substance S-metolachlor a TSCF value of 0.3 would be appropriate for the crop maize and a value of 0.39 would be appropriate for other crops for which experimental data on those crops were not available.

This means that for the representative uses on sunflower the TSCF of 0.39 can be used.

The experts also considered the available PEC_{GW} values calculated with an TSCF value of 0.17 sufficient for a Tier 1 groundwater risk assessment. Therefore, only the PEC_{GW} values for the relevant metabolite SYN547977 were re-calculated by the RMS using the updated TSCF values and formation fractions.

PEC_{GW} of S-metolachlor, NOA436611, CGA354743, CGA51202, CGA368208, CGA37735, CGA40172, CGA50720 and CGA357704 from FOCUS PEARL 4.4.4 for pre-emergent sunflower (TSCF = 0.17).

Use pattern	Compound	PEC_{GW} at 1 m soil depth [µg/L]	
		Piacenza	Sevilla
Sunflower, pre-emergence, 1440 g/ha, annual	S-metolachlor	0.027	0.000
	NOA436611	54.928	31.720
	CGA354743 (ESA)	112.035	78.066
	CGA51202 (OXA)	69.060	38.467
	CGA40172	0.056	0.000
	CGA368208	8.049	6.227
	CGA37735	0.116	0.073
	CGA50720	6.039	4.094
	CGA357704	108.074	59.264
Sunflower pre-emergence, 1440 g/ha, biennial	S-metolachlor	0.009	0.000
	NOA436611	20.547	18.673
	CGA354743 (ESA)	42.123	45.865
	CGA51202 (OXA)	26.435	21.959
	CGA40172	0.007	0.000
	CGA368208	3.060	3.596
	CGA37735	0.043	0.043
	CGA50720	2.392	2.487
	CGA357704	40.233	39.061
Sunflower, pre-emergence, 1440 g/ha, triennial	S-metolachlor	0.009	0.000
	NOA436611	13.133	10.619
	CGA354743 (ESA)	27.339	32.126
	CGA51202 (OXA)	17.294	12.288
	CGA40172	0.003	0.000
	CGA368208	1.997	2.560
	CGA37735	0.028	0.030
	CGA50720	1.575	1.427
	CGA357704	26.779	22.191
	SYN547977[1] (ff = 0.1)	1.388	0.161
	SYN547977[1] (ff = 0.2572)	3.866	0.509
Sunflower, pre-emergence, 1250 g/ha, annual	S-metolachlor	0.022	0.000
	NOA436611	47.334	27.334
	CGA354743 (ESA)	97.152	67.612
	CGA51202 (OXA)	59.477	33.186
	CGA40172	0.036	0.000
	CGA368208	6.996	5.411
	CGA37735	0.101	0.063
	CGA50720	5.235	3.555
	CGA357704	93.804	51.452
Sunflower, pre-emergence, 1250 g/ha, biennial	S-metolachlor	0.007	0.000
	NOA436611	17.758	16.040
	CGA354743 (ESA)	36.539	39.719
	CGA51202 (OXA)	22.819	18.819
	CGA40172	0.004	0.000
	CGA368208	2.661	3.124
	CGA37735	0.037	0.037
	CGA50720	2.077	2.157
	CGA357704	34.923	33.916
Sunflower, pre-emergence, 1250 g/ha, triennial	S-metolachlor	0.007	0.000
	NOA436611	11.326	9.124
	CGA354743 (ESA)	23.687	27.828
	CGA51202 (OXA)	14.924	10.534
	CGA40172	0.002	0.000
	CGA368208	1.735	2.224
	CGA37735	0.024	0.026

Use pattern	Compound	PEC_{GW} at 1 m soil depth [µg/L]	
		Piacenza	Sevilla
	CGA50720	1.367	1.235
	CGA357704	23.244	19.266
	SYN547977[1] (ff = 0.1)	1.188	0.135
	SYN547977[1] (ff = 0.2572)	3.313	0.428

[1] During the experts consultation (teleconference 28, 14-16 October 2020), the experts considered that in FOCUS simulation modelling for the active substance S-metolachlor a TSCF value of 0.3 would be appropriate for the crop maize and a value of 0.39 would be appropriate for other crops for which experimental data on those crops were not available. This means that for the representative uses on sunflower the TSCF of 0.39 can be used.
The experts also considered the available PEC_{GW} values calculated with an TSCF value of 0.17 sufficient for a Tier 1 groundwater risk assessment. Therefore, only the PEC_{GW} values for the relevant metabolite SYN547977 were re-calculated by the RMS using the updated TSCF values and formation fractions.

Lysimeter studies: Annual average concentrations in leachates (µg a.s. equivalents/L)

Substance	Lysimeter 17 (study 1) 1250 g/ha			Lysimeter 18 (study 1) 1250 g/ha			Lysimeter 3 (study 2) 1500 g/ha
	1st year	2nd year	3rd year	1st year	2nd year	3rd year	2nd year
S-metolachlor	0.08	< 0.05	< 0.05	< 0.01	< 0.05	< 0.05	< 0.1
CGA354743 (ESA)	9.52	9.10	1.08	16.93	27.96	6.18	29.3
CGA51202 (OXA)	3.86	1.80	0.25	4.76	16.29	0.98	24.1
CGA368208	6.45	3.96	0.05	7.31	7.82	2.73	2.4
CGA50720	1.22	0.03	< 0.05	2.10	4.71	< 0.05	n.d.
CGA357704	n.d.	0.19	0.07	n.d.	5.11	0.40	5.3
CGA37735	n.d.	0.54	0.16	n.d.	0.98	0.70	n.d.
NOA413173	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	3.0
NOA436611	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	1.8
SYN542489	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	5.1
SYN542488	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.8
SYN542490	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	3.1
SYN542491	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	1.2
SYN542492	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	1.7
SYN542607	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	2.4
SYN547969	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	2.0
SYN547977	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.1

Field leaching studies: Annual average concentrations (µg/L)

S-metolachlor		Annual average (µg/L)					
US field leaching study (calculated data at proposed EU GAP)	Year	1st year	2nd year	3rd year	4th year	-	-
	Lysimeter 0.9 m	<0.1	<0.1	<0.1	n.a.	-	-
	Lysimeter 1.8 m	0.08	<0.1	<0.1	n.a.	-	-
	Lysimeter 2.7 m	0.02	<0.1	<0.1	n.a.	-	-
	Lysimeter 4.0 m	0.02	<0.1	<0.1	n.a.	-	-
	Shallow well	<0.1	<0.1	<0.1	<0.1	-	-
	Deep well	<0.1	<0.1	<0.1	<0.1	-	-
German field leaching study	Year	5/1995-5/1996	5/1997-5/1998	5/1999-5/2000	5/2000-4/2001	5/2002-4/2003	6/2003-4/2004
	Well B1	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05

Metabolite OXA		**Annual average (µg/L)**					
US field leaching study (calculated data at proposed EU GAP)	Year	**1st year**	**2nd year**	**3rd year**	**4th year**	-	-
	Lysimeter 0.9 m	0.5	<0.1	<0.1	n.a.	-	-
	Lysimeter 1.8 m	6.1	<0.1	<0.1	n.a.	-	-
	Lysimeter 2.7 m	3.2	0.6	<0.1	n.a.	-	-
	Lysimeter 4.0 m	2.1	1.2	<0.1	n.a.	-	-
	Shallow well	0.1	0.9	0.2	<0.1	-	-
	Deep well	<0.1	0.1	<0.1	<0.1	-	-
German field leaching study	Year	**5/1995-5/1996**	**5/1997-5/1998**	**5/1999-5/2000**	**5/2000-4/2001**	**5/2002-4/2003**	**6/2003-4/2004**
	Well B9	3.85	7.46	7.73	9.02	10.47	10.73

Metabolite ESA		**Annual average (µg/L)**					
US field leaching study (calculated data at proposed EU GAP)	Year	**1st year**	**2nd year**	**3rd year**	**4th year**	-	-
	Lysimeter 0.9 m	1.6	<0.1	<0.1	n.a.	-	-
	Lysimeter 1.8 m	12.4	0.7	0.1	n.a.	-	-
	Lysimeter 2.7 m	7.0	2.8	0.1	n.a.	-	-
	Lysimeter 4.0 m	5.7	5.5	0.3	n.a.	-	-
	Shallow well	0.3	2.5	1.9	0.2	-	-
	Deep well	<0.1	0.1	0.3	<0.1	-	-
German field leaching study	**Year**	**5/1995-5/1996**	**5/1997-5/1998**	**5/1999-5/2000**	**5/2000-4/2001**	**5/2002-4/2003**	**6/2003-4/2004**
	Well B1	0.11	0.1	0.42	1.06	26.47	19.70
	Well B4	9.32	6.42	9.63	14.51	14.58	22.31
	Well B5	20.12	21.71	32.99	34.79	17.48	26.89
	Well B6	12.08	13.25	17.35	16.67	19.00	29.63
	Well B9	19.13	20.67	20.98	26.79	25.97	23.69

PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

Parent

Parameters used in FOCUSsw step 1-4

Version control no. of FOCUS calculator:
Molecular weight: 283.8
Water solubility: 480
DT_{50} soil: 30.1
K_{FOC}: 200 mL/g
DT_{50} Total system: 43.3 d
DT_{50} water: 43.3 (Step 1/2 and 3) and 1000 d (Step 3)
DT_{50} sediment: 43.3 (Step 1/2 and 3/4) and 1000 d (Step 3)
Vapour pressure: 0

	Freundlich exponent (1/n): 0.93 TSCF: 0.3 (maize) / 0.39 (other crops for which experimental data is not available)[1] [1] The simulations were performed by the applicant with a TSCF value of 0.39. During the expert's consultation (teleconference 28, 14-16 October 2020), the experts considered that in FOCUS simulation modelling for the active substance S-metolachlor a TSCF value of 0.3 would be appropriate for the crop maize and a value of 0.39 would be appropriate for other crops for which experimental data on those crops were not available. However, the RMS performed PEC_{SW}/sed simulations with a TSCF value of 0 in order to check the impact of this parameter on the resulting PEC values. The results obtained differed only slightly from the values simulated by the notifier using a TSCF value of 0.39. Therefore, the RMS decided not to repeat the PEC simulations with adjusted TSCF values. For future FOCUS simulations TSCF values of 0.3 (maize) and 0.39 (other crops for which experimental data is not available) should be used.
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of software: PRZM 4.3.1, MACRO 5.5.4 and TOXSWA 4.4.3. Step 4: SWAN 4.0.1 Water solubility (mg/L): 480 Vapour pressure: 0 Pa at 20 °C K_{FOC}: 200mL/g 1/n: 0.93 Q_{10}=2.58, Walker equation coefficient 0.7 Crop uptake factor: 0.39[1]
Application rate	Crop and growth stage: Maize: BBCH 00-10 and 10-18 Sunflower: BBCH 00-10 Number of applications: 1 Application rate(s): BBCH 00-09: 1440, 1250 g a.s./ha BBCH 10-18: 1440, 1250, g a.s./ha Application window:

Growth stage [approx. BBCH]	Scenario	First date of application window	Last date of application window
Maize BBCH 00	D3	21-Apr (111)	21-May (141)
	D4	26-Apr (116)	26-May (146)
	D5	26-Apr (116)	26-May (146)
	D6	06-Apr (96)	06-May (126)
	R1	19-Apr (109)	19-May (139)
	R2	17-Apr (107)	17-May (137)
	R3	17-Apr (107)	17-May (137)
	R4	27-Mar (86)	26-Apr (116)
Sunflower BBCH 00	D5	17-Apr (107)	17-May (137)
	R1	17-Apr (107)	17-May (137)
	R3	01-Apr (91)	01-May (121)
	R4	16-Mar (75)	15-Apr (105)
Maize BBCH 10	D3	09-May(129)	08-June (159)
	D4	14-May(134)	13-June (164)
	D5	13-May(133)	12-June (163)
	D6	23-Apr (113)	23-May (143)
	R1	07-May(127)	06-June (157)
	R2	06-May(126)	05-June (156)
	R3	05-May(125)	04-June (155)
	R4	13-Apr (103)	13-May (133)

Overall initial PEC_{SW} and PEC_{SED} of S-metolachlor (Steps 1-2)

Crop	Step	Number of applications	Region (Timing)	Max. PEC_{SW} [µg/L]	Max. PEC_{SED} [µg/kg]
Maize (1 x 1440 g a.s./ha, BBCH 00-10)	1	1		392.19	766.44
	2	1	North Europe (Mar-May)	79.67	155.35
		1	South Europe (Mar-May)	148.79	291.39

Global maximum Predicted Environmental Concentrations of S-metolachlor in surface water at Step 3 following pre-emergence applications to maize

Application rate and timing [g a.s./ha]	Scenario	Water body	PEC_{SW} [µg/L]	PEC_{SED} [µg/L]	Main route of entry to water body for max. PEC_{SW}
Maize 1 x 1440g BBCH 0 DT_{50}, water 43.3d DT_{50}, sed 1000d	D3	Ditch	7.55	2.10	Drift
	D4	Pond	0.894	2.83	Drainage
	D4	Stream	6.26	1.18	Drift
	D5	Pond	0.585	2.13	Drift
	D5	Stream	6.83	0.883	Drift
	D6	Ditch	7.58	2.40	Drift
	R1	Pond	0.702	1.62	Run-off
	R1	Stream	19.5	4.08	Run-off
	R2	Stream	15.2	3.69	Run-off
	R3	Stream	48.3	41.9	Run-off
	R4	Stream	49.1	14.4	Run-off
Maize 1 x 1440g BBCH 0 DT_{50}, water 1000d DT_{50}, sed 43.3d	D3	Ditch	7.55	2.1	Drift
	D4	Pond	0.974	2.85	Drainage
	D4	Stream	6.26	1.06	Drift
	D5	Pond	0.683	2.11	Drift
	D5	Stream	6.83	0.769	Drift
	D6	Ditch	7.58	2.37	Drift
	R1	Pond	0.770	1.70	Run-off
	R1	Stream	19.6	4.07	Run-off
	R2	Stream	15.3	3.68	Run-off
	R3	Stream	48.3	41.8	Run-off
	R4	Stream	49.1	14.3	Run-off
Maize 1 x 1250g BBCH 0 DT_{50}, water 43.3d DT_{50}, sed 1000d	D3	Ditch	6.55	1.83	Drift
	D4	Pond	0.775	2.46	Drainage
	D4	Stream	5.44	1.03	Drift
	D5	Pond	0.504	1.85	Drift
	D5	Stream	5.93	0.760	Drift
	D6	Ditch	6.58	2.09	Drift
	R1	Pond	0.612	1.42	Run-off
	R1	Stream	16.9	3.54	Run-off
	R2	Stream	13.2	3.20	Run-off
	R3	Stream	41.7	36.6	Run-off
	R4	Stream	42.5	12.5	Run-off
Maize 1 x 1250g BBCH 0 DT_{50}, water 1000d	D3	Ditch	6.55	1.83	Drift
	D4	Pond	0.844	2.48	Drainage
	D4	Stream	5.44	0.924	Drift
	D5	Pond	0.589	1.83	Drift
	D5	Stream	5.93	0.663	Drift
	D6	Ditch	6.58	2.06	Drift

Application rate and timing [g a.s./ha]	Scenario	Water body	PEC_{SW} [µg/L]	PEC_{SED} [µg/L]	Main route of entry to water body for max. PEC_{SW}
DT_{50}, sed 43.3d	R1	Pond	0.673	1.49	Run-off
	R1	Stream	16.9	3.53	Run-off
	R2	Stream	13.2	3.19	Run-off
	R3	Stream	41.7	36.5	Run-off
	R4	Stream	42.5	12.5	Run-off

Global maximum Predicted Environmental Concentrations of S-metolachlor in surface water at Step 3 following pre-emergence applications to sunflower

Application rate and timing [g a.s./ha]	Scenario	Water body	PEC_{SW} [µg/L]	PEC_{SED} [µg/L]	Main route of entry to water body for max. PEC_{SW}
Sunflower 1 x 1440g BBCH 0 DT_{50}, water 43.3d DT_{50}, sed 1000d	D5	Pond	0.534	1.81	Drift
	D5	Stream	6.91	0.811	Drift
	R1	Pond	0.774	1.76	Run-off
	R1	Stream	17.5	3.63	Run-off
	R3	Stream	50.3	9.00	Run-off
	R4	Stream	45.6	13.4	Run-off
Sunflower 1 x 1440g BBCH 0 DT_{50}, water 1000d DT_{50}, sed 43.3d	D5	Pond	0.609	1.78	Drift
	D5	Stream	6.91	0.721	Drift
	R1	Pond	0.850	1.85	Run-off
	R1	Stream	17.5	3.62	Run-off
	R3	Stream	50.4	8.89	Run-off
	R4	Stream	45.6	13.4	Run-off
Sunflower 1 x 1250g BBCH 0 DT_{50}, water 43.3d DT_{50}, sed 1000d	D5	Pond	0.461	1.57	Drift
	D5	Stream	5.99	0.700	Drift
	R1	Pond	0.674	1.54	Run-off
	R1	Stream	15.1	3.15	Run-off
	R3	Stream	43.4	7.84	Run-off
	R4	Stream	39.4	11.7	Run-off
Sunflower 1 x 1250g BBCH 0 DT_{50}, water 1000d DT_{50}, sed 43.3d	D5	Pond	0.526	1.54	Drift
	D5	Stream	5.99	0.623	Drift
	R1	Pond	0.743	1.63	Run-off
	R1	Stream	15.1	3.14	Run-off
	R3	Stream	43.4	7.74	Run-off
	R4	Stream	39.4	11.6	Run-off

Global maximum Predicted Environmental Concentrations of S-metolachlor in surface water at Step 3 following post-emergence applications to maize

Application rate and timing [g a.s./ha]	Scenario	Water body	PEC_{SW} [µg/L]	PEC_{SED} [µg/L]	Main route of entry to water body for max. PEC_{SW}
Maize 1 x 1440g BBCH 11 DT_{50}, water 43.3d DT_{50}, sed 1000d	D3	Ditch	7.56	2.22	Drift
	D4	Pond	1.17	3.52	Drainage
	D4	Stream	6.50	1.48	Drift
	D5	Pond	0.771	2.91	Drainage
	D5	Stream	6.87	1.08	Drift
	D6	Ditch	7.59	2.39	Drift
	R1	Pond	1.28	2.62	Run-off
	R1	Stream	22.4	5.48	Run-off
	R2	Stream	16.2	4.68	Run-off
	R3	Stream	43.0	10.0	Run-off
	R4	Stream	50.8	14.9	Run-off

Maize 1 x 1440g BBCH 11 DT_{50}, water 1000d DT_{50}, sed 43.3d	D3	Ditch	7.56	2.23	Drift
	D4	Pond	1.27	3.60	Drainage
	D4	Stream	6.50	1.35	Drift
	D5	Pond	0.903	2.91	Drainage
	D5	Stream	6.87	0.859	Drift
	D6	Ditch	7.59	2.35	Drift
	R1	Pond	1.37	2.77	Run-off
	R1	Stream	22.4	5.46	Run-off
	R2	Stream	16.2	4.67	Run-off
	R3	Stream	43.0	9.97	Run-off
	R4	Stream	50.8	14.8	Run-off
Maize 1 x 1250g BBCH 11 DT_{50}, water 43.3d DT_{50}, sed 1000d	D3	Ditch	6.56	1.94	Drift
	D4	Pond	1.02	3.06	Drainage
	D4	Stream	5.64	1.29	Drift
	D5	Pond	0.667	2.53	Drainage
	D5	Stream	5.96	0.93	Drift
	D6	Ditch	6.59	2.08	Drift
	R1	Pond	1.12	2.29	Run-off
	R1	Stream	19.4	4.78	Run-off
	R2	Stream	14.0	4.05	Run-off
	R3	Stream	37.2	8.68	Run-off
	R4	Stream	43.9	12.9	Run-off
Maize 1 x 1250g BBCH 11 DT_{50}, water 1000d DT_{50}, sed 43.3d	D3	Ditch	6.56	1.94	Drift
	D4	Pond	1.10	3.13	Drainage
	D4	Stream	5.64	1.18	Drift
	D5	Pond	0.781	2.52	Drainage
	D5	Stream	5.96	0.740	Drift
	D6	Ditch	6.59	2.04	Drift
	R1	Pond	1.19	2.43	Run-off
	R1	Stream	19.4	4.76	Run-off
	R2	Stream	14.0	4.04	Run-off
	R3	Stream	37.2	8.65	Run-off
	R4	Stream	43.9	12.9	Run-off

Global Maximum Predicted Environmental Concentrations of S-metolachlor in surface water at Step 4; 10m Drift Buffer with a 60% run-off buffer and 20m Drift Buffer with a 80% run-off buffer following pre- emergence applications to maize

Application rate and timing [g a.s./ha]	Scenario	Water body	PEC_{SW} [µg/L]	
Spray-drift buffer			10 m	20m
Run-off mitigation			60%	80%
Maize 1 x 1440g BBCH 0 DT_{50}, water 43.3d DT_{50}, sed 1000d	D3	Ditch	1.31	0.682
	D4	Pond	0.890	0.887
	D4	Stream	1.44	1.10
	D5	Pond	0.511	0.509
	D5	Stream	1.62	0.890
	D6	Ditch	1.34	0.714
	R1	Pond	0.34	0.193
	R1	Stream	8.29	4.23
	R2	Stream	6.83	3.56
	R3	Stream	22.0	11.6
	R4	Stream	22.3	11.7
	D3	Ditch	1.31	0.682

Maize 1 x 1440g BBCH 0 DT_{50}, water 1000d DT_{50}, sed 43.3d	D4	Pond	0.959	0.949
	D4	Stream	1.44	1.10
	D5	Pond	0.603	0.593
	D5	Stream	1.62	0.890
	D6	Ditch	1.35	0.714
	R1	Pond	0.373	0.211
	R1	Stream	8.29	4.23
	R2	Stream	6.83	3.56
	R3	Stream	22.0	11.6
	R4	Stream	22.3	11.7
Maize 1 x 1250g BBCH 0 DT_{50}, water 43.3d DT_{50}, sed 1000d	D3	Ditch	1.14	0.592
	D4	Pond	0.772	0.769
	D4	Stream	1.25	0.954
	D5	Pond	0.442	0.440
	D5	Stream	1.41	0.772
	D6	Ditch	1.17	0.619
	R1	Pond	0.297	0.168
	R1	Stream	7.16	3.66
	R2	Stream	5.89	3.07
	R3	Stream	19.0	9.99
	R4	Stream	19.3	10.1
Maize 1 x 1250g BBCH 0 DT_{50}, water 1000d DT_{50}, sed 43.3d	D3	Ditch	1.14	0.592
	D4	Pond	0.832	0.823
	D4	Stream	1.25	0.954
	D5	Pond	0.522	0.513
	D5	Stream	1.41	0.772
	D6	Ditch	1.17	0.619
	R1	Pond	0.326	0.184
	R1	Stream	7.17	3.66
	R2	Stream	5.89	3.07
	R3	Stream	19.0	9.99
	R4	Stream	19.3	10.1

Global Maximum Predicted Environmental Concentrations of S-metolachlor in surface water at Step 4; 10m Drift Buffer with a 60% run-off buffer and 20m Drift Buffer with a 80% run-off buffer following pre- emergence applications to sunflower

Application rate and timing [g a.s./ha]	Scenario	Water body	PEC_{SW} [µg/L]	
Spray-drift buffer			10 m	20m
Run-off mitigation			60%	80%
Sunflower 1 x 1440g BBCH 0 DT_{50}, water 43.3d DT_{50}, sed 1000d	D5	Pond	0.431	0.419
	D5	Stream	1.62	0.879
	R1	Pond	0.369	0.207
	R1	Stream	7.37	3.75
	R3	Stream	21.5	11.0
	R4	Stream	20.7	10.9
Sunflower 1 x 1440g BBCH 0 DT_{50}, water 1000d DT_{50}, sed 43.3d	D5	Pond	0.508	0.487
	D5	Stream	1.62	0.879
	R1	Pond	0.405	0.227
	R1	Stream	7.37	3.75
	R3	Stream	21.5	11.0
	R4	Stream	20.7	10.9
Sunflower 1 x 1250g BBCH 0 DT_{50}, water 43.3d DT_{50}, sed 1000d	D5	Pond	0.373	0.363
	D5	Stream	1.41	0.763
	R1	Pond	0.322	0.181
	R1	Stream	6.37	3.24
	R3	Stream	18.5	9.47
	R4	Stream	17.9	9.39
Sunflower 1 x 1250g BBCH 0 DT_{50}, water 1000d DT_{50}, sed 43.3d	D5	Pond	0.439	0.421
	D5	Stream	1.41	0.763
	R1	Pond	0.355	0.199
	R1	Stream	6.37	3.24
	R3	Stream	18.6	9.48
	R4	Stream	17.9	9.39

Global Maximum Predicted Environmental Concentrations of S-metolachlor in surface water at Step 4; 10m Drift Buffer with a 60% run-off buffer and 20m Drift Buffer with a 80% run-off buffer following post- emergence applications to maize

Application rate and timing [g a.s./ha]	Scenario	Water body	PEC_{SW} [µg/L]	
Spray-drift buffer			10 m	20m
Run-off mitigation			60%	80%
Maize 1 x 1440g BBCH 11 DT_{50}, water 43.3d DT_{50}, sed 1000d	D3	Ditch	1.31	0.682
	D4	Pond	1.17	1.16
	D4	Stream	1.49	1.47
	D5	Pond	0.768	0.765
	D5	Stream	1.64	0.911
	D6	Ditch	1.35	0.719
	R1	Pond	0.577	0.313
	R1	Stream	10.1	5.29
	R2	Stream	7.15	3.70
	R3	Stream	19.4	10.2
	R4	Stream	23.1	12.1
Maize 1 x 1440g BBCH 11 DT_{50}, water 1000d DT_{50}, sed 43.3d	D3	Ditch	1.31	0.682
	D4	Pond	1.25	1.24
	D4	Stream	1.49	1.47
	D5	Pond	0.887	0.875
	D5	Stream	1.64	0.911
	D6	Ditch	1.35	0.719
	R1	Pond	0.621	0.338
	R1	Stream	10.1	5.29
	R2	Stream	7.15	3.70
	R3	Stream	19.4	10.2
	R4	Stream	23.1	12.1
Maize 1 x 1250g BBCH 11 DT_{50}, water 43.3d DT_{50}, sed 1000d	D3	Ditch	1.14	0.593
	D4	Pond	1.01	1.01
	D4	Stream	1.30	1.27
	D5	Pond	0.664	0.662
	D5	Stream	1.43	0.790
	D6	Ditch	1.17	0.623
	R1	Pond	0.504	0.273
	R1	Stream	8.78	4.59
	R2	Stream	6.16	3.19
	R3	Stream	16.8	8.78
	R4	Stream	20.0	10.5
Maize 1 x 1250g BBCH 11	D3	Ditch	1.14	0.593
	D4	Pond	1.09	1.08
	D4	Stream	1.30	1.27
	D5	Pond	0.767	0.756
	D5	Stream	1.43	0.790
	D6	Ditch	1.17	0.624

Application rate and timing [g a.s./ha]	Scenario	Water body	PEC_{SW} [µg/L]	
Spray-drift buffer			10 m	20m
Run-off mitigation			60%	80%
DT_{50}, water 1000d DT_{50}, sed 43.3d	R1	Pond	0.542	0.295
	R1	Stream	8.78	4.59
	R2	Stream	6.16	3.19
	R3	Stream	16.8	8.78
	R4	Stream	20.0	10.5

Metabolites	See separate input boxes below
Parameters used in FOCUSsw step 1 and 2	
Parameters used in FOCUSsw step 3 (if performed)	Not applicable
Application rate	Crop and growth stage: wheat BBCH 00-10 Number of applications: 1 Interval (d): - Application rate(s): 1440 g a.s./ha Application window: not applicable

Summary of input parameters for ESA (CGA354743) used in FOCUS Step 1 & 2 simulations

Parameter	Value	Units	Notes
ESA (CGA354743)			
Molecular weight	329.4	g/mol	
Water solubility	500000	mg/L	Assumed value
Vapour pressure	NA	Pa	
DT_{50} soil	235*	d	Geometric mean (n=11)
Maximum formation	23.6	%	
K_{FOC}	7	L/kg	Geometric mean (n=7)
DT_{50} Total system	1000	d	FOCUS default
DT_{50} water	1000	d	FOCUS default
DT_{50} sediment	1000	d	FOCUS default
Maximum formation in total water/sediment system	8.5		

*In future calculations154.4 should be used

NA – not applicable

Summary of input parameters for OXA (CGA51202) used in FOCUS Step 1 & 2 simulations

Parameter	Value	Units	Notes
CGA51202			
Molecular weight	279.3	g/mol	
Water solubility	360000	mg/L	25ºC
Vapour pressure	NA	Pa	
DT_{50} soil	152*	d	Geometric mean (n=11)
Maximum formation	21.1	%	
K_{FOC}	12	L/kg	Geometric mean (n=7)
DT_{50} Total system	1000	d	FOCUS default
DT_{50} water	1000	d	FOCUS default
DT_{50} sediment	1000	d	FOCUS default
Maximum formation in total water/sediment system	21.2	%	

*In future calculations 98.1 should be used

NA – not applicable

Summary of input parameters for CGA40172 used in FOCUS Step 1 & 2 simulations

Parameter	Value	Units	Notes
CGA40172			
Molecular weight	265.3	g/mol	
Water solubility	500000	mg/L	Conservative assumption
Vapour pressure	NA	Pa	
DT_{50} soil	133	d	FOCUS default
Maximum formation	6.5	%	
K_{FOC}	174	L/kg	Geometric mean (n=3)
DT_{50} Total system	1000	d	FOCUS default
DT_{50} water	1000	d	FOCUS default
DT_{50} sediment	1000	d	FOCUS default
Maximum formation in total water/sediment system	0.01	%	Not observed

NA – not applicable

Summary of input parameters for CGA50720 used in FOCUS Step 1 & 2 simulations

Parameter	Value	Units	Notes
CGA50720			
Molecular weight	207.2	g/mol	
Water solubility	210000	mg/L	
Vapour pressure	NA	Pa	
DT_{50} soil	1000	d	FOCUS default
Maximum formation	8.2	%	
K_{FOC}	1.0	L/kg	Conservative assumption
DT_{50} Total system	1000	d	FOCUS default
DT_{50} water	1000	d	FOCUS default
DT_{50} sediment	1000	d	FOCUS default
Maximum formation in total water/sediment system	0.01	%	Not observed

NA – not applicable

Summary of input parameters for CGA368208 used in FOCUS Step 1 & 2 simulations

Parameter	Value	Units	Notes
CGA368208			
Molecular weight	257.3	g/mol	
Water solubility	500000	mg/L	Conservative assumption
Vapour pressure	NA	Pa	
DT_{50} soil	1000	d	FOCUS default
Maximum formation	7.6	%	
K_{FOC}	1.0	L/kg	Conservative assumption
DT_{50} Total system	1000	d	FOCUS default
DT_{50} water	1000	d	FOCUS default
DT_{50} sediment	1000	d	FOCUS default
Maximum formation in total water/sediment system	0.01	%	Not observed

NA – not applicable

Summary of input parameters for CGA37735 used in FOCUS Step 1 & 2 simulations

Parameter	Value	Units	Notes
CGA37735			
Molecular weight	193.2	g/mol	
Water solubility	500000	mg/L	Conservative assumption
Vapour pressure	NA	Pa	
DT_{50} soil	1000	d	FOCUS default
Maximum formation	7.1	%	
K_{FOC}	10.3	L/kg	Geometric mean (n = 5)
DT_{50} Total system	1000	d	FOCUS default
DT_{50} water	1000	d	FOCUS default
DT_{50} sediment	1000	d	FOCUS default
Maximum formation in total water/sediment system	0.01	%	Not observed

NA – not applicable

Summary of input parameters for NOA436611 used in FOCUS Step 1 & 2 simulations

Parameter	Value	Units	Notes
NOA436611			
Molecular weight	355.45	g/mol	
Water solubility	500000	mg/L	Conservative assumption
Vapour pressure	NA	Pa	
DT_{50} soil	1000	d	FOCUS default
Maximum formation	9.1	%	
K_{FOC}	8.4	L/kg	Geometric mean (n = 5)
DT_{50} Total system	1000	d	FOCUS default
DT_{50} water	1000	d	FOCUS default
DT_{50} sediment	1000	d	FOCUS default
Maximum formation in total water/sediment system	0.01	%	Not observed

NA – not applicable

Summary of input parameters for CGA41507 used in FOCUS Step 1 & 2 simulations

Parameter	Value	Units	Notes
CGA41507			
Molecular weight	244.3	g/mol	
Water solubility	2600	mg/L	25oC
Vapour pressure	NA	Pa	
DT_{50} soil	1000	d	FOCUS default
Maximum formation	0.7	%	
K_{FOC}	86.5	L/kg	Geometric mean (n = 3)
DT_{50} Total system	1000	d	FOCUS default
DT_{50} water	1000	d	FOCUS default
DT_{50} sediment	1000	d	FOCUS default
Maximum formation in total water/sediment system	17.8	%	

NA – not applicable

Summary of input parameters for CGA357704 used in FOCUS Step 1 & 2 simulations (RMS calculation)

Parameter	Value	Units	Notes
CGA357704			
Molecular weight	279.30	g/mol	
Water solubility	500000	mg/L	Conservative assumption
Vapour pressure	NA	Pa	
DT_{50} soil	136	d	
Maximum formation	21.9	%	
K_{FOC}	1.0	L/kg	Conservative assumption
DT_{50} Total system	1000	d	FOCUS default
DT_{50} water	1000	d	FOCUS default
DT_{50} sediment	1000	d	FOCUS default
Maximum formation in total water/sediment system	0.01	%	Not observed

NA – not applicable

Overall initial PEC_{SW} and PEC_{SED} of S-metolachlor (Steps 1-2)

Crop	Step	Number of applications	Region (Timing)	Max. PEC_{SW} [µg/L]	Max. PEC_{SED} [µg/kg]
Maize (1 x 1440 g a.s./ha, BBCH 00-10)	1	1		392.19	766.44
	2	1	North Europe (Mar-May)	79.67	155.35
		1	South Europe (Mar-May)	148.79	291.39

Overall initial PECSW and PECSED of ESA (CGA354743) (Steps 1-2)

Crop	Step	Number of applications	Region (Timing)	Max. PEC_{SW} [µg/L]	Max. PEC_{SED} [µg/kg]
Maize (1 x 1440 g a.s./ha, BBCH 00-10)	1	1		178.49	12.48
	2	1	North Europe (Mar-May)	35.60	2.49
		1	South Europe (Mar-May)	69.91	4.89

Overall initial PEC_{SW} and PEC_{SED} of OXA (CGA51202) (Steps 1-2)

Crop	Step	Number of applications	Region (Timing)	Max. PEC_{SW} [µg/L]	Max. PEC_{SED} [µg/kg]
Maize (1 x 1440 g a.s./ha, BBCH 00-10)	1	1		199.44	23.91
	2	1	North Europe (Mar-May)	39.98	4.79
		1	South Europe (Mar-May)	77.22	9.26

Overall initial PEC_{SW} and PEC_{SED} of CGA40172 (Steps 1-2)

Crop	Step	Number of applications	Region (Timing)	Max. PEC_{SW} [µg/L]	Max. PEC_{SED} [µg/kg]
Maize (1 x 1440 g a.s./ha, BBCH 00-10)	1	1		23.71	41.26
	2	1	North Europe (Mar-May)	4.64	8.08
		1	South Europe (Mar-May)	9.29	16.16

Overall initial PEC_{SW} and PEC_{SED} of CGA50720 (Steps 1-2)

Crop	Step	Number of applications	Region (Timing)	Max. PEC_{SW} [µg/L]	Max. PEC_{SED} [µg/kg]
Maize (1 x 1440 g a.s./ha, BBCH 00-10)	1	1		28.73	0.29
	2	1	North Europe (Mar-May)	5.73	0.06
		1	South Europe (Mar-May)	11.46	0.11

Overall initial PEC_{SW} and PEC_{SED} of CGA368208 (Steps 1-2)

Crop	Step	Number of applications	Region (Timing)	Max. PEC_{SW} [µg/L]	Max. PEC_{SED} [µg/kg]
Maize (1 x 1440 g a.s./ha, BBCH 00-10)	1	1		33.07	0.33
	2	1	North Europe (Mar-May)	6.60	0.07
		1	South Europe (Mar-May)	13.19	0.13

Overall initial PEC_{SW} and PEC_{SED} of CGA37735 (Steps 1-2)

Crop	Step	Number of applications	Region (Timing)	Max. PEC_{SW} [µg/L]	Max. PEC_{SED} [µg/kg]
Maize (1 x 1440 g a.s./ha, BBCH 00-10)	1	1		22.92	2.36
	2	1	North Europe (Mar-May)	4.57	0.47
		1	South Europe (Mar-May)	9.14	0.94

Overall initial PEC_{SW} and PEC_{SED} of NOA436611 (Steps 1-2)

Crop	Step	Number of applications	Region (Timing)	Max. PEC_{SW} [µg/L]	Max. PEC_{SED} [µg/kg]
Maize (1 x 1440 g a.s./ha, BBCH 00-10)	1	1		54.16	4.55
	2	1	North Europe (Mar-May)	10.8	0.91
		1	South Europe (Mar-May)	21.6	1.81

Overall initial PEC_{SW} and PEC_{SED} of CGA41507 (Steps 1-2)

Crop	Step	Number of applications	Region (Timing)	Max. PEC_{SW} [µg/L]	Max. PEC_{SED} [µg/kg]
Maize (1 x 1440 g a.s./ha, BBCH 00-10)	1	1		70.57	60.82
	2	1	North Europe (Mar-May)	14.43	12.42
		1	South Europe (Mar-May)	26.97	23.26

Overall initial PEC_{SW} and PEC_{SED} of CGA357704 (Steps 1-2)

Crop	Step	Number of applications	Region (Timing)	Max. PEC_{SW} [µg/L]	Max. PEC_{SED} [µg/kg]
Maize (1 x 1440 g a.s./ha, BBCH 00-10)	1	1		103.36	1.03
	2	1	North Europe (Mar-May)	20.26	0.20
		1	South Europe (Mar-May)	40.52	0.41

Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation	Not relevant

PEC

Maximum concentration	-

Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
Coturnix japonica	'A9396B' (S-metolachlor EC) syn. DualGold (CGH 060-97)	Acute	LD_{50} LD_{50} (extrapolated) [1]	≥2000 mg/kg bw=3776 mg/kg bw
Anas platyrhynchos	CGA 77102 (S-metolachlor)	Acute	LD_{50} LD_{50} (extrapolated) [1]	≥2510 mg/kg bw =4739 mg/kg bw
Colinus virginianus	CGA 77102 (S-metolachlor)	Acute	LD_{50} LD_{50} (extrapolated) [1]	≥2510 mg/kg bw =4739 mg/kg bw
Anas platyrhynchos	CGA 77102 (S-metolachlor)	Short-term (8 days)	LC_{50}	≥5620 mg/kg diet
Colinus virginianus	CGA 77102 (S-metolachlor)	Short-term (8 days)	LC_{50}	≥5620 mg/kg diet
Anas platyrhynchos	CGA 24705 (metolachlor)	Long-term (17 weeks)	NOAEL	=114 mg/kg bw per day
Colinus virginianus	CGA 24705 (metolachlor)	Long-term	NOAEL	87.5 mg/kg bw per day
Colinus virginianus	CGA 77102 (S-metolachlor)	Long-term	NOAEL	=87.4 mg/kg bw per day
Mammals				
Rat	CGA 77102 (S-metolachlor)	Acute	LD_{50}	≥2000
Rat	A9396B	Acute	LD_{50}	=2149 (females) =3937 (males)
Rat	CGA 24705 (metolachlor)	Long-term (2-generation-study)	Ecological relevant NOAEL	=17.7

Endocrine disrupting properties (Annex Part A, points 8.1.5) The peer review conclusion will be finalised without the ED assessment following the receipt of the mandate in September 2022.

Mammals

The assessment of the endocrine disrupting properties for wild mammals could not by finalized due to missing level 5 test in accordance with the latest test protocols. (To investigate further the missing EAS-mediated parameters. This was triggered by some positive findings related to anti-androgenic endocrine activity.)

Birds

According to the ECHA/EFSA ED guidance the available number of standardised in vivo methods for birds is limited and only little information can be gained from the existing guidelines concerning potential ED-related effects. The avian reproduction toxicity test (OECD TG 206) gives a list of parameters that might be endocrine-sensitive but which cannot be considered specific for the identification of an endocrine MoA (`sensitive to, but not diagnostic of, EATS´).

In two studies with *Colinus virginanus* ([redacted] 1978b and [redacted] et al. 1996a) some egg parameters were significantly decreased in the mid-dose. This comes along with a significantly reduced number of total normal hatchlings in the mid dose and mariginal effects in the highest dose group.

Additional higher tier studies (Annex Part A, points 10.1.1.2):

- Mammals: three generic field studies
  - [redacted] et al. (2013)
  - [redacted] (2010)
  - [redacted] (2005).
- Mammals: One residue study
  - [redacted] (2016)
- Mammals: Bioaccumulation and food chain: two generic field studies
  - [redacted] (2017)
  - [redacted] & [redacted] (2019)

[1] Extrapolation according to EFSA (2009) Chapter 2.1.2. has been applied to the acute endpoint LD_{50} since 10 animals were tested and there were no mortalities at the limit dose (extrapolation factor = 1.888).

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds) Group A S-metolachlor (acute risk for Group B-E is covered with the assessment of group A)					
Bare soil	Small granivorous bird	Acute	35.6	133	10
Maize and sunflower	Small omnivorous bird	Acute	228.7	21	10
Tier 1 (Birds) Group A S-metolachlor (long-term risk for Group B is covered with the assessment of group A)					
Maize/bare soil	Small granivorous bird “finch”	Long-term	8.7	10	5
	Small omnivorous bird “lark”	Long-term	6.3	14	5
	Small insectivorous bird “wagtail”	Long-term	4.5	19	5
Maize/BBCH 10-29	Medium granivorous bird "gamebird"	Long-term	2.3	38	5
Maize/ BBCH 10-19	Small insectivorous/ver-mivorous bird "thrush"	Long-term	4.3	20	5
Maize/ BBCH 10-29	Small omnivorous bird “lark”	Long-term	8.3	10	5

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Maize/ BBCH 10-29	Medium herbivorous/granivorous bird "pigeon"	Long-term	17.2	5.1	5
Maize/ BBCH 10-19	Small insectivorous bird "wagtail"	Long-term	8.6	10	5
Sunflower/ BBCH 00-19	Small granivorous bird "lark"	Long-term	8.3	11	5
	Small insectivorous bird "wagtail"	Long-term	8.6	10	5
Screening Step (Mammals) Acute Risk Group A A9396G (Group B is covered with the assessment of group A)					
Bare soil	Small granivorous mammal	Acute	20.7	104	10
Maize and sunflower	Small herbivorous mammal	Acute	196.4	10.9	10
Screening Step (Mammals) long-term Risk Group A S-metolachlor					
Bare soil	Small granivorous mammal	Long-term	5.0	**3.5**	5
Maize	Small herbivorous mammal	Long-term	36.6	**0.3**	5
Screening Step (Mammals) long-term Risk Group B S-metolachlor					
Bare soil	Small granivorous mammal	Long-term	5.0	**4.1**	5
Maize	Small herbivorous mammal	Long-term	36.6	**0.7** **0.4**	5
Tier 1 (Mammals) long-term-risk Group A S-metolachlor					
Maize/ Bare soils	Small omnivorous mammal "mouse"	Long-term	4.4	**4.1**	5
Maize/ BBCH 10-19	Small insectivorous mammal "shrew"	Long-term	3.2	5.5	5
Maize/ BBCH 10-29	Small herbivorous mammal "vole"	Long-term	54.8	**0.3**	5
Maize/ BBCH 10-29	Small omnivorous mammal "mouse"	Long-term	5.9	**3**	5
Tier 1 (Mammals) long-term-risk Group B S-metolachlor					
Maize/ Bare soils	Small omnivorous mammal "mouse"	Long-term	3.8	**4.7**	5
Maize/ BBCH 10-19	Small insectivorous mammal "shrew"	Long-term	2.8	6.3	5
Maize/ BBCH 10-29	Small herbivorous mammal "vole"	Long-term	47.6	**0.4**	5
Maize/ BBCH 10-29	Small omnivorous mammal "mouse"	Long-term	5.1	**3.5**	5
Higher tier (Mammals): for Group A A9396G (Group B is covered with the assessment of group A) - Wood mouse, hare and rabbit as focal species - Worst case PT = 0.139 (for wood mouse) - f_{twa} for worst case $DissT_{50}$ of 0.22 days = 0.015 (used for hare and rabbit only)					
Higher Tier (Mammals) long-term-risk Group A S-metolachlor					
Maize/ BBCH 10-29*	Small omnivorous mammal "mouse": Wood mouse (*Apodemus sylvaticus*)	Long-term	0.827	21*	5
Maize/ BBCH 10-29	large herbivorous mammal lagomorph: Hare (*Lepus europaeus*)	Long-term	0.391	45.3**	5

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Maize/ BBCH 10-29	large herbivorous mammal lagomorph: Rabbit (*Oryctolagus cuniculus*)	Long-term	0.480	36.9**	5

* Value derived for BBCH 10-18 but the uses for BBCH <10 were also at risk for omnivorous mammals. However, in the opinion of the RMS the earlier BBCH stages are covered by the later in this case (cf. RAR).

** At the Pesticide Peer Review Teleconference 29 (EFSA, 2022), it was agreed to accept the worst case foliar dissipation half-time (DT_{50}) from four studies performed in the central zone. Although the experts agreed that the refined DT_{50} would also cover the southern zone as the major route of dissipation was volatilisation, it could not be demonstrated that the temperature in the available residue decline studies was sufficiently representative of the temperature in the northern zone. Therefore, the revised DT50 was only used to refine the risk to herbivorous focal species for the post-emergence uses in maize in the central and southern zones.

Risk from bioaccumulation and food chain behaviour (S-metolachlor)

Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds	Long-term	6.869	12.7	5
Earthworm-eating mammals	Long-term	8.373	**2.1**	5
Fish-eating birds	Long-term	2.033	43	5
Fish-eating mammals	Long-term	0.733	9.8	5
Earthworm-eating mammals (uses in detail)				
Use group A (0% interception)	Long-term	8.373	**2.1**	
Use group B (0% interception)	Long-term	7.268	**2.4**	

Higher tier: At the Pesticide Peer Review Teleconference 29 (EFSA, 2022), the experts agreed that, overall, there is insufficient information available to define a focal species for the risk assessment for secondary poisoning risk assessment. In the absence of sufficient evidence, the risk for earthworm eating mammals could not be refined for any of the representative uses.

Risk from consumption of contaminated water (S-metolachlor)

Scenario	Time scale	PEC_{dw}xDWR	TER	Trigger
Leaf scenario	Not relevant			
Puddle scenario, Screening step (Group A, Group B is covered with the assessment of group A)	Application rate (1440 g a.s./ha)/relevant endpoint <50 (for koc<500 L/kg, here 200 L/kg), TER calculation not needed for birds (acute and long-term) and mammals (acute)			
Puddle scenario, Tier 1 Mammals (Group A, Group B is covered with the assessment of group A)	Long-term	0.108	164	5

Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)*

* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Laboratory tests				
Fish				
	S-metolachlor		LC_{50}	

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Oncorhynchus mykiss		Acute 96 hr (static)		12.0 nom
Cyprinus carpio				20 mm
Cyprinodon variegatus				17 mm
Pimephales promelas	metolachlor	Acute 96 hr (flow-through)		9.2 mm
Cyprinodon variegatus				9.8 mm
Cyprinodon variegatus				7.5
Oncorhynchus mykiss	CGA354743 (ESA)	Acute 96 hr (static)		>100 nom
	CGA51202 (OXA)			> 100 nom
	CGA368208			> 100 nom
	CGA40172			76.2 nom
	CGA50720			> 100 nom
	CGA37735			> 100 nom
	NOA436611			> 100 nom
	CGA41507			54 nom
	CGA357704			> 100 nom
	CGA50267			> 100 nom
	NOA413137			> 100 nom
Cyprinus carpio	CGA51202 (OXA)			> 100 nom
	CGA40172			76.2 nom
Oncorhynchus mykiss	Preparation (A9396G/L)			7.65 mg a.s./L nom 8.8 mg A9396G/L nom
	Preparation (A9396C/L)			8.6 mg a.s./L mm 9.9 mg A9396C/L mm
Cyprinodon variegatus	S-metolachlor		34d-NOEC (egg hatchability) 34d-NOEC (fry wet/dry weight) 34d-NOEC (fry survival)	1.3 nom

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Pimephales promelas		Chronic 35 d-ELS (flow-through)	35d-NOEC (egg hatchability) 35d-NOEC (fry wet/dry weight) 35d-NOEC (fry survival) 35d-EC_{10} (fry wet weight)) 35d-EC_{10} (fry dry weight)	≥0.87 mm 0.03 mm ≥0.87 mm 0.26 mm 0.22 mm
Oncorhynchus mykiss		Chronic prolonged (flow-through)	21d NOEC (length) 21d NOEC (weight) 21d NOEC (survival)	1.73 mm 1.73 mm 0.89 mm
			21d NOEC (weight) 21d NOEC (survival) 21d NOEC (sublethal effects)	3.0 nom 3.0 nom 1.9 nom
Cyprinodon variegatus	metolachlor	Chronic 34 d-ELS (flow-through)	34d-NOEC (egg hatchability) 34d-NOEC (fry wet/dry weight) 34d-NOEC (fry survival)	2.2 mm
Pimephales promelas		Chronic 35 d-ELS (flow-through)	35d-NOEC (egg hatchability) 35d-NOEC (fry wet/dry weight) 35d-NOEC (fry survival)	1.3 mm
		Chronic 266 d FFLC (flow-through)	35d-NOEC (F0 survival) 266d-NOEC (F0 weight) 35d-NOEC (F1 fry weight) EC_{10} (F0 survival day 64) EC_{20} (F0 survival day 35)	0.78 mm 1.6 mm 1.6 mm 0.934 mm 1.057 mm
Oncorhynchus mykiss		Chronic prolonged flow-through	21d-NOEC	0.25 nom
Aquatic invertebrates				
Daphnia magna	S-metolachlor	Acute 48 hr (static)	Immobility, EC_{50}	26 mm
Mysidopsis bahia		Acute 96 hr (static)		1.4 mm
Crassostrea virginica		Acute 96 hr (flow-through)	Shell growth inhibition	4.0 mm
Mysidopsis bahia	metolachlor	Acute 96 hr (static)	Immobility, EC_{50}	4.9 mm
Crassostrea virginica			Shell growth inhibition	1.8 mm
Daphnia magna	CGA51202 (OXA)	Acute 48 hr (static)	Immobility, EC_{50}	14.1 mm

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
	CGA351916			> 100 nom
	CGA368208			> 100 nom
	CGA40172			97.6 nom
	CGA50720			> 100 nom
	CGA37735			> 100 nom
	NOA436611			> 100 nom
	CGA41507			60 nom
	CGA357704			> 100 nom
	CGA50267			66 nom
	NOA413173			> 100 nom
Daphnia magna	Preparation (A9396G/L)	Acute 48 hr (static)	Immobility, EC_{50}	24.3 mg as/L nom 28 mg A9396G/L nom
	Preparation (A9396C/L)			18 mg as/L mm 20.7 mg A9396C/L mm
Daphnia magna	S-metolachlor	Chronic 21 d (flow-through)	NOEC EC_{10} EC_{20}	5.2 nom 1.29 nom 4.2 nom
Mysidopsis bahia			NOEC EC_{10} EC_{20}	0.15 nom 0.182 nom 0.228 nom
Daphnia magna	metolachlor	Chronic 21 d (semi-static)	NOEC $EC_{10\ reproduction}$ $EC_{20\ reproduction}$	0.6 nom 0.56 nom 1.21 nom
		Chronic 21 d (flow-through)	NOEC $EC_{10\ reproduction}$ $EC_{20\ reproduction}$	5.9 mm 6.0 mm 8.2 mm
Sediment-dwelling organisms				
Chironomus riparius	S-metolachlor	Chronic 28 d (static) spiked water spiked sed.	NOEC $28\text{-d-}EC_{10\ (emergence)}$ $28\text{-d-}EC_{20\ (emergence)}$ NOEC $28\text{-d-}EC_{10\ (emergence)}$ $28\text{-d-}EC_{20\ (emergence)}$	8.0 nom. 2.38 mm 3.6 nom. 5.4 mm 6 nom. 5.7 mm 12.7 mg/kg mm > 12.7 mg/kg mm > 12.7 mg/kg mm
Sediment dwelling organisms : 26 species (Annelids, Arthropods, Molluscs)	metolachlor	Chronic 62 d (flow-through)	$NOEC_{(community)}$	0.54 mm

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Chironomus riparius	CGA41507	21 d, static	NOEC	1 nom
Algae				
Pseudokirchneriella subcapitata	S-metolachlor	72 h (static)	E_yC_{50} E_rC_{50} NOE_rC	0.017 mm 0.056 mm 0.012 mm
Navicula pelliculosa		72 h (static)	E_yC_{50} E_rC_{50} NOE_rC	16 mm 31 mm 9.7 mm
Navicula pelliculosa	metolachlor	72 h (static)	E_yC_{50} E_rC_{50} NOE_yC	0.562 mm 4.092 mm 0.0036 mm
Skeletonema costatum		72 h (static)	E_yC_{50} E_rC_{50} NOE_yC	0.039 mm 0.423 mm < 0.0017 mm
Desmodesmus subspicatus	CGA40172	72 h (static)	E_bC_{50}	80.5 nom *
	CGA51202 (OXA)	72 h (static)	E_bC_{50}	77.6 nom *
Pseudokirchneriella subcapitata	CGA354743 (ESA)	72 h (static)	E_yC_{50} E_rC_{50}	> 100 nom > 100 nom
	CGA41507	72 h (static)	E_bC_{50} E_rC_{50}	26 nom * 39 nom
	CGA50720	72 h (static)	E_yC_{50} E_rC_{50}	> 100 nom > 100 nom
	CGA357704	72 h (static)	E_bC_{50} E_rC_{50}	62 nom 62 nom
	CGA368208	72 h (static)	E_yC_{50} E_rC_{50}	> 100 nom > 100 nom
	CGA351916	72 h (static)	E_yC_{50} E_rC_{50}	> 100 nom > 100 nom
	CGA37735	72 h (static)	E_bC_{50} E_rC_{50}	> 100 nom > 100 nom
	NOA436611	96 h (static)	E_yC_{50} E_rC_{50}	> 100 nom > 100 nom
	SYN542488	96 h (static)	E_yC_{50} E_rC_{50}	71 mm > 105 mm
	SYN542491	72 h (static)	E_yC_{50} E_rC_{50}	> 105 mm > 105 mm

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
	SYN542492	72 h (static)	E_yC_{50} E_rC_{50}	66 nom 66 nom
	SYN542607	96 h (static)	E_yC_{50} E_rC_{50}	> 96.8 mm > 96.8 mm
	SYN547977	96 h (static)	E_yC_{50} E_rC_{50}	1.5 mm 3.4 mm
	SYN542489	96 h (static)	E_yC_{50} E_rC_{50}	>89.8 mm >89.8 mm
	CGA50267	72 h (static)	E_yC_{50} E_rC_{50}	> 100 nom * > 100 nom
	NOA413173	72 h (static)	E_yC_{50} E_rC_{50}	> 100 nom > 100 nom
Anabaena flos-aquae	CGA50720	96 h (static)	E_yC_{50} E_rC_{50}	> 100 nom * > 100 nom
Pseudokirchneriella subcapitata	Preparation (A9396G)	72 h (static) 96 h (static) 72 h (static)	E_yC_{50} E_rC_{50} NOE_rC	0.031 mg A9396G/L mm 0.027 mg a.s./L mm 0.08 mg A9396G/L mm 0.069 mg a.s./L mm 0.009 mg A9396G/L mm 0.008 mg a.s./L mm
Higher plant				
Lemna gibba	S-metolachlor	7 d (semi-static)	E_yC_{50} (fronds) E_rC_{50} (fronds) E_yC_{50} (dry weight) E_rC_{50} (dry weight) NOE_rC (all parameters)	0.037 mm 0.133 mm 0.075 mm > 0.619 mm 0.0021 mm
		7 d (semi-static)	E_yC_{50} (fronds) E_rC_{50} (fronds) E_yC_{50} (dry weight) E_rC_{50} (dry weight) NOE_rC (all parameters)	0.03 mm 0.149 mm 0.037 mm 0.25 mm 0.0038 mm
Elodea canadensis		7 d (static)**	E_yC_{50} (shoot length) E_rC_{50} (shoot length) NOErC (shoot length) 7-d E_yC_{50} (dry weight) 7-d E_rC_{50} (dry weight) NOErC (dry weight)	0.049 mm 0.062 mm 0.0089 mm 0.1 mm 0.12 mm 0.0089 mm
Lemna gibba	CGA51202 (OXA)	14 d (static)	EC_{50} (fronds)	> 88.6 mm *
	CGA354743 (ESA)	14 d (static)	EC_{50} (fronds)	21.7 mm

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Lemna gibba	A9396G	7 d (semi-static)	E_yC_{50} (fronds)	0.052 mg A9396G/L nom 0.045 mg a.s./L nom
			E_rC_{50} (fronds)	0.23 mg A9396G/L nom 0.2 mg a.s./L nom
			NOErC (fronds)	0.0022 mg A9396G/L nom 0.0019 mg a.s./L nom
			E_yC_{50}(dry weight)	0.088 mg A9396G/L nom 0.076 mg a.s./L nom
			E_rC_{50} (dry weight)	> 0.55 mg A9396G/L nom > 0.47 mg a.s./L nom
			NOEC (dry weight)	0.0049 mg A9396G/L nom 0.0042 mg a.s./L nom

Potential endocrine disrupting properties (Annex Part A, point 8.2.3) The peer review conclusion will be finalised without the ED assessment following the receipt of the mandate in September 2022.

The assessment of the endocrine disrupting properties could not be finalized. In order to complete the ED assessment of the EATS modality for non-target organisms according to ECHA/EFSA ED guidance a full detailed study in line with OCED TG 231 (AMA) and a full detailed study in line with OECD GD 148 (Androgenised Female Stickleback Screen) should be submitted.

Amphibians

Several studies testing effects of S-Metolachlor (Hayes et al. 2006; Spolyarich et al. 2010; Williams and Semlistch, 2010) on amphibians are available with no direct indication for ED related effects on development and metamorphosis. However, in the study by Hayes et al. 2006 exposure to 0.1 µg/L S-Metolachlor resulted in damage of thymus and a reduced immune reaction.

Fish

The studies by Jin et al. 2011 and Quintaneiro et al. 2017 reported an inhibition of thyroid related gene expression caused by Metolachlor and S-Metolachlor. However, it could not be concluded that these alterations result in ED activity and adversity.

Other organism

The studies by Mai et al. 2012, 2013, 2016 investigated the effects of S-Metolachlor on *Crassostrea gigas* on embryo-, spermiotoxicity and oocytetoxicity but no direct ED related effects occurred.

Other studies

The study by Ait-Aissia et al. 2010 revealed a moderate anti-androgenic activity in MDAkb2 of S-Metolachlor.

[1] ($_{nom}$) nominal concentration; ($_{mm}$) mean measured concentration; prep.: preparation; a.s.: active substance
*Study not valid for exact ECx derivation but suitable to determine the order of magnitude of the EC_x
**The study did not cover the full life cycle of *E. canadensis* and it was shorter than the duration indicated in the OECD TG 239. Therefore, the study was not considered sufficiently reliable for the hazard characterisation for this species.

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Active substance
$logP_{O/W}$	3.05 at pH 7
Steady-state bioconcentration factor (BCF) (total wet weight, normalised to 5 % lipid content)	BCF: 255 whole fish *
Uptake/depuration kinetics BCF	
Annex VI Trigger for the bioconcentration factor	100
Clearance time (days) (CT_{50})	
(CT_{90})	7.4 d at 0.003 mg/L
Level and nature of residues (%) in organisms after the 14 day depuration phase	Ca. 91 % depuration after 10 d

* based on total ^{14}C compounds

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for S-metolachlor for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of A9396G in maize, 1x1440 g a.s./ha, BBCH 00-09 pre-emergence

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes[a]**	**Sed. dwell. prolonged**
Test species		***4 different species***	***Pimephales promelas***	***Mysidopsis bahia***	***Mysidopsis bahia***	***Pseudokirchn. subcapitata***	***Elodea canadensis***	***26 species (Annelids. Arthropods. Molluscs)***
Endpoint (µg/L)		EC_{50} (geomean) 12400	EC_{10} 220	EC_{50} (geomean) 2600	NOEC 153	E_rC_{50} 56	E_rC_{50} 62	NOEC 540
AF		100	10	100	10	10	10	10
RAC (µg/L)		124	22	26	15.3	5.6	6.2	54
FOCUS Scenario	**PEC glb-max (µg/L)**							
Step 1								
	392.19	**3.16**	**17.83**	**15.08**	**25.63**	**70.03**	**63.26**	**7.26**
Step 2								
N-Europe	79.67	0.64	**3.62**	**3.06**	**5.21**	**14.23**	**12.85**	**1.48**
S-Europe	148.79	**1.20**	**6.76**	**5.72**	**9.72**	**26.57**	**24.00**	**2.76**
Step 3								
D3/ditch	7.55	0.06	0.34	0.29	0.49	**1.35**	**1.22**	0.14
D4/pond	0.974	0.01	0.04	0.04	0.06	0.17	0.16	0.02
D4/stream	6.26	0.05	0.28	0.24	0.41	**1.12**	**1.01**	0.12
D5/pond	0.683	0.01	0.03	0.03	0.04	0.12	0.11	0.01

D5/stream	6.83	0.06	0.31	0.26	0.45	**1.22**	**1.10**	0.13
D6/ditch	7.58	0.06	0.34	0.29	0.50	**1.35**	**1.22**	0.14
R1/pond	0.77	0.01	0.04	0.03	0.05	0.14	0.12	0.01
R1/stream	19.6	0.16	0.89	0.75	**1.28**	**3.50**	**3.16**	0.36
R2/stream	15.3	0.12	0.70	0.59	1.00	**2.73**	**2.47**	0.28
R3/stream	48.3	0.39	**2.20**	**1.86**	**3.16**	**8.63**	**7.79**	0.89
R4/stream	49.1	0.40	**2.23**	**1.89**	**3.21**	**8.77**	**7.92**	0.91

(a): The risk assessment for aquatic macrophytes could not be finalised in the absence of a study covering the full life-cycle of the sensitive species *Elodea canadensis* (data gap and issue not finalised).

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for S-metolachlor for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of A9396G in maize, 1x1250 g a.s./ha, BBCH 00-09 pre-emergence

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes[(a)]**	**Sed. dwell. prolonged**
Test species		***4 different species***	***Pimephales promelas***	***Mysidopsis bahia***	***Mysidopsis bahia***	***Pseudokirchn. subcapitata***	***Elodea canadensis***	***26 species (Annelids. Arthropods. Molluscs)***
Endpoint (µg/L)		EC_{50} (geomean) 12400	EC_{10} 220	EC_{50} (geomean) 2600	NOEC 153	E_rC_{50} 56	E_rC_{50} 62	NOEC 540
AF		100	10	100	10	10	10	10
RAC (µg/L)		124	22	26	15.3	5.6	6.2	54
FOCUS Scenario	**PEC glb-max (µg/L)**							
Step 1								
	392.19	**3.16**	**17.83**	**15.08**	**25.63**	**70.03**	**63.26**	**7.26**
Step 2								
N-Europe	79.67	0.64	**3.62**	**3.06**	**5.21**	**14.23**	**12.85**	**1.48**
S-Europe	148.79	**1.20**	**6.76**	**5.72**	**9.72**	**26.57**	**24.00**	**2.76**

Step 3								
D3/ditch	6.55	0.05	0.30	0.25	0.43	**1.17**	**1.06**	0.12
D4/pond	0.844	0.01	0.04	0.03	0.06	0.15	0.14	0.02
D4/stream	5.44	0.04	0.25	0.21	0.36	0.97	0.88	0.10
D5/pond	0.589	0.00	0.03	0.02	0.04	0.11	0.10	0.01
D5/stream	5.93	0.05	0.27	0.23	0.39	**1.06**	0.96	0.11
D6/ditch	6.58	0.05	0.30	0.25	0.43	**1.18**	**1.06**	0.12
R1/pond	0.673	0.01	0.03	0.03	0.04	0.12	0.11	0.01
R1/stream	16.9	0.14	0.77	0.65	**1.10**	**3.02**	**2.73**	0.31
R2/stream	13.2	0.11	0.60	0.51	0.86	**2.36**	**2.13**	0.24
R3/stream	41.7	0.34	**1.90**	**1.60**	**2.73**	**7.45**	**6.73**	0.77
R4/stream	42.5	0.34	**1.93**	**1.63**	**2.78**	**7.59**	**6.85**	0.79

(a): The risk assessment for aquatic macrophytes could not be finalised in the absence of a study covering the full life-cycle of the sensitive species *Elodea canadensis* (data gap and issue not finalised).

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for S-metolachlor for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of A9396G in maize, 1x1440 g a.s./ha, BBCH 11-18 post-emergence

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes[(a)]**	**Sed. dwell. prolonged**
Test species		***4 different species***	***Pimephales promelas***	***Mysidopsis bahia***	***Mysidopsis bahia***	***Pseudokirchn. subcapitata***	***Elodea canadensis***	***26 species (Annelids. Arthropods. Molluscs)***
Endpoint (µg/L)		EC_{50} (geomean) 12400	EC_{10} 220	EC_{50} (geomean) 2600	NOEC 153	E_rC_{50} 56	E_rC_{50} 62	NOEC 540
AF		100	10	100	10	10	10	10
RAC (µg/L)		124	22	26	15.3	5.6	6.2	54

FOCUS Scenario	PEC glb-max (µg/L)							
Step 1								
	392.19	**3.16**	**17.83**	**15.08**	**25.63**	**70.03**	**63.26**	**7.26**
Step 2								
N-Europe	79.67	0.64	**3.62**	**3.06**	**5.21**	**14.23**	**12.85**	**1.48**
S-Europe	148.79	**1.20**	**6.76**	**5.72**	**9.72**	**26.57**	**24.00**	**2.76**
Step 3								
D3/ditch	7.56	0.06	0.34	0.29	0.49	**1.35**	**1.22**	0.14
D4/pond	1.27	0.01	0.06	0.05	0.08	0.23	0.20	0.02
D4/stream	6.5	0.05	0.30	0.25	0.42	**1.16**	**1.05**	0.12
D5/pond	0.903	0.01	0.04	0.03	0.06	0.16	0.15	0.02
D5/stream	6.87	0.06	0.31	0.26	0.45	**1.23**	**1.11**	0.13
D6/ditch	7.59	0.06	0.35	0.29	0.50	**1.36**	**1.22**	0.14
R1/pond	1.37	0.01	0.06	0.05	0.09	0.24	0.22	0.03
R1/stream	22.4	0.18	**1.02**	0.86	**1.46**	**4.00**	**3.61**	0.41
R2/stream	16.2	0.13	0.74	0.62	**1.06**	**2.89**	**2.61**	0.30
R3/stream	43	0.35	**1.95**	**1.65**	**2.81**	**7.68**	**6.94**	0.80
R4/stream	50.8	0.41	**2.31**	**1.95**	**3.32**	**9.07**	**8.19**	0.94

(a): The risk assessment for aquatic macrophytes could not be finalised in the absence of a study covering the full life-cycle of the sensitive species *Elodea canadensis* (data gap and issue not finalised).

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for S-metolachlor for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of A9396G in maize, 1x1250 g a.s./ha, BBCH ~~10~~11-18 post-emergence

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Aquatic macrophytes[(a)]	Sed. dwell. prolonged
Test species		***4 different species***	***Pimephales promelas***	***Mysidopsis bahia***	***Mysidopsis bahia***	***Pseudokirchn. subcapitata***	***Elodea canadensis***	***26 species (Annelids. Arthropods. Molluscs)***

Endpoint (µg/L)		$EC_{50\ (geomean)}$ 12400	EC_{10} 220	$EC_{50\ (geomean)}$ 2600	NOEC 153	E_rC_{50} 56	E_rC_{50} 62	NOEC 540
AF		100	10	100	10	10	10	10
RAC (µg/L)		124	22	26	15.3	5.6	6.2	54
FOCUS Scenario	**PEC glb-max (µg/L)**							
Step 1								
	392.19	**3.16**	**17.83**	**15.08**	**25.63**	**70.03**	**63.26**	**7.26**
Step 2								
N-Europe	79.67	0.64	**3.62**	**3.06**	**5.21**	**14.23**	**12.85**	**1.48**
S-Europe	148.79	**1.20**	**6.76**	**5.72**	**9.72**	**26.57**	**24.00**	**2.76**
Step 3								
D3/ditch	6.56	0.05	0.30	0.25	0.43	**1.17**	**1.06**	0.12
D4/pond	1.1	0.01	0.05	0.04	0.07	0.20	0.18	0.02
D4/stream	5.64	0.05	0.26	0.22	0.37	**1.01**	0.91	0.10
D5/pond	0.781	0.01	0.04	0.03	0.05	0.14	0.13	0.01
D5/stream	5.96	0.05	0.27	0.23	0.39	**1.06**	0.96	0.11
D6/ditch	6.59	0.05	0.30	0.25	0.43	**1.18**	**1.06**	0.12
R1/pond	1.19	0.01	0.05	0.05	0.08	0.21	0.19	0.02
R1/stream	19.4	0.16	0.88	0.75	**1.27**	**3.46**	**3.13**	0.36
R2/stream	14	0.11	0.64	0.54	0.92	**2.50**	**2.26**	0.26
R3/stream	37.2	0.30	**1.69**	**1.43**	**2.43**	**6.64**	**6.00**	0.69
R4/stream	43.9	0.35	**2.00**	**1.69**	**2.87**	**7.84**	**7.08**	0.81

(a): The risk assessment for aquatic macrophytes could not be finalised in the absence of a study covering the full life-cycle of the sensitive species *Elodea canadensis* (data gap and issue not finalised).

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for S-metolachlor for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of A9396G in sunflower, 1x1440 g a.s./ha, BBCH 00-09 pre-emergence

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes[(a)]**	**Sed. dwell. prolonged**
Test species		***4 different species***	***Pimephales promelas***	***Mysidopsis bahia***	***Mysidopsis bahia***	***Pseudokirchn. subcapitata***	***Elodea canadensis***	***26 species (Annelids. Arthropods. Molluscs)***
Endpoint (µg/L)		EC_{50} (geomean) 12400	EC_{10} 220	EC_{50} (geomean) 2600	NOEC 153	E_rC_{50} 56	E_rC_{50} 62	NOEC 540
AF		100	10	100	10	10	10	10
RAC (µg/L)		124	22	26	15.3	5.6	6.2	54
FOCUS Scenario	**PEC glb-max (µg/L)**							
Step 1								
	392.19	**3.16**	**17.83**	**15.08**	**25.63**	**70.03**	**63.26**	**7.26**
Step 2								
N-Europe	79.67	0.64	**3.62**	**3.06**	**5.21**	**14.23**	**12.85**	**1.48**
S-Europe	148.79	**1.20**	**6.76**	**5.72**	**9.72**	**26.57**	**24.00**	**2.76**
Step 3								
D5/pond	0.609	0.00	0.03	0.02	0.04	0.11	0.10	0.01
D5/stream	6.91	0.06	0.31	0.27	0.45	**1.23**	**1.11**	0.13
R1/pond	0.85	0.01	0.04	0.03	0.06	0.15	0.14	0.02
R1/stream	17.5	0.14	0.80	0.67	**1.14**	**3.13**	**2.82**	0.32
R3/stream	50.4	0.41	**2.29**	**1.94**	**3.29**	**9.00**	**8.13**	0.93
R4/stream	45.6	0.37	**2.07**	**1.75**	**2.98**	**8.14**	**7.35**	0.84

(a): The risk assessment for aquatic macrophytes could not be finalised in the absence of a study covering the full life-cycle of the sensitive species *Elodea canadensis* (data gap and issue not finalised).

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for S-metolachlor for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of A9396G in sunflower, 1x1250 g a.s./ha, BBCH 00-09 pre-emergence

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophytes[(a)]**	**Sed. dwell. prolonged**
Test species		***4 different species***	***Pimephales promelas***	***Mysidopsis bahia***	***Mysidopsis bahia***	***Pseudokirchn. subcapitata***	***Elodea canadensis***	***26 species (Annelids. Arthropods. Molluscs)***
Endpoint (µg/L)		EC_{50} (geomean) 12400	EC_{10} 220	EC_{50} (geomean) 2600	NOEC 153	E_rC_{50} 56	E_rC_{50} 62	NOEC 540
AF		100	10	100	10	10	10	10
RAC (µg/L)		124	22	26	15.3	5.6	6.2	54
FOCUS Scenario	**PEC glb-max (µg/L)**							
Step 1								
	392.19	**3.16**	**17.83**	**15.08**	**25.63**	**70.03**	**63.26**	**7.26**
Step 2								
N-Europe	79.67	0.64	**3.62**	**3.06**	**5.21**	**14.23**	**12.85**	**1.48**
S-Europe	148.79	**1.20**	**6.76**	**5.72**	**9.72**	**26.57**	**24.00**	**2.76**
Step 3								
D5/pond	0.526	0.00	0.02	0.02	0.03	0.09	0.08	0.01
D5/stream	5.99	0.05	0.27	0.23	0.39	**1.07**	0.97	0.11
R1/pond	0.743	0.01	0.03	0.03	0.05	0.13	0.12	0.01
R1/stream	15.1	0.12	0.69	0.58	0.99	**2.70**	**2.44**	0.28
R3/stream	43.4	0.35	**1.97**	**1.67**	**2.84**	**7.75**	**7.00**	0.80
R4/stream	39.4	0.32	**1.79**	**1.52**	**2.58**	**7.04**	**6.35**	0.73

(a): The risk assessment for aquatic macrophytes could not be finalised in the absence of a study covering the full life-cycle of the sensitive species *Elodea canadensis* (data gap and issue not finalised).

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for S-metolachlor for each organism group based on FOCUS Step 4 calculations for the use of A9396G in maize, 1x1440 g a.s./ha, BBCH 00-09 pre-emergence

Group		**Algae**		**Algae**
Test species		***Pseudokirchn. subcapitata***		***Pseudokirchn. subcapitata***
Endpoint (µg/L)		E_rC_{50} 56		E_rC_{50} 56
AF		10		10
RAC (µg/L)		5.6		5.6
FOCUS Scenario	**PEC glb-max (µg/L) 10 m buffer; 60% run off mitigation**		**PEC glb-max (µg/L) 20 m buffer; 80% run off mitigation**	
Step 4				
D3/ditch	1.31	0.23	0.682	0.12
D4/pond	0.959	0.17	0.949	0.17
D4/stream	1.44	0.26	1.1	0.20
D5/pond	0.603	0.11	0.593	0.11
D5/stream	1.62	0.29	0.89	0.16
D6/ditch	1.35	0.24	0.714	0.13
R1/pond	0.373	0.07	0.211	0.04
R1/stream	8.29	**1.48**	4.23	0.76
R2/stream	6.83	**1.22**	3.56	0.64
R3/stream	22	**3.93**	11.6	**2.07**
R4/stream	22.3	**3.98**	11.7	**2.09**

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for S-metolachlor for each organism group based on FOCUS Step 4 calculations for the use of A9396G in maize, 1x1250 g a.s./ha, BBCH 00-10 pre-emergence

Group		**Algae**		**Algae**
Test species		***Pseudokirchn. subcapitata***		***Pseudokirchn. subcapitata***
Endpoint (µg/L)		E_rC_{50} 56		E_rC_{50} 56
AF		10		10
RAC (µg/L)		5.6		5.6
FOCUS Scenario	**PEC glb-max (µg/L) 10 m buffer; 60% run off mitigation**		**PEC glb-max (µg/L) 20 m buffer; 80% run off mitigation**	
Step 4				
D3/ditch	1.14	0.20	0.592	0.11
D4/pond	0.832	0.15	0.823	0.15
D4/stream	1.25	0.22	0.954	0.17
D5/pond	0.522	0.09	0.513	0.09
D5/stream	1.41	0.25	0.772	0.14
D6/ditch	1.17	0.21	0.619	0.11
R1/pond	0.326	0.06	0.184	0.03
R1/stream	7.17	**1.28**	3.66	0.65
R2/stream	5.89	**1.05**	3.07	0.55
R3/stream	19	**3.39**	9.99	**1.78**
R4/stream	19.3	**3.45**	10.1	**1.80**

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for S-metolachlor for each organism group based on FOCUS Step 4 calculations for the use of A9396G in maize, 1x1440 g a.s./ha, BBCH 11-18 post-emergence

Group		**Algae**		**Algae**
Test species		***Pseudokirchn. subcapitata***		***Pseudokirchn. subcapitata***
Endpoint (µg/L)		E_rC_{50} 56		E_rC_{50} 56
AF		10		10
RAC (µg/L)		5.6		5.6
FOCUS Scenario	**PEC glb-max (µg/L) 10 m buffer; 60% run off mitigation**		**PEC glb-max (µg/L) 20 m buffer; 80% run off mitigation**	
Step 4				
D3/ditch	1.31	0.23	0.682	0.12
D4/pond	1.25	0.22	1.24	0.22
D4/stream	1.49	0.27	1.47	0.26
D5/pond	0.887	0.16	0.875	0.16
D5/stream	1.64	0.29	0.911	0.16
D6/ditch	1.35	0.24	0.719	0.13
R1/pond	0.621	0.11	0.338	0.06
R1/stream	10.1	**1.80**	5.29	0.94
R2/stream	7.15	**1.28**	3.7	0.66
R3/stream	19.4	**3.46**	10.2	**1.82**
R4/stream	23.1	**4.13**	12.1	**2.16**

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for S-metolachlor for each organism group based on FOCUS Step 4 calculations for the use of A9396G in maize, 1x1250 g a.s./ha, BBCH 11-18 post-emergence

Group		**Algae**		**Algae**
Test species		***Pseudokirchn. subcapitata***		***Pseudokirchn. subcapitata***
Endpoint (µg/L)		E_rC_{50} 56		E_rC_{50} 56
AF		10		10
RAC (µg/L)		5.6		5.6
FOCUS Scenario	**PEC glb-max (µg/L) 10 m buffer; 60% run off mitigation**		**PEC glb-max (µg/L) 20 m buffer; 80% run off mitigation**	
Step 4				
D3/ditch	1.14	0.20	0.593	0.11
D4/pond	1.09	0.19	1.08	0.19
D4/stream	1.3	0.23	1.27	0.23
D5/pond	0.767	0.14	0.756	0.14
D5/stream	1.43	0.26	0.79	0.14
D6/ditch	1.17	0.21	0.624	0.11
R1/pond	0.542	0.10	0.295	0.05
R1/stream	8.78	**1.57**	4.59	0.82
R2/stream	6.16	**1.10**	3.19	0.57
R3/stream	16.8	**3.00**	8.78	**1.57**
R4/stream	20	**3.57**	10.5	**1.88**

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for S-metolachlor for each organism group based on FOCUS Step 4 calculations for the use of A9396G in sunflower, 1x1440 g a.s./ha, BBCH 00-09 pre-emergence

Group		**Algae**		**Algae**
Test species		***Pseudokirchn. subcapitata***		***Pseudokirchn. subcapitata***
Endpoint (µg/L)		E_rC_{50} 56		E_rC_{50} 56
AF		10		10
RAC (µg/L)		5.6		5.6
FOCUS Scenario	**PEC glb-max (µg/L) 10 m buffer; 60% run off mitigation**		**PEC glb-max (µg/L) 20 m buffer; 80% run off mitigation**	
Step 4				
D5/pond	0.508	0.09	0.487	0.09
D5/stream	1.62	0.29	0.879	0.16
R1/pond	0.405	0.07	0.227	0.04
R1/stream	7.37	**1.32**	3.75	0.67
R3/stream	21.5	**3.84**	11	**1.96**
R4/stream	20.7	**3.70**	10.9	**1.95**

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for S-metolachlor for each organism group based on FOCUS Step 4 calculations for the use of A9396G in sunflower, 1x1250 g a.s./ha, BBCH 00-09 pre-emergence

Group		**Algae**		**Algae**
Test species		***Pseudokirchn. subcapitata***		***Pseudokirchn. subcapitata***

Endpoint (µg/L)		E_rC_{50} 56		E_rC_{50} 56
AF		10		10
RAC (µg/L)		5.6		5.6
FOCUS Scenario	**PEC glb-max (µg/L) 10 m buffer; 60% run off mitigation**		**PEC glb-max (µg/L) 20 m buffer; 80% run off mitigation**	
Step 4				
D5/pond	0.439	0.08	0.421	0.08
D5/stream	1.41	0.25	0.763	0.14
R1/pond	0.355	0.06	0.199	0.04
R1/stream	6.37	**1.14**	3.24	0.58
R3/stream	18.6	**3.32**	9.48	**1.69**
R4/stream	17.9	**3.20**	9.39	**1.68**

Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

* This section does not reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed, and which is currently under revision.

Species	Test substance	Time scale/type of endpoint	End point	Toxicity
Apis mellifera L.	S-metolachlor tech. (CGA 77102)	acute	oral toxicity 72 h (LD_{50})	>85 µg a.s./bee
			contact toxicity 72 h (LD_{50})	>200 µg a.s./bee
	A9396G *	acute	oral toxicity 48 h (LD_{50})	239 µg product/bee
			contact toxicity 48 h (LD_{50})	>1000 µg product/bee
	A9396G *	chronic	10 d chronic oral LDD_{50}	150 µg product/bee/day
			10 d chronic oral LC_{50}	7247 mg product/kg
			NOEC	3600 mg product/kg
			LOEC	7200 mg product/kg
	A9396G *	Bee brood development	8 d chronic oral LD_{50}	191.9 µg a.s./larva
			$NOEC_{larvae}$	290.9 mg a.s./kg diet (equivalent to a cumulative dose of 44.8 µg a.s./larva)
	S-metolachlor tech.	Bee brood development	22 d chronic oral $NOEC_{larvae}$	390 µg a.s./kg diet (equivalent to a cumulative dose of 60.1 µg a.s./larva)

* A9396G: 960 g s-metolachlor/L; density: 1.11 g/cm³

Potential for accumulative toxicity: no data
Semi-field test (cage and tunnel test): no data
Field tests: no data

Risk assessment according to SANCO guidance on terrestrial ecotoxicology (European Commission, 2002)

The recommended use pattern for A9396 (960 g s-metolachlor/L) includes application in maize (1.5 L a.s./ha) and sunflowers (1.3 L a.s./ha) at a maximum application rate of up to 1665 g product/ha (1440 g a.s./ha).

Species	Crop	Test substance	Risk quotient	HQ	Trigger
Apis mellifera L.	maize	s-metolachlor tech.	HQ oral	<16.9	50
			HQ contact	<7.2	
	sunflowers		HQ oral	<14.6	
			HQ contact	<6.24	
	maize	A9396G *	HQ oral	7.0	
			HQ contact	<1.7	
	sunflowers		HQ oral	6.0	
			HQ contact	<1.4	

* A9396G: 960 g s-metolachlor/L; density: 1.11 g/cm³

Risk assessment for honeybees according to EFSA (2013)

Screening step - Acute and Chronic Risk Assessment

Acute, chronic adult and larval honey bee studies have been conducted with S-metolachlor and A9396G according to the data requirements under 1107/2009. The endpoints from these studies have been assessed by using EFSA Bee Guidance (2014) and EFSA Bee Tool Screening step and the results are shown in Tables B.9.5.1.7-3 to B.9.5.1.7-9 for maize and sunflower.

Screening step assessment of the risk for bees due to the use of A9396G in maize and sunflower

Intended use	DW				
Active substance	S-metolachlor				
Test design	**Endpoint (lab.) (µg a.s./bee)**	**Single application rate**	**Shortcut Value**	**HQ/ ETR**	**Trigger**
Acute contact toxicity LD_{50}	85	1440 g a.s./ha	1	16.9	42
		1250 g a.s./ha	1	14.7	42
Acute oral toxicity LD_{50}	200	1.44 Kg a.s./ha	10.6	0.05	0.2
		1.25 Kg a.s./ha	10.6	0.05	0.2
Chronic adult oral toxicity LDD_{50}	129 µg a.s./bee/day	1.44 Kg a.s./ha	10.6	**0.085**	0.03
		1.25 Kg a.s./ha	10.6	**0.074**	0.03
Larval development oral toxicity NOED	44.8 µg a.s./larva/ development period	1.44 Kg a.s./ha	6.1	0.14	0.2
		1.25 Kg a.s./ha	6.1	0.12	0.2
Larval development oral toxicity 22-day NOED	60.1 µg a.s./larva/ development period	1.44 Kg a.s./ha	6.1	0.11	0.2
		1.25 Kg a.s./ha	6.1	0.09	0.2

HQ (hazard quotients) and ETR (exposure toxicity ratio) for oral and contact exposure. HQ/ETR values shown in bold breach the relevant trigger.

The screening step indicated acceptable risk from acute contact and oral exposure to adult honey bees and acceptable risk to chronic oral risk to honey bee larvae, following applications of S-metolachlor according to the proposed use pattern.

However a potential chronic oral risk to honey bee adults was demonstrated. Therefore, a Tier 1 chronic adult assessment for the treated crop is provided below.

Tier 1 - Chronic Adult Oral Risk Assessment

The screening step risk assessment indicated a potential chronic risk to adult bees, therefore a Tier 1 assessment has been provided below for maize and sunflower below.

Applications to maize and sunflower are made pre-flowering, therefore an off-field assessment (adjacent

crop and field margin) is shown below together with a flowering weeds and treated crop assessment (worst case).

First-tier assessment of the chronic risk for bees due to the use of A9396G in maize for the treated crop (BBCH 00-18)

Intended use **Active substance**		DW S-metolachlor					
Test design	**Endpoint (lab.)**	**Single Application rate (kg a.s./ha)**	**Shortcut Value (upward spray)**	**TWA**	**fDep/ Ef**	**HQ/ ETR**	**Trigger**
Chronic adult oral toxicity LDD_{50}	129 µg a.s./bee/day	1.44	0.92	0.72	1	0.007	0.03
		1.25	0.92	0.72	1	0.006	0.03

HQ (hazard quotients) and ETR (exposure toxicity ratio) for oral and contact exposure.

First-tier assessment of the chronic risk for bees due to the use of A9396G in maize for the flowering weeds (BBCH 00-18)

Intended use **Active substance**		DW S-metolachlor					
Test design	**Endpoint (lab.)**	**Single Application rate (kg a.s./ha)**	**Shortcut Value (upward spray)**	**TWA**	**fDep/ Ef**	**HQ/ ETR**	**Trigger**
Chronic adult oral toxicity LDD_{50}	129 µg a.s./bee/day	1.44	2.9	0.72	1	0.023	0.03
		1.25	2.9	0.72	1	0.020	0.03

HQ (hazard quotients) and ETR (exposure toxicity ratio) for oral and contact exposure.

First-tier assessment of the chronic risk for bees due to the use of A9396G in maize for the adjacent crop (BBCH 00-18)

Intended use **Active substance**		DW S-metolachlor					
Test design	**Endpoint (lab.)**	**Single application rate (kg a.s./ha)**	**Shortcut Value (upward spray)**	**TWA**	**fDep/ Ef**	**HQ/ ETR**	**Trigger**
Chronic adult oral toxicity LDD_{50}	129 µg a.s./bee/day	1.44	5.8	0.72	0.0033	0.000	0.03
		1.25	5.8	0.72	0.0033	0.000	0.03

HQ (hazard quotients) and ETR (exposure toxicity ratio) for oral and contact exposure.

First-tier assessment of the chronic risk for bees due to the use of A9396G in maize for field margin (BBCH 00-18)

Intended use **Active substance**		DW S-metolachlor					
Test design	**Endpoint (lab.)**	**Single Application rate (kg a.s./ha)**	**Shortcut Value (upward spray)**	**TWA**	**fDep/ Ef**	**HQ/ ETR**	**Trigger**

Chronic adult oral toxicity LDD_{50}	129 µg a.s./bee/day	1.44	2.9	0.72	0.0092	0.000	0.03
		1.25	2.9	0.72	0.0092	0.000	0.03

HQ (hazard quotients) and ETR (exposure toxicity ratio) for oral and contact exposure.

First-tier assessment of the chronic risk for bees due to the use of A9396G in sunflower for the treated crop (BBCH <10)

Intended use **Active substance**		DW S-metolachlor					
Test design	**Endpoint (lab.)**	**Single application rate (kg a.s./ha)**	**Shortcut Value (upward spray)**	**TWA**	**fDep/ Ef**	**HQ/ ETR**	**Trigger**
Chronic adult oral toxicity LDD_{50}	129 µg a.s./bee/day	1.44	0.54	0.72	1	0.004	0.03
		1.25	0.54	0.72	1	0.004	0.03

HQ (hazard quotients) and ETR (exposure toxicity ratio) for oral and contact exposure.

First-tier assessment of the chronic risk for bees due to the use of A9396G in sunflower for the flowering weeds (BBCH <10)

Intended use **Active substance**		DW S-metolachlor					
Test design	**Endpoint (lab.)**	**Single application rate (kg a.s./ha)**	**Shortcut Value (upward spray)**	**TWA**	**fDep/ Ef**	**HQ/ ETR**	**Trigger**
Chronic adult oral toxicity LDD_{50}	129 µg a.s./bee/day	1.44	2.9	0.72	1	0.023	0.03
		1.25	2.9	0.72	1	0.020	0.03

HQ (hazard quotients) and ETR (exposure toxicity ratio) for oral and contact exposure.

First-tier assessment of the chronic risk for bees due to the use of A9396G in sunflower for the adjacent crop (BBCH <10)

Intended use **Active substance**		DW S-metolachlor					
Test design	**Endpoint (lab.)**	**Single Application rate (kg a.s./ha)**	**Shortcut Value (upward spray)**	**TWA**	**fDep/ Ef**	**HQ/ ETR**	**Trigger**
Chronic adult oral toxicity LDD_{50}	129 µg a.s./bee/day	1.44	5.8	0.72	0.0033	0.000	0.03
		1.25	5.8	0.72	0.0033	0.000	0.03

HQ (hazard quotients) and ETR (exposure toxicity ratio) for oral and contact exposure.

First-tier assessment of the chronic risk for bees due to the use of A9396G in sunflower for field margin (BBCH <10)

Intended use **Active substance**	DW S-metolachlor

Test design	Endpoint (lab.)	Single Application rate (kg a.s./ha)	Shortcut Value (upward spray)	TWA	fDep/ Ef	HQ/ ETR	Trigger
Chronic adult oral toxicity LDD_{50}	129 µg a.s./bee/day	1.44	2.9	0.72	0.0092	0.000	0.03
		1.25	2.9	0.72	0.0092	0.000	0.03

HQ (hazard quotients) and ETR (exposure toxicity ratio) for oral and contact exposure.

The Tier 1 adult chronic assessment for all scenarios shows acceptable risk from oral exposure of adult honey bees following applications of A9396G to maize and sunflower according to the proposed use pattern.

"Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Extended laboratory tests, aged residue tests

Species	Life stage	Test substance[1], substrate	Time scale	Dose (kg a.s./ha)	End point	% effect	ER_{50}
Aphidius rhopalosiphi	< 48 h	A9396C, extended laboratory (Barley plants); 3D	48 h	1,5	Mortality, reproduction	0 % mortality at 48-h at 1.6 L/ha, 13.6 % effect on fecundity	LR_{50} > 1,5 kg a.s./ha, $ER_{reproduction} \geq$ 1,5 kg a.s./ha
Typhlodromus pyri	1 day old	A9396C, extended laboratory (Bean leaf discs); 2D	7 d	1,5	Mortality, reproduction	21 % effect on mortality at 7-d at 1.6L/ha, and a 40 % decrease in fecundity at this rate	LR_{50} > 1,5 kg a.s./ha, $ER_{reproduction} \geq$ 1,5 kg a.s./ha
Additional species							
Aleochara bilineata	1 – 5 day old adult beetles	A9396C, extended laboratory (sand); 2D	28 d	1,5	Reproduction	8.4 % reduction in parasitsation relative to the control at 1.6 L/ha	$ER_{reproduction} \geq$ 1,5 kg a.s./ha
Poecilus cupreus	3 week old adults	A9396C, extended laboratory (sand); 2D	14 d	1,5	Mortality, reproduction	0 % mortality at 14-d at 1.6 L/ha, 27.6 % increase in feeding rate	LR_{50} > 1,5 kg a.s./ha, $ER_{feeding} \geq$ 1,5 kg a.s./ha

[1]All studies were conducted with 960 g a.s./L formulations (ca. 90% a.s. on a w/w basis). Detailed information on the composition of A9396B, A9396C and A9396G can be found in the confidential part of this dossier. Since testing has not been carried out using A9396G, and given the similarity between A9396G and A9396C, the risk assessment was conducted using endpoints derived for the C variant.

Risk assessment for –Maize/Sunflower (BBCH<10), Maize (BBCH11-18) /1 × 1.44 kg a.s./ha based on extended lab test or aged residue tests

Species	ER_{50} (kg a.s./ha)	In-field rate (kg a.s./ha)	Off-field rate (kg a.s./ha)*
Aphidius rhopalosiphi[1]	1.5	1.44	0.199(3D, 1m, 2.77 %)
Typhlodromus pyri[2]	1.5	1.44	0.04(2D, 1m, 2.77 %)
Aleochara bilineata[3]	1.5	1.44	0.04 (2D, 1m, 2.77 %)
Poecilus cupreus[4]	1.5	1.44	0.04 (2D, 1m, 2.77 %)

[1] 3D – extendes laboratory test on barley plants
[2] 2D – extended laboratory test on leaf discs
[3] 2D – extended laboratory test on sand
[4] 2D - extended laboratory test on sand
* Correction Factor is used since a limited number of indicator species are tested when compared to the range of species which could be exposed in off-field habitats, a 5-fold uncertainty (correction) factor was included to the calculation to ensure a higher rate is tested which covers the inter-species variability in sensitivity of off-field non-target arthropod species to plant protection products (ESCORT 2, P18)

Risk assessment for – Maize/Sunflower (BBCH<10), Maize (BBCH11-18) /1 × 1.25 kg a.s./ha based on extended lab test or aged residue tests

Species	ER_{50} (kg a.s./ha)	In-field rate (kg a.s./ha)	Off-field rate (kg a.s./ha)*
Aphidius rhopalosiphi[1]	1.5	1.25	0.173(3D, 1m, 2.77 %)
Typhlodromus pyri[2]	1.5	1.25	0.035(2D, 1m, 2.77 %)
Aleochara bilineata[3]	1.5	1.25	0.035 (2D, 1m, 2.77 %)
Poecilus cupreus[4]	1.5	1.25	0.035 (2D, 1m, 2.77 %)

[1] 3D – extendes laboratory test on barley plants
[2] 2D – extended laboratory test on leaf discs
[3] 2D – extended laboratory test on sand
[4] 2D - extended laboratory test on sand
* Correction Factor is used since a limited number of indicator species are tested when compared to the range of species which could be exposed in off-field habitats, a 5-fold uncertainty (correction) factor was included to the calculation to ensure a higher rate is tested which covers the inter-species variability in sensitivity of off-field non-target arthropod species to plant protection products (ESCORT 2, P18)

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance	Application method of test a.s./ OM	Time scale	End point	Toxicity
Earthworms					
Eisenia fetida	A9396G	Mixed into soil 5 % peat	Chronic	Reproduction	NOEC = 29.4 mg /kg soil dw (equivalent to 25.3 mg a.s./kg) EC_{10} = 37.6 mg /kg soil dw (equivalent to 32.4 mg a.s./kg) $NOEC_{corr}$ = 14.7 mg /kg soil dw (equivalent to 25.3 mg a.s./kg)
Eisenia fetida	CGA354743 (ESA)	Mixed into soil 5 % peat	Chronic	Growth, reproduction, mortality	NOEC = 100 mg/kg soil dw EC_{10} > 100 mg/kg soil dw $NOEC_{corr}$ = 50 mg/kg soil dw
Eisenia fetida	CGA51202 (OXA)	Mixed into soil 5 % peat	Chronic	Reproduction	NOEC = 55.6 mg/kg soil dw EC_{10} = 74.8 mg/kg soil dw $NOEC_{corr}$ = 27.8 mg/kg soil dw
Eisenia fetida	CGA368208	Mixed into soil 5 % peat	Chronic	Reproduction	NOEC = 500 mg/kg soil dw EC_{10} = 340 mg/kg soil dw EC_{10corr} = 170 mg/kg soil dw
Eisenia fetida	CGA40172	Mixed into soil 5 % peat	Chronic	Reproduction	NOEC = 250 mg/kg soil dw EC_{10} = 244 mg/kg soil dw EC_{10corr} = 122 mg/kg soil dw
Eisenia fetida	CGA50720	Mixed into soil 5 % peat	Chronic	Growth, reproduction, mortality	NOEC = 1000 mg/kg soil dw $NOEC_{corr}$ = 500 mg/kg soil dw
Eisenia fetida	CGA37735	Mixed into soil 5 % peat	Chronic	Reproduction	NOEC = 500 mg/kg soil dw EC_{10} = 357 mg/kg soil dw EC_{10corr} = 178.5 mg/kg soil dw
Eisenia fetida	NOA436611	Mixed into soil 5 % peat	Chronic	Reproduction, Biomass	NOEC = 55.6 mg/kg soil dw EC_{10} = 56 mg/kg soil dw $NOEC_{corr}$ = 27.8 mg/kg soil dw
Other soil macroorganisms					

Test organism	Test substance	Application method of test a.s./ OM	Time scale	End point	Toxicity
Folsomia candida	A9396G	Mixed into soil 5 % peat	Chronic	Reproduction	NOEC = 260 mg/kg soil dw EC_{10} = 195.5 mg/kg soil dw EC_{10corr} = 97.75 mg/kg soil dw
Folsomia candida	CGA354743 (ESA)	Mixed into soil 5 % peat	Chronic	Mortality, reproduction	NOEC = 1000 mg/kg soil dw $NOEC_{corr}$ = 500 mg/kg soil dw
Folsomia candida	CGA51202 (OXA)	Mixed into soil 5 % peat	Chronic	Mortality, reproduction	NOEC = 1000 mg/kg $NOEC_{corr}$ = 500 mg/kg soil dw
Folsomia candida	CGA368208	Mixed into soil 5 % peat	Chronic	Mortality, reproduction	NOEC = 1000 mg/kg soil dw $NOEC_{corr}$ = 500 mg/kg soil dw
Folsomia candida	CGA40172	Mixed into soil 5 % peat	Chronic	Reproduction	NOEC = 500 mg/kg soil dw EC_{10} = 567 mg/kg soil dw $NOEC_{corr}$ = 250 mg/kg soil dw
Folsomia candida	CGA50720	Mixed into soil 5 % peat	Chronic	Reproduction	NOEC = 500 mg/kg soil dw EC_{10} = 700 mg/kg soil dw $NOEC_{corr}$ = 250 mg/kg soil dw
Folsomia candida	CGA37735	Mixed into soil 5 % peat	Chronic	Reproduction	NOEC = 31.25 mg/kg soil dw EC_{10} = 17.1 mg/kg soil dw EC_{10corr} = 8.55 mg/kg soil dw
Folsomia candida	NOA436611	Mixed into soil 5 % peat	Chronic	Reproduction	NOEC = 125 mg/kg EC_{10} = 217.5 mg/kg soil dw $NOEC_{corr}$ = 62.5 mg/kg soil dw
Hypoaspis aculeifer	A9396G	Mixed into soil 5 % peat	Chronic	Mortality, reproduction	NOEC = 1000 mg/kg soil dw $NOEC_{corr}$ = 500 mg/kg soil dw
Hypoaspis aculeifer	CGA354743 (ESA)	Mixed into soil 5 % peat	Chronic	Mortality, reproduction	NOEC = 1000 mg/kg soil dw $NOEC_{corr}$ = 500 mg/kg soil dw
Hypoaspis aculeifer	CGA51202 (OXA)	Mixed into soil 5 % peat	Chronic	Mortality, reproduction	NOEC = 1000 mg/kg soil dw $NOEC_{corr}$ = 500 mg/kg soil dw
Hypoaspis aculeifer	CGA368208	Mixed into soil 5 % peat	Chronic	Mortality, reproduction	NOEC = 1000 mg/kg $NOEC_{corr}$ = 500 mg/kg soil dw

Test organism	Test substance	Application method of test a.s./ OM	Time scale	End point	Toxicity
Hypoaspis aculeifer	CGA40172	Mixed into soil 5 % peat	Chronic	Mortality, reproduction	NOEC = 1000 mg/kg soil dw $NOEC_{corr}$ = 500 mg/kg soil dw
Hypoaspis aculeifer	CGA50720	Mixed into soil 5 % peat	Chronic	Mortality, reproduction	NOEC = 1000 mg/kg soil dw $NOEC_{corr}$ = 500 mg/kg soil dw
Hypoaspis aculeifer	CGA37735	Mixed into soil 5 % peat	Chronic	Mortality, reproduction	NOEC = 1000 mg/kg soil dw $NOEC_{corr}$ = 500 mg/kg soil dw
Hypoaspis aculeifer	NOA436611	Mixed into soil 5 % peat	Chronic	Mortality, reproduction	NOEC = 1000 mg/kg soil dw $NOEC_{corr}$ = 500 mg/kg soil dw

A field study in a maize field in southern Germany showed that the application of A9396C, a formulation similar to A9396G, had no significant effects on earthworm numbers and biomass up to 12 months after the application of 1250 and 1900 g a.s./ha.

Soil nitrogen transformation

Test substance	**Test concentration (adverse effects < 25%)** **[mg /kg]**	**PEC SOIL** **[mg/kg]**	Risk acceptable [yes/no]
Use in pre-emergent maize and sunflower crops at 1440 g a.s./ha (worst case)			
A9396G	14.75	2.22	yes
S-metolachlor	14.55	1.92	yes
CGA354743 (ESA)	3.92	2.34	yes
CGA51202 (OXA)	3.12	1.78	yes
CGA368208	1.25	0.150	yes
CGA40172	13.1	0.135	yes
CGA50720	0.92	0.115	yes
CGA37735	9.28	0.093	yes
NOA436611	22.1	0.324	yes

Toxicity/exposure ratios for soil organisms

Use in pre-emergent maize and sunflower crops at 1440 g a.s./ha (worst case use)

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia fetida	A9693G	Chronic	2.22[1]	6.6	5

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Eisenia fetida	CGA354743 (ESA)	Chronic	2.353[2]	21.2	5
Eisenia fetida	CGA51202 (OXA)	Chronic	1.801[2]	15.4	5
Eisenia fetida	CGA368208	Chronic	0.168[2]	1011.9	5
Eisenia fetida	CGA40172	Chronic	0.131[2]	931.3	5
Eisenia fetida	CGA50720	Chronic	0.115[1]	4348	5
Eisenia fetida	CGA37735	Chronic	0.093[1]	1919	5
Eisenia fetida	NOA436611	Chronic	0.421[1]	~~86~~	5
Other soil macroorganisms					
Folsomia candida	A9693G	Chronic	2.22[1]	44	5
Folsomia candida	CGA354743 (ESA)	Chronic	2.353[2]	212.5	5
Folsomia candida	CGA51202 (OXA)	Chronic	1.801[2]	138.8	5
Folsomia candida	CGA368208	Chronic	0.168[2]	2976.2	5
Folsomia candida	CGA40172	Chronic	0.131[2]	1908.4	5
Folsomia candida	CGA50720	Chronic	0.115[1]	2173.9	5
Folsomia candida	CGA37735	Chronic	0.093[1]	92	5
Folsomia candida	NOA436611	Chronic	0.421[1]	148.5	5
Hypoaspis aculeifer	A9693G	Chronic	2.22[1]	225	5
Hypoaspis aculeifer	CGA354743 (ESA)	Chronic	2.353[2]	212.5	5
Hypoaspis aculeifer	CGA51202 (OXA)	Chronic	1.801[2]	277.6	5
Hypoaspis aculeifer	CGA368208	Chronic	0.168[2]	2976.2	5
Hypoaspis aculeifer	CGA40172	Chronic	0.131[2]	3816.8	5
Hypoaspis aculeifer	CGA50720	Chronic	0.115[1]	4347.8	5
Hypoaspis aculeifer	CGA37735	Chronic	0.093[1]	5376.3	5
Hypoaspis aculeifer	NOA436611	Chronic	0.421[1]	1187.6	5

[1]initial PEC

[2]peak accum PEC

Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

Not required for herbicides or plant growth regulators as ER_{50} tests should be provided

Laboratory dose response tests

The hazard and risk assessment to non target terrestrial plants were discussed at the at the Pesticide Peer Review Teleconference 29.[5] The experts agreed that the vegetative vigour and seedling emergence studies available with the representative formulation are reliable.[6] However, the experts concluded that none of the regulatory studies could be used for the hazard characterisation since most non-target plant species tested belonged to labelled crops tolerant to S-metolachlor. Furthermore, a peer-reviewed publication from the systematic literature search[7] indicated a higher sensitivity of non-crop plants. Owing to the lack of suitable endpoints covering non tolerant species, the risk to non target terrestrial plants could not be assessed for any of the representative uses (data gap).

[1] based on Ganzelmeier drift data

[5] See Experts' consultation points 5.7 and 5.8 at the Pesticide Peer Review Teleconference 29 (October 2020) (EFSA, 2023).

[6] In the vegetative vigour study, cucumber was the most sensitive species tested with an ER_{50} based on phytotoxic effects of 610.5 g a.s./ha. In the seedling emergence study, ryegrass was the most sensitive species tested with an ER50 based on the foliar dry weight of 82.9 g a.s./ha.

[7] Boutin, C., Elmegaard, N. & Kjær, C. Toxicity Testing of Fifteen Non-Crop Plant Species with Six Herbicides in a Greenhouse Experiment: Implications for Risk Assessment. Ecotoxicology 13, 349–369 (2004). https://doi.org/10.1023/B:ECTX.0000033092.82507.f3

Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	end point
Activated sludge	NOEC ≥ 100 mg/L

Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

Available monitoring data concerning adverse effect of the a.s.
No data submitted.
Available monitoring data concerning effect of the PPP.
No data submitted.

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds[1]

Compartment	
Soil	metolachlor (mixture of constituent isomers)
Water	metolachlor (mixture of constituent isomers)
Sediment	metolachlor (mixture of constituent isomers)
Groundwater	metolachlor, CGA354743 (ESA), CGA51202 (OXA), CGA357704, CGA368208, CGA37735, CGA40172, CGA50720, NOA413173. NOA436611, SYN542488, SYN542489, SYN542490, SYN542491, SYN542492, SYN542607, SYN545026, SYN545027, SYN547969, SYN547977 all mixtures of isomers

[1] metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance	S-metolachlor
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][8]:	Aquatic Acute 1, H400; Aquatic Chronic 1, H410 (Very toxic to aquatic life with long lasting effects) M-factor: acute: 10; chronic: 10 (for non rapidly degradable substances) Based on the $E_rC_{50\ (shoot\ length)}$ (7d) of 0.062 mg/L for *Elodea canadensis* and the NOEC (14d) of 0.0021 mg/L for *Lemna gibba*
According to the Peer review, the criteria for classification may be met for:	-

[8] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.