Appendix to:
EFSA (European Food Safety Authority), 2019. Conclusion on the peer review of the pesticide risk assessment of the active substance thiacloprid. EFSA Journal 2019;17(2):5595, 109 pp. doi:10.2903/j.efsa.2019.5595
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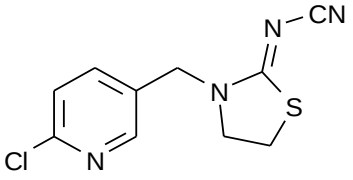
Appendix A – List of end points for the active substance and the representative formulation

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)	Thiacloprid
Function (*e.g.* fungicide)	Insecticide

Rapporteur Member State	United Kingdom
Co-rapporteur Member State	Germany

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

Chemical name (IUPAC)	{(*Z*)-3-[(6-chloro-3-pyridyl)methyl]thiazolidin-2-ylidene}cyanamide
Chemical name (CA)	(*Z*)-3-(6-chloro-3-pyridylmethyl)-1,3-thiazolidin-2-ylidenecyanamide
CIPAC No	631
CAS No	111988-49-9
EC No (EINECS or ELINCS)	A temporary EC number has been allocated (601-147-9)
FAO Specification (including year of publication)	Thiacloprid 631/TC min. 975 g/kg (May 2010)
Minimum purity of the active substance as manufactured	975 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Thiacloprid Technical Grade Active Substance (TGAS) does not contain any relevant impurities.
Molecular formula	$C_{10}H_9ClN_4S$
Molar mass	252.73 g/mol
Structural formula	

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

Melting point (state purity)	133.9 °C (99.0 %), 136 °C (99.3 %)
Boiling point (state purity)	Decomposes at 250 – 300 °C
Temperature of decomposition (state purity)	250 - 300 °C (98.3 % - 99.3 %)
Appearance (state purity)	White/*y*ellowish powder
Vapour pressure (state temperature, state purity)	3 x 10^{-10} Pa at 20°C 8 x 10^{-10} Pa at 25°C 1.6 - 4.5x 10^{-8} Pa at 50°C 1.2 - 1.6 x 10^{-7} Pa at 60°C 1.7 - 6.3 x 10^{-7} Pa at 70°C (99.7 %)
Henry's law constant (state temperature)	4.8 x 10^{-10} Pa m^3 mol^{-1} at 20 °C (calculated) 5.0 x 10-10 Pa m3 mol-1 at 25 °C (calculated)
Solubility in water (state temperature, state purity and pH)	pH 4 186 mg/L at 20°C pH 5.5 185 mg/L at 20°C pH 7.0 184 mg/L at 20°C pH 9.0 185 mg/L at 20°C (99.3 %) pH 6.5 159 mg/L at 20°C (99.0 %)
Solubility in organic solvents (state temperature, state purity)	heptane <0.1 g/L at 20°C xylene 0.30 g/L at 20°C dichloromethane 160 g/L at 20°C 1-octanol 1.4 g/L at 20°C 1-propanol 3.0 g/L at 20°C acetone 64 g/L at 20°C ethyl acetate 9.4g/L at 20°C polyethylene glycol 42 g/L at 20°C acetonitrile 52 g/L at 20°C dimethyl sulfoxide150 g/L at 20°C (98.6 %)
Surface tension (state concentration and temperature, state purity)	72 mN/m at 20 °C (90 % saturated solution) (99.0 %)
Partition coefficient (state temperature, pH and purity)	log P_{OW} = 1.26 – 1.4 at 20 °C (4 - 9) (99.0 – 99.3 %)
Dissociation constant (state purity)	Thiacloprid, pure substance, in the pH-range of 1 < pH < 12

UV/VIS absorption (max.) incl. ε (state purity, pH)	solution: Acetonitrile λ_{max} (nm); 242 ε (L mol^{-1} cm^{-1}) 18195 solution: Methanol λ_{max} (nm); 220 and 243 at neutral pH ε (L mol^{-1} cm^{-1}) 13878 and 19095 λ_{max} (nm); 220 and 243 at pH 2 ε (L mol^{-1} cm^{-1}) 14324 and 19513 λ_{max} (nm); 220 and 243 at pH 10 ε (L mol^{-1} cm^{-1}) 14828 and 19544 The above studies found no UV absorbance above 290 nm Absorabance above 290 nm was observed in photodegradation of thiaclopdrid in water study. This was < 100 L mol^{-1} cm^{-1} and tailed off to zero by 305 nm.
Flammability (state purity)	Not a flammable solid in the sense of Regulation 1272/2008/EC (97.5 % w/w)
Explosive properties (state purity)	Non-explosive (97.5 % w/w)
Oxidising properties (state purity)	Not oxidising (98.3 % w/w)

Summary of representative uses evaluated, for which all risk assessments needed to be completed (*name of active substance or the respective variant*) (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)		
Oilseed rape	EU-N/S	Thiaclop rid OD 240	F	*Meligethes aeneus*, *Ceutorhynchus napi*, *Ceutorhynchus quadridens*	OD	240	Foliar spray	BBCH 30-59	1-2	10	24-72	100-300	72	n.a	Product label rate: Max. 0.3 L/ha
Maize(relevant for all representative uses evaluated; see Sections 1,2)	EU-N/S	Thiaclop rid FS 400	F	Wireworm Frit fly	FS	400	Seed treatment	BBCH 00	1	-	1 mg as/seed or 50g ai/unit	-	110	n.a	Sowing rate: 2.2 unit/ha (1 unit – 50,000 seeds) 0.125L product/unit

(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)

The representative uses/GAPs are supported

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

The representative uses/GAPs are supported

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

The representative uses/GAPs are supported

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

	M30	M34	M46
Activity against target organism	Yes	No	No

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)	CIPAC method 631/TC/M/3
Impurities in technical a.s. (analytical technique)	HPLC-UV
Plant protection product (analytical technique)	HPLC with UV

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		Thiacloprid
Food of animal origin		Thiacloprid
Soil		Thiacloprid
Sediment		Thiacloprid
Water	surface	Thiacloprid and metabolites M29, M30, M34 and M46
	drinking/ground	Thiacloprid and metabolites M30, M34 and M46
Air		Thiacloprid
Body fluids and tissues		Thiacloprid and metabolite M07

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC MS/MS method based on QuEChERS Validation data available for orange fruit (high acid commodity), tomato fruit and potato tuber (high water commodities), dry bean seed (dry commodity), rape seed (high oil commodity) and tea fermented leaves (no group). ILV provided. LOQ: 0.01 mg/kg
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC MS/MS method based on QuEChERS validated in egg, fat, kidney, liver, milk and muscle. ILV data are available for milk and liver. LOQ: 0.01 mg/kg
Soil (analytical technique and LOQ)	HPLC MS/MS LOQ: 2 µg/kg
Water (analytical technique and LOQ)	HPLC MS/MS LOQ: 0.05 µg/L ILV available for drinking water. Data gap: Method required for M29, M30, M34 and M46 in surface water. Method required for M30, M34 and M46 in ground water
Air (analytical technique and LOQ)	HPLC-UV LOQ of 0.0018 mg/m^3

Body fluids and tissues (analytical technique and LOQ)	HPLC MS/MS method based on QuEChERS (identical to that for animal commodities) LOQ: 0.01 mg/kg for tissues and 0.05 mg/L for fluids Data gap: method for M07

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

Substance	Thiacloprid
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]:	Not applicable
Peer review proposal [2] for harmonised classification according to Regulation (EC) No 1272/2008:	Not applicable

[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.

[2] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

Impact on Human and Animal Health

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	> 80% based on the comparison of excretion patterns after i.v and oral administration. (Excretion of radioactivity from i.v. administration showed similar levels of excretion after 48 hrs (m/f: 68/61% in urine and 29/28% in faeces) compared to oral administration after 48 hrs (m/f: 65/60% in urine and 28/21% in faeces)) This value is established for the derivation of the systemic AOEL. There is no need for absorption adjustment.
Toxicokinetics	1 mg/kg bw, intravenous, ^{14}C-methylene-labelled thiacloprid male: $T_{1/2}$[a] plasma (h) 81.4; $AUC_{(0-48h)}$ (µg/mL/h) 9.3 female: $T_{1/2}$[a] plasma (h) 7.4; $AUC_{(0-48h)}$ (µg/mL/h) 12.9 [a] Terminal half-lives, mostly based on two exponential terms. 1 mg/kg bw, gavage, ^{14}C-methylene-labelled thiacloprid male: $T_{1/2}$[a] plasma (h) 82.0; $AUC_{(0-48h)}$ (µg/mL/h) 5.5 female: $T_{1/2}$[a] plasma (h) 25.2; $AUC_{(0-48h)}$ (µg/mL/h) 5.8 1 mg/kg bw, gavage repeat, ^{14}C-methylene-labelled thiacloprid male: $T_{1/2}$[a] plasma (h) 38.1; $AUC_{(0-48h)}$ (µg/mL/h) 5.4 female: $T_{1/2}$[a] plasma (h) 405[b]; $AUC_{(0-48h)}$ (µg/mL/h) 9.1 [b] The report considered this result to be artificial because the unsatisfactory mathematical description of the plasma curve required three elimination terms. 100 mg/kg bw, gavage, ^{14}C-methylene-labelled thiacloprid male: $T_{1/2}$[a] plasma (h) 9.2; $AUC_{(0-48h)}$ (µg/mL/h) 9.0 female: $T_{1/2}$[a] plasma (h) 12.3; $AUC_{(0-48h)}$ (µg/mL/h) 16.8 1 mg/kg bw, gavage, ^{14}C-thiazolidine-labelled thiacloprid male: Cmax (µg/ml) 0.7 female: Cmax (µg/ml) 0.7

	Tmax (h) 2.0 3.0 $T_{1/2}$[a&b] plasma (h) 2.2 3.3 $AUC_{(0-48h)}$ (µg/mL/h) 9.2 10.4 [a&b] Based on the first elimination phase. The terminal elimination half-lives ranged from approx. 10 – 44 hours. <u>100 mg/kg bw, gavage, ^{14}C-thiazolidine-labelled thiacloprid</u> male Cmax (µg/ml) 50.3 Tmax (h) 4.0 $T_{1/2}$[a&b] plasma (h) 4.0 $AUC_{(0-48h)}$ (µg/mL/h) 1560
Distribution	Rapid and relatively even distribution of thiacloprid and/or its metabolites in tissues. Levels in tissues and plasma were highest at 1 – 4 hours following oral administration.
Potential for bioaccumulation	No evidence for accumulation
Rate and extent of excretion	Rapidly excreted. Radioactivity was excreted primarily in urine (53.0 – 82.9%) and largely during the first 24 hours; faecal excretion (13.3 – 39.1%) was also significant and excretion of radiolabelled carbon dioxide in expired air was found to be minimal. Significant biliary excretion. Some excretion in sweat and mucus.
Metabolism in animals	Extensively metabolised. Up to 17 metabolites were identified in urine and/or faeces, accounting for 55.3 – 78.7% of the administered radioactivity. A number of metabolic transformation reactions were proposed, including opening of the thiazolidine ring.
In vitro metabolism	The new comparative *in vitro* metabolism study provides no meaningful information on any potential differences in the metabolism of thiacloprid between rats and humans. Differences in the results of the *in vitro* metabolism study when compared to the *in vivo* studies (where thiacloprid was extensively metabolised) raise concerns regarding whether suitable systems were used (lack of phase II enzyme activity, female rat microsomes and relevant species e.g. rabbit not investigated). A data gap has therefore been identified.
Toxicologically relevant compounds (animals and plants)	Thiacloprid
Toxicologically relevant compounds (environment)	Thiacloprid, M30, M34, M46

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

Rat LD_{50} oral	177 mg/kg bw [a)]	**H301**

Rat LD_{50} dermal	> 2000 mg/kg bw	
Rat LC_{50} inhalation	1.2 mg/L air /4h (directed-flow nose-only)	**H332**
Skin irritation	Slight irritant	
Eye irritation	Slight irritant	
Skin sensitisation	Not sensitising (Guinea Pig (M&K) Maximization Test)	
Phototoxicity	Negative results in *in vitro* (BALB/c 3T3 cells) (data gap) [b)]	

[a)] The endpoint is an extrapolated value from the following studies where 0% mortality was found at 109 mg/kg bw and 100% mortality was observed at 244 mg/kg bw

[b)] It is noted that the test is not adequate for UVB absorbers such as thiacloprid, therefore a data gap has been identified. However there is currently no validated test to address the phototoxicity potential of these substances

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

Target organ / critical effect	**Rat:** liver (increased liver weight, centrilobular hypertrophy and changes in cytoplasm of hepatocytes), body weight and food intake effects **Mice:** liver (increased liver weight, centrilobular hypertrophy, changes in cytoplasm of hepatocytes, increase in lipid content of hepatocytes) **Dog:** liver (enzyme induction), prostate (increased weights, slight to moderate hypertrophy)	
Relevant oral NOAEL	90-day, rat: 7 mg/kg bw per day 14-week, mice: 20 mg/kg bw per day 1-year, dog: 9 mg/kg bw per day	
Relevant dermal NOAEL	28-day, rat: 100 mg/kg bw per day	
Relevant inhalation NOAEL	28-day, rat: 18.2 mg/m^3 air (5.3 mg/kg bw per day)	

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

In vitro studies	Bacterial reverse mutation assays (2) – negative Mammalian cell gene mutation assay – negative Mammalian chromosome aberration test – negative Micronucleus test – negative Supplementary studies:	

	Unscheduled DNA synthesis assay – negative Bacterial DNA repair test – negative	
In vivo studies	Micronucleus test in mice – negative	
Photomutagenicity	No data, phototoxicity inconclusive – data required[c)]	
Potential for genotoxicity	Thiacloprid is unlikely to be genotoxic	

[c)] it is noted that no validated test is available to address this endpoint

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

Long-term effects (target organ/critical effect)	**Rat**: Liver: histopathology Thyroid: histopathology and increased TSH levels Nervous system and muscle: degenerative changes Eye: lesions and ocular effects **Mouse:** Liver: increased weight and hypertrophy Adrenal X-zone: vacuolation Ovaries: histopathology Lymph nodes: vacuolation	
Relevant long-term NOAEL	2-year, rat: 1.2 mg/kg bw per day 2-year, mouse LOAEL: 11 mg/kg bw per day (carcinogenic effects)	
Carcinogenicity (target organ, tumour type)	**Rat**: tumours (uterine adenocarcinoma in females and thyroid follicular cell adenoma in males) **Mouse**: benign ovarian luteoma	**Cat. 2, H351**
Relevant NOAEL for carcinogenicity	2-year, rat: 2.5 mg/kg bw per day 2-year, mouse LOAEL: 11 mg/kg bw per day	

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

Reproduction toxicity

Reproduction target / critical effect	Parental toxicity: bodyweight effects, thyroid and liver (histopathology and increased weights) Reproductive toxicity: dystocia Offspring's toxicity: decreased pup weight and survival	**Repr. 1B H360FD**
Relevant parental NOAEL	2.7 mg/kg bw per day	
Relevant reproductive NOAEL	2.7 mg/kg bw per day	
Relevant offspring NOAEL	2.7 mg/kg bw per day	

Developmental toxicity

Developmental target / critical effect	**Rat:** Maternal toxicity: body weight effects and reduced food intake Developmental toxicity: increased incidence of pelvic dilation, and skeletal variations. Reduced implantation, post-implantation loss, increased resorptions and total malformations were observed at higher dose level **Rabbit:** Maternal toxicity: decreased body weight Developmental toxicity: decreased foetal weight. Early resorption and post-implantation loss were observed at higher dose levels	**Repr. 1B H360FD**
Relevant maternal NOAEL	Rat: 10 mg/kg bw per day Rabbit: 2 mg/kg bw per day	
Relevant developmental NOAEL	Rat: 2 mg/kg bw per day Rabbit: 2 mg/kg bw per day	

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

Acute neurotoxicity	NOAEL: 3.1 mg/kg bw per day Effects at LOAEL: decreases in motor and locomotor activity	**STOT SE 3, H336**
Repeated neurotoxicity	**Generalised toxicity:** NOAEL: 3 mg/kg bw per day Effects at LOAEL: reduced food intake and body weight **Neurotoxicity:** NOAEL: 101 mg/kg bw per day (the highest dose tested)	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	Limited dietary developmental neurotoxicity (DNT) study in rat: **Generalised toxicity:** NOAEL: 4.4 mg/kg bw per day. Effects at LOAEL: decrease in body weight of dams and pups, delay in sexual maturation of pups. **Neurotoxicity:** NOAEL: 41 mg/kg bw per day (the highest dose tested).	

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

Supplementary studies on the active substance	**Mode of action studies for tumours and dystocia**. Definite mode of action for tumours not clearly demonstrated but indicated that uterine and ovarian tumours may have resulted as a consequence of thiacloprid interfering with sex hormone biosynthesis, resulting in changes in circulating plasma sex hormones *in vivo*. Thyroid tumours were a consequence of liver enzyme induction. No clear evidence provided to exclude the relevance of tumours to humans. Ovarian aromatase activity was increased in pregnancy and remained elevated during lactation. An alteration in sex hormone levels and specifically in the oestrogen/progesterone (EP) ratio was proposed as the mode of action for dystocia. However, a causal relationship for this mode of action was not demonstrated. The relevance to humans of these effects could not be dismissed. **90-day immunotoxicity investigations:** There was a slight increase in macrophage activation and a slight increase in males of lipopolysaccharide (LPS) stimulated cells (mitogenic stimulation) in the spleen at the highest dose tested of 123 mg/kg bw per day in a 90-day study in rats. No adverse effects were observed on cell counts, cell size distribution of spleen and lymph node cells, and antibody levels (IgA, IgG and IgM). There was no evidence of an effect on cell proliferation in the liver or kidney evaluations.
Endocrine disrupting properties	Additional studies not performed. Thiacloprid meets the EFSA (2013) criteria and WHO definition for an endocrine disruptor (ED) as it causes adverse effects on the reproductive and endocrine system through an endocrine MoA.
Studies performed on metabolites or impurities	
M01	No toxicological studies available Reliable *in silico* predictions provided no evidence for genotoxicity (genotoxicity and chromosome aberration). It cannot be excluded that the metabolite shares the carcinogenic and reproductive toxicity properties of the parent thiacloprid.
M02 (thiacloprid-amide)	Acute oral toxicity: LD_{50} > 2000 mg/kg bw Genotoxicity (bacterial reverse mutation test): negative Reliable *in silico* predictions provided no evidence for genotoxicity (chromosome aberration) It cannot be excluded that the metabolite shares the carcinogenic and reproductive toxicity properties of the parent thiacloprid.

M03 (6-chloronicotinic acid also known as IC-0)	Acute oral toxicity: LD_{50} > 5000 mg/kg bw Genotoxicity (bacterial reverse mutation test): negative The toxicological profile of the metabolite M03 is covered by the toxicological profile of the active substance **acetamiprid:** ADI and ARfD of acetamiprid are 0.025 mg/kg bw per day (EFSA, 2016). Acetamiprid and metabolite M03 are considered carcinogenic category 2, but not toxic for reproduction (no harmonised classification).
M07	Major metabolite in rats' urine; the metabolite is covered by the parent's toxicological reference values and is expected to share the carcinogenic and reproductive toxicity potential of thiacloprid.
M29 (YRC 2894 Imine)	Reliable *in silico* predictions provided no evidence for genotoxicity (genotoxicity and chromosome aberration). It cannot be excluded that the metabolite shares the carcinogenic and reproductive toxicity properties of the parent thiacloprid.
M30 (thiacloprid-sulfonic acid/sulfonic acid Na-salt)	Acute oral toxicity: LD_{50} > 2000 mg/kg bw Genotoxicity (4 *in vitro* tests on genotoxicity – a bacterial reverse mutation test, a mammalian cell gene mutation test, a mammalian chromosome aberration test and a micronucleus test): negative Unlikely to be genotoxic Liver enzyme induction: metabolites showed no treatment-related influence. Steroidogenesis: negative Reproductive toxicity: negative. It cannot be excluded that the metabolite shares the carcinogenic properties of the parent
M31 (6-chloropicolyl urea)	Reliable *in silico* predictions provided no evidence for genotoxicity (genotoxicity and chromosome aberration).
M34 (thiacloprid-sulfonic acid amide)	Acute oral toxicity: LD_{50} > 2000 mg/kg bw Genotoxicity (4 *in vitro* tests on genotoxicity – a bacterial reverse mutation test, a mammalian cell gene mutation test, a mammalian chromosome aberration test and a micronucleus test): negative Unlikely to be genotoxic Liver enzyme induction: metabolites showed no treatment-related influence. Steroidogenesis: negative Reproductive toxicity: negative It cannot be excluded that the metabolite shares the carcinogenic properties of the parent.
M36 (6-CPA free)	No toxicological studies available Reliable *in silico* predictions provided no evidence for genotoxicity (genotoxicity and chromosome aberration). It cannot be excluded that the metabolite shares the carcinogenic and reproductive toxicity properties of the

	parent thiacloprid.
M37	No toxicological studies available Reliable *in silico* predictions provided no evidence for genotoxicity (genotoxicity and chromosome aberration). It cannot be excluded that the metabolite shares the carcinogenic and reproductive toxicity properties of the parent thiacloprid.
M38 (YRC 2894 olefin)	Reliable *in silico* predictions provided no evidence for genotoxicity (genotoxicity and chromosome aberration).
M46 (thiacloprid-thiadiazine also known as Z5)	Acute oral toxicity: LD_{50} > 2000 mg/kg bw Genotoxicity (3 *in vitro* tests on genotoxicity – a bacterial reverse mutation test, a mammalian cell gene mutation test and a micronucleus test): negative Unlikely to be genotoxic Liver enzyme induction: metabolites showed no treatment-related influence. Steroidogenesis: negative Reproductive toxicity: negative It cannot be excluded that the metabolite shares the carcinogenic properties of the parent.
M49	No toxicological studies available Reliable *in silico* predictions provided no evidence for genotoxicity (genotoxicity and chromosome aberration).

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

Limited; new active substance, no detrimental effects on health in manufacturing personnel

Summary[3] (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)	0.01(1)	rat, 2-year study	100
Acute Reference Dose (ARfD)	0.02(2)	rat, developmental toxicity study	100
Acceptable Operator Exposure Level (AOEL)	0.02(3)	rabbit, developmental toxicity, supported by the rat developmental toxicity study	100(4)
Acute Acceptable Operator Exposure Level (AAOEL)	0.02	rat, developmental toxicity study	100(4)

(1) No changes of the ADI value with regards to the previous review (European Commission, 2004)

[3] If available include also reference values for metabolites

(2) The ARfD value in the previous review was 0.03 mg/kg bw (European Commission, 2004)
(3) No changes of the AOEL value with regards to the previous review (European Commission, 2004)
(4) No correction needed for oral absorption

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

Representative formulation: *'Thiacloprid OD 240', an oil dispersion (OD) formulation containing 240 g/L thiacloprid and 'Thiacloprid FS 400', a flowable suspension (FS) formulation for seed treatment containing 400 g/L thiacloprid*)

Thiacloprid OD 240:
Concentrate (240 g/L thiacloprid): 0.2 %.
Intermediate spray dilution (0.74 g/L thiacloprid): 6 %.
Spray dilution (0.1 g/L thiacloprid): 14 %.
(*In vitro* dermal absorption study using human skin).

Thiacloprid FS 400:
Concentrate (400 g/L thiacloprid): 0.07 %.
In-use dilution (100 g/L thiacloprid): 0.2 %.
(*In vitro* dermal absorption study using human skin).

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2) – including negligible exposure assessment

Operators

'Thiacloprid OD 240'

Use: Oil seed rape, tractor mounted equipment with drift reduction nozzles, application rate 0.144 kg a.s./ha

Model: EFSA Calculator

	% AOEL	% AAOEL
Standard nozzles, no PPE	9.3	80.3
Standard nozzles, PPE (gloves during M&L and application)	1.9	49.2
CTS, standard nozzles, PPE (gloves during application)	1.4	46.4
Drift reduction nozzles, PPE (gloves during mixing, loading and application	0.8	3.9
CTS, drift reduction nozzles, PPE (gloves during application)	0.3	1.1

'Thiacloprid FS 400'

Use: seed treatment to maize, application rate 50 g a.s./50,000 seeds

Higher tier data: Seed treatment studies in seed treatment plants with the following control measures:

- Seed purification before treatment
- Use of binders/stickers in the seed treatment slurry
- Closed transfer systems during mixing/loading
- Automated mixing of co-applied products
- Gentle transport of seed
- Closed treatment line and treatment chamber
- Automated, closed bagging line
- Automated, enclosed palletizing
- Cleaning with the use of vacuum equipment not compressed air

	• Adequate dust aspiration system throughout the seed treatment process The following PPE during seed treatment is required: • Suitable protective coverall* and chemical resistant gloves to be worn during mixing/loading, cleaning and calibration. * Meeting the requirements of EN 14605 Protective clothing against liquid chemicals – Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, • Suitable protective gloves to be worn when coming into contact with contaminated surfaces or treated seeds • FFP3 RPE to be worn during cleaning operations. Seed treatment study with 'Thiacloprid FS 400' % AOEL % AAOEL Plants 1&3 range of tasks 0.5 0.8 Plant 2 range of tasks* 10.9 103.9 Seed treatment study with 'Reagent 500 FS' % AOEL % AAOEL Plants 1-3 range of tasks* 2.1 4.2 Plants 1-3 cleaning* 0.7 2.7 Plants 1-3 bagging 2.2 3.2 * Cleaning was undertaken with compressed air
Workers	**Thiacloprid OD 240'** Use: Oil seed rape, application rate 0.144 kg a.s./ha, exposure during inspection/irrigation Model: EFSA Calculator using refined DFR and DT_{50} from DFR studies % AOEL No PPE (with workwear) 7.6 Workwear & gloves 4.1 Workwear & re-entry restriction of 3 days 1.9 **'Thiacloprid FS 400'** Use: Loading/sowing maize seeds treated with 'Thiacloprid FS 400' at an application rate of 50 g a.s./50,000 seeds, seed sowing rate of 110 g a.s./ha. Higher tier data: seed sowing study with maize seeds treated with 'Thiacloprid FS 400' using pneumatic sowing machines with deflector technology with a drift reduction of at least 90% and closed cabin tractors. % AOEL % AAOEL PPE: protective gloves when handling treated seeds and contaminated surfaces: 2.5 3.4 FFP3 RPE during loading: 0.6 1.2 Worker exposure during re-entry – no dislodgeable foliar residues present therefore re-entry scenario does not exist.
Bystanders and residents	**'Thiacloprid OD 240'** Use: Oil seed rape, tractor mounted equipment with drift

reduction nozzles, application rate 0.144 kg a.s./ha

Model: EFSA Calculator using refined DFR and DT_{50} from DFR studies and refined vapour estimate using theoretical saturated vapour concentration. Spray drift calculated assuming 100 L/ha application volume and 6% dermal absorption. Surface deposits, entry into treated crops & all pathways calculated assuming 300 L/ha application volume and 14% dermal absorption.

Adult Resident	% AOEL
Spray Drift	0.7
Vapour	<0.1
Surface Deposits	0.2
Entry into Treated Crops	5.1
All pathways (mean)	4.5
Child Resident	
Spray Drift	2.9
Vapour	<0.1
Surface Deposits	0.5
Entry into Treated Crops	9.2
All pathways (mean)	9.0(1)
Adult Bystander	% AAOEL
Spray Drift	1.8
Vapour	<0.1
Surface Deposits	0.5
Entry into Treated Crops	5.1
Child Bystander	
Spray Drift	6.8(2)
Vapour	<0.1
Surface Deposits	1.5
Entry into Treated Crops	9.2

'Thiacloprid FS 400'

Use: Sowing maize seeds treated with 'Thiacloprid FS 400' at an application rate of 50 g a.s./50,000 seeds, seed sowing rate of 110 g a.s./ha.

Higher tier data: seed sowing drift study with maize seeds treated with 'Thiacloprid FS 400' using pneumatic sowing machines with deflector technology with a drift reduction of at least 90%.

Adult Resident	% AOEL
Dust Drift	<0.1
Surface Deposits	<0.1
All pathways (mean)	<0.1
Child Resident	
Dust Drift	<0.1
Surface Deposits	<0.1
All pathways (mean)	<0.1
Adult Bystander	%AAOEL
Dust Drift	<0.1
Surface Deposits	<0.1
Child Bystander	
Dust Drift	<0.1
Surface Deposits	<0.1

Vapour – exposure to vapour not expected due to the very low vapour pressure of thiacloprid

	Entry into treated crops – no dislodgeable foliar residues therefore re-entry scenario does not exist. Bystander/resident exposure during seed treatment Treated conducted indoors in professional plants therefore exposure of persons unrelated to the work is considered unlikely.

(1) 10.6% of the AOEL with standard nozzles
(2) 13.5% of the AAOEL with standard nozzles (100 L/ha, 6% dermal absorption)

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

Substance :	Thiacloprid
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][4] :	Acute Tox. 3, H301 'Toxic if swallowed' Acute Tox. 4, H332 'Harmful if inhaled' STOT SE 3, H336 'May cause drowsiness or dizziness' Carc. 2, H351 'Suspected of causing cancer' Repr. 1B, H360FD 'May damage fertility. May damage the unborn child'
Peer review proposal[5] for harmonised classification according to Regulation (EC) No 1272/2008:	Unchanged from harmonised classification.

[4] 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.
[5] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

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)	**Crop groups**	**Crop(s)**	**Application(s)**	**DAT** (days)
	Fruit crops	Apple	2 x 27.0 g a.s./hL, foliar	14
		Tomato	2 x 28.0 g a.s./hL, foliar 43.7 and 46.0 g a.s./ha (89.7 g a.s./ha), soil	3, 14
	Root crops	Potato	3 x 107 g a.s./ha, foliar	14
	Leafy crops			
	Cereals/grass crops	Wheat	2 x 50 g a.s./ha, foliar	21
		Maize	100 g a.s./ha, seed traeatment (1 mg a.s./seed) 500 g a.s./ha, seed treatment (5 mg a.s./seed)	130
		Rice	200 g a.s./ha 1000 g a.s./ha	62 143
	Pulses/Oilseeds	Cotton	3 x ~190 g a.s./ha, foliar	120
		Sunflower	80 g a.s./ha, seed treatment (1 mg a.s./seed) 400 g a.s./ha, seed treatment (5 mg a.s./seed)	138
	Miscellaneous			
	With the exception of maize in all studies only one ring was labelled.			

Rotational crops (metabolic pattern)	**Crop groups**	**Crop(s)**	**PBI** (days)	**Comments**
	Root/tuber crops	Turnip	30, 170 & 354	Bare soil, 1x 0.424 g a.s./ha
	Leafy crops	Lettuce	30, 170 & 354	
	Cereal (small grain)	wheat	30, 170 & 354	
Rotational crop and primary crop metabolism similar?	Thiacloprid is extensively degraded in all rotational crops. However, the four main metabolites resulting from this degradation (M02, M30, M34 and M37) are detected. In all studies only the methylene ring was labelled and further clarification regarding the fate of the thiazolidine moiety is requested..			

Processed commodities (standard hydrolysis study)	**Conditions**	Thiacloprid /% applied
	20 min, 90°C, pH 4	97.54
	60 min, 100°C, pH 5	96.29
	20 min, 120°C, pH 6	96.15

Residue pattern in processed commodities similar to residue pattern in raw commodities?	Thiacloprid is stable under conditions of pasteurisation, baking/brewing/boiling and sterilisation. Data on M03 not available (might not be triggered based on residue trial data in OSR analysing for total thiaclorpid residues <0.05 mg/kg, however it cannot be stated whether M03 free and conjugated, if analysed individually would exceed 0.01 mg/kg)

Plant residue definition for monitoring (RD-Mo)	Thiacloprid (parent only)
Plant residue definition for risk assessment (RD-RA)	**Primary crops**: For cereals (except rice): thiacloprid For oilseeds, provisional: thiacloprid and M03 (free and conjugated). Pending availability of further information on the thiazolidine moiety **Rotational crops, all provisional:** Leafy crops, root crops and cereals category: thiacloprid Pluses/oilseeds category: thiacloprid and M03 Pending relevance assessment with regard to M37 in leafy crops and of M02 and M30 in feed/fodder commodities as well as clarification on the fate of potential metabolites formed from the thiazolidine moiety
Conversion factor (monitoring to risk assessment)	n/a

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)

	Animal	Dose (mg/kg bw/d)	Duration (days)	N rate/comment
Animals covered	Laying hen	10	3	≥5000 N
	Goat/Cow	10	3	≥9090 N
	Pig	-	-	
	Fish	-	-	
	Available studies are considered valid. Studies were conducted with thiacloprid only. Exposure to thiacloprid residues from primary crops is below the trigger value while provisional livestock exposure estimates for metabolites M02 and M30 indicated exceedance of the trigger value. Follow up assessment upon availability of higher tier residue data in rotational crops necessary.			

Time needed to reach a plateau concentration in milk and eggs (days)	Egg. Not observed Milk. 54 hours
Animal residue definition for monitoring (RD-Mo)	Thiacloprid (parent only)
Animal residue definition for risk assessment (RD-RA)	Thiacloprid (provisional default definition); pending finalised relevance assessment of residue transfer of rotational crop metabolites in animal commodities
Conversion factor (monitoring to risk assessment)	n/a

Metabolism in rat and ruminant similar (Yes/No)	Yes
Fat soluble residues (Yes/No)	No

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

Confined rotational crop study (Quantitative aspect)	Thiacloprid is not expected in rotational crops as a result of the proposed use at > 0.01 mg/kg while metabolites M02, M30, M34, M36, M37 are recovered at significant proportions (largely exceeding 10% TRR) in rotational crops. Consideration the soil plateau concentration plus the concentration arising from maximum seasonal rate: M02 expected to occur at > 0.01 mg/kg in root tops and cereal forage (30 d PBI), and cereal hay and straw (170 d PBI) M30 expected to occur at > 0.01 mg/kg in cereal hay and straw (170 d PBI) and cereal forage (254 d PB). M37 expected to occur at $\geq$ 0.01 mg/kg in leafy crops (30 d PBI) M34 expected to occur at $\geq$ 0.01 mg/kg in cereal grain and cereal feed items
Field rotational crop study	Studies to investigate actual occurrence of metabolites M02, M30, M34, M37 in rotational crops under field conditions are requested.

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

Plant products (Category)	Commodity	T (°C)	Stability (Days)			
			Thiacloprid	Amide-YRC2894 (M02)	4-hydroxy YRC2894 Amide (M37)	YRC2894 sodium Sulfonate (M30)
High water content	Apple fruit	-18	539	-	-	-
	Tomato fuit	-18	540	-	-	-
	Soybean forage†	-10	576	576	576	576
	Wheat forage†	-10	568	568	568	568
	Pea (pea with pod)	-18	730	-	-	-
High oil content	Soybean†	-10	649	649	649	649
	Rape (seed)	-18	730	-	-	-
High protein content			-	-	-	-
High starch content	Potato (tuber)	-18	730	-	-	-
	Wheat (grain)†	-10	573	573	573	573
High acid content	Currant (fruit)	-18	730	-	-	-
No group	Wheat (straw) †	-10	573	573	573	573
	Wheat (straw)	-18	730	-	-	-
	Wheat hay†	-10	570	570	570	570
	Soybean hay†	-10	575	575	575	575
	Tobacco (leaf, dry)	-18	730	-	-	-

†Day 0 data are not available. Original study report required (data gap)

Storage period based on first determination to last determination. Also samples fortified with all 4 analytes. This could mask degradation, however as all metabolites are stable for the entire period this is not considered a significant issue.

The storage stability of thiacloprid in high oil, has been demonstrated for 649 days at ≤– 18 °C, for high water for 540 days at ≤ - 18 °C and in high starch commodities for 573 days at ≤ -18 °C.

Animal	Animal commodity	T (°C)	Stability (days)	
			Thiacloprid	Thiacloprid (total)
Cow	Milk	-20	32	32

Storage stability addressed during feeding study

Data gap for honey

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3)

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						
Oilseed Rape (seed)	N EU	**Monitoring: 9 x < 0.01** **Risk assessment: 4 x < 0.05**	0.01 mg/kg dataset for NEU and SEU can be combined Residues of total thiacloprid, oxidised to 6-CNA, expressed as thiacloprid, used as surrogate for oilseed risk assessment	0.01	0.05	0.05
	S EU	**Monitoring: 4 x < 0.01** **Risk assessment: 3 x < 0.05**				
Maize (kernel)	N EU	**8 x < 0.01**	0.01 mg/kg dataset for NEU and SEU can be combined. Data gap for residue data in stover	0.01	0.05	0.05
	S EU	**8 x < 0.01**				
Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)						
Product(s)	**Region**	**Residue data** (mg/kg)	**Recommendations/comments**			
This data requirement has been waived as outlined in SANCO/10181/2013– rev. 2.1 (13 May 2013). Data are available but have not been assessed.						

(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, for primary crops only. No data were available for maize stover from the residues trials. The expected residue in stover is low as the metabolism studies indicate the TRR is < 0.05 mg/kg and residues of thiacloprid in green material are < 0.05 mg/kg in the residues trials, however data should be generated to confirm this (data gap).
Provisional animal intake estimates for M02 and M30 from rotational crops indicate relevant animal expsoure and trigger a refined assessment (data gap)
The animal dietary burden cannot be concluded.

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Representative uses				
Corn, field stover (fodder)	0.05	Metabolism data and data for green material used as a surrogate to estimate residues in maize stover (< 0.05 mg/kg). Included for indicative purposes only.	0.05	Metabolism data and data for green material used as a surrogate to estimate residues in maize stover (< 0.05 mg/kg). Included for indicative purposes only.
Corn, pop stover (fodder)	0.05		0.05	
Corn, field grain	0.01	Residues of total thiacloprid, oxidised to 6-CNA, expressed as thiacloprid, used as surrogate for oilseed risk assessment	0.01	Residues of total thiacloprid, oxidised to 6-CNA, expressed as thiacloprid, used as surrogate for oilseed risk assessment
Canola meal	0.05		0.05	
Distiller's grain	0.01		0.01	
Maize/corn milled by products	0.01		0.01	
Maize/corn – hominy meal	0.01		0.01	
Maize/corn – gluten feed	0.01		0.01	
Maize/corn – gluten meal	0.01		0.01	

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)

Feeding study with thiacloprid and assessment of thiacloprid transfer not relevant due to insignificant livestock exposure to thiacloprid alone.
Data not available for refined assessment of residue transfer of M02 and M30 from rotational crops in animal commodities (data gap)

MRL calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Highest expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.0011	Ram/Ewe	0.0007	Breeding	0.0010	Broiler	0.0020	Carp	-
	Dairy cattle	0.0010	Lamb	0.0009	Finishing	0.0009	Layer	0.0013	Trout	-
							Turkey	0.0020	Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	No		No		No		No		Finalisation pending	
Feeding study submitted	No		No		No		No		No	
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level n/a	Beef: N Dairy: N	Level n/a	Lamb: N Ewe: N	Level n/a	N rate Breed/Finish	Level n/a	B or T: N Layer: N	Level n/a	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	-	-	-	-	-	-	-	-	-	-
Fat	-	-	-	-	-	-	-	-	-	-
Meat[(b)]	-		-		-		-			
Liver	-	-	-	-	-	-	-	-		
Kidney	-	-	-	-	-	-	-	-		
Milk[(a)]	-	-	-	-						
Eggs							-	-		

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

Based on thiacloprid only

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				
Oilseed extract	4	1.2, 1.4, 1.5, 1.6	1.45	RD for RA provisonal
Oilseed pomace	4	0.92, 1.0, 1.0, 1.2	1.0	RD for RA provisonal

[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
Studies are considered valid.

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

Consumer risk assessment limited to the representative uses

The risk assessment is provisional with regard to unfinalised assessments for primary oilseed crops, rotational crops and the potential transfer of residues in animal commodities.

ADI	0.01 mg/kg bw per day
TMDI according to EFSA PRIMo	Highest TMDI:0.3 % ADI (WHO Cluster diet B, diet)
NEDI (% ADI), according to (UK model)	Highest NEDI: 4 % ADI (UK toddler)
Factors included in the calculations	n/a
ARfD	0.03 mg/kg bw
IESTI (% ARfD), according to EFSA PRIMo	Highest IESTI: 0.3 % ARfD (Maize)
NESTI (% ARfD), according to (UK Model)	Highest NESTI: 3.6 % ARfD (UK 4-6 year old child; oilseeds)
Factors included in IESTI and NESTI	n/a

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			
0401060	Rapeseeds/canola seeds	0.01*	
0500030	Maize/corn	0.01*	

(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	*6.5-33.6*% after *100* d, [^{14}C-*Methylene*]- thiacloprid (n= *5*) *41.5* % after *120* d, [^{14}C-*Thiazolidine*]- thiacloprid]- (n= *1*)
Non-extractable residues after 100 days	*21.7-29.9* % after *100* d, [^{14}C-*Methylene*]- thiacloprid (n= *5*) *29.4* % after *120*d, [^{14}C-*Thiazolidine*]-thiacloprid (n= *1*)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	*M02*=86.6 % at *2* d (n= *1*) [^{14}C- *Thiazolidine*] & 73.8% [^{14}C- *Methylene*]- labels (n=5) *M29 33.2* % at *72*d (n= *1*) [^{14}C- *Thiazolidine*]] & 5.7% 60 d [^{14}C- *Methylene*] labels *M30 19.7* % at *60* d (n= *5)* [^{14}C- *Methylene*] & 15.1% at 21 [^{14}C- *Thiazolidine* labels

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

Mineralisation after 100 days	*0.1* % after *126* d, [^{14}C- *Thiazolidine*]-label (n= *1*)
Non-extractable residues after 100 days	*27.0* % after *126* d, [^{14}C- *Thiazolidine*]-label (n= *1*)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	*M02 – 85.1* % at *8*d (n= *1*) [^{14}C- *Thiazolidine*] label

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)	*M02 – 23.8*% at19 d (n= *2*) [^{14}C-*Methylene*] irradiated *M02 – 69.6*% at19 d (n= *2*) [^{14}C-*Methylene*] dark control
Mineralisation at study end	*0.3* % after *19* d, [^{14}C- *Methylene*] (n= *2*)
Non-extractable residues at study end	*9.5* % after *19* d, [^{14}C- *Methylene*]-label (n= *2*)

Rate of degradation in soil (aerobic) laboratory studies active 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)

Thiacloprid (YRC 2894)	Dark aerobic conditions					
Soil type	pH[a)]	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Sand	5.9	20/40%MWHC	1.62/5.38	1.62	13.0	SFO
Loamy sand	6.3	20/40%MWHC	0.78/2.60	0.78	20.1	SFO
Silt loam	6.0	20/40%MWHC	0.40/1.31	0.36	14.5	SFO
Sandy loam	6.7	20/40%MWHC	3.35/11.1	2.58	15.6	SFO
Sandy loam	6.3	20/49%MWHC	1.3/4.3	1.2	13.3	SFO
Silt loam	6.3	20/55%MWHC	0.33/1.1	0.33	6.7	SFO
Geometric mean (if not pH dependent)				0.88		
pH dependence				No		

a) Measured in calcium chloride solution
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

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)

M02	Dark aerobic conditions, derived from thiacloprid dosed studies kinetic formation from thiacloprid						
Soil type	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
Sand	5.9	20/40%MWHC	42.2/140	0.71	42.0	11.6	SFO-SFO
Loamy sand	6.3	20/40%MWHC	100.6/334.0	0.75	100.6	4.3	SFO-SFO
Silt loam	6.0	20/40%MWHC	37.3/124	0.74	33.2	7.97	SFO-SFO
Sandy loam	6.7	20/40%MWHC	167/554.7	0.75	128.7	6.6	SFO-SFO
Sandy loam	6.3	20/49%MWHC	83.9/279	0.68	77.2	9.37	SFO-SFO
Silt loam	6.3	20/55%MWHC	15.1/50.1	0.89	15.1	6.6	SFO-SFO
Geometric mean (if not pH dependent)					52.5		
Arithmetic mean				0.75			
pH dependence					No		

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

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)

M29	Dark aerobic conditions, derived from thiacloprid dosed studies kinetic formation from M02 or where no kinetic formation fraction, metabolite dosed studies						
Soil type	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
Sand	5.9	20/40%MWHC	-	0.18*	-	-	-
Loamy sand	6.3	20/40%MWHC	-	0.21*	-	-	-
Silt loam	6.0	20/40%MWHC	-	0.16*	-	-	-
Sandy loam	6.7	20/40%MWHC	109/363	0.25	84.3	10.3	SFO-SFO
Loamy sand	6.4	20/55%MWHC	323.4/1074	-	323.4	3.33	SFO
Clay loam	7.2	20/55%MWHC	83.4/277	-	83.4	8.42	SFO
Silt loam	6.3	20/55%MWHC	247/991#	-	320.2 [c)]	2.04	DFOP
Sandy loam	5.4	20/55%MWHC	635/>1000^	-	835.5[c)]	1.32	HS
Geometric mean (if not pH dependent)					227.4		
Arithmetic mean				0.20			
pH dependence					No		

[a)] Measured in calcium chloride
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[c)] derived from slow phase (K2) of DFOP/HS model: ln(2)/K2

*Fit not suitable for modelling endpoints but acceptable for creation of formation fraction values, due to the limited number of degradation points available.

K1=0.389, K2=0.002165, g=0.146
^ K1=0.01711, K2=0.0008296, tb= 10.2.

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)

M30	Dark aerobic conditions , derived from thiacloprid dosed studies kinetic formation from M02 or where no kinetic formation fraction, metabolite dosed studies						
Soil type	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
Sand	5.9	20/40%MWHC	38.8/128.9	0.82	38.7	11.8	SFO-SFO
Loamy sand	6.3	20/40%MWHC	13.9/46.2	0.79	13.9	25.4	SFO-SFO
Silt loam	6.0	20/40%MWHC	16.1/53.6	0.31	14.3	22.0	SFO-SFO
Sandy loam	6.7	20/40%MWHC	31.0/102.9	0.75	23.9	21.9	SFO-SFO
Silt loam	6.3	20/55%MWHC	10.3/34.2	0.55	10.3	11.1	SFO-SFO
Sand	5.9	20/45%MWHC	73.5/244	-	65.3	4.45	SFO
Loamy sand	6.0	20/45%MWHC	19.7/65.6	-	19.7	4.04	SFO

Sandy loam	6.7	20/45%MWHC	22.3/74.2	-	19.3	6.74	SFO
Sandy loam	6.3	20/40%MWHC	24.7/82.2	-	19.8	6.50	SFO
Geometric mean (if not pH dependent)					21.4		
Arithmetic mean				0.64			
pH dependence					No		

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

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)

M34	Dark aerobic conditions, derived from M30 dosed studies kinetic formation from M30						
Soil type	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
Sand	5.9	20/45%MWHC	55.0/183	0.70	48.8	4.45	SFO-SFO
Loamy sand	6.0	20/45%MWHC	16.5/55	0.42	16.5	14.7	SFO-SFO
Sandy loam	6.3	20/40%MWHC	3.65/12.1	0.53	2.93	9.1	SFO-SFO
Geometric mean (if not pH dependent)					13.3		
Arithmetic mean				0.55			
pH dependence					No		

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

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)

M46	Dark aerobic conditions M46 dosed studies						
Soil type	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
Loamy sand	6.4	20/55%MWHC	26.2/87.0	-	26.2	2.29	SFO
Loam	7.1	20/55%MWHC	9.54/31.7	-	9.54	2.51	SFO
Silt loam	6.4	20/55%MWHC	29.3/97.2	-	29.3	2.46	SFO
Silt loam	5.5	20/55%MWHC	21.0/69.6	-	21.0	1.58	SFO
Geometric mean (if not pH dependent)					19.8		
Arithmetic mean				-			
pH dependence					No		

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

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	Aerobic conditions							
Soil type.	Location (country or USA state).	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	DT_{50} (d) Norm[b)] [c)].	Method of calculation
Silty clay loam	Germany#	6.7	0-30	5.95	19.8	3.12	N/A	SFO
Sandy loam	Germany~	6.7	0-30	9.09	30.2	12.7	7.78	SFO
Sandy silt loam	Germany#	6.7	0-30	12.8	42.5	9.2	4.16	SFO
Loamy sand	UK#	6.9	0-30	13.8	45.7	11.7	10.8	SFO
Sandy loam	UK~	6.0	0-30	16.8*	55.9	17.7	9.71	SFO
Loamy sand	France~	7.5	0-30	11.6	38.5	7.79	10.3	SFO
Clay loam	France#	7.8	0-30	7.92	26.3	16.8	N/A	SFO
Clay loam	Spain#	7.7	0-30	16.5	54.9	5.12	8.16	SFO
Geometric mean (if not pH dependent)							8.11	
pH dependence				No				

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix
c) EFSA DegT50 guidance used, insuffient timepoints after 10mm of rainfall to generate a fit.
* Worst case non-normalised value used for PECsoil modelling.
# Plot maintained bare
~ Plot cropped with grass

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)

M02		Aerobic conditions Peak occurrence down calculations.							
Soil type	Location	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm[b)] [C)].	f. f. k_f / k_{dp}	Method of calculation
Silty clay loam	Germany#	6.7	0.-30	26.2	197	4.79	-	-	FOMC
Sandy loam	Germany~	6.7	0-30	153	509	15.4	-	-	SFO
Sandy silt loam	Germany#	6.7	0-30	24.3	304	7.98	-	-	FOMC
Loamy sand	UK#	6.9	0-30	322	1070	9.05	-	-	SFO
Sandy loam	UK~	6.0	0-30	165	547	5.74	-	-	SFO
Loamy sand	France~	7.5	0-30	151	500	16.0	-	-	SFO
Clay loam	France#	7.8	0-30	110	366	7.94	-	-	SFO
Clay loam	Spain#	7.7	0-30	75.9	252	8.1	-	-	SFO
Geometric mean (if not pH dependent)							-		
Arithmetic mean								-	
pH dependence					No				

a) Measured in calcium chloride
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 values are DegT50matrix
c) EFSA DegT50 guidance used. Significant degradation noted before 10mm had occurred. Fits not considered reliable.
Plot maintained bare
~ Plot cropped with grass

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)

M30		Aerobic conditions Peak occurrence down calculations.							
Soil type	Location	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm[b)] [c)].	f. f. k_f / k_{dp}	Method of calculation
Sandy loam	Germany~	6.7	0-30	122	406	13.7	-	-	SFO
Sandy silt loam	Germany#	6.7	0-30	190	630	14.1	-	-	SFO
Geometric mean (if not pH dependent)							-		
Arithmetic mean								-	
pH dependence					No				

a) Measured in calcium chloride
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 values are DegT50matrix
c) EFSA DegT50 guidance used. Significant degradation noted before 10mm had occurred. Fits not considered reliable.
Plot maintained bare
~ Plot cropped with grass

Combined laboratory and field kinetic endpoints for modelling (when not from different populations)*

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)	2.67 (d) (SFO)
Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)	Laboratory values used, as significant degradation of metabolite or precursor metabolite noted before the 10 mm of rainfall.
Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean	Laboratory values used,as significant degradation of metabolite or precursor metabolite noted before the 10 mm of rainfall.

* Only relevant after implementation of the published EFSA guidance describing how to amalgamate laboratory and field endpoints.

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					
Soil type	pH[a)]	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C[b)]	St. (χ^2)	Method of calculation
Silt Loam	6.4	20/55%MWHC*	0.88/15.00^	0.88	2.01	FOMC
Geometric mean (if not pH dependent)				0.88		

a) Measured in calcium chloride
b) Normalised using a Q10 of 2.58
* Preflooding
^ alpha=0.6623, beta=0.4783

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)

M02	Dark anaerobic conditions Peak occurrence down calculation

Soil type	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20°C[b)]	St. (χ^2)	Method of calculation
Silt Loam	6.4	20/55%MWHC *	296/984	-	296	1.22	SFO
Geometric mean (if not pH dependent)					296		
Arithmetic mean				-			

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) Normalised using a Q10 of 2.58
* Preflooding

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. °C / % MWHC	DT_{50} / DT_{90} (d) calculated at 33°N	St. (r^2)	Method of calculation
Sandy Loam	7.1	25/75%[b]	74/246	0.98	SFO linear regression

a) Measured in calcium chloride
b) In this case it is 75% of moisture at 0.33 bar
* Dark control DT50 was 6.3 days, so shorter than in the illuminated samples.

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)

Thiacloprid							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Sandy Loam	1.15	6.3	-	-	4.52	393	0.855
Sandy Loam	0.75	7.1	-	-	5.65	753	0.841
Silty Clay	1.05	5.6	-	-	5.48	522	0.937
Sandy Loam	0.45	6.7	-	-	3.91	870	0.868
Loam	0.99	7.7	-	-	5.76	582	0.833
Geometric mean (if not pH dependent)					5.01	601	
Arithmetic mean (if not pH dependent)							0.87
pH dependence			No				

a) Measured in water

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 M02							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Loamy Sand	0.69	5.9	-	-	1.54	223	0.808
Sandy Loam	1.12	6.7	-	-	3.38	302	0.811
Silty Clay	1.2	5.6	-	-	3.76	313	0.907
Sandy Loam	0.45	6.7	-	-	1.97	438	0.808
Sandy loam	1.02	6.3	-	-	3.19	313	0.848
Geometric mean (if not pH dependent)					2.62	311	
Arithmetic mean (if not pH dependent)							0.84
pH dependence			No				

a) Measured in water

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 M30							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Loamy sand	0.69	5.9	-	-	0.106	15.4	0.981
Sandy loam	1.12	6.7	-	-	0.293	26.2	0.924
Silty clay loam	1.2	6.1	-	-	0.259	17.4	0.974
Sandy loam	0.45	6.7	-	-	0.127	28.2	0.917
Sandy loam	1.02	6.3	-	-	0.227	22.0	0.934
Geometric mean (if not pH dependent)					0.188	21.3	
Arithmetic mean (if not pH dependent)							0.95

pH dependence	No

a) Measured in water

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 M29							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Sandy Loam	2.0	5.1	-	-	6.8	338.2	0.834
Silt Loam	2.9	6.3	-	-	11.1	383	0.849
Loam	4.4	7.3	-	-	16	364.2	0.852
Loamy Sand	2.0	5.9	-	-	7.2	361	0.833
Silt Loam	2.9	5.2	-	-	11.8	407.2	0.844
Geometric mean (if not pH dependent)					10.1	370	
Arithmetic mean (if not pH dependent)							0.84
pH dependence			No				

a) Measured in calcium chloride

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 M46							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Sandy Loam	2.0	5.1	-	-	0.234	11.71	0.979
Silt Loam	2.9	6.3	-	-	0.234	7.98	1
Loam	4.4	7.3	-	-	0.246	5.58	0.92
Loamy Sand	2.0	5.9	-	-	0.176	8.8	0.937
Silt Loam	2.9	5.2	-	-	0.395	13.63	0.911
Geometric mean (if not pH dependent)					0.25	9.1	
Arithmetic mean (if not pH dependent)							0.95
pH dependence			No				

a) Measured in calcium chloride

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 M34

Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Silt Loam	1.9	6.6	0.15	7.7	-	-	1
Loam	5.2	7.4	0.19	3.6	-	-	1
Loamy Sand	2.0	6.3	0.15	7.3	-	-	1
Silt Loam	2.9	5.7	0.28	9.7	-	-	1

Geometric mean (if not pH dependent)	0.19	6.7	-	-	
Arithmetic mean (if not pH dependent)					1
pH dependence	No				

a) Measured in calcium chloride

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	Elution (mm): *400* mm Time period (d): *2* d
	Leachate: *14.5*% total residues/radioactivity in leachate *0* % active substance, *0.1* % *M02*, *11.6* % *M30*, *Unknown 2%*. >*89*% total residues/radioactivity retained in top *30* cm

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	Elution (mm): *300* mm Time period (d): *2* d
	Leachate: *63.07* % total residues DD soil Leachate: *83.84* % total residues HaH soil Leachate: *80.11*% total residues AX soil Leachate: *57.47* % total residues HH soil *All leachate M34* Koc (mL/g) = 6.7

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)

Lysimeter/ field leaching studies	Location: Monheim Germany Study type: *lysimeter* Soil properties: Sandy loam, pH = 7.0, OC=1.41 (outdoor study) Dates of application : 17/05/1994, 31/05/1994, 16/05/1995, 30/05/1995. Crop : Interception estimated 50%: Number of applications: **2** years, **2** applications per year Duration. 3 years Application rate: **400 +365** g/ha/year Average annual rainfall (mm): **845** mm (plus irrigation 869 mm) Average annual leachate volume (mm): **372** mm (including irrigation) % radioactivity in leachate (maximum/year):3 % AR Annual average leachate concentrations (e.g. 1st, 2nd, 3rd yr): <LOD (0.001 µg/L) years 1 to 3 thiacloprid and M02. 2.39 µg/L, year 1, **6.92** µg/L year 2, 1.48 µg/L year 3 metabolite M30. 0.23 µg/L, year 1, **0.52** µg/L year 2, 0.16 µg/L year 3 metabolite M34. **0.30** µg/L, year 1, 0.26 µg/L year 2, 0.05 µg/L year 3 metabolite M46. 0.02 µg/L, year 1, 0.03 µg/L year 2, **0.06** µg/L year 3 metabolite M32. Unidentified radioactivity, 6 components, *0.21* µg/L parent equivalents year 1. Unidentified radioactivity, 6 components, *0.36* µg/L parent equivalents year 2. Unidentified radioactivity, 6 components, *0.21*µg/L parent equivalents year 3. Amount of radioactivity in the soils at the end of the study = 56% AR; *0*% AR as parent, *3.6*% AR as *M29*, *2.1* % AR as *M30*, *6.0* % AR as *M02*, *7.9* % AR as *M32*. *3.3* % AR as *unknown.*

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: *30d* at 25 °C *Stable, no degradation products*
	pH 7: *30d* at 25 °C *Stable, no degradation products*
	pH 9: *30d* at 25 °C *Stable, 2 Minor products <2% AR.*

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 %	DT_{50} : 79.7 d Natural light, *33.4* °N; DT_{50} *324* days *Met M35 5.4* % AR (*18*d)
Quantum yield of direct phototransformation in water at □ > 290 nm	*0.000352*

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

Readily biodegradable	*No data submitted, substance considered not readily biodegradable*

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										
System identifier	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 *x* °C[c]		At study temp	Normalised to 12°C[c]		
Biederthal (fresh) low dose	8.2	NA	21	-	-	-	127/401	295.6/ 933	2.89	HS
Biederthal (fresh) high dose	8.2	NA	21	-	-	-	71.1/205	165.5/ 477.2	2.78	HS

[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 Q10 of 2.58 to the temperature of 12°C according to ECHA Chapter R11 (2014, 2017) guidance.

Mineralisation and non extractable residues (for parent dosed experiments)					
System identifier	pH water phase	pH sed	Mineralisation % after d. (end of the study).	Non-extractable residues. max % after d (suspended sediment test)	Non-extractable residues. max % after d (end of the study) (suspended sediment test)
Biederthal (fresh) low dose	8.2	NA	0.2% after 62 d	NA	NA
Biederthal (fresh) high dose	8.2	NA	0.7% after 62d	NA	NA

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	Distribution *max in water 95.9% after 0d. Max. sed 51.1 % after 3d*									
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[b]	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Sandy silt loam	7.2	5.6	20	18.0/59.9	4.17	1000/1000	-	18.0/59.9	4.17	SFO
Sand	8.3	7.5	20	12.1/40.1	3.97	1000/1000	-	12.1/40.1	3.97	SFO
Geometric mean at 20°C				14.8/49		1000/1000		14.8/49.0		SFO

[a] Measured in usually calcium chloride solution
[b] Dissipation in water is modelled so default values are used

Metabolite *M02*	Distribution (*max in water 62.2% after 35 d. Max. sed 37.2 % after 62 d*). Max in total system 69.88 % after 35days, kinetic formation fraction (k_f/k_{dp}): 0.844									
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[c]	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Sandy silt loam	7.2	5.6	20	70.9/ 235	4.43	70.9/235	4.43	1000/1000	-	SFO-SFO
Sand	8.3	7.5	20	145.2/ 482.4	3.98	145.2/482.4	3.98	1000/1000	-	SFO
Geometric mean at 20°C				101.5/336.7		101.5/336.7		1000/1000		SFO

[a] Measured in calcium chloride solution

Metabolite *M30*	Distribution (*max in water 9.5% after 100 d. Max. sed 1.2 % after 100 d*). Max in total system 9.8 % after 100 days,

Mineralisation and non extractable residues (from parent dosed experiments)				
Water / sediment system	pH water phase	pH sed	Mineralisation	Non-extractable residues in sed.
Sandy silt loam	7.2	5.6	4.0% after 100 d	22.3% after 100 d
Sand	8.3	7.5	4.3% after 100 d	17.2% after 100 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 *1.5* hours derived by the Atkinson model (version *1.55*).

Volatilisation	Vapour pressure of $3x10^{-10}$ Pa Henry's law constant of $5x10^{-10}$ Pa m^3 mol Volatilisation from soil surfaces: 12% loss under field conditions during 24 hour duration (n =3, indirect method). Volatilisation from plant surfaces: 15% loss under field conditions during 24 hour duration (n =3, indirect method).
Metabolites	-

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:	Thiacloprid (YRC 2894) YRC 2894-amide, M02 YRC 2894-des-cyano, M29 YRC 2894-sulfonic acid, M30
	Surface water:	Thiacloprid (YRC 2894) YRC 2894-amide, M02 YRC 2894-des-cyano, M29 YRC 2894-sulfonic acid, M30 YRC 2894-sulfonic acid amide, M34* YRC 2894-thiadiazine, M46*
	Sediment:	Thiacloprid (YRC 2894) YRC 2894-amide, M02
	Ground water:	Thiacloprid (YRC 2894) YRC 2894-amide, M02 YRC 2894-des-cyano, M29 YRC 2894-sulfonic acid, M30 YRC 2894-sulfonic acid amide, M34 YRC 2894-thiadiazine, M46
	Air:	Thiacloprid (YRC 2894)

* Precautionary, for groundwater becoming surface water.

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)	-
Surface water (indicate location and type of study)	-
Ground water (indicate location and type of study)	-
Air (indicate location and type of study)	-

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

Parent Method of calculation	DT_{50} (d): *16.8* days Kinetics: *SFO* Field
Application data	Crop: *Oilseed Rape* Depth of soil layer: *5cm* Soil bulk density: *1.5g/cm³* % plant interception: *80%* Number of applications: *2* Interval (d): *10* Application rate(s): *72* g a.s./ha

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.019		0.032	
Short term	24h	0.018	0.019	0.031	0.031
	2d	0.018	0.018	0.029	0.031
	4d	0.016	0.018	0.027	0.029
Long term	7d	0.014	0.017	0.024	0.028
	28d	0.006	0.011	0.010	0.019
	48d	0.003	0.008	0.004	0.014
	100d	0.000	0.005	0.000	0.008
Plateau concentration		*Not required*			

Parent Method of calculation	DT_{50} (d): *16.8* days Kinetics: *SFO* Field

Application data	
	Crop: *Maize (seed treatment)* Depth of soil layer: *5cm* Soil bulk density: *1.5g/cm^3* % plant interception: Pre-emergence therefore no crop interception Number of applications: *1* Interval (d): *NA* Application rate(s): *110* g a.s./ha

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.147		-	
Short term	24h	0.141	0.144	-	-
	2d	0.135	0.141	-	-
	4d	0.124	0.135	-	-
Long term	7d	0.109	0.127	-	-
	28d	0.045	0.086	-	-
	48d	0.020	0.063	-	-
	100d	0.002	0.034	-	-
Plateau concentration		*Not required*			

Metabolite M02 (Oilseed rape) Method of calculation			Molecular weight relative to the parent: DT_{50} (d): *322* days Kinetics: Field		
Application data			Application rate assumed: *66.87 g/ha (assumed Met M02 is formed at a maximum of 86.7 % of the applied dose) Maximum formation of 86.6% should be used for future modelling.*		
$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.018		0.035	
Short term	24h	0.018	0.018	0.035	0.035
	2d	0.018	0.018	0.035	0.035
	4d	0.018	0.018	0.035	0.035
Long term	7d	0.018	0.018	0.035	0.035
	28d	0.017	0.017	0.033	0.034
	48d	0.016	0.017	0.032	0.034
	100d	0.014	0.016	0.028	0.032
Plateau concentration		*0.066* mg/kg after *8* yr			

Metabolite M02 (Maize) Method of calculation			Molecular weight relative to the parent: DT_{50} (d): *322* days Kinetics: *SFO*, Field		
Application data			Application rate assumed: 102.2 *g/ha (assumed Met M02 is formed at a maximum of 86.7 % of the applied dose) Maximum formation of 86.6% should be used for futuremodelling.*		
$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.136		-	
Short term	24h	0.136	0.136	-	-
	2d	0.136	0.136	-	-
	4d	0.135	0.136	-	-
Long term	7d	0.134	0.135	-	-
	28d	0.128	0.132	-	-
	48d	0.123	0.129	-	-
	100d	0.110	0.123	-	-
Plateau		*0.250* mg/kg after			

concentration	*8* yr

Metabolite M30 (Oilseed rape) Method of calculation	Molecular weight relative to the parent: DT_{50} (d): *190* days Kinetics: Field
Application data	Application rate assumed: *18.91 g/ha (assumed Met M30 is formed at a maximum of 19.7 % of the applied dose)*

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.005		0.010	
Short term	24h	0.005	0.005	0.010	0.010
	2d	0.005	0.005	0.010	0.010
	4d	0.005	0.005	0.010	0.010
Long term	7d	0.005	0.005	0.010	0.010
	28d	0.005	0.005	0.009	0.009
	48d	0.004	0.005	0.008	0.009
	100d	0.004	0.004	0.007	0.008
Plateau concentration		0.013 mg/kg after 4 years (concentration immediately before an application 0.004mg/kg)			

Metabolite M30 (Maize) Method of calculation	Molecular weight relative to the parent: DT_{50} (d): *190* days Kinetics: Field
Application data	Application rate assumed: *28.88 g/ha (assumed Met M30 is formed at a maximum of 19.7 % of the applied dose)*

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.039		-	
Short term	24h	0.038	0.038	-	-
	2d	0.038	0.038	-	-
	4d	0.038	0.038	-	-
Long term	7d	0.038	0.038	-	-
	28d	0.035	0.037	-	-
	48d	0.032	0.035	-	-
	100d	0.027	0.032	-	-

Plateau concentration	0.052 mg/kg after 8 years (concentration immediately before an application 0.014mg/kg)

Metabolite M29 (Oilseed rape)	Molecular weight relative to the parent:
Method of calculation	DT_{50} (d): *K1 40.5, K2 836* days tb =10.2, K1=0.01711, K2=0.0008296 Kinetics: HS Lab
Application data	Application rate assumed: *21.54 g/ha (assumed Met M29 is formed at a maximum of 33.2 % of the applied dose)*

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.006		0.011	
Short term	24h	0.006	0.006	0.011	0.011
	2d	0.006	0.006	0.011	0.011
	4d	0.006	0.006	0.011	0.011
Long term	7d	0.006	0.006	0.011	0.011
	28d	0.006	0.006	0.011	0.011
	48d	0.005	0.006	0.011	0.011
	100d	0.005	0.006	0.010	0.011
Plateau concentration		0.035 mg/kg (concentration immediately before an application 0.024mg/kg)			

Metabolite M29 (Maize)	Molecular weight relative to the parent:
Method of calculation	DT_{50} (d): *K1 40.5, K2 836* days tb =10.2, K1=0.01711, K2=0.0008296 Kinetics: HS Lab
Application data	Application rate assumed: *32.91 g/ha (assumed Met M02 is formed at a maximum of 33.2 % of the applied dose)*

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.044		-	
Short term	24h	0.043	0.044	-	-
	2d	0.042	0.043	-	-
	4d	0.041	0.042	-	-

Long term	7d	0.039	0.041	-	-
	28d	0.036	0.038	-	-
	48d	0.036	0.037	-	-
	100d	0.034	0.036	-	-
Plateau concentration		0.117mg/kg after *11* yr			

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)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: *PEARL V4.4.4, PELMO V5.5.3, MACRO V5.5.4* Crop: Oilseed rape, Winter and Spring Maize (seed treatment) Crop uptake factor: 0 Water solubility (mg/L): *159* at pH 7 and 20°C Vapour pressure: *3.00^{E}-10* Pa at 20°C Geometric mean parent $DT_{50\ lab+\ field}$ *2.67 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).* K_{OC}: *parent, geometric* mean 601 mL/g, arithmetic mean $^{1}/_{n}$=0.87.* Metabolites: **M02** Crop uptake factor: 0 Water solubility (mg/L): *660* at pH 7 and 20°C Vapour pressure: *3.40^{E}-10* Pa at 20°C Geometric mean parent $DT_{50\ lab}$ *52.5 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).* K_{OC}: *parent, geometric* mean 311 mL/g, arithmetic mean $^{1}/_{n}$=0.84.* *Formation fraction =0.75(PEARL) 0.00845 to M30, 0.00264 to M29 (PELMO +MACRO)* **M30** Crop uptake factor: 0 Water solubility (mg/L): *56000*at pH 7 and 20°C Vapour pressure: *3.80^{E}-4* Pa at 20°C Geometric mean parent $DT_{50\ lab}$ *21.4 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).* K_{OC}: *parent, geometric* mean 21.3 mL/g, arithmetic mean $^{1}/_{n}$=0.95.* *Formation fraction =0.64(PEARL), 0.0324 to M46, 0.0145 to M34 simulation 1 and 0.0178 to M34 simulation 2 (PELMO+ MACRO)^* **M46** Crop uptake factor: 0 Water solubility (mg/L): *130000* at pH 7 and 20°C Vapour pressure: *2.30 ^{E}-5* Pa at 20°C Geometric mean parent $DT_{50\ lab}$ 19.8*d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).* K_{OC}: *parent, geometric* mean 9.1 mL/g, arithmetic mean $^{1}/_{n}$=.0.95*

	Formation fraction =1/0.45(PEARL) – (PELMO+MACRO) **M29** Crop uptake factor: 0 Water solubility (mg/L): *57000* at pH 7 and 20°C Vapour pressure: *1.10 E-4* Pa at 20°C Geometric mean parent $DT_{50\ lab}$ *227.4d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).* K_{OC}: *parent, geometric* mean 370 mL/g, arithmetic mean* $^1/_n$*=0.84.* *Formation fraction =0.20 (PEARL), - (PELMO+MACRO)* **M34** Crop uptake factor: 0 Water solubility (mg/L): *135000* at pH 7 and 20°C Vapour pressure: *5.90 E-07* Pa at 20°C Geometric mean parent $DT_{50\ lab}$ *13.3d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).* K_{OC}: *parent, geometric* mean 6.7 mL/g, arithmetic mean* $^1/_n$*=1.0.* *Formation fraction =0.55(PEARL), - (PELMO + MACRO)*
Application rate	Gross application rate: 2*72g/ha (spring and winter Oilseed rape). *110* g/ha (Maize). Crop growth stage: 30-59 (Spring and winter Oilseed rape). 00 (Maize) Canopy interception %: 80% (Spring and winter Oilseed rape) 0% (Maize) Application rate net of interception: *14.4* g/ha (Spring and winter Oilseed rape). 110 g/ha (Maize). No. of applications: 2 (Spring and winter Oilseed rape) 1 (Maize) Time of application (absolute or relative application dates): *Absolute dates, May/ June for spring sown Oilseed, April May for wintersown oilseed.* *Sowing dates for Maize.*

* Only relevant after implementation of the published EFSA guidance.

^ Formation fraction of M46 is unknown, 2 sets of calculations have been performed to address the issue. 1 with a ff of 1 for M46 aand 1 with a ff of 0.45. 0.45 is derived from the other

metabolite degrading from M30 (M34) having a known ff fraction (0.55). A 100- approach was taken from M30. Maxiumum PECgw values resulting from both simulations are presented below.

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

	Scenario	Parent (µg/L)	*Metabolite* (µg/L)		
			M02	*M30**	*M46#*
PELMO /Spring Oilseed rape	Jokioinen	<0.001	<0.001	0.347	0.636
	Okehampton	<0.001	<0.001	0.300	0.370
	Porto	<0.001	<0.001	0.173	0.211

*M46 ff= 0.45.
#M46 ff= 1.

	Scenario	Metabolite (µg/L)	
		M29	*M34**
PELMO/Spring Oilseed rape	Jokioinen	<0.001	0.593
	Okehampton	<0.001	0.276
	Porto	<0.001	0.157

*M46ff= 0.45.

	Scenario	Parent (µg/L)	*Metabolite* (µg/L)		
			M02	*M30**	*M46#*
PELMO/Winmter Oilseed rape	Chateaudun	<0.001	<0.001	0.076	0.169
	Hamburg	<0.001	<0.001	0.365	0.581
	Kremsmunster	<0.001	<0.001	0.207	0.339
	Okehampton	<0.001	<0.001	0.305	0.377
	Piacenza	<0.001	<0.001	0.220	0.266
	Porto	<0.001	<0.001	0.167	0.214

*M46 ff=0.45.
#M46 ff=1.

	Scenario	Metabolite (µg/L)	
		M29	*M34*
PELMO /Winter Oilseed rape	Chateaudun	<0.001	0.130
	Hamburg	<0.001	0.461
	Kremsmunster	<0.001	0.253
	Okehampton	<0.001	0.287
	Piacenza	<0.001	0.172
	Porto	<0.001	0.203

	Scenario	Parent (µg/L)	*Metabolite* (µg/L)		
			M02	*M30*	*M46#*
PEARL/Spring Oilseed rape	Jokioinen	<0.001	<0.001	0.313	1.012
	Okehampton	<0.001	<0.001	0.271	0.617
	Porto	<0.001	<0.001	0.128	0.314

M46 ff= 1.

	Scenario	Metabolite (µg/L)	
		M29	*M34*
PEARL/Spring Oilseed rape	Jokioinen	<0.001	0.528
	Okehampton	<0.001	0.263
	Porto	<0.001	0.129

	Scenario	Parent (µg/L)	*Metabolite* (µg/L)		
			M02	*M30*	*M46#*
PEARL /Winter Oilseed rape	Chateaudun	<0.001	<0.001	0.080	0.356
	Hamburg	<0.001	<0.001	0.386	1.058
	Kremsmunster	<0.001	<0.001	0.183	0.541
	Okehampton	<0.001	<0.001	0..257	0.595
	Piacenza	<0.001	<0.001	0.158	0.277
	Porto	<0.001	<0.001	0.108	0.390

M46 ff=1

	Scenario	Metabolite (µg/L)	
		M29	*M34*
PEARL/Winter Oilseed rape	Chateaudun	<0.001	0.124
	Hamburg	<0.001	0.485
	Kremsmunster	<0.001	0.218
	Okehampton	<0.001	0.264
	Piacenza	<0.001	0.166
	Porto	<0.001	0.105

	Scenario	Parent (µg/L)	*Metabolite* (µg/L)		
			M02	*M30**	*M46#*
PELMO /Maize	Chateaudun	<0.001	<0.001	0.487	0.776
	Hamburg	<0.001	<0.001	1.564	1.730
	Kremsmunster	<0.001	<0.001	0.986	1.118
	Okehampton	<0.001	<0.001	1.322	1.187
	Piacenza	<0.001	<0.001	0.767	0.808
	Porto	<0.001	<0.001	0.574	0.567
	Sevilla	<0.001	<0.001	0.107	0.205
	Thiva	<0.001	<0.001	0.228	0.434

*M46 ff=0.45.
#M46 ff=1.

	Scenario	Metabolite (µg/L)	
		M29	*M34#*
PELMO/Maize	Chateaudun	<0.001	0.638
	Hamburg	0.001	1.724
	Kremsmunster	<0.001	1.017
	Okehampton	0.003	1.169
	Piacenza	0.005	0.683
	Porto	0.001	0.517
	Sevilla	<0.001	0.169
	Thiva	<0.001	0.330

#M46 ff=1.

	Scenario	Parent (µg/L)	*Metabolite* (µg/L)		
			M02	*M30*	*M46#*
PEARL /Maize	Chateaudun	<0.001	<0.001	0.683	2.156
	Hamburg	<0.001	<0.001	1.696	4.909
	Kremsmunster	<0.001	<0.001	0.892	2.286
	Okehampton	<0.001	<0.001	1.223	2.755
	Piacenza	<0.001	<0.001	0.692	1.583
	Porto	<0.001	<0.001	0.439	1.194
	Sevilla	<0.001	<0.001	0.128	0.531
	Thiva	<0.001	<0.001	0.264	1.090

M46 ff=1

	Scenario	Metabolite (µg/L)	
		M29	*M34*
PAERL /Maize	Chateaudun	<0.001	0.814
	Hamburg	0.003	2.160
	Kremsmunster	0.001	0.919
	Okehampton	0.004	1.165
	Piacenza	0.003	0.596
	Porto	<0.001	0.474
	Sevilla	<0.001	0.210
	Thiva	<0.001	0.340

	Scenario	Parent (µg/L)	*Metabolite* (µg/L)		
			M02	*M30**	*M46*^
MACRO /Winter OSR	Chateaudun	<0.001	<0.001	0.0642	0.0632

	Scenario	Metabolite (µg/L)	
		*M29**	*M34*^
MACRO /Winter OSR	Chateaudun	0.003	0.006

	Scenario	Parent (µg/L)	*Metabolite* (µg/L)		
			M02	*M30**	*M46*^
MACRO /Maize	Chateaudun	<0.001	<0.001	0.406	0.404

	Scenario	Metabolite (µg/L)	
		*M29**	*M34*^
MACRO /Maize	Chateaudun	0.049	0.0412

* Calculated as M02 as parent, Application date adjusted by +3 days to reflect the formation of M02. Application rates adjust for MW and peak occurrence.
^ Calculated as M30 as parent, Application date adjusted by +53 days to reflect the formation of M30. Application rates adjust for MW and peak occurrence

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 and 2

Version control no. of FOCUS calculator: STEPS 1-2 v3.2.

Molecular weight (g/mol):252.7

K_{OC}/K_{OM} (mL/g): 601/ 348.6

DT_{50} soil (d): *2.67 days (Lab and field. In accordance with FOCUS SFO)*

DT_{50} water/sediment system (d): *14.8d (geomean from sediment water studies if not pH dependent)*

DT_{50} water (d): 1000

	DT_{50} sediment (d): 14.8 Crop interception (%): *Average (Oilseed rape)* *No interception (Maize)*
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: SWASH v5.3 MACRO v5.5.4 PRZM v4.3.1 TOXSWA v4.4.3 Water solubility (mg/L): Vapour pressure: *3.0E-10* Pa at 20°C Kom (mL/g): 348.6 1/n: 0.87 Q10=2.58, Walker equation coefficient 0.7 Crop uptake factor: 0
Application rate	Crop and growth stage: Oilseed Rape BBCH 30-59 Number of applications: *2* Interval (d): *10* Application rate(s): *72* g a.s./ha Application window: *Winter Oilseed rape/ March to May/ NEU, SEU.* *Spring Oilseed rape/ March to May/ NEU, SEU.* Crop and growth stage: Maize BBCH 00 Number of applications: *1* Interval (d): - Application rate(s): *110* g a.s./ha Application window: *Maize/ March to May/ NEU, SEU.*

Metabolite *M02* Parameters used in FOCUSsw step 1 and 2	Molecular weight:270.7 Soil or water metabolite: Soil and Water Koc/Kom (mL/g): 311/ 180.9 DT_{50} soil (d): *52.5 days (Lab In accordance with FOCUS SFO)* DT_{50} water/sediment system (d): *101.5d (representative worst case from sediment water studies)* DT_{50} water (d): 101.5 DT_{50} sediment (d):1000 Crop interception (%): *Average crop cover.* Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: 69.9 % Soil: 86.7% *(Maximum formation of 86.6% should be used for future modelling)*

Parameters used in FOCUSsw step 3 (if performed)	Water solubility (mg/L): Vapour pressure: *3.4^{E}-10* Pa at 20°C Kom/Koc (mL/g): 311/ 180.9 1/n: (Freundlich exponent general or for soil, susp. solids or sediment respectively) Q10=2.58, Walker equation coefficient 0.7 Crop uptake factor: 0 Metabolite kinetically generated in simulation (yes): Formation fraction in soil (k_f/k_{dp}): *(0.85 from parent)* Formation fraction in sediment water (k_f/k_{dp}): *(0.75 from parent)*
Application rate	Crop and growth stage: Oilseed Rape BBCH 30-59 Number of applications: 2 Interval (d): 10 Application rate(s): 72 g a.s./ha Application window: Winter Oilseed rape/ March to May/ NEU, SEU. Spring Oilseed rape/ March to May/ NEU, SEU. Crop and growth stage: Maize BBCH 00 Number of applications: 1 Interval (d): - Application rate(s): 110 g a.s./ha Application window: Maize/ March to May/ NEU, SEU.
Main routes of entry	Spraydrift and runoff.
Metabolite *M30* Parameters used in FOCUSsw step 1 and 2	Molecular weight:336.8 Soil or water metabolite:Soil and water Koc/Kom (mL/g): 21.3/ 12.4 DT_{50} soil (d): *21.4 days (Lab In accordance with FOCUS SFO)* DT_{50} water/sediment system (d): *1000 d (representative worst case from sediment water studies)* DT_{50} water (d):1000 DT_{50} sediment (d):1000 Crop interception (%): *Model derrived* Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: 9.5% Water, 1.2% in sediment. Soil: *19.7%*
Parameters used in FOCUSsw step 3 (if performed)	Not required

Application rate	Crop and growth stage: Oilseed Rape BBCH 30-59 Number of applications: 2 Interval (d): 10 Application rate(s): 72 g a.s./ha Application window: Winter Oilseed rape/ March to May/ NEU, SEU. Spring Oilseed rape/ March to May/ NEU, SEU. Crop and growth stage: Maize BBCH 00 Number of applications: 1 Interval (d): - Application rate(s): 110 g a.s./ha Application window: Maize/ March to May/ NEU, SEU.
Main routes of entry	

Metabolite *M29* Parameters used in FOCUSsw step 1 and 2	Molecular weight: 227.7 Soil or water metabolite: Soil only Koc/Kom (mL/g): 370/ 214.6 DT_{50} soil (d): *227.4 days (Lab. In accordance with FOCUS SFO)* DT_{50} water/sediment system (d): *1000d (Default worst case)* DT_{50} water (d):*1000d (Default worst case)* DT_{50} sediment (d):*1000d (Default worst case)* Crop interception (%): *Model derrived* Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: Not observed Soil: *33.2%*
Parameters used in FOCUSsw step 3 (if performed)	Water solubility (mg/L): Vapour pressure: *1.1E-4* Pa at 20°C Kom/Koc (mL/g): 370/ 214.6 1/n: 0.84 Q10=2.58, Walker equation coefficient 0.7 Crop uptake factor: 0 Metabolite kinetically generated in simulation (yes): Formation fraction in soil (k_f/k_{dp}): *0.20 from M02* (*0.15 from thiacloprid to M29 directly, as modelled)* Formation fraction in sediment water (k_f/k_{dp}): *Not observed.*

Application rate	Crop and growth stage: Oilseed Rape BBCH 30-59 Number of applications: 2 Interval (d): 10 Application rate(s): 72 g a.s./ha Application window: Winter Oilseed rape/ March to May/ NEU, SEU. Spring Oilseed rape/ March to May/ NEU, SEU. Crop and growth stage: Maize BBCH 00 Number of applications: 1 Interval (d): - Application rate(s): 110 g a.s./ha Application window: Maize/ March to May/ NEU, SEU.
Main routes of entry	Spraydrift and drainflow.

Spring Oilseed rape 1x72g/ha*	Step 1		Step 2	
	PECsw (µg/L)	PEC sed (µg/kg)	PECsw (µg/L)	PECsed (µg/kg)
Northern Europe				
Thiacloprid	13.99	80.07	0.70	3.60
M02	28.96	88.99	2.32	7.11
M30	9.17	1.95	0.47	0.10
M29	4.81	17.79	0.28	1.05
Southern Europe				
Thiacloprid	13.99	80.07	0.98	5.23
M02	28.96	88.99	2.71	8.32
M30	9.17	1.95	0.85	0.18
M29	4.81	17.79	0.57	2.11

* Time weighted average (TWA) not required by eco-toxicology, not listed here to aid the simplicilty of data presentation.

Winter Oilseed rape 1x72g/ha	Step 1		Step 2	
	PECsw (µg/L)	PEC sed (µg/kg)	PECsw (µg/L)	PECsed (µg/kg)
Northern Europe				
Thiacloprid	13.99	80.77	0.70	3.60
M02	28.96	88.99	1.55	4.69
M30	9.17	1.95	0.47	0.10
M29	4.81	17.79	0.28	1.05
Southern Europe				
Thiacloprid	13.99	80.07	0.98	5.23
M02	28.96	88.99	4.27	13.15
M30	9.17	1.95	0.85	0.18
M29	4.81	17.79	0.57	2.11

* TWA not required by eco-toxicology, not listed here to aid the simplicilty of data presentation.

Spring Oilseed rape 2x72g/ha	Step 1		Step 2	
	PECsw (µg/L)	PEC sed (µg/kg)	PECsw (µg/L)	PECsed (µg/kg)
Northern Europe				
Thiacloprid	27.97	160.15	0.98	4.98

M02	57.91	177.98	3.94	12.05
M30	18.33	3.87	0.77	0.16
M29	9.62	35.58	0.56	2.08
Southern Europe				
Thiacloprid	27.97	160.15	1.28	6.72
M02	57.91	177.98	4.60	14.09
M30	18.33	3.90	1.39	0.30
M29	9.62	35.58	1.12	4.15

* TWA not required by eco-toxicology, not listed here to aid the simplicilty of data presentation.

Winter Oilseed rape 2x72g/ha	Step 1		Step 2	
	PECsw (µg/L)	PEC sed (µg/kg)	PECsw (µg/L)	PECsed (µg/kg)
Northern Europe				
Thiacloprid	27.97	160.15	0.98	4.98
M02	57.91	177.02	3.94	7.96
M30	18.33	3.90	0.77	0.16
M29	9.62	35.58	0.56	2.07
Southern Europe				
Thiacloprid	27.97	160.15	1.28	6.72
M02	57.91	177.98	7.23	22.27
M30	18.33	3.87	1.39	0.30
M29	4.81	17.79	1.12	4.15

* TWA not required by eco-toxicology, not listed here to aid the simplicilty of data presentation.

Maize 1x110g/ha*	Step 1		Step 2	
	PECsw (µg/L)	PEC sed (µg/kg)	PECsw (µg/L)	PECsed (µg/kg)
Northern Europe				
Thiacloprid	20.53	122.34	1.44	8.66
M02	43.48	135.22	5.94	18.48
M30	13.88	2.96	1.96	0.42
M29	7.35	27.18	1.45	5.37
Southern Europe				
Thiacloprid	20.53	122.34	2.88	17.32
M02	43.48	135.22	11.88	36.95
M30	13.88	2.96	3.93	0.84
M29	7.35	27.18	2.90	10.74

* TWA not required by eco-toxicology, not listed here to aid the simplicilty of data presentation.

FOCUS scenario Step 3 #	Spring oilseed rape. 1 × 72 g a.s./ha						
	YRC 2894 (Thiacloprid)			YRC 2894- amide (M02)		YRC 2894- des cyano (M29)~	
	Entry route*	PECsw [µg/L]	PECsed [µg/kg]	PECsw [µg/L]	PECsed [µg/kg]	PECsw [µg/L]	PECsed [µg/kg]
D1 (ditch)	S	0.4611	0.9655	0.5231	3.851	0.1298	1.304
D1 (pond)	S	0.4035	0.2017	0.2372	0.2058	0.0871	0.2017
D3 (ditch)	S	0.4563	0.2723	0.0004	0.0325	<0.001	<0.001
D4 (pond)	S	0.0158	0.0539	0.0506	0.3525	0.0191	0.1732

D4 (stream)	S	0.3944	0.0777	0.0701	0.1229	0.0320	0.060
D5 (pond)	S	0.0158	0.0593	0.0263	0.1971	0.0214	0.2342
D5 (stream)	S	0.3931	0.2130	0.3986	0.0482	0.0301	0.0513
R1 (pond)	R	0.0302	0.1068	0.0260	0.2435	0.0102	0.1187
R1 (stream)	S	0.3013	0.4418	0.2993	0.3263	0.0766	0.1014

~ Due to technical limitations of the models used for the calculation of PECsw. Special treatment is needed for YRC 2894 des-cyano (M29). The metabolite is considered here to be a direct degradation product of the parent substance. The evaluation of the soil degradation studies indicates that YRC 2894-des-cyano (M29) is formed from the YRC 2894-amide (M02) metabolite (this set up cannot be directly reproduced in Step 3 of FOCUSsw). M29 entry route is drainflow and runoff as the metabolite is soil only.
* S=spray drift, D=drainflow, R=Runoff.
# TWA not required by eco-toxicology, not listed here to aid the simplicilty of data presentation.

FOCUS scenario Step 3 #	Spring oilseed rape, 2 × 72 g a.s./ha						
	YRC 2894 (Thiacloprid)			YRC 2894- amide (M02)		YRC 2894- des cyano (M29)~	
	Entry route*	PECsw	PECsed	PECsw	PECsed	PECsw	PECsed
		[µg/L]	[µg/kg]	[µg/L]	[µg/kg]	[µg/L]	[µg/kg]
D1 (ditch)	S	0.6712	1.590	1.044	6.236	0.2558	0.2445
D1 (pond)	S	0.3489	0.2177	0.6554	3.282	0.1604	1.410
D3 (ditch)	S	0.3996	0.2999	0.0007	0.0656	<0.0001	<0.0001
D4 (pond)	S	0.0232	0.0857	0.1856	1.059	0.0575	0.0855
D4 (stream)	S	0.3408	0.0797	0.2026	0.4223	0.0839	0.0781
D5 (pond)	S	0.0227	0.0917	0.0564	0.3806	0.0403	0.0917
D5 (stream)	S	0.3443	0.0650	0.0811	0.103	0.0642	0.0250
R1 (pond)	R	0.0403	0.1467	0.0581	0.4658	0.0136	0.1467
R1 (stream)	S	0.2604	0.4857	0.6676	0.4930	0.0844	0.4857

~ Due to technical limitations of the models used for the calculation of PECsw. Special treatment is needed for YRC 2894 des-cyano (M29). The metabolite is considered here to be a direct degradation product of the parent substance. The evaluation of the soil degradation studies indicates that YRC 2894-des-cyano (M29) is formed from the YRC 2894-amide (M02) metabolite (this set up cannot be directly reproduced in Step 3 of FOCUSsw). M29 entry route is drainflow and runoff as the metabolite is soil only.
* S=spray drift, D=drainflow, R=Runoff.
# TWA not required by eco-toxicology, not listed here to aid the simplicilty of data presentation.

FOCUS scenario Step 3 #	Winter oilseed rape, 1 × 72 g a.s./ha						
	YRC 2894 (Thiacloprid)			YRC 2894- amide (M02)		YRC 2894- des cyano (M29)~	
	Entry route	PECsw	PECsed	PECsw	PECsed	PECsw	PECsed
		[µg/L]	[µg/kg]	[µg/L]	[µg/kg]	[µg/L]	[µg/kg]
D2 (ditch)	S	0.4615	0.8383	0.8138	1.983	0.2877	1.613
D2 (Stream)	S	0.4109	0.7482	0.5101	1.204	0.1801	0.9713
D3 (ditch)	S	0.4564	0.2761	0.0004	0.0323	<0.001	<0.0001
D4 (pond)	S	0.1575	0.0578	0.2362	0.2015	0.0164	0.1493
D4 (stream)	S	0.3842	0.0412	0.0406	0.0556	0.0263	0.0539
D5 (pond)	S	0.0158	0.0607	0.0160	0.1529	0.0152	0.1817
D5 (stream)	S	0.4065	0.0348	0.0257	0.0328	0.0237	0.0348
R1 (pond)	S	0.0157	0.0703	0.0336	0.2223	0.0100	0.0855

R1 (stream)	S	0.2998	0.0560	0.2936	0.1523	0.0746	0.0560
R3 (stream)	S	0.4239	0.4014	0.3637	0.2582	0.0785	0.0918

~ Due to technical limitations of the models used for the calculation of PECsw. Special treatment is needed for YRC 2894 des-cyano (M29). The metabolite is considered here to be a direct degradation product of the parent substance. The evaluation of the soil degradation studies indicates that YRC 2894-des-cyano (M29) is formed from the YRC 2894-amide (M02) metabolite (this set up cannot be directly reproduced in Step 3 of FOCUSsw). M29 entry route is drainflow and runoff as the metabolite is soil only.
* S=spray drift, D=drainflow, R=Runoff.
# TWA not required by eco-toxicology, not listed here to aid the simplicilty of data presentation.

FOCUS scenario step 3 #	Winter oilseed rape, 2 × 72 g a.s./ha						
	YRC 2894 (Thiacloprid)			YRC 2894- amide (M02)		YRC 2894- des cyano (M29)~	
	Entry route*	PECsw	PECsed	PECsw	PECsed	PECsw	PECsed
		[µg/L]	[µg/kg]	[µg/L]	[µg/kg]	[µg/L]	[µg/kg]
D2 (ditch)	S	0.4085	1.006	1.286	3.721	0.4853	2.844
D2 (Stream)	S	0.3550	0.6511	0.8089	2.096	0.3037	1.724
D3 (ditch)	S	0.3993	0.3015	0.0006	0.0589	<0.001	<0.001
D4 (pond)	S	0.0235	0.0904	0.0815	0.5448	0.0426	0.3551
D4 (stream)	S	0.3383	0.0635	0.1063	0.1955	0.0610	0.1319
D5 (pond)	S	0.0228	0.0934	0.0364	0.2929	0.0296	0.3835
D5 (stream)	S	0.3676	0.0426	0.0551	0.0709	0.0540	0.0736
R1 (pond)	R	0.0337	0.1503	0.0887	0.5309	0.0215	0.1720
R1 (stream)	R	0.2762	0.2419	0.6789	0.3897	0.1541	0.1132
R3 (stream)	S	0.3677	0.4035	0.8066	0.4083	0.1811	0.1277

~ Due to technical limitations of the models used for the calculation of PECsw. Special treatment is needed for YRC 2894 des-cyano (M29). The metabolite is considered here to be a direct degradation product of the parent substance. The evaluation of the soil degradation studies indicates that YRC 2894-des-cyano (M29) is formed from the YRC 2894-amide (M02) metabolite (this set up cannot be directly reproduced in Step 3 of FOCUSsw). M29 entry route is drainflow and runoff as the metabolite is soil only.
* S=spray drift, D=drainflow, R=Runoff.
# TWA not required by eco-toxicology, not listed here to aid the simplicilty of data presentation.

FOCUS scenario step 3 #	Maize, 1 × 110 g a.s./ha						
	YRC 2894 (Thiacloprid)			YRC 2894- amide (M02)		YRC 2894- des cyano (M29)~	
	Entry route*	PECsw	PECsed	PECsw	PECsed	PECsw	PECsed
		[µg/L]	[µg/kg]	[µg/L]	[µg/kg]	[µg/L]	[µg/kg]

D3 (ditch)	D	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
D4 (pond)	D	<0.001	<0.001	0.001	0.004	0.001 (0.002)	0.012 (0.0016)
D4 (stream)	D	<0.001	<0.001	0.003	0.002	0.003 (0.004)	0.004 (0.006)
D5 (pond)	D	<0.001	<0.001	<0.001	0.004	0.002 (0.004)	0.002 (0.037)
D5 (stream)	D	<0.001	<0.001	<0.001	<0.001	0.003 (0.005)	0.005 (0.009)
D6 (ditch)	D	<0.001	<0.001	0.001	0.001	0.003 (0.005)	0.006 (0.009)
R1 (pond)	R	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
R1 (stream)	R	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
R2 (stream)	R	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
R3 (stream)	R	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
R4 (stream)	R	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

~ Due to technical limitations of the models used for the calculations a special treatment is needed for YRC 2894 des-cyano. The metabolite is considered here to be a direct degradation product of the parent substance even though the evaluation of the soil degradation studies indicates that YRC 2894-des-cyano (M29) is formed from the YRC 2894-amide (M02) metabolite (this set up cannot be directly reproduced in Step 3 of FOCUSsw). Runs were validated via calculations for M02 degrading to M29 which produced similar values (where different included in parenthesis). M29 entry route is drainflow and runoff as the metabolite is soil only.
* S=spraydrift, D=drainflow, R=runoff.
# TWA not required by eco-toxicology, not listed here to aid the simplicilty of data presentation.

Step 4 calculations.

According to the guidance Landscape and Mitigation Factors in the Aquatic Ecological Risk Assessment (2007). Maximum mitigation factors of 95% of the step 3 values for spray drift entry and 90% for runoff entry are applicable. The regulatory acceptable concentration (RAC) provided by Eco-toxicology for Thiacloprid (YRC-2894) is 0.019µg/L and for YRC 2894- des cyano (M29) a value of 0.435µg/L was provided by ecotoxicology. It was noted that some step 3 concentrations may not be sufficiently reducible at step 4. The tables below identify where a theoritical pass can be achived via mitigation at step 4 given unlimited mitigation. With regards to metabolite M29 at step 3, for winter oils seed rape, 1 exceedance of the RAC is noted in D2 ditch (0.485 µg/L). Due to the current limitations of the models, this value could not be further reduced, as M29 is a soil only metabolite and drainflow was the primary route of entry. For all other crops and scenarios YRC 2894- des cyano (M29) passed the risk assessment at step 3.

Lowest maximum PEC achieveable under EFSA Landcape and mitigation (2007), values where an acceptable use cannot be achieved are highlighted.

Spring Oilseed Rape						
FOCUS scenario Step 3 #	1 × 72 g a.s./ha			2 × 72 g a.s./ha		
	YRC 2894 (Thiacloprid)			YRC 2894 (Thiacloprid)		
	Entry route*	PECsw [µg/L]	PECsed [µg/kg]	Entry route*	PECsw [µg/L]	PECsed [µg/kg]
D1 (ditch)	S	0.0231#	0.0483	S	0.0336#	0.0795
D1 (stream)	S	0.0202#	0.0101	S	0.0174	0.0109
D3 (ditch)	S	0.0228#	0.0136	S	0.0200#	0.0150
D4 (pond)	S	0.0008	0.0027	S	0.0012	0.0043
D4 (stream)	S	0.0197#	0.0039	S	0.0170	0.0040
D5 (pond)	S	0.0008	0.0030	S	0.0011	0.0046
D5 (stream)	S	0.0393#	0.0213	S	0.0172	0.0033

R1 (pond)	R	0.0015	0.0053	R	0.0040	0.0147
R1 (stream)	S	0.0151	0.0221	S	0.0130	0.0243

Step 4 calculations cannot reduce the PEC sufficiently.
* S=spray drift, D=drainflow, R=runoff.

Lowest maximum PEC achieveable under EFSA Landcape and mitigation (2014), values where an acceptable use cannot be achieved are highlighted.

Winter Oilseed Rape						
FOCUS scenario Step 3 #	1 × 72 g a.s./ha			2 × 72 g a.s./ha		
	YRC 2894 (Thiacloprid)			YRC 2894 (Thiacloprid)		
	Entry route*	PECsw [µg/L]	PECsed [µg/kg]	Entry route*	PECsw [µg/L]	PECsed [µg/kg]
D2 (ditch)	S	0.0231#	0.0419	S	0.0204#	0.0503
D2 (Stream)	S	0.0205#	0.0374	S	0.0178	0.0326
D3 (ditch)	S	0.0228#	0.0138	S	0.0200#	0.0151
D4 (pond)	S	0.0079	0.0029	S	0.0012	0.0045
D4 (stream)	S	0.0192	0.0021	S	0.0169	0.0032
D5 (pond)	S	0.0008	0.0030	S	0.0011	0.0047
D5 (stream)	S	0.0203#	0.0017	S	0.0184	0.0021
R1 (pond)	S	0.0008	0.0035	R	0.0034	0.0150
R1 (stream)	S	0.0150	0.0028	R	0.0276#	0.0242
R3 (stream)	S	0.0212#	0.0201	S	0.0184	0.0202

Step 4 calculations cannot reduce the PEC sufficiently.
* S=spray drift, D=drainflow, R=runoff.

Lowest maximum PEC achieveable under EFSA Landcape and mitigation (2007), values where an acceptable use cannot be achieved are highlighted. YRC 2894- des cyano (M29).

Spring Oilseed Rape						
FOCUS scenario Step 3 #	1 × 72 g a.s./ha			2 × 72 g a.s./ha		
	YRC 2894- des cyano (M29)			YRC 2894- des cyano (M29)		
	Entry route*	PECsw [µg/L]	PECsed [µg/kg]	Entry route*	PECsw [µg/L]	PECsed [µg/kg]
D1 (ditch)	D	0.01298	0.1304	D	0.02558	0.02445
D1 (pond)	D	0.00871	0.02017	D	0.01604	0.141
D3 (ditch)	D	<0.001	<0.001	D	<0.001	<0.001
D4 (pond)	D	0.00191	0.01732	D	0.00575	0.00855
D4 (stream)	D	0.0032	0.006	D	0.00839	0.00781
D5 (pond)	D	0.00214	0.02342	D	0.00403	0.00917
D5 (stream)	D	0.00301	0.00513	D	0.00642	0.0025
R1 (pond)	D	0.00102	0.01187	D	0.00136	0.01467
R1 (stream)	D	0.00766	0.01014	D	0.00844	0.04857

* S=spray drift, D=drainflow, R=runoff.

Lowest maximum PEC achieveable under EFSA Landcape and mitigation (2007), values where an acceptable use cannot be achieved are highlighted. YRC 2894- des cyano (M29).

Winter Oilseed Rape						
FOCUS scenario Step 3 #	1 × 72 g a.s./ha			2 × 72 g a.s./ha		
	YRC 2894- des cyano (M29)			YRC 2894- des cyano (M29)		
	Entry route*	PECsw [µg/L]	PECsed [µg/kg]	Entry route*	PECsw [µg/L]	PECsed [µg/kg]
D2 (ditch)	D	0.02877	0.1613	D	0.4853	2.844
D2 (stream)	D	0.01801	0.09713	D	0.3037	1.724
D3 (ditch)	D	<0.001	<0.001	D	<0.001	<0.001
D4 (pond)	D	0.00164	0.01493	D	0.0426	0.3551
D4 (stream)	D	0.00263	0.00539	D	0.061	0.1319
D5 (pond)	D	0.00152	0.01817	D	0.0296	0.3835
D5 (stream)	D	0.00237	0.00348	D	0.054	0.0736
R1 (pond)	D	0.001	0.00855	D	0.0215	0.172
R1 (stream)	D	0.00746	0.0056	D	0.1541	0.1132
R3 (stream)	D	0.00785	0.00918	D	0.1811	0.1277

* S=spray drift, D=drainflow, R=runoff.

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

Method of calculation	

PEC

Maximum concentration	Exposure from PECair is determined to be negligible with a DT50 in air of 1.5hrs.

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/day)
Birds				
Serinus canaria	a.s.	Acute	LD_{50}	35
			$NOAEL_{mortality}$	**15** †
Colinus virginianus	a.s.	Acute	LD_{50}	2716 [a]
Gallus domesticus	a.s.	Acute	LD_{50}	> 2000
Geometric mean endpoint	a.s.	Acute	LD_{50}	>575 (based on acute studies above) [b]
Serinus canaria	a.s.	Long-term	LD_{50}/10	**3.5**
Anas platyrhynchos	a.s.	Long-term	NOAEL	10.5 [c]
Colinus virginianus	a.s.	Long-term	NOAEL	≥33.7 [c]
Mammals				
Rats (Fischer)	a.s.	Acute (neurotoxicity)	LD_{50}	**177** [d]
Rats (Wistar)	a.s.	Acute, 14 day	LD_{50}	Males: 621 Females: 396
Rats (Wistar)	a.s.	Acute, 14 day	LD_{50}	Males: 836 Females: 444
Rats (Wistar)	'Thiacloprid FS400'	Acute	LD_{50}	120 - 800 [e]
Rats (Wistar) female	'Thiacloprid OD240'	Acute	LD_{50}	71 - 473 [f]
Rabbit developmental study	a.s.	Long-term	NOAEL	2
Rat developmental study	a.s.	Long-term	NOAEL	2
Rat multiple generation study	a.s.	Long-term	$NOAEL_{males}$ $NOAEL_{females}$	2.7 **3.3** (dystocia and reduced pup weight)

Endocrine disrupting properties (Annex Part A, points 8.1.5)

Specific studies to investigate endocrine disruption have not been submitted.

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

Birds

Barfknecht (2001): Scan sampling was used to monitor the number and species of birds frequenting three freshly drilled maize fields (BBCH 00) in Germany. The bird species, the number of individuals of each species and their behaviour were recorded; food intake was also recorded (through observation). Carrion Crow, Pheasant, and Wood Pigeon most frequently observed in the study fields. In this study, exposure density of seeds on the soil surface was also estimated. This study was used to help define focal bird species in freshly drilled maize fields in the risk assessment. The exposure density estimate was not used in the risk assessment.

Schwarz (2006): Scan and transect sampling was used to measure frequency of occurrence, abundance and

dominance of bird species in 10 freshly drilled maize fields (BBCH 00) in southern France. Carrion crow, Magpie, Yellow-legged gull and Starlings were the most abundant and dominant species, with Carrion Crow, Magpie, Starling, Crested Lark and Woodpigeon the most frequently occurring species in drilled maize fields. This study was used to help define focal bird species in freshly drilled maize fields in the risk assessment.

Wolf (2005): Scan and transect sampling was used to monitor bird species in maize fields in Austria from BBCH 00 - 14. In addition, 29 radio-tracking sessions with 16 radio-tagged Skylarks were conducted for 1 to 4 daylight periods from BBCH 00 – 14. Skylarks, Carrion Crow and Pheasant were the most abundant species occurring in drilled maize fields, with Skylark, Carrion Crow and Linnet the most the most abundant species in germinated maize. Radio-tracking data demonstrated that the 90th percentile PT value for skylark was 96.4 % (potentially foraging in maize) and the worst case individual was 100 %. This study was used to help define the focal species for freshly sown maize fields and fields of maize seedlings.

Funkenhaus and Giessing (2010b): This study was submitted during the commenting period following a request from EFSA for the applicant to submit further supporting data to demonstrate that skylarks mainly fed on invertebrates at the time of maize drilling. Radiotracking was used to monitor the pre-defined focal species carrion crow, skylark, woodpigeon, starling and crested lark in this study conducted in freshly drilled and early maize fields in southern France and PT values estimated, although not considered in the risk assessment. Diet selection of these species was determined by inspection of faecal samples. In addition other birds were monitored in the fields using scan sampling. This study was used as supporting information in the risk assessment for the consideration of a mixed diet for the skylark.

Funkenhaus and Giessing (2010a): Estimated the exposure density of seeds on the soil surface and presence of seed spills. The data on exposure density from this study was not used in the risk assessment as the drilling rate was not provided in the study report.

Dittrich & Giessing (2010): A field study was conducted in Southern Germany to investigate potential effects on birds of exposure to maize seeds treated with 'Thiacloprid FS 400' from BBCH 00 – 15/16. This study used a 216 ha area with 9 drilled fields used as study fields.

Observations conducted included scan sampling (for characterization of bird abundance, activity, and behaviour), radio-tracking (non-continuous) of species considered to be focal species for freshly drilled maize fields (Woodpigeon, Magpie, Grey Partridge and Pheasant), carcass searches, and counting of seeds exposed on the soil surface (including disappearance from seed spills over time). Dehusking was briefly mentioned in this study but data were not presented and it was not considered in the risk assessment.

A total of 805 bird contacts, comprising 22 species were recorded during the 775 bird scans carried out. Small songbirds were the most abundant species, but were not observed feeding on maize seeds.Within the monitoring period, 21 of the 26 tagged birds remained alive; one magpie was found to have lost its tag and four grey partridges were killed by predation.

This study was used as supporting information in the risk assessment.

Wilkens (2007): The number of seeds on the soil surface was counted using four transects of 50 metres in study fields containing maize seeds. Every 5 m a sampling frame (0.5 m x 0.5 m) was placed on the ground and the number of maize seeds counted within the frame. This was repeated 20 times in the headland area and 20 times in the midfield area. The exposure density of seeds on the soil surface was estimated to be 0.10 seeds/m^2 (midfield mean), 0.10 seeds/m^2 (midfield 90th %ile), 0.20 seeds/m^2 (end row mean) and 0.40 seeds/m^2 (end row 90th %ile). The data from this study were used in the risk assessment to refine the focal species' foraging area.

De Leeuw *et al.* (1995): The exposure density of maize seeds on the soil surface was estimated by counting the number of seeds in a 1m x 1m frame, repeated ten times in the midfield and headland area. The number of maize seed spills and ranges of seeds within spills was also recorded. The exposure density was not used in the risk assessment as the drilling rate was not provided in the study report.

Defra (2009): The exposure density of seeds on the soil surface was estimated. This resulted in a 90th%ile of 1.88 seeds/m^2 and 1.68 seeds/m^2 in the midfield and end row area respectively; mean values were 1.12 and 0.83 in the midfield and endrow area respectively. These values were used in the risk assessment to refine the focal species' foraging area.

Mammals

Hecht-Rost *et al.* (2013): Surveyed the small mammal populations found in maize fields at BBCH 19-75 and throughout harvesting, tilling and replanting of new cereal crops in the same fields. This study was designed to trap the wood mouse (Apodemus sylvaticus). No woodmice were trapped during trapping session 1 when the

maize plants were at BBCH19 but were trapped after BBCH19.

Wolf (2005): Small mammal live traps, scan sampling and 24-hour continuous radio tracking were conducted for different mammalian species occuring in maize and sugar beet fields in Austria at BBCH00 - 14. Woodmice were trapped in the maize crop and one individual was radio-tracked in the crop but did not forage the maize. It is noted that the trapping results from freshly-drilled and germinated maize have been grouped together in this study so it is unclear at which BBCH stage these trappings took place. Using scan sampling, the Brown Hare (*Lepus europaeus*), was observed in maize, BBCH 00, at 0.002 ind./ha. This study was used to help define the focal species for freshly sown maize fields and fields of maize seedlings.

Funkenhaus and Giessing (2010b): Small mammal traps, diurnal scan sampling and thermographic scan sampling were conducted in drilled maize fields in France. During small mammal trapping at BBCH 00 (freshly drilled maize), the most abundant species found was the wood mouse (*Apodemus sylvaticus*). Besides the wood mouse, the common vole (*Microtus arvalis*) and the greater white-toothed shrew (*Crocidura russula*) were captured. Diurnal (day time) scan sampling at BBCH 00 recorded the European Brown Hare (*Lepus europaeus*) only. During the thermographic scan sampling (nocturnal) the European Brown Hare and European Rabbit (*Oryctolagus cuniculus*) were the most abundant species at BBCH 00 each with 0.04 individuals per hectare. Wood mice were not visualised via thermographic scan sampling on the field at BBCH 00.

The results changed later on in development (after BBCH 10 – seedling emergence) of the maize. While the Wood mouse was still the most abundant species, the European brown hare (*Lepus europaeus*) and the European rabbit *(Oryctolagus cuniculus*) were the relevant species monitored as potentially foraging during thermographic scan sampling sessions. However, the European rabbit was not observed in the diurnal scanned fields at the stages of BBCH 12-16. The hare was the only mammal species observed during daylight scan sampling.

Overall, mammals showed low abundances but the Wood mouse was the most abundant throughout the growth stages of the maize. While the European Brown Hare and European Rabbit were also seen at growth stage BBCH 00, they were more abundant after BBCH10. This study was used to help to define the focal species for freshly sown maize fields and fields of maize seedlings.

Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):

No data was relied on for the risk assessment under data requirements 8.14 or 10.1.3.

† As agreed at the EFSA Peer Review Meeting 183, the NOAEL with an assessment factor of 1 should be used in the acute risk assessment for birds.

[a] This is an extrapolated value beyond the tested range

[b] The geomean calculation includes a value that was extrapolated beyond the tested range and is therefore a > value

[c] Conversions based on the respective mean food consumption and mean body weight (based on study reports)

[d] The endpoint is an extrapolated value where 0 % mortality was found at 109 mg a.s./kg bw and 100 % mortality was observed at 244 mg a.s./kg bw.

[e] This value represents the potential range of the LD_{50}, where 0% mortality was observed at the lowest end (120 mg a.s./kg), and 100% mortality was observed at the upper end (800 mg a.s./kg).

[f] This value represents the potential range of the LD_{50}, where 0 % mortality was observed at the lowest end (71 mg a.s./kg), and 100 % mortality was observed at the upper end (473 mg a.s./kg).

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

'Thiacloprid OD 240' use on Oilseed Rape (BBCH 30-59) at 72 g a.s./ha [x 2 applications, with a 10 day interval]

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous bird	Acute	14.9	1.01	1 [a]
All	Small omnivorous bird	Long-term	3.7	**0.94**	5
Tier 1 (Birds)					
late – late (with seeds) (BBCH 30-	Small insectivorous bird "dunnock"		0.15	22.6	5

99)		Long-term, active substance			
BBCH 30 - 39	Small omnivorous bird “lark”		0.19	18.5	
BBCH ≥ 40	Small omnivorous bird “lark”		0.15	22.6	
BBCH 30 - 39	Medium herbivorous/granivorous bird "pigeon"		0.06	55.6	
BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon"		0.05	67.9	

Risk from bioaccumulation and food chain behaviour (birds)

Not relevant as the Log kow of Thiacloprid is ≤ 3

Risk from consumption of contaminated water (birds)

Not relevant as the ratio of the effective application rate to the relevant endpoint does not exceed 3000 (where the Koc > 500). The Koc of thiacloprid is 601 and the ratio of application rate to the long term endpoint is 41.1

Risk from metabolites of thiacloprid (birds)

Acute risk assessment (birds)				
Metabolite	Generic focal species	DDD (mg/kg bw/d)	NOAEL [a] (mg/kg bw)	TER_a
6-CNA	small granivorous bird ‘finch‘ BBCH 30 – 88 (late with seeds)	0.036	1.5 *	41.7
6-CNA conjugate		0.023		65.2
6-CNA + 6-CNA conjugate		0.059		25.4

* 10x toxicity of parent compound assumed.

Long-term risk assessment (birds)				
Metabolite	Generic focal species	DDD (mg/kg bw/d)	NOEL (mg/kg bw/d)	TER_a
6-CNA	small granivorous bird ‘finch‘ BBCH 30 – 88 (late with seeds)	0.036	0.35*	9.7
6-CNA conjugate		0.023		15.0
6-CNA + 6-CNA conjugate		0.059		5.9

* 10x toxicity of parent compound assumed.

Screening Step (Mammals)					
All	Small herbivorous mammal	Acute, active substance	11.1	15.9	10
All	Small herbivorous mammal	Acute, formulation	11.1	**> 6.4**	10
All	Small herbivorous mammal	Long-term screen	2.76	**1.2**	5
Tier 1 (Mammals)					
BBCH ≥ 20	Small insectivorous mammal “shrew”	Acute, formulation	0.505	140	10
BBCH ≥ 40	Small herbivorous mammal “vole”		3.19	22	
All season	Large herbivorous mammal “lagomorph”		3.29	22	
BBCH 30-39	Small omnivorous mammal “mouse”		0.500	146	
BBCH ≥ 40	Small omnivorous mammal “mouse”		0.402	176	
All season	Large herbivorous mammal “lagomorph”	Long term, active substance	0.82	**4.02**	5

BBCH ≥ 20	Small insectivorous mammal "shrew"		0.11	30.0	
BBCH 30-39	Small omnivorous mammal "mouse"		0.13	25.3	
BBCH ≥ 40	Small omnivorous mammal "mouse"		0.11	30.0	
BBCH ≥ 40	Small herbivorous mammal "vole"		1.04	**3.17**	

Higher tier (mammal):

The proposed use is between BBCH 30 – 59, principal growth stages 3 -5, therefore deposition factor of 0.2 was taken into account in the risk assessment (intead of 0.25).

Generic focal species	Shortcut value (excluding deposition)	Shortcut value (including deposition of 0.2)	Application rate (kg a.s./ha)	MAF	DDD (mg a.s./kg bw/d)	NOAEL (mg a.s./kg bw/day)	TER_{LT}	Trigger
Small herbivorous mammal "vole", BBCH ≥ 40	72.4 *	14.48	0.072	1.5	0.82	3.3	**4.02**	5

** The default Tier 1 short-cut value of 18.1 accounts for a deposition factor of 0.25 for the 'small herbivorous mammal', hence this value reflects the shortcut value without deposition (18.1/0.25)*

A DT50 value of 7 days was used in a refined risk assessment below:

Refined DT_{50}: long-term mammal risk assessment

Generic focal species	FIR/bw	RUD	Application rate (kg a.s./ha)	MAF	DF	fTWA	DDD (mg a.s./kg bw/d)	NOAEL (mg a.s./kg bw/day)	TER_{LT}	Trigger
Large herbivorous mammal "lagomorph", All season	0.5	28.7	0.072	1.37	1	0.4208	0.596	3.3	5.5	5
Small herbivorous mammal "vole", BBCH ≥ 40	1.33	54.2			0.2		0.598		5.5	

Risk from bioaccumulation and food chain behaviour (mammals)

Not relevant as the Log kow of Thiacloprid is ≤ 3

Risk from consumption of contaminated water (mammals)

Not relevant as the ratio of the effective application rate to the relevant endpoint does not exceed 3000 (where the Koc > 500). The Koc of thiacloprid is 601 and the ratio of application rate to the long term endpoint is 6.9.

Risk from metabolites of thiacloprid (mammals)

Metabolite	Generic focal species	**DDD (mg/kg bw/d)**	**LD_{50} (mg/kg bw)**	**TER_A**
6-CNA	Small omnivorous mammal	0.031	17.7 *	571
6-CNA conjugate		0.020		885
6-CNA + 6-CNA conjugate		0.051		347

**10x toxicity of the active substance.*

Metabolite	Generic focal species	**DDD (mg/kg bw/d)**	**NOEL (mg/kg bw/d)**	**TER_{LT}**
6-CNA	Small omnivorous mammal	0.031	0.33 *	10.7
6-CNA conjugate		0.020		16.5
6-CNA + 6-CNA conjugate		0.051		6.4

** 10 x toxicity of the active substance.*

[a] For the acute risk assessment, use of the NOAEL with an assessment factor of 1, rather than the LD_{50}, was agreed at EFSA Peer Review Meeting 183 (see discussion in Section B.9.1.1).

'Thiacloprid FS 400' use on Maize (BBCH 00) at 1 mg a.s./seed with a sowing rate of 110000 seeds/ha

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Tier 1 (Birds)					
Consumption of treated seeds (BBCH 00)	Large granivorous bird	Acute, active substance	222.2 – 500 [a]	**0.03 – 0.07**	1 [b]
		Long-term, active substance	222.2 – 500.0 [a]	**0.007 - 0.016**	5
Consumption of treated seedlings	Small omnivorous bird	Acute, active substance	222.2 – 500 [a]	**0.03 – 0.07**	1 [b]
	Large herbivorous bird		133.3 - 300	**0.05 – 0.11**	1 [b]
	Small omnivorous bird	Long-term, active substance	117.8- 265	**0.013 - 0.030**	5
	Large herbivorous bird		70.6 -159	**0.022 - 0.050**	5

Higher tier (birds):

Treated seeds

Exposure density of the seed on the surface of the field to refine the foraging area required for the focal bird species to achieve the 'acceptable dose' was estimated. In addition further supporting information was considered.

Long-term risk

The long-term risk from consumption of seedlings emerged from treated seeds was refined using the Skylark and Woodpigeon as focal species, both initially consuming a 100 % seedling diet. In addition, the diet of the Skylark was refined to a mixed diet.

	Woodpigeon	Skylark (100 % seedling diet)	Skylark (mixed diet)
Long-term toxicity endpoint (mg a.s./kg bw)	3.5		
Daily Dietary Dose (mg a.s./kg bw/d)	94.2 - 212	242 - 546	25.9 – 58.3
TER_{LT}	**0.017 – 0.037**	**0.0064 – 0.014**	**0.060 – 0.14**

Values in bold are below the Annex VI trigger value of 5

Tier 1(Mammals)					
Scenario	Generic focal species	Compound	DDD (mg a.s./kg bw/d)	TER	Trigger
Consumption of treated seeds (BBCH 00)	Small omnivorous mammal	Acute, active substance	533 – 1200 [a]	**0.15 - 0.33**	10
	Small omnivorous mammal	Acute, formulation		**0.10 - 0.23**	
Consumption of seedlings	Small omnivorous mammal	Acute, active substance	107 – 240 [a]	**0.74 - 1.65**	10

	Small omnivorous mammal	Acute, formulation		**0.50 - 1.12**	
Consumption of treated seeds (BBCH 00)	Small omnivorous mammal	Long-term	533 – 1200 [a]	**2.75×10^{-3} - 6.19×10^{-3}**	5
Consumption of seedlings			56.71 - 127.2 [a]	**0.026 - 0.058**	

Higher tier (Mammals):
Exposure density of the seed on the surface of the field to refine the foraging area required for the wood mouse to achieve the 'acceptable dose' was estimated.

Seedling shoots
The diet of the wood mouse as focal specie was considered as a 100% seedling as well as a mixed diet (containing 25% seedlings). *L. europaeus* and *O. cuniculus* were assessed based on a diet of 100% crop shoots.

Growth Stage	Species	DDD (mg/kg bw/day)	TER	Trigger
BBCH 12-18	Wood mouse (*Apodemus sylvaticus*), Single diet (100% seedling shoots)	578 - 1300	**0.136 – 0.306**	10
BBCH 12-18	Wood mouse (*Apodemus sylvaticus*), Mixed diet (25% seedling shoots)	111 – 250	**0.708 – 1.59**	
BBCH 12-18	Rabbit (*Oryctolagus cuniculus*), feeding on seedling shoots.	169 - 380	**0.466 – 1.05**	
BBCH 12-18	European brown hare (*Lepus europaeus*) feeding on seedling shoots.	142 - 320	**0.553 – 1.24**	

Growth Stage	Species	DDD (mg/kg bw/day)	TER	Trigger
BBCH 12-18	Wood mouse (*Apodemus sylvaticus*) Single diet (100% seedling shoots)	306 – 689	**0.0048 – 0.011**	5
BBCH 12-18	Wood mouse (*Apodemus sylvaticus*) Mixed diet (25% seedling shoots)	58.9 – 133	**0.025 – 0.056**	5
BBCH 12-18	European brown hare (*Lepus europaeus*) feeding on seedling shoots.	75.4 – 170	**0.020 – 0.044**	5
BBCH 12-18	European Rabbit (*Oryctolagus cuniculus*).	89.5 - 201	**0.016 – 0.037**	5

Risk from bioaccumulation and food chain behaviour
Not relevant as the Log kow of Thiacloprid is ≤ 3

Risk from consumption of contaminated water
Not relevant as the ratio of the effective application rate to the relevant endpoint does not exceed 3000 (where the Koc > 500). The Koc of thiacloprid is 601 and the ratio of application rate to the long term endpoint is 33.3.

[a] Range is due to a range in the thousand grain weight of the seeds of 200-450 g.

[b] For the acute risk assessment, use of the NOAEL with an assessment factor of 1, rather than the LD_{50}, was agreed at EFSA Peer Review Meeting 183 (see discussion in Section B.9.1.1).

Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part Apoints 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]
Laboratory tests				
Fish				
Cyprinodon variegatus	a.s.	Acute: Static, 96 hours, marine fish	LC_{50}	**19700 µg a.s./L (mm)**
Oncorhynchus mykiss	M02	Acute: Static, 96 hours, limit test	LC_{50}	> 79400 µg a.s./L (mm)
Lepomis macrochirus	M02	Acute: Static, 96 hours, limit test	LC_{50}	**> 78600 µg a.s./L (mm)[a]**
Oncorhynchus mykiss	M30	Acute: Static, 96 hours	LC_{50}	**> 90100 µg a.s./L (nom)**
Pimephales promelas	a.s.	Chronic: 33 days, flow-through	NOEC	No definitive NOEC could be established[X]
Pimephales promelas	a.s.	Chronic: 260 days, flow-through, full-life-cycle	NOEC	No definitive NOEC could be established (lowest tested concentration was ≤ 100 µg a.s./L (mm))
Pimephales promelas	a.s.	Chronic: Partial life cycle, maturation, flow-through	NOEC	116 µg a.s./L (mm) [b]
Cyprinus carpio	a.s.	Early life stage study, based on a modified version of OECD 210, non-GLP	NOEC	**4.5 µg a.s./L (nom)**
Aquatic invertebrates *				
Ecdyonurus sp.	a.s.	Acute: Static, 48 hours	LC_{50}	23.8 µg a.s./L (nom) [d]
			EC_{50}	7.7 µg a.s./L (nom) [d] †
Mysidopsis bahia	a.s.	Acute: 96 hours, flow through	LC_{50}	31 µg a.s./L (nom)
Chironomus riparius	a.s.	Acute: Static, 48 hours	EC_{50}	10.8 µg a.s./L (nom) †
Geometric mean endpoint	a.s.	Acute	EC_{50}	**9.12 µg a.s./L †**
Hyalella azteca	M02	Static, 96 hours	LC_{50}	**> 47600 µg a.s./L (mm)**
Daphnia magna	M02	Static, 48 hours	EC_{50}	> 103000 µg a.s./L (mm)
Daphnia magna	M30	Static, 48 hours	EC_{50}	**> 100000 µg a.s./L (nom)**
Chironomus riparius	Lysimeter leachate	Static, 28 hours, larvae study	-	- [f]
Mysidopsis bahia	a.s.	Chronic: 32 days, flow through, saltwater test medium	EC_{10}	0.608 µg a.s./L (mm) [g]

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Laboratory tests				
Sediment-dwelling organisms				
Chironomus riparius	a.s.	Chronic: Static, 29 days, water sediment system, F1 generation [i]	NOEC	0.19 µg a.s./L (mm) [j] **(0.63 µg a.s./kg sed. d.w.)**
Chironomus riparius	'Thiacloprid OD240'	28 days, static, water sediment system [i]	NOEC	0.13 µg a.s./L (equivalent to 0.56 µg prep./L) (mm) [k]
Chironomus riparius	'Thiacloprid FS400'	28 days, static, water sediment system, spiked water [i]	NOEC	0.226 µg a.s./L (mm)
Chironomus riparius	M02	28 days, static, water sediment system, spiked water [i]	NOEC	**100 µg a.s./L (nom initial)**
Chironomus riparius	M29	28 days, static, water sediment system, spiked water [i]	EC_{10}	**4.35 µg a.s./L (mm)**
Chironomus riparius	M30	28 days, static, water sediment system, spiked water [i]	NOEC	**≥ 100000 µg a.s./L (nom initial)**
Algae				
Scenedesmus subspicatus	a.s.	Static, 72 hours	E_rC_{50}	**96700 µg a.s./L (nom) [L]**
			E_bC_{50}	44700 µg a.s./L (nom) [L]
Pseudo -kirchneriella subcapitata (*Selenastrum capricornutum*)	M02	Static, 72 hours	E_rC_{50}	**> 100000 µg a.s./L (nom)**
			E_bC_{50}	> 100000 µg a.s./L (nom)
Scenedesmus subspicatus	M30	Static, 72 hours	E_rC_{50}	**> 100000 µg a.s./L (nom)**
			E_bC_{50}	> 100000 µg a.s./L (nom)
Other aquatic organisms – Amphibians				
Xenopus laevis	a.s.	Static, 48 hours	LC_{50}	> 100000 µg a.s./L (nom)
Further testing on aquatic organisms: **Heimbach (1997):** The effects of exposure to thiacloprid were investigated using the formulation 'YRC 2894 SC 480'. Two treatments at a 14 day interval were applied with no incorporation of the test item into the water column. Nominal treatment concentrations were 0.0, 0.32, 0.56, 1.0, 1.8, 3.2, 5.6, 10, 18, 32 µg a.s./L. Three replicates were established for the control, only single ponds were established for each of the treatment groups. The most sensitive taxa identified in the study was the *Ephemeroptera*, with effects on abundance apparent at the lowest treatment concentration (0.32 µg a.s./L). A ETO RAC or ERO RAC could not be established based on the effects observed in the study, and due to the limitations of the study design.				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3) No additional information.				

[1] (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; a.s.: active substance

† The acute geometric mean endpoint is based on the results from the acute *Ecdyonurus* and *C. riparius* studies.
* Note that there is no agreed Tier-1 endpoint, and therefore RAC, for use in risk assessment with regard to the long-term risk to aquatic invertebrates (exposed via water). A data gap has been set to resolve this issue.
[a] This endpoint was presented in the original DAR without a study summary; the study has not been re-evaluated but the endpoint is considered for use in the risk assessment.
[b] This study was conducted as a follow up to Dionne (1999). It was intended to further investigate observations of early maturation observed in Dionne (1999) and is not conducted to specific study guidelines. See the study summary in B.9.2.2 (AS) for further details.
[c] Endpoint based on immobilistaion (considered equivalent to mortaility), the value in parentheses is the EC_{50} taking into account observations of 'floaters' on the surface.
[d] The LC_{50} is based on mortaility only, the EC_{50} is based on immobilisation and mortaility.
[f] The study reports results of exposure to lysimeter leachates based on the OECD 202 guideline, no mortality greater than 3.3 % was observed during the study and it was concluded that the leachates did not affect the larvae. The study was not used in risk assessment.
[g] See discussion of appropriate endpoint in section B.9.4.1.1. (PPP).
[h] Endpoint reported as the nominal initial concentration however the concentration of the test item was observed to decline over the course of the test (to 15.7% of nominal by day 28)
[i] Water-sediment test system with the test item added to the overlying water.
[j] The studies Bruns (2014a) and Bruns (2014b) are discussed further in the risk assessments (Section B.9.4.1.1. (PPP). Bruns (2014b) was conducted to further inform the results of Bruns (2014a) and both have been considered with regard to setting an appropriate endpoint.
[k] Endpoint set by the RMS based on the limitations of the analytical methods used to establish the treatment concentrations and the limited information regarding abnormal behavioural observations during the test.
[L] It is noted that the treatment concentration was only established at the start of the test (no measurements were performed at test termination). However, the study Anderson (1995b) demonstrated the test item is stable over 5 days, compared to three days exposure in Anderson (1995a). Therefore, the endpoints from the study (Anderson, 1995a) have been retained for use in risk assessment despite this uncertainty.
[X] It is noted that reduced larval survival compared to the control, 30 days post-hatch, of between 6.6 – 13.2 % was observed in the study. No dose response was apparent for the treatment groups. However, given the effects observed a definitive NOEC cannot be set for the study (as agreed at EFSA Peer Review Meeting 183).

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Active substance	M02	M29	M30
$logP_{O/W}$	1.26 - 1.4 [a]	0.71 - 0.74 [b]	-2.3 - 1.1 [b]	-3.0 - -2.5 [b]
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	-	-	-	-
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)	-	-	-	-
Annex VI Trigger for the bioconcentration factor	-	-	-	-
Clearance time (days) (CT_{50})	-	-	-	-
(CT_{90})	-	-	-	-
Level and nature of residues (%) in organisms after the 14 day depuration phase	-	-	-	-
Higher tier study				
n/a				

[a] Range produced because the $LogP_{O/W}$ of 1.26 is from the original DAR of thiacloprid, and the 1.4 LogPow is from a study submitted for the renewal of thiacloprid.

[b] Range produced because the $LogP_{O/W}$ differed depending on the pH.

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

'Thiacloprid OD 240' – Risk assessment for the proposed uses

FOCUS$_{sw}$ step 1-3 – Risk assessment for Thiacloprid – Spring oilseed rape at 72 g a.s./ha x 1 application

Scenario	PEC global max (µg L) [a]	Fish acute	Fish chronic	Aquatic invertebrates	Algae	Sed. dweller prolonged
		Cyprinodon variegatus	*Cyprinus carpio*	*Ecdyonurus sp.*	*Scenedesmus subspicatus*	*Chironomus riparius*
		RAC (LC_{50})	RAC (NOEC)	RAC (EC_{50})	RAC (EC_{50})	RAC (NOEC)
		197 µg/L	0.45 µg/L	0.077 µg/L	9670 µg/L	0.63 µg/kg sed dw
FOCUS Step 1						
	13.99 (80.07)	14.1	**0.0322**	**0.00550**	691	**0.000787**
FOCUS Step 2						
North Europe	0.70 (3.60)	-	**0.643**	**0.110**	-	**0.0175**
South Europe	0.98 (5.23)	-	**0.459**	**0.0786**	-	**0.0120**
FOCUS Step 3						
D1 (ditch)	0.4611 (0.9655)	-	**0.976**	**0.17**	-	**0.0653**
D1 (pond)	0.4035 (0.2017)	-	1.12	**0.19**	-	**0.312**
D3 (ditch)	0.4563 (0.2723)	-	**0.986**	**0.17**	-	**0.231**
D4 (pond)	0.0158 (0.0539)	-	28.5	4.87	-	1.17
D4 (stream)	0.3944 (0.0777)	-	1.14	**0.20**	-	**0.811**
D5 (pond)	0.0158 (0.0539)	-	28.5	**4.87**	-	1.06
D5 (stream)	0.3931 (0.2130)	-	1.15	**0.20**	-	**0.296**
R1 (pond)	0.0302 (0.1068)	-	14.9	2.55	-	**0.590**
R1 (stream)	0.3013 (0.4418)	-	1.49	**0.26**	-	**0.143**

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

* No RAC has been agreed to consider the long-term risk to aquatic invertebrates, the risk is therefore unresolved and a data gap has been set to address this issue.

[a] Values in parentheses are the PECsed values (µg/kg sed dw) used in the risk assessment for sediment dwellers exposed via sediment (toxicity expressed as µg/kg sed dw)

FOCUS$_{sw}$ step 1-3 – Risk assessment for Thiacloprid – Spring oilseed rape at 72 g a.s./ha x 2 applications with 10 day interval

Scenario	PEC global max (µg L) [a]	Fish acute	Fish chronic	Aquatic invertebrates	Algae	Sed. dweller prolonged

		Cyprinodon variegatus	*Cyprinus carpio*	*Ecdyonurus sp.*	*Scenedesmus subspicatus*	*Chironomus riparius*
		RAC (LC_{50})	RAC (NOEC)	RAC (EC_{50})	RAC (EC_{50})	RAC (NOEC)
		197 µg/L	0.45 µg/L	0.077 µg/L	9670 µg/L	0.63 µg/kg sed dw
FOCUS Step 1						
	27.97 (160.15)	7.04	**0.0161**	**0.00275**	346	**0.000393**
FOCUS Step 2						
North Europe	0.98 (4.98)	-	**0.459**	**0.0786**	-	**0.0127**
South Europe	1.28 (6.72)	-	**0.352**	**0.0602**	-	**0.00938**
FOCUS Step 3*						
D1 (ditch)	0.6712 (1.590)	-	**0.670**	**0.11**	-	**0.0396**
D1 (pond)	0.3489 (0.2177)	-	1.29	**0.22**	-	**0.289**
D3 (ditch)	0.3996 (0.2999)	-	1.13	**0.19**	-	**0.210**
D4 (pond)	0.0232 (0.0857)	-	19.4	3.32	-	**0.735**
D4 (stream)	0.3408 (0.0797)	-	1.32	**0.23**	-	**0.790**
D5 (pond)	0.0227 (0.0917)	-	19.8	3.39	-	**0.687**
D5 (stream)	0.3443 (0.0650)	-	1.31	**0.22**	-	**0.969**
R1 (pond)	0.0403 (0.1467)	-	11.2	1.91	-	**0.429**
R1 (stream)	0.2604 (0.4857)	-	1.73	**0.30**	-	**0.130**

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

* No RAC has been agreed to consider the long-term risk to aquatic invertebrates, the risk is therefore unresolved and a data gap has been set to address this issue.

[a] Values in parentheses are the PECsed values (µg/kg sed dw) used in the risk assessment for sedment dwellers exposed via sediment (toxicity expressed as µg/kg sed dw)

$FOCUS_{sw}$ step 1-3 – Risk assessment for Thiacloprid – Winter oilseed rape at 72 g a.s./ha x 1 application

Scenario	**PEC global max (µg L)** [a]	**Fish acute**	**Fish chronic**	**Aquatic invertebrates**	**Algae**	**Sed. dweller prolonged**
		Cyprinodon variegatus	*Cyprinus carpio*	*Ecdyonurus sp.*	*Scenedesmus subspicatus*	*Chironomus riparius*
		RAC (LC_{50})	RAC (NOEC)	RAC (EC_{50})	RAC (EC_{50})	RAC (NOEC)
		197 µg/L	0.45 µg/L	0.077 µg/L	9670 µg/L	0.63 µg/kg sed dw
FOCUS Step 1						
	13.99 (80.77)	14.1	**0.0322**	**0.00550**	691	**0.000780**
FOCUS Step 2						

North Europe	0.70 (3.60)	-	**0.643**	**0.110**	-	**0.0175**
South Europe	0.98 (5.23)	-	**0.459**	**0.0786**	-	**0.0120**
FOCUS Step 3*						
D2 (ditch)	0.4615 (0.8383)	-	**0.975**	**0.17**	-	**0.0752**
D2 (stream)	0.4109 (0.7482)	-	1.10	**0.19**	-	**0.0849**
D3 (ditch)	0.4564 (0.2761)	-	**0.986**	**0.17**	-	**0.228**
D4 (pond)	0.1575 (0.0578)	-	2.86	**0.49**	-	1.09
D4 (stream)	0.3842 (0.0413)	-	1.17	**0.20**	-	1.53
D5 (pond)	0.0158 (0.0607)	-	28.5	4.87	-	1.04
D5 (stream)	0.4065 (0.0348)	-	1.11	**0.19**	-	1.81
R1 (pond)	0.0157 (0.0703)	-	28.7	4.90	-	**0.896**
R1 (stream)	0.2998 (0.0560)	-	1.50	**0.26**	-	1.13
R3 (stream)	0.4239 (0.4014)	-	1.06	**0.18**	-	**0.16**

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

* No RAC has been agreed to consider the long-term risk to aquatic invertebrates, the risk is therefore unresolved and a data gap has been set to address this issue.

[a] Values in parentheses are the PECsed values (µg/kg sed dw) used in the risk assessment for sediment dwellers exposed via sediment (toxicity expressed as µg/kg sed dw)

FOCUS$_{sw}$ step 1-3 – Risk assessment for Thiacloprid – Winter oilseed rape at 72 g a.s./ha x 2 applications with 10 day interval

Scenario	**PEC global max (µg L)** [a]	**Fish acute**	**Fish chronic**	**Aquatic invertebrates**	**Algae**	**Sed. dweller prolonged**
		Cyprinodon variegatus	*Cyprinus carpio*	*Ecdyonurus sp.*	*Scenedesmus subspicatus*	*Chironomus riparius*
		RAC (LC_{50})	RAC (NOEC)	RAC (EC_{50})	RAC (EC_{50})	RAC (NOEC)
		197 µg/L	0.45 µg/L	0.077 µg/L	9670 µg/L	0.63 µg/kg sed dw
FOCUS Step 1						
	27.97 (160.15)	7.04	**0.0161**	**0.00275**	346	**0.000393**
FOCUS Step 2						
North Europe	0.98 (4.98)	-	**0.459**	**0.0786**	-	**0.0127**
South Europe	1.28 (6.72)	-	**0.352**	**0.0602**	-	**0.00938**
FOCUS Step 3*						
D2 (ditch)	0.4085 (1.006)	-	1.10	**0.19**	-	**0.0626**
D2 (stream)	0.3550 (0.6511)	-	1.27	**0.22**	-	**0.0968**
D3 (ditch)	0.3993 (0.3015)	-	1.13	**0.19**	-	**0.209**
D4 (pond)	0.0235 (0.0904)	-	19.1	3.28	-	**0.697**

D4 (stream)	0.3383 (0.0635)	-	1.33	**0.23**	-	**0.992**
D5 (pond)	0.0228 (0.0934)	-	19.7	3.38	-	**0.675**
D5 (stream)	0.3676 (0.0426)	-	1.22	**0.21**	-	1.48
R1 (pond)	0.0337 (0.1503)	-	13.4	2.28	-	**0.419**
R1 (stream)	0.2762 (0.2419)	-	1.63	**0.28**	-	**0.260**
R3 (stream)	0.3677 (0.4035)	-	1.22	**0.21**	-	**0.156**

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

* No RAC has been agreed to consider the long-term risk to aquatic invertebrates, the risk is therefore unresolved and a data gap has been set to address this issue.

[a] Values in parentheses are the PECsed values (µg/kg sed dw) used in the risk assessment for sedment dwellers exposed via sediment (toxicity expressed as µg/kg sed dw)

FOCUS$_{sw}$ step 4 – Risk assessment for Thiacloprid – Spring oilseed rape at 72 g a.s./ha x 2 applications with 10 day interval.

Organisms: Invertebrates, acute
(Tier-2 geomean RAC, **surface water exposure**)

RAC: 0.0912 µg/L

Mitigation options	[x] m non-spray buffer zone	[x] m vegetated buffer strip	PECsw (µg/L)	RAC/PEC	Trigger
FOCUS Step 4					
D1 (ditch)	10 m buffer zone	-	0.0886	1.03	1
D1 (stream)	10 m buffer zone	-	0.0780	1.17	1
D3 (ditch)	10 m buffer zone	-	0.0654	1.39	1
D4 (pond)	Risk resovled at FOCUS step 3	-	-	-	-
D4 (stream)	10 m buffer zone	-	0.0762	1.20	1
D5 (pond)	Risk resovled at FOCUS step 3	-	-	-	-
D5 (stream)	10 m buffer zone	-	0.0760	1.20	1
R1 (pond)	Risk resovled at FOCUS step 3	-	-	-	-
R1 (stream)	Maximum possible mitigation	-	0.0151	6.04	1

Organisms: *C. riparius*
(Sediment dwelling organism, **sediment exposure**)

RAC: 0.063 µg/kg sed

Mitigation options	[x] m non-spray buffer zone	[x] m vegetated buffer strip	PECsed (µg/kg sed)	RAC/PEC	Trigger
FOCUS Step 4					
D1 (ditch)	**Risk not resolved** [a]	-	-	-	-
D1 (stream)	10 m buffer zone	-	0.0424	1.49	1
D3 (ditch)	10 m buffer zone	-	0.0436	1.44	1
D4 (pond)	10 m buffer zone	-	0.0537	1.17	1

D4 (stream)	5 m buffer zone	-	0.0288	2.19	1
D5 (pond)	10 m buffer zone	-	0.0576	1.09	1
D5 (stream)	5 m buffer zone	-	0.0090	7.00	1
R1 (pond)	Maximum possible mitigation	-	0.0147	4.29	1
R1 (stream)	Maximum possible mitigation	-	0.0243	2.59	1

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable risk.

NOTE: The summary table only states the worst-case results from the PECsw derived for single or multiple applications, and presents appropriate mitigation to account for those worst-case exposures.

NOTE: The long-term risk to aquatic invertebrates is unresolved for all scenarios, due to the absence of an agreed RAC. A data gap has been set to address this issue. The mitigation identifed above, for the surface water exposure, only addresses the acute risk for aquatic invertebrates and the chronic risk to fish.

[a] Risk not resolved even using the maximum permissable reduction in exposure, as defined in the guidance 'Landscape and Mitigation Factors in the Aquatic Ecological Risk Assessment' (2007) (95% reduced exposure for spraydrift driven scenarios and 90% reductions for runoff driven scenarios)

$FOCUS_{sw}$ step 4 – Risk assessment for Thiacloprid – Winter oilseed rape at 72 g a.s./ha x 2 applications with 10 day interval.

Organisms: Invertebrates, acute
(Tier-2 geomean RAC, **surface water exposure**)

RAC: 0.0912 µg/L

Mitigation options	[x] m non-spray buffer zone	[x] m vegetated buffer strip	PECsw (µg/L)	RAC/PEC	Trigger
FOCUS Step 4					
D2 (ditch)	10 m buffer zone	10 m vegetated buffer zone	0.0551	1.66	1
D2 (Stream)	10 m buffer zone	-	0.0794	1.15	1
D3 (ditch)	10 m buffer zone	10 m vegetated buffer zone	0.0537	1.70	1
D4 (pond)	5 m buffer zone	-	0.0136	6.71	1
D4 (stream)	10 m buffer zone	-	0.0743	1.23	1
D5 (pond)	Risk resovled at FOCUS step 3	-	-	-	-
D5 (stream)	10 m buffer zone	-	0.0786	1.16	1
R1 (pond)	Risk resovled at FOCUS step 3	-	-	-	-
R1 (stream)	Maximum possible mitigation	-	0.0276	3.30	1
R3 (stream)	Maximum possible mitigation	-	0.0212	4.30	1

Organisms: *C. riparius*
(Sediment dwelling organism, **sediment exposure**)

RAC: 0.063 µg/kg sed

Mitigation options	[x] m non-spray buffer zone	[x] m vegetated buffer strip	PECsed (µg/kg sed)	RAC/PEC	Trigger
FOCUS Step 4					
D2 (ditch)	Maximum possible mitigation	-	0.0503	1.25	1

D2 (Stream)	40 m buffer zone	-	0.0444	1.43	1
D3 (ditch)	10 m buffer zone	10 m vegetated buffer zone	0.0439	1.44	1
D4 (pond)	10 m buffer zone	-	0.0567	1.11	1
D4 (stream)	5 m buffer zone	-	0.0229	2.75	1
D5 (pond)	10 m buffer zone	-	0.0586	1.08	1
D5 (stream)	Risk resovled at FOCUS step 3	-	-	-	-
R1 (pond)	Maximum possible mitigation	-	0.0150	4.20	1
R1 (stream)	Maximum possible mitigation	-	0.0242	2.60	1
R3 (stream)	Maximum possible mitigation	-	0.0202	3.12	1

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable risk.

NOTE: The summary table only states the worst-case results from the PECsw derived for single or multiple applications, and presents appropriate mitigation to account for those worst-case exposures.

NOTE: The long-term risk to aquatic invertebrates is unresolved for all scenarios, due to the absence of an agreed RAC. A data gap has been set to address this issue. The mitigation identifed above, for the surface water exposure, only addresses the acute risk for aquatic invertebrates and the chronic risk to fish.

[a] Risk not resolved even using the maximum permissable reduction in exposure, as defined in the guidance 'Landscape and Mitigation Factors in the Aquatic Ecological Risk Assessment' (2007) (95% reduced exposure for spraydrift driven scenarios and 90% reductions for runoff driven scenarios)

Metabolites

FOCUS$_{sw}$ step 1-3 – Risk assessment for M02 – Spring oilseed rape at 72 g a.s./ha x 1 application

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged
		Lepomis macrochirus	-	*Hyalella azteca*	-	*P. subcapitata*	-	*Chironomus riparius*
		RAC (LC_{50})	-	RAC (LC_{50})	-	RAC (E_rC_{50})	-	RAC (NOEC)
		> 786 µg/L	-	> 476 µg/L	-	> 10000 µg/L	-	10 µg/L
FOCUS Step 1								
	28.96	> 27.1	-	> 16.4	-	> 345	-	**0.345**
FOCUS Step 2								
North Europe	2.32	-	-	-	-	-	-	4.31
South Europe	2.71	-	-	-	-	-	-	3.69

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

FOCUS$_{sw}$ step 1-3 – Risk assessment for M02 – Spring oilseed rape at 72 g a.s./ha x 2 applications with 10 day interval

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged
		Lepomis macrochirus	-	*Hyalella azteca*	-	*P. subcapitata*	-	*Chironomus riparius*
		RAC (LC_{50})	-	RAC (LC_{50})	-	RAC (E_rC_{50})	-	RAC (NOEC)
		> 786 µg/L	-	> 476 µg/L	-	> 10000 µg/L	-	10 µg/L
FOCUS Step 1								
	57.91	> 13.6	-	> 8.22	-	> 173	-	**0.173**
FOCUS Step 2			-	-	-	-	-	
North Europe	3.94	-	-	-	-	-	-	2.54
South Europe	4.60	-	-	-	-	-	-	2.17

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

FOCUS$_{sw}$ step 1-3 – Risk assessment for M02 – Winter oilseed rape at 72 g a.s./ha x 1 application

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged
		Lepomis macrochirus	-	*Hyalella azteca*	-	*P. subcapitata*	-	*Chironomus riparius*
		RAC (LC_{50})	-	RAC (LC_{50})	-	RAC (E_rC_{50})	-	RAC (NOEC)
		> 786 µg/L	-	> 476 µg/L	-	> 10000 µg/L	-	10 µg/L
FOCUS Step 1								
	28.96	> 27.1	-	> 16.4	-	> 345	-	**0.345**
FOCUS Step 2								
North Europe	1.55	-	-	-	-	-	-	6.45
South Europe	4.27	-	-	-	-	-	-	2.34

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

FOCUS$_{sw}$ step 1-3 – Risk assessment for M02 – Winter oilseed rape at 72 g a.s./ha x 2 applications with 10 day interval

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged
		Lepomis macrochirus	-	*Hyalella azteca*	-	*P. subcapitata*	-	*Chironomus riparius*
		RAC (LC_{50})	-	RAC (LC_{50})	-	RAC (E_rC_{50})	-	RAC (NOEC)
		> 786 µg/L	-	> 476 µg/L	-	> 10000 µg/L	-	10 µg/L
FOCUS Step 1								
	57.91	> 13.6	-	> 8.22	-	> 173	-	**0.173**
FOCUS Step 2								
North Europe	2.63	-	-	-	-	-	-	3.80
South Europe	7.23	-	-	-	-	-	-	1.38

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

$FOCUS_{sw}$ step 1-3 – Risk assessment for M29 – Spring oilseed rape at 72 g a.s./ha x 1 application

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged
		-	-	-	-	-	-	*Chironomus riparius*
		-	-	-	-	-	-	RAC (NOEC)
		-	-	-	-	-	-	0.435 µg/L
FOCUS Step 1		-	-	-	-	-	-	
	4.81	-	-	-	-	-	-	**0.09**
FOCUS Step 2		-	-	-	-	-	-	
North Europe	0.28	-	-	-	-	-	-	1.55
South Europe	0.57	-	-	-	-	-	-	**0.76**
FOCUS Step 3								
D1 (ditch)	0.1298	-	-	-	-	-	-	3.35
D1 (pond)	0.0871	-	-	-	-	-	-	4.99
D3 (ditch)	< 0.001	-	-	-	-	-	-	> 435
D4 (pond)	0.0191	-	-	-	-	-	-	22.8

D4 (stream)	0.0320	-	-	-	-	-	-	13.6
D5 (pond)	0.0214	-	-	-	-	-	-	20.3
D5 (stream)	0.0301	-	-	-	-	-	-	14.5
R1 (pond)	0.0102	-	-	-	-	-	-	42.7
R1 (stream)	0.0766	-	-	-	-	-	-	5.68

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

FOCUS$_{sw}$ step 1-3 – Risk assessment for M29 – Spring oilseed rape at 72 g a.s./ha x 2 applications with 10 day interval

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged
		-	-	-	-	-	-	*Chironomus riparius*
		-	-	-	-	-	-	RAC (NOEC)
		-	-	-	-	-	-	0.435 µg/L
FOCUS Step 1		-	-	-	-	-	-	
	9.62	-	-	-	-	-	-	**0.0452**
FOCUS Step 2		-	-	-	-	-	-	
North Europe	0.56	-	-	-	-	-	-	**0.777**
South Europe	1.12	-	-	-	-	-	-	**0.388**
FOCUS Step 3								
D1 (ditch)	0.2558	-	-	-	-	-	-	1.70
D1 (pond)	0.1604	-	-	-	-	-	-	2.71
D3 (ditch)	< 0.0001	-	-	-	-	-	-	> 4350
D4 (pond)	0.0575	-	-	-	-	-	-	7.57
D4 (stream)	0.0839	-	-	-	-	-	-	5.18
D5 (pond)	0.0403	-	-	-	-	-	-	10.8
D5 (stream)	0.0642	-	-	-	-	-	-	6.78
R1 (pond)	0.0136	-	-	-	-	-	-	32.0
R1 (stream)	0.0844	-	-	-	-	-	-	5.15

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

FOCUS$_{sw}$ step 1-3 – Risk assessment for M29 – Winter oilseed rape at 72 g a.s./ha x 1 application

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged
		-	-	-	-	-	-	*Chironomus riparius*
		-	-	-	-	-	-	RAC (NOEC)
		-	-	-	-	-	-	0.435 µg/L
FOCUS Step 1		-	-	-	-	-	-	
	9.62	-	-	-	-	-	-	**0.0904**
FOCUS Step 2		-	-	-	-	-	-	
North Europe	0.56	-	-	-	-	-	-	1.55
South Europe	1.12	-	-	-	-	-	-	**0.763**
FOCUS Step 3								
D2 (ditch)	0.2877	-	-	-	-	-	-	1.51
D2 (Stream)	0.1801	-	-	-	-	-	-	2.41
D3 (ditch)	<0.001	-	-	-	-	-	-	> 435
D4 (pond)	0.0164	-	-	-	-	-	-	26.5
D4 (stream)	0.0263	-	-	-	-	-	-	16.5
D5 (pond)	0.0152	-	-	-	-	-	-	28.6
D5 (stream)	0.0237	-	-	-	-	-	-	18.4
R1 (pond)	0.01	-	-	-	-	-	-	43.5
R1 (stream)	0.0746	-	-	-	-	-	-	5.83
R3 (stream)	0.0785	-	-	-	-	-	-	5.54

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

FOCUS$_{sw}$ step 1-3 – Risk assessment for M29 – Winter oilseed rape at 72 g a.s./ha x 2 applications with 10 day interval

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged
		-	-	-	-	-	-	*Chironomus riparius*
		-	-	-	-	-	-	RAC (NOEC)
		-	-	-	-	-	-	0.435

								µg/L
FOCUS Step 1		-	-	-	-	-	-	
	9.62	-	-	-	-	-	-	**0.0452**
FOCUS Step 2		-	-	-	-	-	-	
North Europe	0.56	-	-	-	-	-	-	**0.777**
South Europe	1.12	-	-	-	-	-	-	**0.388**
FOCUS Step 3								
D1 (ditch)	0.4853	-	-	-	-	-	-	**0.896** [a]
D1 (pond)	0.3037	-	-	-	-	-	-	1.43
D3 (ditch)	< 0.001	-	-	-	-	-	-	> 435
D4 (pond)	0.0426	-	-	-	-	-	-	10.2
D4 (stream)	0.061	-	-	-	-	-	-	7.13
D5 (pond)	0.0296	-	-	-	-	-	-	14.7
D5 (stream)	0.0540	-	-	-	-	-	-	8.06
R1 (pond)	0.0215	-	-	-	-	-	-	20.2
R1 (stream)	0.1541	-	-	-	-	-	-	2.82
R3 (stream)	0.1811	-	-	-	-	-	-	2.40

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

[a] Further mitigation is not possible as the primary route of exposure is via drainflow

FOCUS$_{sw}$ step 1-3 – Risk assessment for M30 – Spring oilseed rape at 72 g a.s./ha x 1 application

Scenario	**PEC global max (µg L)**	**fish acute**	**fish chronic**	**Aquatic invertebrates**	**Aquatic invertebrates prolonged**	**Algae**	**Higher plant**	**Sed. dweller prolonged**
		Oncorhynchus mykiss	-	*Daphnia magna*	-	*Scenedesmus subspicatus*	-	*Chironomus riparius*
		RAC (LC_{50})	-	RAC (EC_{50})	-	RAC (E_rC_{50})	-	RAC (NOEC)
		> 901 µg/L	-	> 1000 µg/L	-	> 10000 µg/L	-	≥ 10000 µg/L
FOCUS Step 1								
	9.17	> 98.3	-	> 109	-	> 1091	-	≥ 1091

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

FOCUS$_{sw}$ step 1-3 – Risk assessment for M30 – Spring oilseed rape at 72 g a.s./ha x 2 applications with 10 day interval

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged
		Oncorhynchus mykiss	-	*Daphnia magna*	-	*Scenedesmus subspicatus*	-	*Chironomus riparius*
		LC_{50}	-	EC_{50}	-	E_rC_{50}	-	NOEC
		> 901 µg/L	-	> 1000 µg/L	-	> 10000 µg/L	-	≥ 10000 µg/L
FOCUS Step 1								
	18.33	> 49.2	-	> 5.46	-	> 546	-	≥ 546

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

$FOCUS_{sw}$ step 1-3 – Risk assessment for M30 – Winter oilseed rape at 72 g a.s./ha x 1 application

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged
		Oncorhynchus mykiss	-	*Daphnia magna*	-	*Scenedesmus subspicatus*	-	*Chironomus riparius*
		RAC (LC_{50})	-	RAC (EC_{50})	-	RAC (E_rC_{50})	-	RAC (NOEC)
		> 901 µg/L	-	> 1000 µg/L	-	> 10000 µg/L	-	≥ 10000 µg/L
FOCUS Step 1								
	9.17	> 98.3	-	> 10.9	-	> 1091	-	≥ 1091

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

$FOCUS_{sw}$ step 1-3 – Risk assessment for M30 – Winter oilseed rape at 72 g a.s./ha x 2 applications with 10 day interval

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged
		Oncorhynchus mykiss	-	*Daphnia magna*	-	*Scenedesmus subspicatus*	-	*Chironomus riparius*
		RAC (LC_{50})	-	RAC (EC_{50})	-	RAC (E_rC_{50})	-	RAC (NOEC)

		> 901 µg/L	-	> 1000 µg/L	-	> 10000 µg/L	-	≥ 10000 µg/L
FOCUS Step 1								
	18.33	> 49.2	-	> 5.46	-	> 546	-	≥ 546

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

FOCUS$_{gw}$ – Risk assessment for M34 and M46

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged
		Oncorhynchus mykiss	-	*Daphnia magna*	-	*Scenedesmus subspicatus*	-	*Chironomus riparius*
		RAC (LC_{50})	-	RAC (EC_{50})	-	RAC (E_rC_{50})	-	RAC (NOEC)
		> 901 µg/L [a]	-	> 1000 µg/L [a]	-	> 10000 µg/L [a]	-	≥ 10000 µg/L [a]
Metabolite M34								
Ground water (Hamburg)	0.551 [b]	> 1640	-	> 1810	-	> 18100	-	≥ 18100
Metabolite M46								
Ground water (Hamburg)	1.058 [b]	> 852	-	> 945	-	> 9450	-	≥ 9450

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment. (TERs are presented to 3 siginficant figures.)

[a] Assuming equivalent toxicity to the precursor metabolite M30

[b] Exposure values are the relevant worst case ground water exposure estimates for the two metabolites, for any of the proposed uses

'Thiacloprid FS 400' – Risk assessment for the proposed uses

FOCUS$_{sw}$ step 1-3 – Risk assessment for Thiacloprid – Maize seed treatment at 110 g a.s./ha

Scenario	PEC global max (µg L) [a]	Fish acute	Fish chronic	Aquatic invertebrates	Algae	Sed. dweller prolonged
		Cyprinodon variegatus	*Cyprinus carpio*	*Ecdyonurus sp.*	*Scenedesmus subspicatus*	*Chironomus riparius*
		RAC (LC_{50})	RAC (NOEC)	RAC (EC_{50})	RAC (EC_{50})	RAC (NOEC)

		197 µg/L	0.45 µg/L	0.077 µg/L	9670 µg/L	0.63 µg/kg sed dw
FOCUS Step 1						
	20.53 (122.34)	9.60	**0.0219**	**0.00375**	471	**0.000515**
FOCUS Step 2						
North Europe	1.44 (8.66)	-	**0.313**	**0.0535**	-	**0.00727**
South Europe	2.88 (17.32)	-	**0.156**	**0.0267**	-	**0.00364**
FOCUS Step 3						
D3 (ditch)	< 0.001 (< 0.001)	-	450	77.0	-	63
D4 (pond)	< 0.001 (< 0.001)	-	450	77.0	-	63
D4 (stream)	< 0.001 (< 0.001)	-	450	77.0	-	63
D5 (pond)	< 0.001 (< 0.001)	-	450	77.0	-	63
D5 (stream)	< 0.001 (< 0.001)	-	450	77.0	-	63
D6 (ditch)	< 0.001 (< 0.001)	-	450	77.0	-	63
R1 (pond)	< 0.001 (< 0.001)	-	450	77.0	-	63
R2 (stream)	< 0.001 (< 0.001)	-	450	77.0	-	63
R3 (stream)	< 0.001 (< 0.001)	-	450	77.0	-	63
R4 (stream)	< 0.001 (< 0.001)	-	450	77.0	-	63

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

* No RAC has been agreed to consider the long-term risk to aquatic invertebrates, the risk is therefore unresolved and a data gap has been set to address this issue.

[a] Values in parentheses are the PECsed values (µg/kg sed dw) used in the risk assessment for sedment dwellers exposed via sediment (toxicity expressed as µg/kg sed dw)

Metabolites

FOCUS$_{sw}$ step 1-3 – Risk assessment for M02 – Maize seed treatment at 110 g a.s./ha

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged
		Lepomis macrochirus	-	*Hyalella azteca-*	-	*P. subcapitata*	-	*Chironomus riparius*
		RAC (LC_{50})	-	RAC (EC_{50})	-	RAC (EC_{50})	-	RAC (NOEC)
		786 µg/L	-	476µg/L	-	10000 µg/L	-	10 µg/L

FOCUS Step 1								
	43.5	18.1	-	10.9	-	230	-	**0.230**
FOCUS Step 2								
North Europe	5.94	-	-	-	-	-	-	1.68
South Europe	11.88	-	-	-	-	-	-	**0.842**
FOCUS Step 3								
D3 (ditch)	< 0.001	-	-	-	-	-	-	> 10000
D4 (pond)	0.001	-	-	-	-	-	-	10000
D4 (stream)	0.003	-	-	-	-	-	-	3333
D5 (pond)	< 0.001	-	-	-	-	-	-	> 10000
D5 (stream)	< 0.001	-	-	-	-	-	-	> 10000
D6 (ditch)	0.001	-	-	-	-	-	-	10000
R1 (pond)	< 0.001	-	-	-	-	-	-	> 10000
R1 (stream)	< 0.001	-	-	-	-	-	-	> 10000
R2 (stream)	< 0.001	-	-	-	-	-	-	> 10000
R3 (stream)	< 0.001	-	-	-	-	-	-	> 10000
R4 (Stream)	< 0.001	-	-	-	-	-	-	> 10000

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

FOCUS$_{sw}$ step 1-3 – Risk assessment for M29 – Maize seed treatment at 110 g a.s./ha

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged
		-	-	-	-	-	-	*Chironomus riparius*
		-	-	-	-	-	-	RAC (NOEC)
		-	-	-	-	-	-	0.435 µg/L
FOCUS Step 1		-	-	-	-	-	-	
	7.35	-	-	-	-	-	-	**0.0592**
FOCUS Step 2		-	-	-	-	-	-	
North Europe	1.45	-	-	-	-	-	-	**0.300**
South Europe	2.9	-	-	-	-	-	-	**0.150**
FOCUS Step 3 [a]								
D3 (ditch)	< 0.001 (< 0.001)	-	-	-	-	-	-	>435 (> 435)

D4 (pond)	0.001 (0.002)	-	-	-	-	-	-	435 (218)
D4 (stream)	0.003 (0.004)	-	-	-	-	-	-	145 (109)
D5 (pond)	0002 (0.004)	-	-	-	-	-	-	218 (109)
D5 (stream)	0.003 (0.005)	-	-	-	-	-	-	145 (87)
D6 (ditch)	0.003 (0.005)	-	-	-	-	-	-	145 (87)
R1 (pond)	< 0.001 (< 0.001)	-	-	-	-	-	-	> 435 (> 435)
R1 (stream)	< 0.001 (< 0.001)	-	-	-	-	-	-	> 435 (> 435)
R2 (stream)	< 0.001 (< 0.001)	-	-	-	-	-	-	> 435 (> 435)
R3 (stream)	< 0.001 (< 0.001)	-	-	-	-	-	-	> 435 (> 435)
R4 (stream)	< 0.001 (< 0.001)	-	-	-	-	-	-	> 435 (> 435)

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

[a] Values in parentheses relate to the metabolite, M29, when modelling is performed assuming formation as a degradant of the metabolite M02; values outside the parentheses are based on modelling where M29 is assumed to be formed as a metabolite of the parent active substance (see Section B.9.4.5 (PPP, 'Thiacloprid FS400').

FOCUS$_{sw}$ step 1-3 – Risk assessment for M30 – Maize seed treatment at 110 g a.s./ha

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged
		Oncorhynchus mykiss	-	*Daphnia magna*	-	*Scenedesmus subspicatus*	-	*Chironomus riparius*
		RAC (LC_{50})	-	RAC (EC_{50})	-	RAC (E_rC_{50})	-	RAC (NOEC)
		> 901 µg/L	-	> 1000 µg/L	-	> 10000 µg/L	-	≥ 10000 µg/L
FOCUS Step 1			-		-		-	
	13.88	> 64.9	-	> 72.0	-	> 720	-	≥ 720

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment.

FOCUS$_{gw}$ – Risk assessment for M34 and M46

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Higher plant	Sed. dweller prolonged
		Oncorhynchus	-	*Daphnia magna*	-	*Scenedesmus*	-	*Chironomus*

		mykiss				*subspicatus*		*riparius*
		RAC (LC_{50})	-	RAC (EC_{50})	-	RAC (E_rC_{50})	-	RAC (NOEC)
		> 901 µg/L [a]	-	> 1000 µg/L [a]	-	> 10000 µg/L [a]	-	≥ 10000 µg/L [a]
Metabolite M34								
Ground water (Hamburg)	0.551 [b]	> 1090	-	> 1220	-	> 12200	-	≥ 12200
Metabolite M46								
Ground water (Hamburg)	1.058 [b]	> 184	-	> 204	-	> 2040	-	≥ 2040

NOTE: TERs in the table are calculated by dividing RAC by PEC (RAC/PEC) and comparing this to a value of 1. Values above 1 demonstrate an acceptable level of risk. Values < 1 (emboldened) need further refinement and must progress to the next step of the risk assessment. (TERs are presented to 3 siginficant figures.)

[a] Assuming equivalent toxicity to the precursor metabolite M30

[b] Exposure values are the relevant worst case ground water exposure estimates for the two metabolites

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 reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

Species	Test substance	Time scale/type of endpoint	End point	Toxicity
Apis mellifera	a.s.	Acute , 48h	Oral toxicity (LD_{50})	**17.32 µg a.s./bee**
Apis mellifera	Thiacloprid OD240	Acute, 48h	Oral toxicity (LD_{50})	26.2 µg form./bee (equivalent to 6.01 µg a.s./bee)
Apis mellifera	Thiacloprid OD240	Acute, 48h	Oral toxicity (LD_{50})	30 µg form./bee (equivalent to 6.98 µg a.s./bee)
Apis mellifera	Thiacloprid FS400	Acute, 48h	Oral toxicity (LD_{50})	1.9 µg a.s./bee
Apis mellifera	Metabolite, M02	Acute, 48h	Oral toxicity (LD_{50})	> 108.1 µg t.m./bee
Apis mellifera	Metabolite, M03	Acute, 48h	Oral toxicity (LD50)	> 107.1 µg a.i./bee
Apis mellifera	Metabolite M36	Acute, 48h	Oral toxicity (LD50)	> 106.7 µg p.m./bee
Apis mellifera	a.s.	Acute, 48h	Contact toxicity (LD_{50})	**38.82 µg a.s./bee**
Apis mellifera	Thiacloprid OD240	Acute, 48h	Contact toxicity (LD_{50})	82.7 µg form./bee (equivalent to 19 µg a.s./bee)
Apis mellifera	Thiacloprid OD240	Acute, 48h	Contact toxicity (LD_{50})	25.7 µg form./bee (equivalent to 5.92 µg a.s./bee)
Bombus terrestris	Thiacloprid OD240	Acute, 48h	Contact toxicity (LD_{50})	> 434.8 µg form./bee (equivalent to > 100 µg a.s./bumblebee)
Apis mellifera	Thiacloprid FS400	Acute, 72h	Contact toxicity (LD_{50})	92.3 µg a.s./bee
Apis mellifera	Metabolite, M02	Acute, 48h	Contact toxicity (LD_{50})	> 100 µg t.m./bee
Apis mellifera	Metabolite, M03	Acute, 48h	Contact toxicity (LD50)	> 100 µg a.i./bee
Apis mellifera	Metabolite M36	Acute, 48h	Contact toxicity (LD50)	> 100 µg p.m./bee
Apis mellifera	a.s.,	Chronic, 10d adults	LDD_{50}	3.1 µg a.s./bee/day
			NOED	0.5 µg a.s./bee/day (equivalent to 17 mg a.s./kg diet) [b,c]
Apis mellifera	Metabolite, M02	Chronic, 10d	NOED	4.20 µg t.m./bee[a]

		adults		
Apis mellifera	Metabolite, M03	Chronic, 10d adults	NOED	4.18 µg a.i./bee[a]
Apis mellifera	Metabolite M36	Chronic, 10d adults	NOED	4.13 µg a.i./bee[a]
Apis mellifera	a.s.,	Bee brood development (Laboratory in vitro, single exposure test design-one feeding event over 24 hours)	$NOEC_{larvae}$	0.59 µg a.s./larva (equivalent to 18 mg a.s./kg diet)
			8 day- LD_{50}	> 5.34 µg a.s./larva

Bold values are used in the risk assessment.
t.m. = test material
[a] No reference item was tested, no information is available wheter the evaporation of the food item was taken into consideration
[b] Endpoint based on sublethal effects (reduced coordination)
[c] There are uncertainties linked to this study, please see RAR Part B9 for additional information.

Semi-field test (Tunnel tests)

'Thiacloprid OD240':

Kling (2002): 1 application of 'Thiacloprid OD240' was sprayed at a rate of 73.19 g a.s./ha (300 L/ha) on *Brassica napus*. *Apis mellifera* were exposed to the sprayed crop for 7 days. Results indicated lowered flight intensity after application in the treatment group.

Rentschler (2012): 1 application of 'Thiacloprid OD240' was sprayed at a rate of 72 g a.s./ha (200L/ha) on *Phacelia tanacetifolia*. *Apis mellifera* were exposed to the sprayed crop for 7 days, and monitored for a further 21 days. The results indicated a decrease in flight intensity in the test item group after application and the flight intensity in the test item group was statistically significantly lower than the control. A reduction in egg and larval abundance in one replicate was also observed. Transient behavioural effects were observed in the treatment group.

Nikolakis *et al.* (2014): 1 application of 'Thiacloprid OD240' was sprayed at 72 g a.s./ha (300L/ha) on 2 sets of *Phacelia tanacetifolia* crops, 1 week apart. *Apis mellifera* were exposed to both crops so the bees were actually exposed to 2 x 72 g.a.s./ha for a total of 16 days. The overwintering success of the bees was monitored. The results indicated reduced flight intensity after each application of the test item (although not statistically significant).

'Thiacloprid FS400':

Rentschler (2010): *Apis mellifera* were exposed over a crop of maize (BBCH 59-61) that was treated with 'Thiacloprid FS400' at 1.09 mg a.s./seed, (planting density = 90000 seeds/ha) for 9 days. The bees were then monitored for 25/26 days post-exposure. The results indicated that mortality was higher in the treatment group than the control.

Field tests

'Thiacloprid OD240':

Rexer (2014a): 3 applications of 'Thiacloprid OD240' were sparyed at 96 g a.s./ha on *Phacelia tanacetifolia*. *Apis mellifera* were exposed for 25 days, after which there was an 8 month monitoring period (to determine overwintering success). The results indicated transient behavioural effects of the test item.

Rexer (2014b): 2 applications of 'Thiacloprid OD240' were sprayed at 72 g a.s./ha on *Brassica napus*, with a 7 day interval between applications. *Apis mellifera* were exposed for 19 days, after which there was a 15 day monitoring period. The results indicated a decreased flight intensity after both applications of the test item and transient behavioural effects of the test item.

'Thiacloprid FS400':

Rexer (2010): *Apis mellifera* were exposed over a crop of maize (BBCH 59 - 61) that was treated with

'Thiacloprid FS400' at 1.0 mg a.s./seed, (planting density range = 85762 - 94743 seeds/ha) for 15 days. The bees were then monitored for 15 days post-exposure. The results indicated that there were no apparent effects of the test item. The data indicate that the bees did not actively forage either the control or treated crop to any great extent. This is further substantiated by the pollen identification which indicated that the majority of the pollen came from *Calluna vulgaris* (ling heather) for the test item group and *Vaccinium* spp. (blueberry-type) and *Buddleja* spp. (butterfly bush) in the control group. This could indicate that maize is not a preferential food source for *A. mellifera*, and it does indicate that exposure in this study is low.

Risk assessment for 'Thiacloprid OD 240' – Oilseed rape at 72 g a.s./ha x2 applications

Species	Test substance	Risk quotient	HQ	Trigger
Apis mellifera	a.s., 'Thiacloprid OD240'	HQoral	4.2 12	50
Apis mellifera	a.s., 'Thiacloprid OD240'	HQcontact	1.9 12	50

Risk assessment for 'Thiacloprid FS 400' – Maize (seed treatment) at 1.0 mg a.s./seed at 110000 seeds/ha

The Risk assessment has been considered qualitatively so no hazard quotients (HQs) have been calculated.

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)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity
Typhlodromus pyri	'Thiacloprid OD 240'	Mortality, LR_{50}	0.331 g a.s./ha
Aphidius rhopalosiphi	'Thiacloprid OD 240'	Mortality, LR_{50}	< 0.4 g a.s./ha
Additional species			
No tier 1 studies for additional species submitted			

First tier risk assessment for 'Thiacloprid OD 240' on oilseed rape at 72 g a.s./ha x 2

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
'Thiacloprid OD 240'	*Typhlodromus pyri*	0.331 g a.s./ha	370	8.8	2
'Thiacloprid OD 240'	*Aphidius rhopalosiphi*	< 0.4 g a.s./ha	> 306	> 7.3	2

[1]Calculated using a 1 metre distance

Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (g a.s./ha)[1,2]	End point	% effect[3]	ER_{50} (g a.s/ha)
Aphidius rhopalosiphi	Adult	'Thiacloprid OD 240', detached apple leaves (2D)	24 h 10d	0.30 [1] 0.95 [1] 3.00 [1] 9.49 [1] 30.00 [1]	Mortality Reproduction Mortality Reproduction Mortality Mortality Mortality	0.0 28.0 7.0 26.0 53.0 80.0 83.0	> 0.95
Typhlodromus pyri	Protonymph	'Thiacloprid OD 240', detached maize leaves (2D)	7 d 14 d	2 [1] 4 [1] 7 [1] 12 [1] 22 [1]	Mortality Reproduction[4] Mortality Mortality Mortality Mortality	28.3 6.0 85.9 96.7 98.9 98.9	> 2.0
Coccinella septempunctata	Larvae and adults	'Thiacloprid OD 240', whole plant treated, then detached apple leaves tested (3D)	28 d 14 d	3.125 [1] 6.25 [1] 12.50 [1] 25.00 [1] 50.00 [1]	Mortality Reproduction Mortality Reproduction Mortality Mortality Mortality	17.9 55.4 15.4 89.2 71.8 74.4 100.0	< 3.125
Chrysoperla carnea	Larvae and adults	'Thiacloprid OD 240', detached maize leaves (2D)	18 d 7 d	22.1 [1] 39.3 [1] 69.9 [1] 124.3 [1] 221.0 [1]	Mortality Reproduction Mortality Reproduction Mortality Reproduction Mortality Reproduction Mortality	33.3 -4.0 10.6 8.7 20.5 -11.5 46.2 -18.9 84.6	> 124.3
Aphidius rhopalosiphi	Adults	'Thiacloprid OD 240', whole maize plants (3D)	28DAT3, 10 day interval	3 applications: 2 x 96 g a.s/ha, 1 x 110 g a.s/ha [2]	0DAT3: Mortality 14DAT3: Mortality Reproduction 28DAT3: Mortality Reproduction	 100 50 -6.0 3.3 2.9	28 DAT3: < 50 % effects
Typhlodromus pyri	Protonymphs	'Thiacloprid OD 240', whole maize plants (3D)	28DAT3, 10 day interval	3 applications: 2 x 96 g a.s/ha, 1 x 110 g a.s/ha [2]	0DAT3: Mortality 14DAT3: Mortality Reproduction[4] 28DAT3: Mortality Reproduction[4]	84.3 7.8 5.8 -2.2 -4.7	14 DAT3: < 50 % effects

Species	Life stage	Test substance, substrate	Time scale	Dose (g a.s./ha)[1,2]	End point	% effect[3]	ER_{50} (g a.s/ha)
Aphidius rhopalosiphi	Adult	'Thiacloprid FS 400', detached bean leaves	48 h 10 – 12 d	1st run 0.15 [1] 0.30 [1] 0.61 [1] 1.24 [1] 2.50 [1] 2nd run* 0.25 [1] 0.53 [1] 1.12 [1] 2.36 [1] 5.00 [1]	Mortality Reproduction Mortality Reproduction Mortality Reproduction Mortality Reproduction Mortality Reproduction Mortality Reproduction Mortality Reproduction Mortality Reproduction Mortality	-7.1 -38.7 0.0 -5.8 -7.1 -25.7 7.1 37.2 46.4 61.8 -1.7 34.7 5.1 47.0 -1.7 32.6 28.8 83.8 74.6	> 1.24
Coccinella septempunctata	Larvae and adults	'Thiacloprid FS 400', detached bean leaves	28 d 14 d	5.0 [1] 10.6 [1] 22.4 [1] 47.3 [1] 100.0 [1]	Mortality Reproduction Mortality Reproduction Mortality Mortality Mortality	27.3 3.8 18.2 17.7 75.1 100.0 90.9	> 10.6

[1] Initial residues
[2] Aged residues
[3] Negative values indicate lower mortality and higher reproduction rate than in the control
[4] some uncertainties were noted to these endpoints as the substrate was not treated at day 0 for reproductive phase
Mortality- corrected based on control, Reproduction effects relative to control
DAT3 = Days After Treatment 3
*The study was repeated with a second range of concentrationsas 50 % mortality was not achieved in the 1st run.

Risk assessment for 'Thiacloprid OD 240' - Oilseed rape at at 72 g a.s./ha x 2 applications based on extended lab test or aged residue tests

Species	ER_{50} (g a.s./ha)	In-field rate	Off-field rate[1]
Extended laboratory tests			
Aphidius rhopalosiphi	> 0.95	122.4	1.5[2]
Typhlodromus pyri	> 2.0	122.4	1.5[2]
Coccinella septempunctata	< 3.125	122.4	14.6[3]
Chrysoperla carnea	> 124.3	122.4	1.5[2]
Aged residue tests			
Aphidius rhopalosiphi	< 50 % effects 28DAT3# (2 x 96 g a.s/ha plus 1 x 110 g a.s/ha)	122.4	14.6[3]

Species	ER_{50} (g a.s./ha)	In-field rate	Off-field rate[1]
Typhlodromus pyri	< 50 % effects 14DAT3[#] (2 x 96 g a.s/ha plus 1 x 110 g a.s/ha)	122.4	14.6[3]

[1]At 1 metre distance
[2] Based on a 2D application
[3] Based on a 3D application
# Three applications in total; 2 x 96 g a.s/ha, 1 x 110 g a.s/ha
DAT = Days After Treatment

Semi-field tests
None submitted
Field studies
Field studies carried out in grassland (both studies used a single application of the test item at 0.56, 1.2, 4.7, 10.2 and 27 g a.s/ha) ***Central zone study (54 taxa analysed at the population level)*** **0.56** g a.s./ha: No population effects were identified **1.2** g a.s/ha: Signficant adverse effects in Sminthuridae (suction) **4.7** g a.s./ha: Signficant adverse effects in Sminthuridae (suction) **10.2** g a.s./ha: Significant adverse effects in Sminthuridae (suction), Sminthuridae (pitfall) and Drosophilidae (suction). **27** g a.s./ha: Significant adverse effects in *Erigone* adults (pitfall), *Loricera pilicornis* (pitfall), Staphylinidae juveniles and adults (pitfall), Cicadellidae juveniles (suction), Lonchopteridae (suction), Drosophilidae (suction), Sminthuridae (suction), Sminthuridae (pitfalls) and Isotomidae (pitfalls). Community NOER: **4.7** g a.s/ha Population NOER: **0.56** g a.s/ha ***Southern zone study (95 taxa analysed at the population level)*** **0.56** g a.s./ha: Signficant adverse effects in Sminthuridae (suction) and Curculionidae (pitfall) **1.2** g a.s/ha: Signficant adverse effects in Sminthuridae (suction), Curculionidae (pitfall), and Symphypleona (pitfall) **4.7** g a.s./ha: Signficant adverse effects in Sminthuridae (suction), Curculionidae (pitfall), Symphypleona (pitfall), Altcinae (pitfall), and Apion (pitfall). **10.2** g a.s./ha: Significant adverse effects in Staphylinidae juveniles and other (pitfall), Coccinellidae (pitfall), Altcinae (pitfall), and Apion (pitfall), Curculionidae (pitfall), Sminthuridae (suction), and Symphypleona (pitfall). **27** g a.s./ha: Significant adverse effects in Thomisidae, Araneidae, Staphylinidae juveniles and other (pitfall), Coccinellidae (pitfall), Nitidulidae (pitfall), Altcinae (pitfall), and Apion (pitfall), Curculionidae (pitfall), Pteromalidae (suction), Isotomidae (pitfall), Sminthuridae (suction), Symphypleona (pitfall) and Thysanoptera (suction). Community NOER: **None could be established** Population NOER: **< 0.56** g a.s/ha ***Thiacloprid OD240 risk off-field risk assessment for the proposed GAP*** ***Southern Zone*** **The risk to non-target terrestrial arthropods in the Southern Zone remains unresolved.** No further risk mitigation measures have been considered as the population NOER is less than the lowest tested rate of 0.56 g

a.s/ha and no community NOER could be determined. **Therefore member states in the Southern Zone should consider the off-field risk to non-target arthropods for the proposed use further during national registration.** ***Central Zone*** **For the Central Zone, an acceptable off-field risk was demonstrated** as the NOER value of 0.56 g a.s/ha exceeded the PER of 0.29 g a.s/ha at 10 metres. The following mitigation phrase (SPe 3) should be used: 'To protect non-target insects/arthropods respect an untreated buffer zone of 10 m to non-crop land.' **This is a mitigation measure and thus, the risk to non-target arthropods for the proposed use of OD240 should be considered by Member States during National Authorisations.**
Additional specific test
None submitted

Risk assessment for 'Thiacloprid FS 400' - Maize seed treatment at 1.0 mg a.s./seed, at 110000 seeds/ha

The soil macro-invertebrates *H.aculeifer* and *F.candida* risk assessment demonstrated an acceptable risk for the proposed use of 'Thiacloprid FS 400' with a wide margin of safety (> factor of 5).

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	a.s.	Mixed/10%	Acute, 14 d	Mortality	LC_{50} 105 mg a.s./kg d.w.soil (mg a.s/ha)
Annelid worm *(Enchytraeus crypticus)* [1]	a.s.	Mixed/1.6%	Chronic, 21 d	Reproduction	NOEC (reproduction) 3.0 mg a.s./kg dws
Eisenia andrei [1]	'Calypso 480 SC'	Mixed/5%	Chronic 56 d	Reproduction	**EC_{10} (reproduction) 0.04 mg a.s./kg dws** [2]
Annelid worm *(Enchytraeus crypticus)* [1]	'Calypso 480 SC'	Mixed/5%	Chronic, 28 d	Reproduction	EC_{10} (reproduction) 0.62 mg a.s./kg dws

Test organism	Test substance	Application method of test a.s./ OM	Time scale	End point	Toxicity
Eisenia fetida	Thiacloprid 'OD 240'	Mixed/5%	Chronic, 56 d	Mortality, growth, reproduction	**NOEC (reproduction) 0.185 mg a.s./kg dws (0.8 mg formulation/kg dws)**
Eisenia fetida	Metabolite, M02	Mixed/10%	Acute, 14 d	Mortality	**LC_{50} > 1000 mg metabolite/kg dws**
Eisenia fetida	Metabolite, M02	Mixed/10%	Chronic, 56 d	Mortality, growth, reproduction	**NOEC (reproduction) 10.6 mg metabolite/kg dws**
Eisenia fetida	Metabolite, M29	5 %, mixed	Chronic, 56 d	Mortality, growth, reproduction	**NOEC (reproduction) 3.1 mg metabolite/kg dws**
Eisenia fetida	Metabolite, M30	Mixed / 10%	Acute, 14 d	Mortality	**LC_{50} > 1000 mg metabolite/kg dws**
Eisenia fetida	Metabolite, M30	Mixed / 10%	Chronic, 56 d	Mortality, growth, reproduction	**NOEC (reproduction) 10 mg metabolite/kg dws**
Other soil macroorganisms					
Folsomia candida	'Thiacloprid OD240'	Mixed / 5%	Chronic, 28 d	Mortality, reproduction	**NOEC (mortality) 4.4 mg formulation/kg dws ≙ 1.0 mg a.s./kg dws [2]**
	'Calypso 480 SC' [1]	Mixed / 5%	Chronic, 28 d	Mortality, reproduction	EC_{10} (reproduction) 1.20 mg a.s./kg dws
	Metabolite M02	Mixed / 10%	Chronic, 28 d	Mortality, reproduction	**EC_{10} 9.63 mg metabolite/kg dws**
	Metabolite, M29	Mixed / 5%	Chronic, 28 d	Mortality, reproduction	**NOEC 5.6 mg metabolite/kg dws**

Test organism	Test substance	Application method of test a.s./ OM	Time scale	End point	Toxicity
	Metabolite, M30	Mixed / 10%	Chronic, 28 d	Mortality, reproduction	**NOEC 1000 mg metabolite/kg dws**
	Metabolite M02	Mixed / not stated	Chronic, 28 d	Mortality, reproduction	NOEC 1.25 mg metabolite/kg dws*
Hypoaspis aculeifer	Metabolite M02	Mixed, 5 %	Chronic, 14 d	Mortality, reproduction	**NOEC 10 mg metabolite/kg dws***
	Metabolite, M29	Mixed, 5 %	Chronic 14 d	Mortality, reproduction	**NOEC 100 mg metabolite/kg dws**
	Metabolite, M30	Mixed, 5 %	Chronic 14 d	Mortality, reproduction	**NOEC 100 mg metabolite/kg dws**

1 From the literature review
2 This endpoint was agreed to be used in the long-term risk assessment of the active substance at EFSA Peer Review Meeting 183.
* Two studies were available for metabolite M02; the endpoint in bold is used in the risk assessment as this study was conducted to modern guidelines and no effects were observed at the single highest tested concentration (see Vol 3 B9 AS section 9.4.2 for more details).

Higher tier testing

'Thiacloprid FS 400'

Other soil macroorganisms:

For *Folsomia candida* and *Hypoaspis aculeifer* studies were submitted where 'Thiacloprid FS 400' was applied as a seed dressing to a single maize seed and the effect on mortality and reproductive output assessed over 28 and 14 days respectively.

The application rate was determined based on the number of seeds per unit area and was as follows:

Folsomia candida: 615.6 g a.s/ha (11.30 units of seeds/ha, where one unit of seeds = 54.48 g a.s)

Hypoaspis aculeifer: 5164.3 g a.s/ha (102 units of seeds/ha, where one unit of seeds = 50.61 g a.s)

NOEC values were as follows:

Folsomia candida: 615.6 g a.s/ha

Hypoaspis aculeifer: 5164.3 g a.s/ha

'Thiacloprid OD 240'

An earthworm field study was submitted testing the formulation 'Thiacloprid OD 240' at 2 application rates: 3 x 100 g a.s./ha and 3 x 250 g a.s./ha. A NOER of 3 x 100 g a.s./ha was derived from this study, which corresponds to a NOEC of 0.2955 mg a.s./kg dws, based on the concentration in the top 5cm of soil.

Nitrogen transformation	Thiacloprid OD240	28 days	14.4% effect at day 28 at 1.56 mg a.s./kg d.w. soil (equivalent to 6.93 mg formulation/kg d.w. soil)

	Thiacloprid FS400	28 days	16.3% effect at day 28 at 0.74 mg a.s./kg d.w. soil (equivalent to 2.13 mg formulation/kg d.w. soil)
	Metabolite, M02	28 days	9% effect at day 28 at 16 mg metabolite/kg d.w. soil
	Metabolite, M29	28 days	1.4% effect at day 28 at 5.00 mg metabolite/kg d.w. soil.
	Metabolite, M30	28 days	2% effect at day 28 at 4.00 mg metabolite/kg d.w. soil.

Toxicity/exposure ratios for soil organisms

Risk assessment for 'Thiacloprid OD 240' - Oilseed rape at at 72 g a.s./ha x 2 applications

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia fetida	a.s.	Acute	0.032	3281	10
Eisenia andrei [2]	'Calypso 480 SC' [3]	Chronic	0.032	**1.25**	5
Eisenia fetida	'Thiacloprid OD240'	Chronic	0.032	5.8	5
Eisenia fetida	Metabolite, M02	Chronic	0.066	161	5
Eisenia fetida	Metabolite, M29	Chronic	0.035	89	5
Eisenia fetida	Metabolite, M30	Chronic	0.013	769	5
Other soil macroorganisms					
Folsomia candida [4]	'Thiacloprid OD240'	Chronic	0.032	31.3	5
Folsomia candida	Metabolite, M02	Chronic	0.066	146	5
Folsomia candida	Metabolite, M29	Chronic	0.035	160	5
Folsomia candida	Metabolite, M30	Chronic	0.013	76923	5
Hypoaspis aculeifer	Metabolite, M02	Chronic	0.066	152	5
Hypoaspis aculeifer	Metabolite, M29	Chronic	0.035	2857	5
Hypoaspis aculeifer	Metabolite, M30	Chronic	0.013	7692	5

[1] PEC soil max
[2] Studies from the literature review
[3] The endpoint for the formulation 'Calypso 480 SC' was used to address the risk from the active substance
[4] NOEC based on mortality

Risk assessment for 'Thiacloprid FS 400' - Maize seed treatment at 1.0 mg a.s./seed, at 110000 seeds/ha

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia fetida	a.s.	Acute	0.147	714	10
Eisenia andrei [2]	'Calypso 480 SC' [3]	Chronic	0.147	**0.272**	5
Eisenia fetida	Metabolite, M02	Acute	0.250	4000	10

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Eisenia fetida	Metabolite, M02	Chronic	0.250	42.4	5
Eisenia fetida	Metabolite, M29	Chronic	0.117	26.5	5
Eisenia fetida	Metabolite, M30	Acute	0.052	> 19231	10
Eisenia fetida	Metabolite, M30	Chronic	0.052	192.3	5
Other soil macroorganisms					
Folsomia candida	'Thiacloprid OD 240' [5]	Chronic	0.147	6.80	5
Folsomia candida	'Thiacloprid FS 400'	Chronic	Margin of safety: 5.6 [4]		
Folsomia candida	Metabolite, M02	Chronic	0.250	38[5]	5
Folsomia candida	Metabolite, M29	Chronic	0.117	47.9	5
Folsomia candida	Metabolite, M30	Chronic	0.052	19231	5
Hypoaspis aculeifer	'Thiacloprid FS400'	Chronic	Margin of safety: 46.9 [4]		
Hypoaspis aculeifer	Metabolite, M02	Chronic	0.250	40.0	5
Hypoaspis aculeifer	Metabolite, M29	Chronic	0.117	855	5
Hypoaspis aculeifer	Metabolite, M30	Chronic	0.052	1923	5

[1] PEC soil max
[2] Studies from the literature review
[3] The endpoint for the formulation 'Calypso 480 SC' was used to address the risk from the active substance
[4] TER value was not calculated, instead the margin of safety was calculated based on the NOEC divided by the maximum application rate (110 g a.s/ha)
[5] This endpoint is used to reflect the risk from the active substance (as agreed at EFSA Peer Review Meeting 183)

Risk assessment for **'Thiacloprid OD240'** – Oilseed rape at 72 g a.s./ha x 2 applications

Test substance	Nitrogen transformation rate (< 25 % effects after 28 days) (mg/kg soil)	Maximum PEC_{Soil} (mg/kg soil)	< 25 % effects at maximum PEC_{soil}
'Thiacloprid OD240'	1.56 mg a.s./kg soil d.w. (equivalent to 6.93 mg form/kg soil d.w.)	0.032	Yes
Metabolite, M02	16.00	0.066	Yes
Metabolite, M29	5.00	0.051	Yes
Metabolite, M30	4.00	0.010	Yes

Risk assessment for **'Thiacloprid FS400'** – Maize seed treatment at 1.0 mg a.s./seed at 110000 seeds/ha

Test substance	Nitrogen transformation rate (< 25 % effects after 28 days) (mg/kg soil)	Maximum PEC_{Soil} (mg/kg soil)	< 25 % effects at maximum PEC_{soil}
'Thiacloprid FS400'	0.74 mg a.s./kg soil d.w. (equivalent to 2.13 mg form.kg soil d.w)	0.147	Yes
Metabolite, M02	16.00	0.250	Yes

Test substance	Nitrogen transformation rate (< 25 % effects after 28 days) (mg/kg soil)	Maximum PEC_{Soil} (mg/kg soil)	< 25 % effects at maximum PEC_{soil}
Metabolite, M29	5.00	0.194	Yes
Metabolite, M30	4.00	0.039	Yes

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)

Laboratory dose response tests

Species	Test substance	ER_{50} (L formulation/ha) vegetative vigour	ER_{50} (L formulation/ha) seedling emergence	Exposure[1] (L formulation/ha)	Risk assessment
Beta vulgaris *Brassica napus* *Cucumis sativus* *Glycine max* *Helianthus annus* *Lycopersicon esculentum* *Allium cepa* *Avena sativa* *Triticum aestivum* *Zea mays*	'Thiacloprid OD 240'	Data gap[2]	> 0.4	0.3	< 50 % effects at 0.4 L formulation/ha, which is above the maximum application rate i.e. 0.3 L formulation/ha indicating acceptable risk
Extended laboratory studies: No studies submitted Semi-field and field test: No studies submitted					

[1] Maximum application rate
[2] No valid study available

'Thiacloprid FS 400'
A risk assessment was not necessary for terrestrial non-target higher plants due to negligible exposure from a seed treatment.

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	EC_{50} based on respiration rate: 6330000 (µg a.s/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.; Available monitoring data concerning effect of the PPP. No study had been submitted.

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

Compartment	
soil	Thiacloprid
water	Thiacloprid, M29
sediment	Thiacloprid
groundwater	Thiacloprid

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

Substance	Thiacloprid
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][6]:	Aquatic Acute 1, H400 (M-factor = 100) Aquatic Chronic 1, H410 (M-factor = 100)

[6] 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.

Used compounds code(s)

Code/Trivial name*	IUPAC name/SMILES notation	Structural formula

* The compound code / trivial name in bold is the name used in the list of endpoints.