European Commission

Draft Renewal Assessment Report
prepared according to Regulation (EC) N° 1107/2009

METCONAZOLE

List of Endpoints

Rapporteur Member State: Belgium
Co-Rapporteur Member State: United Kingdom

Version History

When	What
January 2006	List of Endpoints prepared in the context of the application for the first inclusion of the a.s. in Annex I to Council Directive 91/414/EEC - revised version after EU peer review (EFSA, 2006)
January 2018	Draft Renewal Assessment Report (DRAR) – prepared by RMS BE in the context of the application for renewal of approval of the a.s. according to Reg (EU) No 844/2012. - List of Endpoints, based on the template provided in SANCO/12483/2014-rev.2 (12 Dec. 2014) *Note: The revision of the initial DAR has been done in accordance with SANCO/10180/2013 rev.1 (March 2013). New/additional info and proposed changes in the List of Endpoints have been highlighted yellow shading.*

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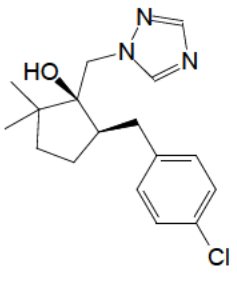
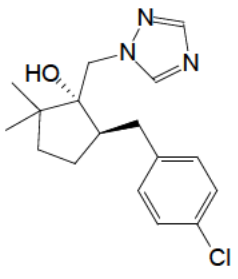
Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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)	Metconazole
Function (*e.g.* fungicide)	Fungicide

Rapporteur Member State	Belgium
Co-rapporteur Member State	United Kingdom

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

Chemical name (IUPAC)	(1RS,5RS:1RS,5SR)-5-(4-chlorobenzyl)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl) cyclopentanol
Chemical name (CA)	5-[(4-chlorophenyl)methyl]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl) cyclopentanol
CIPAC No	706
CAS No	125116-23-6 (unstated stereochemistry)
EC No (EINECS or ELINCS)	603-031-03 (EC No.)
FAO Specification (including year of publication)	No FAO specification
Minimum purity of the active substance as manufactured	Min. 940 g/kg (sum of cis- and trans-isomers), with cis-metconazole (CL 354801) level not less than 800 g/kg and not more than 950 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Two relevant impurities but not of concern at the specified levels
Molecular formula	$C_{17}H_{22}ClN_3O$
Molar mass	319.8 g/mol
Structural formula	 cis-isomer CL 354801  trans-isomer CL 354802 The active ingredient of Metconazole is a mixture of 4 diastereomers: CL 354801 (“cis-metconazole”) is a mixture of S(OH), R and R(OH), S diastereomers,

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whereas CL 354802 (“trans-metconazole”) is a mixture of S(OH), S and R(OH), R diastereomers.

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

Melting point (state purity)	Melting point range: 100.0 – 108.4 °C (98.6%)
Boiling point (state purity)	315 °C (98.1%)
Temperature of decomposition (state purity)	Not applicable (melting and boiling point were determined)
Appearance (state purity)	White powdered solid, odourless (98.6%)
Vapour pressure (state temperature, state purity)	2.1 x 10^{-8} Pa at 20 °C (98.6%)
Henry's law constant (state temperature)	2.21 x 10^{-7} $Pa.m^3.mol^{-1}$ at 20 °C (98.6%)
Solubility in water (state temperature, state purity and pH)	30.4 mg/L at 20 °C in distilled Milli-Q water (pH ca. 7.5) (98.6%) no effect of pH
Solubility in organic solvents (state temperature, state purity)	Solubility at 20 °C (98.6%) in: hexane : 1.40 g/L toluene : 103 g/L dichloromethane : 481 g/L methanol : 403 g/L 2-propanol : 132 g/L acetone : 363 g/L ethyl acetate : 260 g/L
Surface tension (state concentration and temperature, state purity)	~~64.8 mN/m at 20 °C (90% saturated solution)~~ 48.6 mN/m at 20 °C (90% saturated solution in pure water) (98.7 %, cis/trans ratio not reported)
Partition coefficient (state temperature, pH and purity)	3.85 at 20 °C (pH 7.2 - 8) (98.6%, 83% Cis and 15.7% Trans) Effect of pH was not investigated since there is no dissociation in water in the environmentally relevant pH-range
Dissociation constant (state purity)	pKa_1 = 11.38 (98.6%) pKa_2 = 1.08 (98.6%)

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UV/VIS absorption (max.) incl. ε (state purity, pH)	Acetonitrile solution : λ_{max} (nm) ε (L.mol^{-1}.cm^{-1}) 196 17700 221 5900 226 (shoulder) 4600 262 150 268 190 measurement of pH dependency is not necessary (pKa values are outside of the environmentally relevant pH-range) at λ > 290 nm : 2 maxima (determined in pH 7 buffer containing 0.1% acetonitrile) : at 310 nm : ε-value = 2686 L mol^{-1}.cm^{-1} at 372.5 nm : ε-value = 1921 L.mol^{-1}.cm^{-1} Additional results for renewal: solution (3.0985 10^{-3} mol/L) in watery medium (methanol/water (1:9)) at pH = 5.8: λ_{max} (nm) ε (L·mol^{-1}·cm^{-1}) 268 364.73 276 285.25 290 3.08 295 2.82 The molar absorption coefficient was found to be less than 10 L mol^{-1} cm^{-1} at wavelengths of 290 and 295 nm.
Flammability (state purity)	Not highly flammable (96%)
Explosive properties (state purity)	Not explosive (96%)
Oxidising properties (state purity)	Not oxidising properties (96%)

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Summary of representative uses evaluated, for which all risk assessments needed to be completed (metconazole) (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	kg a.s./ha min-max (l)		
Wheat (winter, spring, durum, spelt) *Triticum aestivum, T. durum, T. spelta* TRZAW, TRZAS, TRZDU, TRZSP Barley (winter, spring) *Hordeum vulgare* HORVW, HORVS Rye *Secale cereale* SECCW Triticale *Triticum X Secale* TTLWI Oats *Avena sativa* AVESA	NEU CEU SEU	BAS 555 01 F	F	*Septoria* spp. *Puccinia spp.* *Fusarium spp.* *E. graminis* *P. teres* *P. tritici-repentis* *Rhynchosporium secale*	EC	90 g/L	Spraying	30-69	1-2	21	22.5 – 81.8	110-400	0.090	35	Some pathogens or pathogen species are specific to a few crops only.
Oilseed rape *Brassica napus* BRSNW	NEU CEU SEU	BAS 555 01 F	F	*Leptosphaeria maculans (Leptosphaeria biglobosa)* *Pyrenopeziza brassicae* *Alternaria*	EC	90 g/L	Spraying	13-20 (autumn) 21-71 (spring)	1-2	14	16.4 – 65.5	110-440	0.072	56	Either 1 application in autumn + 1 application in spring Or 2 applications in

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					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	kg a.s./ha min-max (l)		
				brassicae Winter hardiness Plant growth regulation *Sclerotinia sclerotiorum* *Erysiphe crucifrerarum*											spring

(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

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Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Further information, Efficacy

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

Metconazole is a systemic fungicide, which is used worldwide in cereals and oilseed rape for the control of a broad range of important pathogens. Metconazole is active against different fungal stages on and in the plant. When applied protectively, metconazole inhibits further development of germinated fungal spores. Due to its ability to enter into the leaf and its further translocation as well as its high intrinsic activity, it can also control fungal stages that have already become established in deeper tissue layers. Metconazole is thus suitable for preventative and curative treatments.
Metconazole belongs to the triazole group of fungicides and the primary mode of action is the blocking of ergosterol biosynthesis through inhibition of cytochrome P450 sterol 14α-demethylase (CYP51). The depletion of ergosterol and accumulation of non-functional 14α-methyl sterols results in inhibition of growth and cell membrane disruption. Because of the mode of action triazoles belong to the demethylation inhibitors (DMI).
Due to the excellent suppression of Fusarium Head Blight and a resulting reduced contamination of cereal grain by mycotoxins, metconazole containing products are frequently used for ear treatment in wheat during flowering stage (BBCH 61-69) in the case of a likely attack with *Fusarium* spp.
In addition to the use as a fungicide, metconazole is used for plant growth regulation in oilseed rape.

A more detailed assessment should be performed for products authorization applications.

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

Metconazole has been applied in all EU member states since many years with several different formulations across a wide range of crops without reports of phytotoxic effects on target or succeeding crops. Consequently no negative impact is expected on treated crops.

A more detailed assessment should be performed for products authorization applications.

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

There is no evidence of any undesirable or unintended side-effect.

A more detailed assessment should be performed for products authorization applications.

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

Activity against target organism	*1,2,4-triazole (M555 F020)*	*Met2*	*Met3*	*Met4*	*Met5*	*Met6*
	yes	*yes/no*	*yes/no*	*yes/no*	*yes/no*	*yes/no*

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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)	HRGC-FID (methods APL 0437/01 and APL 0427/02)
Impurities in technical a.s. (analytical technique)	HRGC-FID
Plant protection product (analytical technique)	HPLC-UV (method RLA 12495.00)

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		Metconazole
Food of animal origin		Metconazole
Soil		Metconazole
Sediment		Metconazole
Water	surface	Metconazole
	drinking/ground	Metconazole
Air		Metconazole
Body fluids and tissues		Metconazole

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	~~Enforcement method DFG S19 : GC-NPD (Metconazole, as sum of *cis*- and *trans* isomer);~~ ~~LOQ = 0.01 mg/kg for each isomer (wheat grain, grapes, pea, oilseed rape seed)~~ DFG S19: LC-MS/MS (monitoring of two mass transitions) LOQ = 0.005 mg/kg for cis- (pair of enantiomers) and trans- (pair of enantiomers) metconazole (each) (corresponding to 0.01 mg/kg for total metconazole) in high water, high acid, dry [high starch] and oily matrices Independently validated.

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Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	~~*A method has to be required, if the proposed MRL for liver is confirmed.*~~ ~~Multi-residue method DFG S19: GC-NPD (Metconazole, as sum of *cis*- and *trans* isomer);~~ ~~LOQ = 0.01 mg/kg for each isomer (milk, meat, eggs, fat)~~ DFG S19: LC-MS/MS (monitoring of two mass transitions) LOQ = 0.005 mg/kg for cis- (pair of enantiomers) and trans- (pair of enantiomers) metconazole (each) (corresponding to 0.01 mg/kg for total metconazole) in milk, muscle, liver, kidney, fat and egg. Independently validated.
Soil (analytical technique and LOQ)	Enforcement methods FAMS 055-02 ~~and DFG S19~~: GC-NPD (Metconazole, as sum of *cis*- and *trans*-isomer); LOQ = 0.01 mg/kg for each isomer but better recoveries obtained with: **L0206/01**: LC-MS/MS (monitoring of two mass transitions) LOQ = 0.002 mg/kg for each of the four enantiomers in soil **L0203/01:** LC-MS/MS (monitoring of two mass transitions) LOQ = 0.002 mg/kg for cis- (pair of enantiomers) and trans- (pair of enantiomers) of metconazole (each) and 0.002 mg/kg for metabolite 1,2,4-(1H)-triazole
Water (analytical technique and LOQ)	~~Enforcement method FAMS 058-01 : GC-NPD (Metconazole, as sum of *cis*- and *trans* isomer);~~ ~~LOQ = 0.05 µg/L for each isomer (drinking water, surface water)~~ **D0501/01 (L0273/01):** LC-MS/MS (monitoring of two mass transitions) LOQ = 25 ng/L for each of the four enantiomers in surface and drinking water Independently validated in drinking and surface water.

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Air (analytical technique and LOQ)	~~Enforcement method FAMS 067-01 : GC-NPD (Metconazole, as sum of *cis-* and *trans-* isomer); LOQ = 0.28 µg/m^3 for each isomer~~ LC-MS/MS (monitoring of two mass transitions) LOQ = 0.0429 µg/m^3 for total metconazole (but cis- and trans-metconazole chromatographically resolved)
Body fluids and tissues (analytical technique and LOQ)	**OPEN: method is missing**

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

Substance	Metconazole
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][1]:	No classification with regard to physical and chemical properties (index No. 613-284-00-1)
Peer review proposal [2] for harmonised classification according to Regulation (EC) No 1272/2008:	/

[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. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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Section 2 Mammalian Toxicology

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	Metconazole *cis* is well absorbed (95-97% after 48h); after 48h , up to 83% is eliminated in the bile, while up to 12% is eliminated renally; by 72h about 93-96% of metconazole *cis/trans* is excreted.
Toxicokinetics	(*Cmax, Tmax, Plasma T1/2 not derived in the absence of studies allowing blood kinetics determination)*
Distribution	Metconazole is widely distributed, but adrenals, gastro-intestinal tract (GIT) and liver tended to concentrate the compound, in contrast to the blood.
Potential for bioaccumulation	No evidence for accumulation
Rate and extent of excretion	Excretion is rapid (about 95% after 72 h) and extensive. After 48h, the major route of elimination of Metconazole *cis* in the rat was predominately *via* the bile, accounting for 83%. Elimination *via* the urine occurred up to 12%. Without bile cannulation, about 59-72% Metconazole *cis/trans* was voided *via* the feces, and 14-24% was eliminated renally after 48h .
Metabolism in animals	Extensive metabolism, as ≤2% of dose was recovered in the faeces. There was no indication that the metabolisation in the rat of the isomer mix was different than that of the *cis*-isomer. The metabolic breakdown was not affected by sex. It was proposed that the main rat metabolites of Metconazole were: - monohydroxy-metabolites, as a result of oxidation of benzylic methylene groups, or the methyl or methylene groups of the cyclopentane ring (such as M1 and M21) - hydroxyphenyl-metabolites (M15 and M19) - carboxy-metabolites (M12 and M13) - multi hydroxy metabolites (M18) - mixed-function metabolites - various sulphate conjugates of the abovementioned metabolites (M22) .
In vitro metabolism	In an *in vitro* comparative metabolism in human, rat and rabbit liver microsomes, it was concluded that no human-specific metabolites were found and that the metabolic degradation in the tested species was similar
Toxicologically relevant compounds (animals and plants)	Metconazole, TA , TLA ,TAA, and 1,2,4-triazole

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Toxicologically relevant compounds (environment)	Metconazole and 1,2,4-triazole

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

Rat LD_{50} oral	595 mg/kg bw	**Acute Tox 4, H302**
Mouse LD50 oral	410 mg/kg bw	**Acute Tox 4, H302**
Rat, rabbit LD_{50} dermal	> 2000 mg/kg bw	
Rat LC_{50} inhalation	>5.2 mg/L air /4h	
Skin irritation	Not irritant	
Eye irritation	Not irritant	
Skin sensitisation	Not sensitising (M&K/Buehler)	
Phototoxicity	Not necessary	

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

Target organ / critical effect	Rat: liver (↑weight, hypertrophy/fatty vacuolation, ↑AST/ALT/γ-GT), mild hypochromic microcytic anaemia, adrenal (↑weight, cortical vacuolation) Classification (suggested): STOT-RE2 (H373) for liver/adrenal effects (adrenal/ hepatocellular vacuolation/hypertrophy) at doses < 100 mg/kg bw/d in rats. However, such effects are not seen in dog at these doses. Mouse: liver (↑weight, hypertrophy/vacuolation, AST/ALT increase), spleen (↑weight increase, lymphoid hyperplasia), slight microcytic anaemia at highest dose Dog: ↓body weight gain, ↑ AP; lens degeneration	**STOT-RE2 (H373)**
Relevant oral NOAEL	90-day rat: 6.4 mg/kg bw/day 90-day mouse: 4.6 mg/kg bw/day 1-year dog: 1.1 mg/kg bw/day	
Relevant dermal NOAEL	No data - not required	
Relevant inhalation NOAEL	No data - not required	

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

In vitro studies	Ames test: Negative Mouse Lymphoma Assay: Negative Chromosome aberration assay in human lymphocytes: Negative Chromosome aberration assay in CHO cells: clastogenic with S9 at 24h but not at 48h sampling time, neither without S9	
In vivo studies	Mouse micronucleus assay: Negative UDS assay: Negative	
Photomutagenicity	Not required	
Potential for genotoxicity	No evidence for genotoxic potential	

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

Long-term effects (target organ/critical effect)	Liver toxicity (↑liver weight, hepatocellular vacuolation/hypertrophy, and cell foci in mouse and rat; ↑ALT/AST in mouse, single cell necrosis/sinusoidal hypercellularity/ pigmentation in mouse); ↑spleen weight in rat, spleen atrophy, corticomedullary adrenal pigmentation and ↓ cholesterol/triglyceride levels in mouse.	**STOT. RE 2** **H371**
Relevant long-term NOAEL	Chronic (2-year rat): 4.3 mg/kg bw/d (100 ppm)	
Carcinogenicity (target organ, tumour type)	Mouse: ↑liver adenoma/carcinoma (♀). Identified key events from mechanistic studies and effects on liver (i.e.↑liver weight, liver hypertrophy/vacuolation, specific hepatic CYP induction (mainly CYP2B), hepatocellular proliferation, cell foci, multifocal hyperplasia) suggest a phenobarbital-like mode of action (CAR-mediated), which is not considered relevant for humans Rat: no carcinogenic effects	
Relevant NOAEL for carcinogenicity	18-month mouse: 4.4 mg/kg bw/d (30 ppm)	

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

Reproduction toxicity

Reproduction target / critical effect	Parental toxicity: ↓bodyweight, ↑liver & ovarian weights, hepatocyte fatty change and centrilobular hypertrophy. Reproductive toxicity: ↑gestation length and ↓gestation index. (dystocia at toxic doses). No other fertility findings. Offspring's toxicity: pre-birth loss, ↑ pup loss at birth,	

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	↓ bodyweight gain,	
Relevant parental NOAEL	10 mg/kg bw per day (from 2-gen study with *cis/trans*)	
Relevant reproductive NOAEL	10 mg/kg bw per day (from 2-gen study with cis/trans)	
Relevant offspring NOAEL	10 mg/kg bw per day (from 2-gen study with cis/trans)	

Developmental toxicity

Developmental target / critical effect	<u>Rat:</u> Maternal toxicity: ↓food consumption, ↓bodyweight gain Foetal toxicity: ↓litter/foetal weight, ↑resorption/post-implantation loss, ↑placental weight Developmental toxicity: ↑bilateral hydroureter, ↑lumbar and cervical ribs, ↑unossified sternebrae, ↑ventricular septal defect (VSD) <u>Rabbit</u>: Maternal toxicity: ↓feed consumption, ↓bodyweight gain Foetal toxicity: ↓litter/foetal weight, ↑late embryonic deaths, ↑ post-implantation loss, ↑late resorptions. Developmental toxicity: ↑hydrocephaly	**Repr. Cat. 2, H361d**
Relevant maternal NOAEL	Rat: 10 mg/kg bw/day Rabbit: 4 mg/kg bw/day	
Relevant developmental NOAEL	Rat: 10 mg/kg bw/day Rabbit: 4 mg/kg bw/day	

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

Acute neurotoxicity	No findings indicative of neurotoxic potential.	
Repeated neurotoxicity	No neurotoxicity in 2-week and 4-week neurotoxicity studies: Neurotoxicity NOAEL: 47.08 mg/kg bw (rat, ♂) 49.82 mg/kg bw (rat, ♀) (highest dose tested) Systemic NOAEL: 4.8 / 5.1 mg/kg bw/day	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	No data submitted for delayed neurotoxicity or developmental neurotoxicity - not required	

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

Supplementary studies on the active substance	Metconazole *cis*: 28-day mechanistic study (male rats and mice): hepatic CYP induction (rat, mouse). Pattern similar, but not identical to Phenobarbital. Metconazole *cis/trans*: 14-day mechanistic study in female mice: CYP2B induction (protein and enzyme activity) and transient hepatocellular proliferation after 3 and 7 days at 300 and 1000 ppm. "Phenobarbital-like" pattern 28-day immunotoxicity study in rats: no immunotoxin potential Mechanistic 1-generation study: ↑ gestation length and dystocia may be associated with ↓ E/P (oestradiol/progesterone) ratio during late gestation, mainly due to ↓ in serum oestradiol. Metconazole *cis/trans*, *cis*, and *trans*: Recombinant aromatase assay in rat and human enzyme: inhibition of aromatase activity (human < rat; cis/trans = cis > trans): Whole Embryo culture: general embryotoxicity potential cis/trans > cis > trans. Metconazole *cis* and *cis/trans*: Comparative metabolome analysis: high level of similarity of metabolite profile between cis and cis/trans metconazole

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Endocrine disrupting properties	• A <u>likely MoA</u> explaining adverse findings, including **↑post-implantation loss, foetotoxicity and ↑gestation length**, subsequent to aromatase inhibition and decrease in circulating levels of oestradiol can be established for rodents. While the post-implantation loss could be regarded an early developmental effect, the increased gestation length is considered a weak effect, not justifying any classification for fertility, in the absence of severe fertility findings. Regarding adrenal toxicity, a possible link could exist between aromatase/steroidogenic effects, but the level of concern is lowered by the absence of severe adrenocortical findings, and the absence of aggravation of effects with study duration. However, LT effects may be different from ST-effects, and residual uncertainty exists on the impact of adrenal effects on human health. • From a read-across consideration, it could be postulated that the observed MoA may be relevant for rodents, but not necessarily for humans. Considering the no-effect in guinea pigs, and inferring that the guinea pig could well be a better model than rodents for human health, the **<u>relevance for human</u>** is questionable. However, RMS acknowledges that the non-relevance of aromatase-inhibition for human was seriously challenged (RAC opinion). • In addition, since no final demonstration exists that the data observed with the related a.s. epoxiconazole can be extrapolated to metconazole, a data gap exists for this MoA. • Final uncertainty estists on other MoA not covered by the EATS pathways (like the retinoic acid pathways described in open scientific literature – however out of scope in the framework of the GD). **The decision wether metconazole meets the endocrine disruption criteria is thus not finalised and should be further discussed during expert consultation.**
Studies performed on metabolites or impurities	The existing studies, as well as QSAR considerations indicate that the metabolites and impurities of metconazole are not more toxic than metconazole itself

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

(i) All persons handling crop protection products are surveyed by regular medical examinations. There are no specific parameters available for effect monitoring of Metconazole. Thus, the medical monitoring programme is designed as a general health check-up, with special interest in the primary target organs presumed to be relevant by analogy from animal experiments.

(ii) The surveillance program includes a general physical examination including neurological status, red and white blood cell counts, liver enzymes. Adverse health effects suspected to be related to Metconazole exposure have not been observed.

(iii) Some cases of slight irritation of the eyes have been reported to BASF in persons exposed to Metconazole in combination with other products. These reports could not be verified, and it is not clear whether Metconazole was the cause for these irritations.

(iv) A generic problem which emerged during the last years in the open scientific literature, namely the question wether the widespread use of triazoles in agriculture could be the cause of observed resistances to medical triazoles in the treatment of lung aspergillosis (*Aspergillus fumigatus*). The problem is particularly threatening in highly immunocompromised patients facing invasive aspergillosis (IA).

As reported for bacteria, the spread of antifungal resistance in filamentous fungi has become an issue of concern. Specifically, resistance among *Aspergillus* species to azole antifungals is increasingly being reported. There has been a sudden rise in the frequency of azole resistance in *Aspergillus* since 2004, and many isolates have shown cross-resistance between all the currently licensed azole options. In The Netherlands the emergence of resistance to clinically used triazoles of *Aspergillus fumigatus* isolates has been linked to the use of azole antifungal products in agriculture. Several scientific papers were dedicated to this problem

In conclusion, the current scientific knowledge indicates that there are certainly good scientific reasons to hypothesise an environmental driver for resistance induction of therapeutic triazoles, possibly due to the use of triazoles as agricultural fungicides. However, the current lines of evidence, although plausible, lack direct proof. As such direct causal relationship is of course difficult to prove, and certainly if it comes to reveal a clear link between specific substances (like metconazole) to such resistance, the question remains what risk-mitigating measures should be installed to tackle this potential problem.

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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**	rabbit, developmental	400
Acute Reference Dose (ARfD)	**0.01**	rabbit, developmental	400
Acceptable Operator Exposure Level (AOEL)	**0.01**	rabbit, developmental	400
Acute Acceptable Operator Exposure Level (AAOEL)	**0.01**	rabbit, developmental	400

* Including correction for limited oral absorption/bioavailability (100 %).

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

Representative formulation (*indicate name, type e.g.* EC *and concentration of active substance*)	Concentrate (90.2 g/L): 4% Spray dilution (0.46 g/L): 13% Spray dilution (0.22 g/L): 28%

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

Operators

Application method Crop	**Model**	**PPE**	**Total systemic exposure[1] (mg/kg bw/day)[2]**	**AOEL covered[3]**
Tractor mounted boom sprayer application wheat, cereals, oilseed rape	BBA	gloves - M/L + gloves / coverall / sturdy footwear - Appl.	0.0011	**11%**
	UK POEM	gloves - M/L + gloves - Appl.	0.0262	262%
	AOEM	NO PPE	0.0224	224%
	AOEM	Gloves/workwear / sturdy footwear, - M/L + gloves/workwear/ sturdy footwear, - Appl	0.001	**9.9%**

[3] If available include also reference values for metabolites

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Workers

Model	Absorbed dose (mg/kg bw/day)	AOEL covered[2]
Europoem draft model adopted with more specific transfer coefficient published by the US EPA	Unprotected worker[1] 0.00554	**55.4%**
EFSA Guidance Model	Unprotected worker[1] 0.0061	**60.8%**

[1] Worker wearing shoes, socks, long-sleeved shirt and long trousers
[2] Based on a systemic AOEL of 0.01 mg/kg bw/day for metconazole

Bystanders and residents

Model		Route of exposure	Estimated bystander exposure[1] (mg/kg bw/day)	AOEL covered[2]
German model	Bystander (adults)	Vapour and surface deposits	0.00012	**1.2%**
	Bystander (children)		0.00010	**1.0%**
German model	Resident (adults)		0.000015	**0.15%**
	Resident (children)		0.000026	**0.3%**

[1] German model for bystander and resident exposure assessment; Martin S. et al. (2008)
[2] Based on a systemic AOEL of 0.01 mg/kg bw/day for metconazole

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

Substance :	metconazole
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 4 (H302 – "*Harmful if swallowed*"),** **REPR. 2 (H361d – "*Suspected of damaging the unborn child*")**
Peer review proposal [5] for harmonised classification according to Regulation (EC) No 1272/2008:	**ACUTE TOX 4 (H302 – "*Harmful if swallowed*")** **STOT-RE2 (H373 – "*May cause damage to organs through prolonged or repeated exposure*"),** **REPR. 2 (H361d – "*Suspected of damaging the unborn child*")**

[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. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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Residues in or on treated products food and feed

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

Primary crops (Plant groups covered) OECD Guideline 501	**Crop groups**	**Crop(s)**	**Application(s)**	**DAT** (days)
	Fruit crops	Banana	Foliar; greenhouse; from flowering stage on; 5 x 139-143 g a.s./ha (total: 0.7 kg a.s./ha), interval 14 days; [triazole-3,5-^{14}C]- or [*p*-chlorophenyl-U-^{14}C]-metconazole (*cis:trans* 80:20)	56 DAT1 = 0.08 DALA (2 hrs after last/5thappl.)
		Mandarin	Foliar; greenhouse; fruit-growing stage; 1 x 189-192 g a.s./ha; [triazole-3,5-^{14}C]-metconazole (*cis:trans* 83:17) or [cyclopentyl-^{14}C]-metconazole (*cis:trans* 87:13)	56 DAT
	Root crops	-	-	-
	Leafy crops	-	-	-
	Cereals/grass crops	Wheat	Foliar; field; BBCH 57-60; 1 x 360-370 g a.s./ha (2N) [triazole-3,5-^{14}C]-***cis***-metconazole (*cis:trans* 98:2) or [cyclopentyl-^{14}C]-metconazole (*cis:trans* 78:22)	74

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	Pulses/Oilseeds	Oilseed rape	Foliar; field; at early flowering stage; 2 x 264-265 g a.s./ha (3.7N), interval 14 days; [triazole-3,5-^{14}C]-metconazole (*cis:trans* 82:18) or [*p*-chlorophenyl-U-^{14}C]-metconazole (*cis:trans* 79:21)	0, 14, 28, 42 DAT1 and at maturity (58/64 DAT1 = 44/50 DALA)
		Peas	Foliar; field; (a) 2 x 205-211 g a.s./ha (total 416-418 g a.s./ha) (2.9N) (b) 3 x 205-211 g a.s./ha (total 624-626 g a.s./ha) (4.3N) Interval 13-14 days; [triazole-3,5-^{14}C]- or [*p*-chlorophenyl-U-^{14}C]-metconazole (*cis:trans: not reported*)	Foliage 0, 13, 27 DAT1 (=0 DAT) Straw/seed: (a) 26 DAT1 (=13 DALA); BBCH 79 (b) 42 DAT1 (=15 DALA); BBCH 89
	Miscellaneous	-	-	-
	Metabolism of metconazole was similar in the 3 different crop groups investigated. The primary metabolic pathway of metconazole proceeds by oxidative hydroxylation of the benzylic methylene group, the methyl side chain on the cyclopentyl ring, and potentially the cyclopentyl ring to produce monohydroxylated metabolites of metconazole which are further conjugated through glycosidation. Triazole alanine was found in the non-vegetative parts of plants (wheat grain, rape seed, pea seeds and banana); triazole acetic acid in wheat grain.			

Rotational crops (metabolic pattern) **OECD Guideline 502**	**Crop groups**	**Crop(s)**	**PBI** (days)	**Comments**
	Root/tuber crops	Radish	30 120	[triazole-^{14}C]- or [cyclopentyl-^{14}C]-metconazole (*cis:trans* 80:20) bare soil application, glasshouse, 0.4 kg a.s./ha *(ca. 2.2N – cf. cGAP cereals 2x0.09 kg a.s./ha)*
	Leafy crops	Lettuce	30 120	
	Cereal (small grain)	Wheat	30 120	
	Other	-	-	
Rotational crop and primary crop metabolism similar?	Yes. Metconazole was taken up from the soil, since it was present in all crops tested (except wheat grain). Besides the parent, major compounds in all crops were the metabolites triazole alanine (TA) and/or triazole acetic acid (TAA), as well as carboxy metabolite M12 in radish foliage.			

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Processed commodities (standard hydrolysis study) OECD Guideline 507	Conditions	Recovery of total radio-activity (%)	Comment
	20 min, 90°C, pH 4	95	[triazole-3,5-^{14}C]-metconazole
	60 min, 100°C, pH 5	97	
	20 min, 120°C, pH 6	97	
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes. Isomer distribution of metconazole did not change during all tested conditions; The *cis:trans* isomer ratio was approximately 98.5:1.5 before and after processing.		

Plant residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31	Metconazole
Plant residue definition for risk assessment (RD-RA)	(1) Metconazole (2) TA and TLA # (3) TAA # (4) 1,2,4-triazole # # *provisional, pending confirmation in the framework of the EU peer review of the confirmatory data for TDMs*
Conversion factor (monitoring to risk assessment)	Not applicable

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

OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish)	Animal	Dose (mg/kg bw/d)	Duration (days)	N rate/comment
Animals covered	Laying hen	0.75	4.5	11 N ([redacted], 2006a) [triazole-^{14}C]- or [cyclopentyl-^{14}C]-metconazole (*cis:trans* 85:15)
		0.6-0.8	28	([redacted]., 1991)* [cyclopentyl-^{14}C]-***cis***-metconazole
		0.6-0.8	14	[redacted] 1992)* [cyclopentyl-^{14}C]-***cis***-metconazole

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Goat	0.46	4	5.2 N (cattle), 2.4 N (lamb), 3.0 N (ram/ewe); [redacted], 2006b) [triazole-^{14}C]-metconazole (*cis:trans* 87:13)
	0.48	3 (goat A) 4 (goat B)	5.5 N (cattle), 2.5 N (lamb), 3.2 N (ram/ewe); [redacted] 1992) [cyclopentyl-^{14}C]-metconazole (*cis:trans* 80:20)
	0.36	4	4.1 N (cattle), 1.9 N (lamb), 2.4 N (ram/ewe); ([redacted]1993) [cyclopentyl-^{14}C]-***cis***-metconazole
Pig	-	-	-
Fish	-	-	No metabolism study required; fish feed burden <0.1 mg/kg diet

** No stand-alone OECD guideline-compliant study; only providing supportive/supplementary information*

- Metconazole residues (when administered orally) are rapidly metabolized and eliminated from the hen and goat via excreta.
- Preferential metabolism of the *cis*-isomers of metconazole was observed in hen and goat.

Hen:

Major residue components (>10%TRR): 1,2,4-triazole (all tissues and eggs) and metconazole (fat and skin); In addition, M1, M12, M31, M32 and a number of minor hydroxylated and carboxylated metabolites, as well as their sulfate ester conjugates, were identified.

Goat:

Low TRR levels (<0.01 mg/kg) in milk, muscle and fat; Highest TRR levels were found in liver and kidney.

Major residue components (>10%TRR): metconazole (liver, fat, muscle), M12 (kidney), glucuronic acid conjugate of M31 (liver and kidney), glucuronic acid conjugate of M1 (kidney).

Time needed to reach a plateau concentration in milk and eggs (days)	Whole egg: within 8 days Egg white: 3-4 days Egg yolk: no plateau reached within 4.5 days Milk: within 4 days (cyclopentyl label; inconclusive for triazole label)

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Animal residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Metconazole
Animal residue definition for risk assessment (RD-RA)	(1) Metconazole (2) TA and TLA [#] (3) TAA (poultry and ruminant matrices) [#] (4) 1,2,4-triazole [#] [#] *provisional, pending confirmation in the framework of the EU peer review of the confirmatory data for TDMs*
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (Yes/No)	Yes
Fat soluble residues (Yes/No) **(FAO, 2009)**	Yes (log P*ow* metconazole = 3.85)

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

Confined rotational crop study (Quantitative aspect) **OECD Guideline 502**	CRC study on wheat, lettuce, radish; [triazole-^{14}C]- or [cyclopentyl-^{14}C]-metconazole (*cis:trans* 80:20); bare soil application, glasshouse, 0.4 kg a.s./ha *(ca. 2.2N – cf. cGAP cereals 2x0.09 kg a.s./ha)*: A slight increase of TRR with increasing planting interval was observed, but with time, levels of metconazole appeared to be more or less constant in the respective crop parts, indicating that accumulation of metconazole in rotational crops is unlikely. Highest TRR (as metconazole equivalents) for 120-day PBI and triazole label: 0.71 mg/kg in radish root, 0.20 mg/kg in lettuce foliage and 0.49 mg/kg in wheat grain. - Metconazole (sum of *cis*- and *trans*-isomers) was found in wheat straw, lettuce, radish root, radish foliage (4-39%TRR; 0.01-0.13 mg/kg); - TA: in wheat grain, radish root and radish foliage (3.3-59%TRR; 0.03-0.29 mg parent eq./kg) - TAA: in wheat grain and lettuce (21-33%TRR; 0.05-0.10 mg parent eq./kg)
Field rotational crop study **OECD Guideline 504**	Rotational field study 30-31 days (carrots, lettuce) and 98-99 days (wheat) after bare soil application at 2x0.09 kg a.s./ha. *Cis*-metconazole and *trans*-metconazole not detected (< LOD 0.003 mg/kg per isomer pair; <LOD 0.01 mg/kg for wheat straw), except *cis*-metconazole in immature carrots in one trial (< LOQ 0.01 mg/kg). *<u>TDMs:</u> non-EU studies (wheat, dry bean, sorghum, sunflower) indicated potentially higher levels of TAA in rotational cereal grain and oilseeds compared to primary crops.*

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

OECD Guideline 506

Plant products (Category)	Commodity	T (°C)	Stability (Months)			
			Metconazole (*cis*- and *trans*-)	M21 (M555F 021)	M11 (M555F 011)	M30 (M555F 030)
High water content	Cereal green plant Lettuce	≤ -18	12	-	-	-
	Radish tops	≤ -5	-	26	26	26
High oil content	Oilseed rape seed Oilseed rape oil	≤ -18	12	-	-	-
	Soya bean seed	≤ -5	26	26	26	26
High protein content	-	-	-	-	-	-
High starch content	Cereal grain Carrot	≤ -18	12	-	-	-
	Cereal grain	≤ -5	-	26	26	26
	Radish root Sugar beet root	≤ -5 ≤ -5	26 -	- 26	- ≥ 12*	- 26
High acid content	-	-	-	-	-	-
No group	Cereal straw	≤ -18	12	-	-	-
	Wheat hay Wheat straw	≤ -5 ≤ -5	26 -	26 26	26 26	26 26

Residues of metconazole expressed as *cis*- and *trans*-isomers are considered stable under frozen storage conditions in commodities with high water content or high starch content (for at least 12 months), in oilseeds (for at least 26 months) and in cereal straw and hay (for at least 26 months).

* For M11 in sugar beet root, recovery results after 26 months of storage were inconsistent.

TDMs: see EU peer review of the confirmatory data for TDMs; additional study demonstrated stability of TLA for 48 months in wheat grain (high starch content), navy bean (high protein content), orange (high acid content), canola seed (high oil content) and lettuce (high water content)

Animal	Animal commodity	T (°C)	Stability (Months)
			Metconazole (*cis* and *trans*)
Cow	Muscle	≤ -10	3.7 (112 days)
Cow	Liver	≤ -10	3.6 (108 days)
Cow	Fat	≤ -10	3.7 (111 days)

All treated samples of milk, skim milk, and cream were extracted for analysis within 19 days of collection. Egg and poultry tissue samples were extracted for *cis*- and *trans*-metconazole analysis within 26 days of collection. Storage stability data are not required for these matrices.

Residues of metconazole were proven to be stable in muscle, liver and fat for at least 3.6 months. A similar stability of metconazole in kidney (stored for less than 50 days) can reasonably be expected.

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

Crop (cGAP)	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						
Wheat, grain (2x 90 g/ha; interval 21 days; BBCH 30-69 / PHI 35 days)	NEU	~~<0.002, <0.01 (4x), <0.02 (2x), 0.04 *[cf. EFSA, 2006/2011]*~~ *Old (n=8):* <0.01 (5x), <0.02 (2x), 0.04 *New (n=13):* <0.01 (3x), 0.01 (2x), 0.011 (3x), 0.012 (2x), 0.016, 0.023, 0.025 ***Old + new (n=21):*** <0.01 (8x), 0.01 (2x), 0.011 (3x), 0.012 (2x), 0.016, <0.02 (2x), 0.023, 0.025, 0.04	Calculated MRL_{OECD}: NEU 0.05 mg/kg; SEU 0.06 mg/kg; Maintain current EU MRL based on import tolerance (0.15 mg/kg)	0.15	0.04	**0.011**
	SEU	~~<0.02 (6x), 0.03, 0.05 *[cf. EFSA, 2006]*~~ *Old (n=7):* <0.02 (5x), 0.03, 0.05 *New (n=10):* <0.01 (6x), 0.01 (3x), 0.012 ***Old + new (n=17):*** <0.01 (6x), 0.01 (3x), 0.012, 0.02 (5x), 0.03, 0.05			**0.05**	0.010
Rye, grain (see wheat)	NEU	<0.01	Extrapolation from wheat; Maintain current EU MRL	0.06	<0.01	n.a.
Triticale, grain (see wheat)	NEU	*Old:* <0.01 *New:* <0.01	Extrapolation from wheat; Maintain current EU MRL based on import tolerance (0.15 mg/kg)	0.15	<0.01	<0.01
Wheat, straw	NEU	~~0.25, 0.44, 0.53, 0.57, 0.64, 0.75, 0.76, 0.87 *[cf. EFSA, 2006/2011]*~~ *Old (n=8):* 0.25, 0.49, 0.53, 0.57, 0.64, 0.75, 0.76, 1.56 *New (n=13):* 0.56, 0.71, 0.84, 1.15, 1.20, 1,40, 1.80, 2.1, 2.7, 2.8 (2x), 3.5, 7.3 ***Old + new (n=21):*** 0.25, 0.49, 0.53, 0.56, 0.57, 0.64, 0.71, 0.75, 0.76, 0.84, 1.15, 1.20, 1.40, 1.56, 1.80, 2.1, 2.7, 2.8 (2x), 3.5, 7.3	Results for wheat straw (NEU) were pooled with those for rye straw and triticale straw (NEU). Calculated MRL_{OECD}: NEU 8.0 mg/kg; SEU 10 mg/kg;	n.a.	7.3	**0.80**

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Crop (cGAP)	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)
	SEU	~~0.16, 0.23 (3x), 0.27, 0.30, 0.30, 0.57 *[cf. EFSA, 2006/2011]*~~ *Old (n=7):* 0.23, 0.30, 0.38, 0.39, 0.44, 0.48, 0.57[a] *New (n=10):* 0.36, 0.55, 1.20, 1.40 (2x), 2.6, 2.9, 3.0, 4.0, 8.4 ***Old + new (n=17):*** 0.23, 0.30, 0.36, 0.38, 0.39, 0.44, 0.48, 0.55, 0.57, 1.20, 1.40 (2x), 2.6, 2.9, 3.0, 4.0, 8.4	[a] Highest value derived from two replicate trials.		**8.4**	0.57
Rye, straw	NEU	0.37	Results for rye straw were pooled with those for wheat straw (NEU).	See wheat straw (NEU)	See wheat straw (NEU)	See wheat straw (NEU)
Triticale, straw	NEU	*Old:* 0.16 *New:* 0.20	Results for triticale straw were pooled with those for wheat straw (NEU).			
Barley, grain (2x 90 g/ha; interval 21 days; BBCH 30-69 / PHI 35 days) Extrapolation to **oat** grain	NEU	*Old (n=16):* <0.01 (4x), 0.01 (3x), 0.02, 0.03 (5x), 0.05 (2x), 0.09 *[cf. EFSA, 2006/2011]* *New (n=14)* [a]*:* 0.01 (2x), 0.011, 0.017, 0.019, 0.020, 0.021, 0.023, 0.058, 0.060, 0.065, 0.087 (2x), 0.20 ***Old + new (n=30):*** <0.01 (4x), 0.01 (5x), 0.011, 0.017, 0.019, 0.020 (2x), 0.021, 0.023, 0.030 (5x), 0.050 (2x), 0.058, 0.060, 0.065, 0.087 (2x), 0.090, 0.20	[a] Highest value derived from two replicate trials. Calculated MRL_{OECD}: NEU 0.2 mg/kg; SEU 0.4 mg/kg; Maintain current EU MRL (0.4 mg/kg); Extrapolation to oat	0.4	0.20	0.022
	SEU	~~*Old (n=4): 0.03, 0.03, 0.04, 0.05 [cf. EFSA, 2006]*~~ *Old (n=3):* 0.03, 0.03, 0.05[a] *New (n=14):* 0.012[a], 0.014[a], 0.014, 0.017, 0.020[a], 0.020, 0.030[a], 0.037[a], 0.039[a], 0.041[a], 0.053, 0.067[a], 0.19[a], 0.26[a] ***Old + new (n=17):*** 0.012, 0.014 (2x), 0.017, 0.020 (2x), 0.030 (3x), 0.037, 0.039, 0.041, 0.050, 0.053, 0.067, 0.19, 0.26			**0.26**	**0.030**

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Belgium	January 2018	Metconazole

Section 3 Residues

Crop (cGAP)	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)
Barley, straw	NEU	*Old (n=16):* 0.03, 0.13, 0.15, 0.18, 0.22, 0.23, 0.32, 0.37, 0.73, 0.74, 0.82, 0.99, 1.06, 1.33, 1.37, 1.61 *[cf. EFSA, 2006/2011]* *New (n=14)* [a]*:* 0.09, 0.26, 0.27, 0.28, 0.33, 0.45, 0.59, 0.65, 1.0, 1.1, 1.3, 1.6, 2.5, 3.1 ***Old + new (n=30):*** 0.03, 0.09, 0.13, 0.15, 0.18, 0.22, 0.23, 0.26, 0.27, 0.28, 0.32, 0.33, 0.37, 0.45, 0.59, 0.65, 0.73, 0.74, 0.82, 0.99, 1.0, 1.06, 1.1, 1.3, 1.33, 1.37, 1.6, 1.61, 2.5, 3.1	Calculated MRL_{OECD}: NEU 4 mg/kg; SEU 8 mg/kg	n.a.	3.1	0.62
	SEU	~~*Old (n=4): 1.3, 1.4, 1.5, 2.6 [cf. EFSA, 2006]*~~ *Old (n=3):* 1.3, 1.5, 2.6[a] *New (n=14):* 0.082, 0.18, 0.29[a], 0.34, 0.39, 0.58[a], 0.65[a], 0.71[a], 0.76[a], 1.08[a], 2.0[a], 2.5 (2x)[a], 6.7[a] ***Old + new (n=17):*** 0.082, 0.18, 0.29, 0.34, 0.39, 0.58, 0.65, 0.71, 0.76, 1.08, 1.3, 1.5, 2.0, 2.5 (2x), 2.6, 6.7			**6.7**	**0.76**
Oilseed rape, seed (2x 72 g/ha; interval 14 days; PHI 56 days)	NEU	~~*Old (n=8): <0.01 (5x), 0.04, 0.06, 0.07 [cf. EFSA, 2006/2011]*~~ *Old (n=6):* <0.01 (4x), 0.04, 0.07 *New (n=4):* 0.024, 0.025, 0.046, 0.072 ***Old + new (n=10):*** <0.01 (4x), 0.024, 0.025, 0.04, 0.046, 0.07, 0.072	Calculated MRL_{OECD}: NEU 0.15 mg/kg; SEU 0.1 mg/kg; NEU+SEU (merged) 0.15 mg/kg Maintain current EU MRL (0.2 mg/kg);	0.2	**0.072**	0.025
	SEU	~~*Old (n=9): <0.01, 0.02 (3x), 0.03, 0.04, 0.05 (2x), 0.11 [cf. EFSA, 2006/2011]*~~ *Old (n=4):* <0.01, 0.02, 0.04, 0.05, ~~*0.11 (PHI 39 days)*~~ *New (n=4):* 0.015[a], 0.016, 0.037, 0.051 ***Old + new (n=8):*** <0.01, 0.015[a], 0.016, 0.020, 0.037, 0.04, 0.05, 0.051	[a] trial parameters deviated from cGAP: interval of 40 days (i.o. 14 days), last application at BBCH 75 (i.o. 71), seed sampled 41 DALA (i.o. 56 DALA)		0.051	**0.029**

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Section 3 Residues

Crop (cGAP)	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)
Summary of the data on formulation equivalence OECD Guideline 509						
Crop	**Region**	**Residue data** (mg/kg)	**Recommendations/comments**			
Wheat/rye	NEU & SEU	See data for representative uses above	Several side-by-side trials were conducted in parallel with different EC formulations containing metconazole. Residues were comparable.	-	-	-
Barley/oats	NEU & SEU	See data for representative uses above	These trials were considered as replicate trials (i.e. not independent) and the highest value from two replicate trials was selected for MRL derivation (see above).	-	-	-
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**			
Pollen	NEU	<0.01 (4x)	Trials on oilseed rape with single application at full flowering (BBCH 65) at 90 g a.s./ha	0.05*	<0.01	<0.01
Honey	NEU	<0.01 (4x)			<0.01	<0.01

(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 ($STMR_{Mo}$).

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Section 3 Residues

Inputs for animal burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Risk assessment residue definition: metconazole				
Barley straw	0.76	STMR (S EU)	6.7	HR (S EU)
Oat straw	0.76	STMR (S EU) (barley straw)	6.7	HR (S EU) (barley straw)
Rye straw	0.80	STMR (N EU) (wheat straw)	8.4	HR (S EU) (wheat straw)
Triticale straw	0.80	STMR (N EU) (wheat straw)	8.4	HR (S EU) (wheat straw)
Wheat straw	0.80	STMR (N EU)	8.4	HR (S EU)
Barley grain	0.030	STMR (SEU)	0.030	STMR (SEU)
Oat grain	0.030	STMR (SEU) (barley grain)	0.030	STMR (SEU) (barley grain)
Rye grain	0.011	STMR (wheat grain)	0.011	STMR (wheat grain)
Triticale grain	0.011	STMR (wheat grain)	0.011	STMR (wheat grain)
Wheat grain	0.011	STMR	0.011	STMR
Brewer's grain, dried	0.066	$STMR_{barley\ grain}$ x PF (2.2)	0.066	$STMR_{barley\ grain}$ x PF (2.2)
Canola, meal Rape, meal	0.028	$STMR_{rape\ seed}$ x PF (0.96)	0.028	$STMR_{rape\ seed}$ x PF (0.96)
Distiller's grain, dried	0.036	$STMR_{wheat\ grain}$ x $PF_{default}$ (3.3)	0.036	$STMR_{wheat\ grain}$ x $PF_{default}$ (3.3)
Wheat gluten, meal	0.020	STMR x $PF_{default}$ (1.8)	0.020	STMR x $PF_{default}$ (1.8)
Wheat, milled byproducts	0.022	STMR x $PF_{wheat\ bran}$ (2)	0.022	STMR x $PF_{wheat\ bran}$ (2)

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Section 3 Residues

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)

OECD Guideline 505 and OECD Guidance, series on pesticides No 73

MRL calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Highest expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.055	Ram/Ewe	0.151	Breeding	0.001	Broiler	0.002	Carp	0.066
	Dairy cattle	0.088	Lamb	0.193	Finishing	0.001	Layer	0.068	Trout	0.062
							Turkey	0.002	Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	Yes		Yes		No		Yes		No	
Feeding study submitted	Yes Lactating cow (29 days, 3 levels, 3 cows/level)		No; MRLs derived from the cow feeding study		No; not required (intake <0.004 mg/kg bw/day)		Yes Laying hen (28 days, 3 levels, 12 hens/level)		No	
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level 1 0.20	Beef: 3.7 N Dairy: 2.3 N	Level 1 0.20	Lamb: 1.0 N Ewe: 1.3 N	Level	N rate Breed/Finish	Level 1 0.15	B or T: 69 N Layer: 2.2 N	Level	N rate Carp/Trout
	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals
Muscle	<0.02	0.02*	<0.02	0.02*	-	-	<0.02	0.02*		
Fat	<0.02	0.02*	<0.02	0.02*	-	-	<0.02	0.02*		
Meat[(b)]	<0.02		<0.02		-		<0.02			
Liver	<0.02	0.02*	<0.02	0.02*	-	-	<0.02	0.02*		
Kidney	<0.02	0.02*	<0.02	0.02*	-	-	n.a.	0.02*		
Milk[(a)]	<0.02	0.02*	<0.02	0.02*						
Eggs							<0.02	0.02*		
Method of calculation[(c)]	No measurements at feeding level 1, but residue levels deduced from non-detectable residues at feeding level 2 for liver and feeding level 3 for other		See cattle		Not required (insignificant intake)		No residues of either isomer pair of metconazole (*cis*- and *trans*-) detected at lowest feeding level (LOD=0.01 mg/kg for each isomer pair)		Not required (insignificant intake)	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Section 3 Residues

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)

OECD Guideline 505 and OECD Guidance, series on pesticides No 73

MRL calculations	Ruminant		Pig/Swine	Poultry	Fish
	matrices (LOD=0.01 mg/kg for each isomer pair of metconazole)				

(a): Estimated HR calculated at 1N level (**estimated mean level for milk**).
(b): HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry
(c): The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

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Rapporteur Member State	Month and year	Active Substance (Name)
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Section 3 Residues

STMR calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Median expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.007	Ram/Ewe	0.018	Breeding	0.001	Broiler	0.002	Carp	0.066 (max.)
	Dairy cattle	0.011	Lamb	0.023	Finishing	0.001	Layer	0.009	Trout	0.062 (max.)
							Turkey	0.002		
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level 1 0.20	Beef: 29 N Dairy: 18 N	Level 1 0.20	Lamb: 11N Ewe: 8.7N	Level	N rate Breed/Finish	Level 1 0.15	B or T: 75N Layer: 17N	Level	N rate Carp/Trout
	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N
Muscle	<0.02	0.02*	<0.02	0.02*	-	-	<0.02	0.02*		
Fat	<0.02	0.02*	<0.02	0.02*	-	-	<0.02	0.02*		
Meat[(a)]	<0.02	0.02*	<0.02	0.02*	-	-	<0.02	0.02*		
Liver	<0.02	0.02*	<0.02	0.02*	-	-	<0.02	0.02*		
Kidney	<0.02	0.02*	<0.02	0.02*	-	-	<0.02	0.02*		
Milk	<0.02	0.02*	<0.02	0.02*						
Eggs							<0.02	0.02*		
Method of calculation[(c)]	No measurements at feeding level 1, but residue levels deduced from non-detectable residues at feeding level 2 for liver and feeding level 3 for other matrices (LOD=0.01 mg/kg for each isomer pair of metconazole)		See cattle		Not required (insignificant intake)		No residues of either isomer pair of metconazole (*cis*- and *trans*-) detected at lowest feeding level (LOD 0.01 mg/kg for each isomer pair)		Not required (insignificant intake)	

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

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Rapporteur Member State	Month and year	Active Substance (Name)
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Section 3 Residues

Conversion Factors (CF) for monitoring to risk assessment

Not applicable

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

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

Crop (RAC)/Edible part or Crop (RAC)/Processed product	Number of studies[a]	Processing Factor (PF)		Conversion Factor (CF_P) for RA[b]
		Individual values	Median PF	
Representative uses				
Oilseed rape, meal	4	0.91, 1.09, 1.00, 0.92	0.96	N/A
Oilseed rape, crude oil	4	1.61, 1.57, 1.60, 1.79	1.61	N/A
Oilseed rape, refined oil	4	1.61, 1.47, 1.60, 1.79	1.61	N/A
Oilseed rape, soapstock	4	0.28, 0.21, 0.30, 0.21	0.25	N/A
Oilseed rape, press cake	4	1.22, 1.26, 1.30, 1.21	1.24	N/A
Wheat, cleaned grain	4	0.94, 1.13, 0.89, 0.90	0.92	N/A
Wheat, epidermis/husk	4	29, 56, 347, 53	55	N/A
Wheat, coarse bran	4	2.0, 1.6, 1.8, 2.1	1.9	N/A
Wheat, fine bran	4	2.2, 1.6, 2.1, 1.8	2.0	N/A
Wheat, middlings	4	0.81, 1.1, 5.1, 0.98	1.1	N/A
Wheat, shorts	4	2.2, 2.4, 2.2, 1.5	2.2	N/A
Wheat, germ	4	0.92, 0.64, 1.2, 1.1	1.0	N/A
Wheat, straight flour	4	0.14, 0.14, 0.31, 0.23	0.19	N/A
Wheat, low grade meal	4	0.66, 0.78, 0.81, 0.56	0.72	N/A
Wheat, whole meal flour	4	0.91, 0.60, 0.88, 0.39	0.74 [1)]	N/A
Wheat, flour type 550	4	0.18, 0.21, 0.42, 0.24	0.23	N/A
Wheat, bread	4	0.63, 0.44, 0.70, 0.58	0.61	N/A
Barley, pot barley	4	0.47, 0.51, 0.54, 0.09	0.51 [2)]	N/A
Barley, flour	4	1.54, 2.29, 2.83, 2.89	2.6	N/A
Barley, bran	4	2.56, 2.71, 4.04, 4.89	3.4	N/A
Barley, beer	4	<0.13, <0.07, <0.42, <0.002	<0.1	N/A
Brewer's grain (dried)	4	2.18, 1.93, 2.17, 0.38	2.2 [2)]	N/A
Brewer's yeast	4	0.37, 0.19, 0.54, 0.05	0.28	N/A
Oat, flour	4	0.14, 0.22, 0.20, 0.16	0.18	N/A
Oat, groats/rolled oats	4	0.07, 0.17, 0.12, <0.15	0.13	N/A
Oat, husks	4	2.21, 4.44, 4.00, 2.09	3.1	N/A
Oat, dust	4	1.64, 4.60, 3.73, 4.03	3.9	N/A
Oat, bran	4	0.16, 0.43, 0.50, 0.31	0.37	N/A

[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
N/A Not applicable

1) A slightly different processing factor of 0.75 was previously proposed by EFSA in the framework of the MRL review (EFSA 2011), on the basis of the same study; the slight difference is due to rounding.
2) Three values used for determining the median. Value underlined was considered not consistent with other values.

List of end points

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Section 3 Residues

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

Including all uses (representative uses and uses related to an MRL application).

ADI	(1) Metconazole: 0.01 mg/kg bw per day (2) TA & TLA: 0.3 mg/kg bw per day (3) TAA: 1.0 mg/kg bw per day (4) T: 0.023 mg/kg bw per day
TMDI according to EFSA PRIMo	Not applicable; see representative uses
NTMDI, according to (to be specified)	Not applicable
IEDI (% ADI), according to EFSA PRIMo	Not applicable; see representative uses
NEDI (% ADI), according to (to be specified)	Not applicable
Factors included in the calculations	Not applicable; see representative uses
ARfD	(1) Metconazole: 0.01 mg/kg bw (2) TA & TLA: 0.3 mg/kg bw (3) TAA: 1.0 mg/kg bw (4) T: 0.1 mg/kg bw
IESTI (% ARfD), according to EFSA PRIMo	Not applicable
NESTI (% ARfD), according to (to be specified)	Not applicable; see representative uses
Factors included in IESTI and NESTI	Not applicable; see representative uses

Consumer risk assessment limited to the representative uses

TMDI (% ADI), according to EFSA PRIMo (rev.2)	Highest TMDI: (1) 16 % ADI (DK child)
NTMDI (% ADI), according to (to be specified)	Not applicable
IEDI (% ADI), according to EFSA PRIMo (rev.2)	Highest IEDI: (1) 8.9 % ADI (FR toddler) (2) < 1% ADI (3) < 1% ADI (4) ***OPEN***
NEDI (% ADI), according to (to be specified)	Not applicable
Factors included in the calculations	TDMI calculation: EU MRLs IEDI calculation: (1) STMR (plant), EU MRL (animal) (2) - (3) STMR (plant) (4) *not applicable*
IESTI (% ARfD, according to EFSA PRIMo rev.2)	Highest IESTI: (1) 24.8 % ARfD (milk and milk products, UK infant) (2) < 1% ARfD (3) < 1% ARfD ***(4) OPEN***

List of end points

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Section 3 Residues

NESTI (% ARfD, according to (to be specified)	Not applicable
Factors included in IESTI and NESTI	(1) Metconazole: HR (plant), EU MRL (animal) (2) Sum of TA and TLA: HR (3) TAA: HR *(4) Not applicable*

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	0.2	Retain current EU MRL
0500010	Barley	0.4	Retain current EU MRL
0500050	Oat	0.4	Retain current EU MRL (extrapolated from barley)
0500070	Rye	0.06	Retain current EU MRL (extrapolated from wheat)
0500090	Wheat	0.15	Retain current EU MRL (based on import tolerance)
Animal commodities			
1000000-1030990	Products of animal origin – terrestrial animals	0.02*	Retain current EU MRL
1040000	Honey	0.05*	Retain current EU MRL

(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.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
Belgium	January 2018	Metconazole

Section 4 Environmental fate and behaviour

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	10.30 % after 120 d, [^{14}C-3,5-triazole]-metconazole (n= 1) 14.1 % after 119 d, [^{14}C-phenyl]-metconazole (n= 1) 1.1 % after 119 d, [^{14}C-3,5-triazole]-metconazole (n= 1)
Non-extractable residues after 100 days	39.24 % after 120 d, [^{14}C-3,5-triazole]-metconazole (n= 1) 12.5-28.3 % after 112 d, [^{14}C-cyclopentanol]-label (n= 5) 23.1 % after 119 d, [phenyl-^{14}C]-metconazole (n= 1) 41.7 % after 119 d, [^{14}C-3,5-triazole]-metconazole (n= 1)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	Polar fraction assigned to 1,2,4-triazole: 9.1% after 120 d [^{14}C-3,5-triazole]-metconazole (n= 1) Sterile conditions: No data available

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

Mineralisation after 100 days	0.26 % after 120 d, [^{14}C-3,5-triazole]-metconazole (n= 1) 2.9 % after 30 days aerobic + 119 days anaerobic conditions, [^{14}C-phenyl]-metconazole (n= 1)
Non-extractable residues after 100 days	8.58 % after 120 d, [^{14}C-3,5-triazole]-metconazole (n= 1) 19.4 % after 30 days aerobic + 119 days anaerobic conditions, [^{14}C-phenyl]-metconazole (n= 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No chromatographically resolved metabolite exceeding 5% AR Sterile conditions: No data available

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)	Unknown 1 – 5.5 and 5.0 % after 10 and 15 d, respectively (n= 1) [^{14}C-3,5-triazole]-metconazole Unknown 4 – 5.8 and 6.7 % after 2 and 4 d, respectively (n= 1) [^{14}C-3,5-triazole]-metconazole
Mineralisation at study end	< 0.05 % after 30 d, [^{14}C-3,5-triazole]-metconazole (n= 1) 1 % after 15 d, [^{14}C-3,5-triazole]-metconazole (n= 1) 1.5 % after 15 d, [^{14}C-phenyl]-metconazole (n= 1)

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Non-extractable residues at study end	0.8 % after 15 d, [^{14}C-3,5-triazole]-metconazole (n= 1) 7.8 % after 30 d, [^{14}C-3,5-triazole]-metconazole (n= 1) 9 % after 15 d, [^{14}C-3,5-triazole]-metconazole (n= 1) 7.4 % after 15 d, [^{14}C-phenyl]-metconazole (n= 1) 9 % after 15 d, [^{14}C-3,5-triazole]-metconazole (n= 1)

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)

Parent	Dark aerobic conditions						
Soil type	*X*[6]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa[d)]	St. (χ^2) [e)]	Method of calculation [e)]
Sandy loam (Bog Farm, Study No. MK-620-002)		7.4[a)]	22/40	251.5/906.8	198.4	0.9/2.3	DFOP/SFO
Silty clay loam (Chesnut Street, Study No. MK-620-002)		8.0[a)]	22/40	184.1/681.8	124.8	1.0/2.8	DFOP/SFO
Sandy loam II (Elm Farm, Study No. MK-620-002)		6.7[a)]	22/40	558.0/>1000	143.7	2.7/5.2	FOMC/SFO
Clay (Woodstock, Study No. MK-620-002)		6.6[a)]	22/40	249.8/908.2	162.4	0.5/2.3	FOMC/SFO
Sand (Speyer soil 2.2, Study No. MK-620-002)		5.3[a)]	22/40	>1000/>1000	568.6	1.3/2.1	FOMC/SFO
Sandy loam (Ipswitch, Study No. MK-620-020)		6.8[b)]	20/50	87.7/291.3	69.0	4.3/4.3	SFO/SFO
Sandy loam (LUFA 5M, Study No. 2014/1000901)		7.4[c)]	20/45	128.4/426.6	93.9	1.23/1.23	SFO/SFO
Geometric mean (if not pH dependent)					154.8		
pH dependence					No		

[a)] No method stated for pH measurement in the study report
[b)] Measured in KCl 100 mM
[c)] Measured in $CaCl_2$
[d)] Normalised using a Q_{10} of 2.58 and Walker equation coefficient of 0.7

[6] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

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[e] χ^2 error level and method of calculation (kinetic model) are provided for trigger endpoints (actual DT_{50}/DT_{90}) and modelling endpoints (normalised DT_{50}), respectively)

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)

1,2,4-triazole	Dark aerobic conditions. Metabolite applied as parent.							
Soil type	*X*[7]	pH[b]	t. °C / % MWHC	DT_{50} fast phase/ DT_{50} slow phase [c] (d)/ g	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C [d]	St. (χ^2)	Method of calculation
Sandy loam (Laacherhof aXXa, Slangen, 2000) [a]		6.4	20/40	0.9/ 59.2/ 0.683	na [e]	na [e]	na [e]	DFOP
Loamy sand (BBA 2.2, Slangen, 2000) [a]		5.8	20/40	1.5/247.6/0.580	na [e]	na [e]	na [e]	DFOP
Silt loam (Laacherhof A III, Slangen, 2000) [a]		6.7	20/40	0.8/20.6/0.443	na [e]	na [e]	na [e]	DFOP
Geometric mean (if not pH dependent)				1.0/67.1/0.569				DFOP
Arithmetic mean					na			
pH dependence						No		

[a] Endpoints validated at EU level (CRD (2014): Triazole Derived Metabolite: 1,2,4-Triazole, Proposed revision to DT_{50}. Summary, Scientific Evaluation and Assessment, July 2011, revised September 2011 and January 2013, 24 Oct 2014)
[b] Measured in $CaCl_2$
[c] Remark: slow phase DFOP values are significantly longer than those agreed at PRAPeR 12
[d] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[e] na: Not available

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 (indicate if bare or cropped soil was used).	Location (country or USA state).	Appl. Rate (g a.s./ha)	pH [a]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm [b].	Method of calculation
Silty loam (bare soil, Study No. MK-790-11))	Schwabenheim, Germany	225	5.7	10	40	442	na	- [i]	Square root first order
Silty clay loam (bare soil, Study No. MK-790-11))	Kloppenheim, Germany	225	6.1	10	33	363	na	- [i]	Square root first order

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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 (indicate if bare or cropped soil was used).	Location (country or USA state).	Appl. Rate (g a.s./ha)	pH [a)]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm [b)].	Method of calculation
Sandy clay loam (bare soil, Study No. MK-790-12)	Biscester, UK	225	6.1 [a]	10	34	370	na	- [i)]	Square root first order
Sandy loam (bare soil, Study No. MK-790-12)	Horncastle, UK	225	7.2 [a]	10	138	457	na	- [i)]	First order
Clay loam (bare soil, Study No. MK-620-010)	Hoath, UK	175	8.0 [a]	15	133	434 [d)]	na	- [i)]	First order
		350			182	609 [e)]			
		250			161	539 [f)]			
		350			147	483 [g)]			
Sandy loam (bare soil, Study No. MK-620-010)	Reculver, UK	175	4.1 [a]	15	112	371 [d)]	na	- [i)]	First order
		350			203	665 [e)]			
		250			231	770 [f)]			
		350			259	854 [g)]			
Sandy silt loam (bare soil, Study No. MK-620-010)	Quincieux, France	175	na [a]	15	28	98 [d)]	na	- [i)]	First order
		350			28	98 [e)]			
		250			7	28 [f)]			
		350			14	42 [g)]			
Silty clay loam (bare soil, Study No. MK-620-010)	Espiet, France	175	na [a]	15	70	238 [d)]	na	- [i)]	First order
		350			70	238 [e)]			
		250			70	231 [f)]			
		350			49	168 [g)]			
Sandy loam (bare soil, Study No. MK-620-010)	Schwabenheim, Germany	175	7.5 [a]	15	77	259 [d)]	na	- [i)]	First order
		350			154	504 [e)]			
		250			133	441 [f)]			
		350			112	371 [g)]			
Silty clay loam (bare soil, Study No. MK-620-010)	Schonau, Germany	175	7.0 [a]	15	70	224 [d)]	na	- [i)]	First order
		350			91	287 [e)]			
		250			56	189 [f)]			
		350			56	189 [g)]			

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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 (indicate if bare or cropped soil was used).	Location (country or USA state).	Appl. Rate (g a.s./ha)	pH [a)]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm [b)].	Method of calculation
Sandy loam (soil covered with a sand layer, Study No. 2015/1137154)	Bogense, Denmark	90	6.29 [b]	50	202.8 [k)]	673.7 [k)]	18.1/ 12.5	57.5	SFO/SFO
Loamy sand (soil covered with a sand layer, Study No. 2015/1137154)	Brunne, Germany	90	5.01 [b]	50	258.5 [k)]	858.6 [k)]	13.2/ 6.4	80.3	SFO/SFO
Silt loam (soil covered with a sand layer, Study No. 2015/1137154)	Goch-Nierswalde, Germany	90	6.55 [b]	50	152.4 [k)]	506.1 [k)]	17.0/ 11.8	73.4	SFO/SFO
Silt (soil covered with a sand layer, Study No. 2015/1137154)	Schaeffershei, France	90	7.63 [b]	50	31.0 [k)]	102.9 [k)]	8.3/5 .6	26.6	SFO/SFO
Silt loam (soil covered with a sand layer, Study No. 2015/1137154)	Poggio Renatico, Italy	90	7.75 [b]	50	449.2 [k)]	>1000 [k)]	7.8/8 .7	368.5	SFO/SFO
Sand (soil covered with a sand layer, Study No. 2015/1137154)	Utrera, Spain	90	7.33 [b]	50	136.3 [k)]	452.8 [k)]	14.3/ 17.5	202.0	SFO/SFO
Geometric mean (if not pH dependent)								93.6	
pH dependence					No				

[a)] Measured in: [a]: no information on the method is available; [b]: $CaCl_2$
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix
[c)] Calculated from organic matter (OM) content by OC = OM/1.724
[d)] Formulation 60 g/L SL, dose rate 175 g a.s./ha
[e)] Formulation 60 g/L SL, dose rate 350 g a.s./ha
[f)] Formulation 100 g/L SL, dose rate 250 g a.s./ha
[g)] Formulation 100 g/L SL, dose rate 350 g a.s./ha
[h)] All degradation half-lives for Study No. MK-620-010 (Davies, 1993) are given in weeks in original study report and multiplied by 7 for $DisT_{50}$/$DisT_{90}$ in days.
[i)] It was stated by EFSA that for the exposure assessment only the worst-case non-normalized value should be used. Due to the poor data quality no normalization of the data could be performed. Nevertheless, the study results are considered suitable for derivation of persistence endpoints.
[kj)] Covered field dissipation study. Only to derive modelling endpoints in the soil matrix, excluding surface loss processes [EFSA (2010): EFSA Panel on Plant Protection Products: Guidance for evaluating laboratory and field dissipation studies to obtain $DegT_{50}$ values on plant protection products in soil. EFSA Journal 2010:8(12):1936, 67 pp]. Best-fit endpoints should not be used as triggers for additional work.

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Bold: worst-case $DisT_{50}$ for modelling.

1,2,4-triazole [d]	Aerobic conditions Metabolite dosed as parent. Kinetic assessment for ambient conditions. Grass sown immediately after application (with exception of Spain site where no grass was sown).

Soil type	Location	pH[a]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm[b].	f. f. k_f / k_{dp}	Method of calculation
Silt loam (CRD, 2014)	Burscheid, Germany	6.4	0-30	7.8	366.7	15.2	See below	-	FOMC
Silty clay loam (CRD, 2014)	Albaro, Italy	7.6	0-40	21.2	207.4	10.7		-	DFOP
Sandy loam (CRD, 2014)	Little Shelford, UK	7.4	0-40	6.8	109.3	17.8		-	DFOP
Loam (CRD, 2014)	Vilobi d'Onyar, Spain	5.8	0-30	28.1	717.6	13.3		-	DFOP
Geometric mean (if not pH dependent)							-		
Arithmetic mean								-	
pH dependence					No				

[a] Measured in $CaCl_2$
[b] Agreed endpoints
[c] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 values are $DegT_{50}$matrix
[d] Endpoints for 1,2,4-triazole accepted at EU level [CRD (2014): Triazole Derived Metabolite: 1,2,4-Triazole. Proposed revision to DT50 Summary, Scientific evaluation and Assessment July 2011, revised September 2011 (after comments from MS and EFSA) and further revised January 2013 (minor clarifications added post-commenting), 24 Oct. 2014]

1,2,4-triazole [d]	Aerobic conditions Metabolite dosed as parent. Kinetics calculated timestep normalised to 20°C and pF2 moisture. Grass sown immediately after application (with exception of Spain site where no grass was sown).

Soil type	Location	pH [a]	Depth (cm)	DT_{50} [b] (d) Fast phase	DT_{50} [b] (d) Slow phase	'g'	St (χ^2)	Method of calculation
Silt loam (CRD, 2014)	Burscheid, Germany	6.4	0-30	2.5	70.7	0.655	18.8	DFOP
Silty clay loam (CRD, 2014)	Albaro, Italy	7.6	0-40	1.4	59.8	0.364	10.6	DFOP
Sandy loam (CRD, 2014)	Little Shelford, UK	7.4	0-40	0.5	25.1	0.458	18.1	DFOP
Loam (CRD, 2014)	Vilobi d'Onyar, Spain	5.8	0-30	4.6	126.0	0.489	12.7	DFOP
Geometric mean ('g' value is arithmetic mean)				1.68	60.5	0.489		DFOP

Measured in $CaCl_2$ solution

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[b)] Agreed endpoints
[c)] Endpoints for 1,2,4-triazole accepted at EU level [CRD (2014): Triazole Derived Metabolite: 1,2,4-Triazole. Proposed revision to DT50 Summary, Scientific evaluation and Assessment July 2011, revised September 2011 (after comments from MS and EFSA) and further revised January 2013 (minor clarifications added post-commenting), 24 Oct. 2014]

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)	Metconazole: 93.6 d (geometric mean normalized field $DegT_{50}$)
Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)	1,2,4-triazole: DT_{50} = 1.68 d (fast phase) / 60.5 d (slow phase) (geometric mean normalized field DT_{50}), g = 0.489 (arithmetic mean normalized field DT_{50})
Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean	1,2,4-triazole from metconazole: f.f = 0.2836 Conservative formation fraction derived from model run with the degradation parameters of 1,2,4-triazole

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

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

Soil accumulation and plateau concentration	Metconazole: Accumulation concentration of 0.071 mg/kg after multiyear use (based on calculation: $PEC_{soil,\ accu}$ = $PEC_{soil,\ max}$ + $PEC_{plateau}$ = 0.058 mg/kg + 0.013 mg/kg) 1,2,4-triazole: Accumulation concentration of 0.001 mg/kg after multiyear use (based on calculation: $PEC_{soil,\ accu}$ = $PEC_{soil,\ max}$ + $PEC_{plateau}$ = 0.001 mg/kg + <0.001 mg/kg)

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	*X*[7]	pH[a)]	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C[b)]	St. (χ^2)	Method of calculation
Sandy loam (Ipswich (UK), Study No. MK-620-018)		6.5	20°C/ flooded	>120 (study duration)	Not calculated	-	No calculation

[7] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

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Sandy loam (Bromsgrove (UK), Study No. 2014/1000922)		5.7	20°C/ 19.9 % (= pF2) for 30 days before flooding	555 [c] / > 1000	555 [c]	1.9	SFO
Geometric mean (if not pH dependent)					Not calculated		

[a] Measured in KCl (Ipswitch), $CaCl_2$ (Bromsgrove)
[b] Normalised using a Q10 of 2.58
[c] Anaerobic incubation phase

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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)

Met 1	Dark anaerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was *xxx.*							
Soil type	*X*[10]	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
No metabolites > 5% were observed in any of the anaerobic soil metabolism studies.								
Geometric mean (if not pH dependent)								
Arithmetic mean								

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

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	*X*[8]	pH[a)]	t. °C / % MWHC	DT_{50} / DT_{90} (d) calculated at ??°N	St. (χ^2)	Method of calculation
Loamy sand (Speyer 2.2, Study No. MK-620-005)		6.0 [1)]	22°C / not given	DT_{50} of 63 days (light/dark cycle of 12 hours)		First-order
Loamy sand (Speyer 2.2, Study No. MK-620-013)		5.6 [1)]	20°C / not given	DT_{50} of 73 days (light/dark cycle of 12 hours)		Square-root second order kinetics
Loamy sand (Speyer 5M (Germany), Study No. 2014/1000923)		7.3 [2)]	22°C / 53.5% (pF2)	68.3/226.9 (continuous irradiation, intensity corresponding to that at 49°N)	1.1	SFO

a) Measured in [1)] Medium not stated; [2)] $CaCl_2$

[8] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

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

Parent							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Sand (Godstone, Study No. MK-620-003)	0.6	6.7 [1)]	-	-	9.6	1592	0.942
Sandy loam (Elm Farm, Study No. MK-620-003)	1.8	7.1 [1)]	-	-	21.9	1217	0.895
Silty clay (Woodstock, Study No. MK-620-003)	3.1	6.8 [1)]	-	-	31.6	1019	0.910
Loamy sand (Keycol, Study No. MK-620-003)	1.4	6.7 [1)]	-	-	17.0	1214	0.887
Silt loam (Engelstadt/Benz, Study No. MK-620-012)	2.24	7.4 [2)]	-	-	18.72	836	0.917
Sandy loam (Ingelheim Flur 43 Nr. 153 (“Moers”), Study No. MK-620-012)	1.33	7.6 [2)]	-	-	10.80	812	0.928
Loamy sand (Nieder-Ingelheim Auf dem Sand, Study No. MK-620-012)	0.74	7.1 [2)]	-	-	6.74	911	0.983
Silt loam (Schwabenheim Schlag III/B, Study No. MK-620-012)	1.09	5.9 [2)]	-	-	7.91	726	0.911
Loamy sand (Speyer 2.2, Study No. MK-620-012)	2.29	5.8 [2)]	-	-	39.35	1718	0.950
Geometric mean (if not pH dependent)*						1071	
Arithmetic mean (if not pH dependent)							0.925
pH dependence			No				

[a)] Measured in [1)] $CaCl_2$; [2)] method not stated

[b)] * Only relevant after implementation of the published EFSA guidance.

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)

1,2,4-triazole [b)]							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Silty clay (Alpaugh)	0.70	8.8	-	-	0.833	120	0.897
Clay loam (Hollister)	1.74	6.9	-	-	0.748	43	0.827

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Silty clay loam (Lawrenceville)	0.70	7.0	-	-	0.722	104	0.922
Geometric mean (if not pH dependent)*					0.756	89	
Arithmetic mean (if not pH dependent)							0.916
pH dependence, *Yes or No*	No						

a) Measured in $CaCl_2$

b) Endpoints for 1,2,4-triazole accepted at EU level (CRD (2014): Triazole Derived Metabolite: 1,2,4-Triazole. Proposed revision to DT_{50} Summary, Scientific Evaluation and Assessment July 2011, revised September 2011 (after comments from MS and EFSA) and further revised January 2013 (minor clarifications added post-commenting) 24 Oct. 2014)

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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): 200 mm Time period (d): 90 d Study No. MK-620-007
	Leachate: 0.54-0.87 % total residues/radioactivity in leachate (metconazole only) 92.0-93.66 % total residues/radioactivity retained in top 10 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	
	Not determined due to the lack of breakdown products in the leachate.

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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	The leaching risk of metconazole and its metabolites is addressed by PEC_{gw} calculations using results from degradation rate and adsorption/desorption studies.

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

Hydrolytic degradation of the active substance and metabolites > 10 %	Metconazole was stable for all pH values tested (4, 7, 9) at 50°C No metabolites were formed Study No. MK-322-001

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 %	Study No. MK-324-003: DT_{50} : 83 days at pH 7 (continuous irradiation, xenon arc light source with UV filter, 20°C) Study No. 2014/1000925: DT_{50} : no degradation at pH 7 (continuous irradiation, xenon arc light source with UV filter, 22°C)
Quantum yield of direct phototransformation in water at Σ > 290 nm	$2.19 \cdot 10^{-7}$ mol · Einstein $^{-1}$ (Study No. MK-324-003) No quantum yield calculated (metconazole stable) (Study No. 2014/1000925)

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

Readily biodegradable (yes/no)	No (Studies No. MK-690-001 and MK-690-002)

List of end points

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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 (indicate fresh, estuarine or marine)	pH water phase	pH sed [a]	t. °C[b]	DT_{50} /DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50} /DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to *x* °C[c]		At study temp	Normalised to x °C[c]		
Fresh river water (low concentration: 10 µg/L metconazole), phenyl- and triazole-label, Study No. 2014/1000924	8.04	7.1	20	Not performed			Parent stable [d]			
Fresh river water (high concentration: 100 µg/L metconazole), phenyl- and triazole-label, Study No. 2014/1000924	8.04	7.1	20	Not performed			Parent stable [d]			

[a] Measured in $CaCl_2$
[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 the environmental media at the point of sampling. (note temp of x should be stated)
[d] Parent (metconazole) stable; no degradation rate calculated

Metabolite *X*	No metabolite > 1.8% AR									
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed [a]	t. °C[b]	DT_{50} /DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50} /DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to x °C[c]		At study temp	Normalised to x °C[c]		

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Fresh river water (low concentration: 10 µg/L metconazole), phenyl- and triazole-label, Study No. 2014/1000924	8.04	7.1	20	Not performed						
Fresh river water (high concentration: 100 µg/L metconazole), phenyl- and triazole-label, Study No. 2014/1000924	8.04	7.1	20	Not performed						

[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 the environmental media at the point of sampling. (note temp of x should be stated).

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Mineralisation and non extractable residues (for parent dosed experiments)					
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed	Mineralisation *x* % after *n* d. (end of the study).	Non-extractable residues. max *x* % after *n* d (suspended sediment test)	Non-extractable residues. max *x* % after *n* d (end of the study) (suspended sediment test)
Fresh river water (low concentration: 10 µg/L metconazole), phenyl- and triazole-label, Study No. 2014/1000924	8.04	7.1	3.1 (phenyl-label) 0.4 (triazole-label)	Not applicable	Not applicable
Fresh river water (high concentration: 100 µg/L metconazole), phenyl- and triazole-label, Study No. 2014/1000924	8.04	7.1	3.7 (phenyl-label) 0.2 (triazole-label)	Not applicable	Not applicable

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	Study No. MK-630-002: max. in water: 1.6-23.7% after 100 d, 2.7-24.3% after 182 d. Max. in sediment: 72.5-97.9% after 100 d, 68.0-96.5% after 182 d. Study No. 2014/1000921: max. in water: 2.4-4.6% after 99 d. Max. in sediment: 79.7-84.1% after 29-60 d, 76.6-83.6% after 99 d.									
Water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Hellersberger Weiher pond (Study No. MK-630-002, $DT_{50/90}$ from Study No. MK-630-006)	7.7	7.4	20	814/ >1000	-	1/3 Rice	-	Not calculated	-	First order/first order/-
Glan river (Study No. MK-630-002, $DT_{50/90}$ from Study No. MK-630-006)	7.8	6.8	20	116/384	-	13/112	-	Not calculated	-	First order/biphasic first order/-

Calwich Abbey Lake (Study No. 2014/1000921)	8.51	7.2	20	660.4/ >1000	2.1	2.9/55.6	1.0	Not calculated	-	SFO/DFOP/ -
Swiss Lake (Study No. 2014/1000921)	7.06	5.2	20	306.7/ >1000	1.6	3.9/52.1	6.6	Not calculated	-	SFO/HS/-
Geometric mean at 20°C[b)]										

[a)] Measured in $CaCl_2$
[b)] Normalised using a Q10 of 2.58

Parent										
Water/sediment system	pH water phase	pH sed [a)]	t. °C	Modeling DT_{50} /DT_{90} whole syst [c)]	St. (χ^2)	Modeling $DisT_{50}$ Water [d)]	St. (χ^2)	Modeling $DisT_{50}$ Sed [d)]	St. (χ^2)	Method of calculation
Hellersberger Weiher pond (Study No. MK-630-002, $DT_{50/90}$ from Study No. 2014/1010791)	7.7	7.4	20	777.5	8.9	1.4[e)]	5.9	369.4	3.3	SFO/HS/SFO
Glan river (Study No. MK-630-002, $DT_{50/90}$ from Study No. 2014/1010791)	7.8	6.8	20	138.0	4.0	28.5[e)]	7.0	213.0	4.5	SFO/DFOP/ SFO
Calwich Abbey Lake (Study No. 2014/1000921)	8.51	7.2	20	660.4	2.1	16.7 [e)]	1.0	Not calculated	-	SFO/DFOP/ -
Swiss Lake (Study No. 2014/1000921)	7.06	5.2	20	306.7	1.6	15.7 [e)]	6.6	Not calculated	-	SFO/HS/-
Geometric mean at 20°C[b)]				384.0		Not calculated		Not calculated		

[a)] Measured in $CaCl_2$
[b)] Normalised using a Q10 of 2.58
[c)] Degradation rate
[d)] Dissipation rate
[e)] Calculated as $DisT_{90}$ / 3.32 as required by FOCUS kinetics (less than 10% of initial concentration at end of study)

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Metabolite M555F013 (M555F013cis, M13, CL359139, Reg. No. 4543816)	Distribution (max in water 9% and 8.5% after 152 and 182 d, respectively. Max. sed 1.9% and 1.8% after 152 and 182 d, respectively). Max in total system 10.9% after 152 days, kinetic formation fraction (k_f/k_{dp}): no kinetic evaluation conducted, no formation fraction available Study No. MK-630-002									
Water / sediment system	pH water phase	pH sed [a]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
	Not calculated since no dissipation of the metabolite was observed									
Geometric mean at 20°C[b]										

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

Mineralisation and non extractable residues (from parent dosed experiments)					
Water / sediment system	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Hellersberger Weiher pond (Study No. MK-630-002)	7.7	7.4	No CO_2 detected over the 182 day incubation period	28.5% after 14 d	11.8% after 100 d 14.6% after 182 d
Glan river (Study No. MK-630-002)	7.8	6.8	No CO_2 detected over the 182 day incubation period	19.7% after 182 d	18.9% after 100 d 19.7% after 182 d
Calwich Abbey Lake (Study No. 2014/1000921)	8.51	7.2	1.2% after 99 d	12.9% after 99 d	12.9% after 99 d
Swiss Lake (Study No. 2014/1000921)	7.06	5.2	0.9% after 99 d	19.9% after 99 d	19.9% after 99 d

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

Direct photolysis in air	Please see below
Photochemical oxidative degradation in air	DT_{50} of 6.5 hours derived by the Atkinson model. OH (12 h) concentration assumed = 1.5×10^6 mol. cm^{-3}
Volatilisation	from plant surfaces (BBA guideline No. IV, 6-1, of July 1990): 87 % remained on the plants (beans) after 24 hours Study No MK-640-005

	from soil surfaces (BBA guideline No. IV, 6-1, of July 1990): 86 % remained in the soil after 24 hours Study No MK-640-005
Metabolites	None

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: Metconazole (sum cis/trans) and its aerobic soil metabolite M555F020 (1,2,4-triazole) Surface water: Metconazole (sum cis/trans) and its metabolites M555F013 cis, M555F020 (1,2,4-triazole) Sediment: Metconazole (sum cis/trans) and its metabolites M555F013 cis, M555F020 (1,2,4-triazole) Ground water: Metconazole (sum cis/trans) and its aerobic soil metabolite M555F020 (1,2,4-triazole). Air: Metconazole (sum cis/trans)

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)	No data available
Surface water (indicate location and type of study)	USA, environmental monitoring of various pesticides in US streams Measurement of metconazole in periods around occurrences of soybean rust: a concentration of <0.01 µg/L was detected once. Metabolites were not determined.
Ground water (indicate location and type of study)	No data available
Air (indicate location and type of study)	No data available

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

Parent Method of calculation	DT_{50} (d): 259 days Kinetics: SFO Field or Lab: representative non-normalised worst case from field studies (Davies, 1991/1992, 1993, trial Reculver, UK)
Application data	Crop: winter oil seed rape (autumn application) as worst-case scenario for risk envelope covering all other uses Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 40 (BBCH 13 to 20) / 80 (BBCH 21 to 71) Number of applications: 2 Interval (d): 150 d Application rate(s): 2 x 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		Not calculated [a)]		0.058	
Short term	24h	Not calculated [a)]	Not calculated [a)]	0.058	0.058
	2d	Not calculated [a)]	Not calculated [a)]	0.057	0.058
	4d	Not calculated [a)]	Not calculated [a)]	0.057	0.057
Long term	7d	Not calculated [a)]	Not calculated [a)]	0.057	0.057
	28d	Not calculated [a)]	Not calculated [a)]	0.054	0.056
	50d	Not calculated [a)]	Not calculated [a)]	0.051	0.054
	100d	Not calculated [a)]	Not calculated [a)]	0.051	0.051
Plateau concentration		0.071 mg/kg after multi-year use [b)]			

[a)] Only values for the multiple application are reported as worst-case
[b)] Assuming $PEC_{soil,accu} = PEC_{soil,plateau} + PEC_{soil,max} = 0.013 + 0.058$ mg/kg

1,2,4-Triazole Method of calculation	Molecular weight relative to the parent: 0.216 DT_{50} (d): 28.1 days ($k1 = 0.0632\ d^{-1}$, $k2 = 0.0020\ d^{-1}$, g = 0.5732) Kinetics: DFOP Field or Lab: non-normalised worst case from field studies.
Application data	Application rate assumed: 2 x 1.4 g/ha (assumed 1,2,4-

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			triazole is formed at a maximum of 9.1 % 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				0.001	
Short term	24h	Not calculated [a)]	Not calculated [a)]	Not reported [b)]	Not reported [b)]
	2d	Not calculated [a)]	Not calculated [a)]	Not reported [b)]	Not reported [b)]
	4d	Not calculated [a)]	Not calculated [a)]	Not reported [b)]	Not reported [b)]
Long term	7d	Not calculated [a)]	Not calculated [a)]	Not reported [b)]	Not reported [b)]
	28d	Not calculated [a)]	Not calculated [a)]	Not reported [b)]	Not reported [b)]
	50d	Not calculated [a)]	Not calculated [a)]	Not reported [b)]	Not reported [b)]
	100d	Not calculated [a)]	Not calculated [a)]	Not reported [b)]	Not reported [b)]
Plateau concentration		0.001 mg/kg after multi-year use [c)]			

[a)] Only values for multiple application are reported as worst-case
[b)] Only maximum values are reported which can be considered as worst-case estimates of short-term and long-term exposure
[c)] Assuming $PEC_{soil,accu} = PEC_{soil,plateau} + PEC_{soil,max} = <0.001 + 0.001$ mg/kg

List of end points

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Belgium	January 2018	Metconazole

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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 FOCUS gw scenarios, according to FOCUS guidance. Model(s) used: PEARL 4.4.4, PELMO 5.5.3, MACRO 5.5.4 Crop: winter cereals, spring cereals, winter oilseed rape **Substance parameters for metconazole** Crop uptake factor: 0.5 Water solubility (mg/L): 30.4 at pH 7 and 20°C Vapour pressure: 2.1 x 10^{-8} Pa at 20°C Geometric mean parent $DT_{50\ field}$ 93.6 d (n = 6, normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7). K_{OC}: geometric mean 1071 mL/g (n = 9), arithmetic mean $^1/_n$= 0.925 (n = 9) **Substance parameters for 1,2,4-triazole** Crop uptake factor: 0 Water solubility (mg/L): 700000 at pH 7 and 20°C Vapour pressure: 0.22 Pa at 20°C Geometric mean $DT_{50\ field}$ Fast degrading compartment 1.68 d Slow degrading compartment 60.5 d (n = 4, normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7). K_{OC}: geometric mean 89.0 mL/g (n = 4), arithmetic mean $^1/_n$= 0.916 (n = 4) Formation fraction from parent: 0.284
Application rate	**Cereals (winter/spring)** Gross application rate: 2 x 90 g/ha. Crop growth stage: BBCH 30 Canopy interception %: 80 / 80 Application rate net of interception: 2 x 18 g/ha. No. of applications: 2 Time of application (absolute or relative application dates): Winter cereals: First application set to 1st of May for the scenarios in Central Europe, to 15th of March for the scenarios in South Europe and to 1st of June for the scenario in North Europe. The subsequent application date was scheduled by the minimum application interval of 21 days.

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Spring cereals:

First application date at BBCH 30 was set to 28 days after emergence. The subsequent application date was scheduled by the minimum application interval of 21 days.

Winter oilseed rape (autumn/spring application)

Gross application rate: 2 x 72 g/ha.

Crop growth stage: BBCH 13 (autumn) / 21 (spring)

Canopy interception %: 40 / 80

Application rate net of interception: 43.2 + 14.4 g/ha.

No. of applications: 2

Time of application (absolute or relative application dates):

First application date at BBCH 13 set to 21 days after emergence. Second application date at BBCH 21 set to 15th of March and 15th of February for the scenarios in Central and South Europe, respectively.

Winter oilseed rape (spring application)

Gross application rate: 2 x 72 g/ha.

Crop growth stage: BBCH 21 (spring)

Canopy interception %: 80 / 80

Application rate net of interception: 2 x 14.4 g/ha.

No. of applications: 2

Time of application (absolute or relative application dates):

First application date at BBCH 21 set to 15th of March and 15th of February for the scenarios in Central and South Europe, respectively. The subsequent application date was scheduled by the minimum application interval of 14 days.

* Only relevant after implementation of the published EFSA guidance.

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

Metconazole				
	Scenario	PEC_{gw} (µg/L)		
		PEARL 4.4.4	PELMO 5.5.3	MACRO 5.5.4
Winter cereals	Châteaudun	<0.001	<0.001	<0.001
	Hamburg			- a)
	Jokioinen			
	Kremsmünster			
	Okehampton			
	Piacenza			
	Porto			
	Sevilla			
	Thiva			

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	Scenario	PEC_{gw} (µg/L)		
		PEARL 4.4.4	PELMO 5.5.3	MACRO 5.5.4
Spring cereals	Châteaudun	<0.001	<0.001	<0.001
	Hamburg			- a)
	Jokioinen			
	Kremsmünster			
	Okehampton			
	Porto			
	Scenario	PEC_{gw} (µg/L)		
		PEARL 4.4.4	PELMO 5.5.3	MACRO 5.5.4
Winter oilseed rape, autumn application	Châteaudun	<0.001	<0.001	<0.001
	Hamburg			- a)
	Kremsmünster			
	Okehampton			
	Piacenza			
	Porto			
	Scenario	PEC_{gw} (µg/L)		
		PEARL 4.4.4	PELMO 5.5.3	MACRO 5.5.4
Winter oilseed rape, spring application	Châteaudun	<0.001	<0.001	<0.001
	Hamburg			- a)
	Kremsmünster			
	Okehampton			
	Piacenza			
	Porto			

a) Scenario not defined for the model

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1,2,4-triazole				
	Scenario	PEC_{gw} (µg/L)		
		PEARL 4.4.4	PELMO 5.5.3	MACRO 5.5.4
Winter cereals	Châteaudun	0.001	0.001	<0.001
	Hamburg	0.006	0.007	- [a)]
	Jokioinen	0.002	0.003	
	Kremsmünster	0.004	0.004	
	Okehampton	0.006	0.007	
	Piacenza	0.003	0.004	
	Porto	0.003	0.005	
	Sevilla	<0.001	<0.001	
	Thiva	<0.001	<0.001	

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Spring cereals	Scenario	PEC_{gw} (µg/L)		
		PEARL 4.4.4	PELMO 5.5.3	MACRO 5.5.4
	Châteaudun	0.001	0.001	0.001
	Hamburg	0.007	0.006	- [a)]
	Jokioinen	0.002	0.002	
	Kremsmünster	0.004	0.004	
	Okehampton	0.006	0.005	
	Porto	0.003	0.004	
Winter oilseed rape, autumn application	Scenario	PEC_{gw} (µg/L)		
		PEARL 4.4.4	PELMO 5.5.3	MACRO 5.5.4
	Châteaudun	0.003	<0.001	0.003
	Hamburg	0.012		- [a)]
	Kremsmünster	0.008		
	Okehampton	0.011		
	Piacenza	0.005		
	Porto	0.007		
Winter oilseed rape, spring application	Scenario	PEC_{gw} (µg/L)		
		PEARL 4.4.4	PELMO 5.5.3	MACRO 5.5.4
	Châteaudun	0.001	0.001	<0.001
	Hamburg	0.005	0.005	- [a)]
	Kremsmünster	0.003	0.003	
	Okehampton	0.004	0.005	
	Piacenza	0.002	0.002	
	Porto	0.002	0.004	

[a)] Scenario not defined for the model

$PEC_{(gw)}$ From lysimeter / field studies

Parent	1st year	2nd year	3rd year
No data available			

1,2,4-triazole	1st year	2nd year	3rd year
No data available			

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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: FOCUS steps 1-2, version 3.2 Molecular weight (g/mol): 319.8 K_{OC}/K_{OM} (mL/g): 1071 (geomean, n = 9) DT_{50} soil (d): 93.6 days (geomean of normalised field $DegT_{50}$ values (20°C, pF2), n = 6) DT_{50} water/sediment system (d): 384.0 d (geomean of total system DT_{50} (Level P-I, n = 4)) DT_{50} water (d): 384.0 (geomean of total system DT_{50} (Level P-I, n = 4)) DT_{50} sediment (d): 384.0 (geomean of total system DT_{50} (Level P-I, n = 4)) Crop interception winter cereals (covering spring cereals) (%): 20 % (average crop cover) Crop interception winter oilseed rape, autumn application (covering spring application) (%): 40 % (minimum crop cover)
Parameters used in FOCUSsw step 3 and 4	Version control No.'s of FOCUS software: SWASH 5.3 in combination with MACRO 5.5.4, PRZM 4.3.1 and TOXSWA 4.4.3 Water solubility (mg/L): 30.4 Vapour pressure: 2.1 x 10^{-8} Pa at 20°C K_{OC}/K_{OM} (mL/g): 1071 (geomean, n = 9) 1/n: 0.925 (arithmetic mean, n = 9) DT_{50} water (d): 384.0 (geomean of total system DT_{50} (Level P-I, n = 4)) DT_{50} sediment (d): 1000, conservative assumption (default value) Q10=2.58, Walker equation coefficient 0.7 Crop uptake factor: 0.5 DT_{50} crop (d): Tier 1: 10 d (default); Tier 2 and 3: 2 d (cereals, n = 1), 8.7 d (winter oilseed rape, n = 1) Crop interception in MACRO adapted in Tier 3 (%): for cereals and winter oilseed rape (spring application) all interception values <80% were set to 80%; for winter oilseed rape (autumn application) all interception values <40% for the first application were set to 40% and values <80% for the second application were set to 80% (recommended values according to FOCUS for the respective BBCH stages).
Application rate	Crop and growth stage: **Cereals (winter)**

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BBCH 30-69

Number of applications: 1 - 2

Interval (d): 21

Application rate(s): single rate 90 g a.s./ha

Application window (single/multiple application):

First possible application date set to 1st of May for the scenarios in Central Europe, to 15th of March for the scenarios in South Europe and to 1st of June for the scenario in North Europe (Skousbo: set to 27.5. instead of 1.6. for appropriate length of application window 2-fold application). Last possible application date set to 35 days (PHI) before harvest.

Cereals (spring)

BBCH 30-69

Number of applications: 1 - 2

Interval (d): 21

Application rate(s): single rate 90 g a.s./ha

Application window (single/multiple application):

First possible application date set to 28 days after emergence. Last possible application date set to 35 days (PHI) before harvest.

Winter oilseed rape (autumn / spring application)

BBCH 13-20 (autumn) and 21-71 (spring)

Number of applications: 1 - 2

Interval (d): 150 (to account for interval between autumn and spring application)

Application rate(s): single rate 72 g a.s./ha

Application window (single/multiple application):

First possible application date set to 21 days after emergence. Last possible application date set to 56 days (PHI) before harvest.

Winter oilseed rape (spring application)

BBCH 21-71

Number of applications: 1 - 2

Interval (d): 14

Application rate(s): single rate 72 g a.s./ha

Application window (single/multiple application):

First possible application date set to 15th of April, 15th of March and 15th of February for the scenarios in North, Central and South Europe, respectively. Last possible application date set to 56 days (PHI) before harvest.

List of end points

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FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Winter cereals (twofold application), covering use in spring cereals	0 h	26.367		271.474	
	24 h	25.348	25.857	Not reported [a)]	Not reported [a)]
	2 d	25.302	25.591	Not reported [a)]	Not reported [a)]
	4 d	25.211	25.424	Not reported [a)]	Not reported [a)]
	7 d	25.075	25.303	Not reported [a)]	Not reported [a)]
	14 d	24.760	25.110	Not reported [a)]	Not reported [a)]
	21 d	24.449	24.941	Not reported [a)]	Not reported [a)]
	28 d	24.142	24.780	Not reported [a)]	Not reported [a)]
	42 d	23.540	24.466	Not reported [a)]	Not reported [a)]

[a)] Only initial values are reported as worst-case estimated of short-term and long-term exposure

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Winter cereals (twofold application), covering use in spring cereals Southern EU, Oct-Feb. (covering Northern EU)	0 h	7.855		82.437	
	24 h	7.697	7.776	Not reported [a)]	Not reported [a)]
	2 d	7.683	7.733	Not reported [a)]	Not reported [a)]
	4 d	7.656	7.701	Not reported [a)]	Not reported [a)]
	7 d	7.614	7.673	Not reported [a)]	Not reported [a)]
	14 d	7.519	7.620	Not reported [a)]	Not reported [a)]
	21 d	7.424	7.570	Not reported [a)]	Not reported [a)]
	28 d	7.331	7.522	Not reported [a)]	Not reported [a)]
	42 d	7.148	7.428	Not reported [a)]	Not reported [a)]

[a)] Only initial values are reported as worst-case estimated of short-term and long-term exposure

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Winter oilseed rape, autumn application (twofold application), covering spring application	0 h	21.094		217.179	
	24 h	20.278	20.686	Not reported [a)]	Not reported [a)]
	2 d	20.242	20.473	Not reported [a)]	Not reported [a)]
	4 d	20.169	20.339	Not reported [a)]	Not reported [a)]
	7 d	20.060	20.243	Not reported [a)]	Not reported [a)]
	14 d	19.808	20.088	Not reported [a)]	Not reported [a)]

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FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	21 d	19.559	19.953	Not reported [a)]	Not reported [a)]
	28 d	19.314	19.824	Not reported [a)]	Not reported [a)]
	42 d	18.832	19.573	Not reported [a)]	Not reported [a)]

[a)] Only initial values are reported as worst-case estimated of short-term and long-term exposure

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Winter oilseed rape, autumn application (twofold application), covering spring application Northern EU, Oct-Feb. (covering Southern EU)	0 h	4.352		45.420	
	24 h	4.241	4.296	Not reported [a)]	Not reported [a)]
	2 d	4.233	4.267	Not reported [a)]	Not reported [a)]
	4 d	4.218	4.246	Not reported [a)]	Not reported [a)]
	7 d	4.195	4.229	Not reported [a)]	Not reported [a)]
	14 d	4.143	4.199	Not reported [a)]	Not reported [a)]
	21 d	4.091	4.172	Not reported [a)]	Not reported [a)]
	28 d	4.039	4.145	Not reported [a)]	Not reported [a)]
	42 d	3.938	4.093	Not reported [a)]	Not reported [a)]

[a)] Only initial values are reported as worst-case estimated of short-term and long-term exposure

Maximum PECsw and PECsed values

Step 1 and 2

$FOCUS_{sw}$ Crop	**Step 1**		**Step 2**			
			$PEC_{sw,max}$ [µg L^{-1}]		**$PEC_{sed,max}$ [µg kg^{-1}]**	
	$PEC_{sw,max}$ [µg L^{-1}]	**$PEC_{sed,max}$ [µg kg^{-1}]**	**Single application**	**Multiple application**	**Single application**	**Multiple application**
Winter cereals [a]	26.367	271.474	4.260	7.855	44.654	82.437
Winter oilseed rape, autumn application [b]	21.094	217.179	3.216	4.352	33.672	45.420

[a] Worst-case application scenario covering use in spring cereals
[b] Worst-case application scenario covering spring application

Step 3 and 4

Spring cereals

	PEC_{sw} [µg L^{-1}] [a]	**$PEC_{sed,max}$**

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									[µg kg^{-1}] [a]
	Step 3		**Step 4**						**Step 3**
	Edge-of-Field		**05mD**		**10mD**		**10mD+R**		**Edge-of-Field**
	Max	**21d twa**	**Max**	**21d twa**	**Max**	**21d twa**	**Max**	**21d twa**	
Tier 1	1.227	1.143	1.227	1.143	1.227	1.143	1.227	1.143	13.060
Tier 2	0.919	0.719	0.775	0.718	0.775	0.718	0.775	0.718	not reported
Tier 3	0.811	0.584	0.241	0.176	0.193	0.168	not calculated		

D = Drift mitigation by no-spray buffer zones [m]
R = Runoff mitigation by vegetated filter strips [m]
[a] Worst-case scenario: D1 ditch, multiple application

Winter cereals

	PEC$_{sw}$ [µg L^{-1}] [a]								**PEC$_{sed,max}$ [µg kg^{-1}] [a]**
	Step 3		**Step 4**						**Step 3**
	Edge-of-Field		**05mD**		**10mD**		**10mD+R**		**Edge-of-Field**
	Max	**21d twa**	**Max**	**21d twa**	**Max**	**21d twa**	**Max**	**21d twa**	
Tier 1	2.065	*0.939*	2.065	*0.939*	2.065	*0.939*	2.065	*0.939*	11.510
Tier 2	1.635	0.731	1.635	0.727	1.635	0.727	1.635	0.727	not reported
Tier 3	*0.814*	*0.588*	0.589	*0.270*	0.589	*0.270*	not calculated		

D = Drift mitigation by no-spray buffer zones [m]
R = Runoff mitigation by vegetated filter strips [m]
[a] Worst-case scenario: D2 ditch, multiple application (regular font), D1 ditch, multiple application (*italic font*)

Winter oilseed rape, autumn application

	PEC$_{sw}$ [µg L^{-1}] [a]								**PEC$_{sed,max}$ [µg kg^{-1}] [a]**
	Step 3		**Step 4**						**Step 3**
	Edge-of-Field		**05mD**		**10mD**		**10mD+R**		**Edge-of-Field**
	Max	**21d twa**	**Max**	**21d twa**	**Max**	**21d twa**	**Max**	**21d twa**	
Tier 1	1.527	0.606	1.527	0.606	1.527	0.606	1.527	0.606	7.361
Tier 2	1.527	*0.606*	1.527	0.605	1.527	0.605	1.527	0.605	not reported
Tier 3	0.868	*0.405*	0.868	0.383	0.868	0.383	not calculated		

D = Drift mitigation by no-spray buffer zones [m]
R = Runoff mitigation by vegetated filter strips [m]
[a] Worst-case scenario: D2 ditch, multiple application (regular font), D2 ditch, single application (*italic font*)

Winter oilseed rape, spring application

	PEC$_{sw}$ [µg L^{-1}] [a]								**PEC$_{sed,max}$ [µg kg^{-1}] [a]**
	Step 3		**Step 4**						**Step 3**
	Edge-of-Field		**05mD**		**10mD**		**10mD+R**		**Edge-of-Field**
	Max	**21d**	**Max**	**21d**	**Max**	**21d**	**Max**	**21d**	

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		twa		twa		twa		twa	
Tier 1	1.605	0.710	1.605	0.710	1.605	0.710	1.605	0.710	9.569
Tier 2	1.587	0.702	1.587	0.702	1.587	0.702	1.587	0.702	not reported
Tier 3	0.808	0.355	0.808	0.334	0.808	0.334	not calculated		

D = Drift mitigation by no-spray buffer zones [m]
R = Runoff mitigation by vegetated filter strips [m]
[a] Worst-case scenario: D2 ditch, multiple application

Metabolite 1,2,4-triazole Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 69.1 Soil or water metabolite: soil metabolite Koc/Kom (mL/g): 89.0 (arithmetic mean, n = 4) DT_{50} soil (d): 60.50 (geometric mean of normalized field values, DFOP slow phase) DT_{50} water/sediment system (d): 1000 d (default worst-case, metabolite not detected in the water-sediment studies) DT_{50} water (d):1000 d (default value) DT_{50} sediment (d): 1000 d (default value) Crop interception (%): step 2: average for winter cereals, minimal for winter oilseed rape (autumn application) Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: 1 x 10^{-2}, default value (not detected in water and sediment) Soil: 9.1 (polar fraction assigned to 1,2,4-triazole, study No. MK-620-020)
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Metabolite formed from parent
Main routes of entry	Drainage, runoff

$FOCUS_{sw}$ Crop	**Step 1 $PEC_{sw,max}$ [µg L^{-1}]**	**Step 2 $PEC_{sw,max}$ [µg L^{-1}]**	
		Single application	**Multiple application**
Winter cereals [a]	1.056	0.161	0.288
Winter oilseed rape,	0.845	0.121	0.143

autumn application [b]			

[a] Worst-case application scenario covering use in spring cereals
[b] Worst-case application scenario covering spring application

FOCUS$_{sw}$ Crop	**Step 1 PEC$_{sed,max}$ [µg kg^{-1}]**	**Step 2 PEC$_{sed,max}$ [µg kg^{-1}]**	
		Single application	**Multiple application**
Winter cereals [a]	0.940	0.144	0.257
Winter oilseed rape, autumn application [b]	0.752	0.108	0.127

[a] Worst-case application scenario covering use in spring cereals
[b] Worst-case application scenario covering spring application

Metabolite M555F013 (M555F013cis, M13, CL359139, Reg. No. 4543816)	Molecular weight (g/mol): 349.8 Soil or water metabolite: water and sediment metabolite Koc/Kom (mL/g): 10.0 (conservative assumption)
Parameters used in FOCUSsw step 1 and 2	DT_{50} soil (d): 1000 (default value, metabolite not detected in soil studies) DT_{50} water/sediment system (d): 1000 d (default value) DT_{50} water (d):1000 d (default value) DT_{50} sediment (d): 1000 d (default value) Crop interception (%): step 2: average for winter cereals, minimal for winter oilseed rape (autumn application) Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: 10.9 (Study No. MK-630-002) Soil: 1 x 10^{-3}, default value (not detected in soil)
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Metabolite formed from parent
Main routes of entry	Spray drift, drainage and runoff

FOCUS$_{sw}$ Crop	**Step 1 PEC$_{sw,max}$ [µg L^{-1}]**	**Step 2 PEC$_{sw,max}$ [µg L^{-1}]**	
		Single application	**Multiple application**
Winter cereals [a]	7.257	1.194	2.207
Winter oilseed rape, autumn application [b]	5.806	0.901	1.225

[a] Worst-case application scenario covering use in spring cereals
[b] Worst-case application scenario covering spring application

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FOCUS$_{sw}$ Crop	**Step 1** **PEC$_{sed,max}$ [µg kg^{-1}]**	**Step 2** **PEC$_{sed,max}$ [µg kg^{-1}]**	
		Single application	**Multiple application**
Winter cereals [a]	0.725	0.119	0.220
Winter oilseed rape, autumn application [b]	0.580	0.090	0.122

[a] Worst-case application scenario covering use in spring cereals
[b] Worst-case application scenario covering spring application

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

Method of calculation	No other routes of exposure are relevant for the representative uses of metconazole

PEC

Maximum concentration	Not applicable

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Section 5 Ecotoxicology

Ecotoxicology

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

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
Bobwhite quail *Colinus virginianus*	Metconazole (83:17 *cis:trans*)	Acute	LD_{50}	787 mg a.s./kg bw
Bobwhite quail *Colinus virginianus*	Metconazole (85:15 *cis:trans*)	Acute	LD_{50}	798 mg a.s./kg bw
Bobwhite quail *Colinus virginianus*	Metconazole (95% *cis*)	Acute	LD_{50}	875 mg a.s./kg bw
Bobwhite quail *Colinus virginianus*	Preparation (BAS 555 01 F)	Acute	LD_{50}	800 mg prep./kg bw < LD_{50} < 2000 mg prep./kg bw (64.8 mg a.s./kg bw < LD_{50} < 162 mg a.s./kg bw)
Bobwhite quail *Colinus virginianus*	Metabolite M555F034 (triazolyl acetic acid)	Acute	LD_{50}	> 2000 mg/kg bw
Bobwhite quail *Colinus virginianus*	Metabolite M555F035 (triazolyl alanine)	Short-term dietary	LC_{50}	> 500 mg/kg bw/day
Mallard duck *Anas platyrhynchos*	Metabolite M555F035 (triazolyl alanine)	Short-term dietary	LC_{50}	> 500 mg/kg bw/day
Mallard duck *Anas platyrhynchos*	Metconazole (95% *cis*)	Long-term	NOEL	9.33 mg a.s./kg bw/day
Bobwhite quail *Colinus virginianus*	Metconazole (83:17 *cis:trans*)	Long-term	NOEL	6.19 mg a.s./kg bw/day
Mammals				
Rat	Metconazole (80:15 *cis:trans*)	Acute	LD_{50}	♂ 727 mg a.s./kg bw ♀ 595 mg a.s./kg bw
Rat	Metconazole (85:15 *cis:trans*)	Acute	LD_{50}	> 500 mg a.s./kg bw and < 2000 mg a.s./kg bw
Rat	Metconazole (95% *cis*)	Acute	LD_{50}	♂ 1627 mg a.s./kg bw ♀ 1312 mg a.s./kg bw
Mouse	Metconazole (80:15 *cis:trans*)	Acute	LD_{50}	♂ 718 mg a.s./kg bw ♀ 410 mg a.s./kg bw

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Rat	Preparation (BAS 555 01 F)	Acute	LD_{50}	2102 mg prep./kg bw (181 mg a.s./kg bw)
Rat	Metconazole (95% *cis*)	Long-term	NOAEL	8 mg a.s./kg bw/day

Endocrine disrupting properties (Annex Part A, points 8.1.5)

Potential endocrine-related effects were observed in mammalian toxicity studies (dystocia associated with maternal deaths and extended gestation lengths at 750 ppm (53 mg/kg bw/d) in the rat 2-generation study, significant inhibition of ↑ in the 17β-oestradiol/progesterone (E/P) ratio at 750 ppm in a mechanistic 1-generation study in rats, increased incidences of cranial/head malformations at 10 to 30 mg/kg bw/d in rabbit developmental toxicity studies). Based on these effects, it was concluded in the toxicology section that metconazole has a potential endocrine effect, but not necessarily an endocrine disruptive effect in humans. This conclusion took into account the fact that the potential endocrine-related effects only occurred at high doses were there was also a significant maternal toxicity and that the mechanism responsible for the effects observed in pregnant rats are likely to be less relevant in humans. As the latter argument is not necessarily valid for mammals as non-target organisms, it is not clear whether the observed effects in rats should be considered as endocrine disruptive, and whether these effects can be extrapolated to other mammals.

For birds, there is no evidence from the available data for any potential endocrine effects of metconazole, and further studies on the endocrine disrupting potential of metconazole in birds are not considered necessary.

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

Two new field studies investigating the residue behaviour of metconazole on wheat or pea were conducted. From the residue and residue decline data obtained from these studies, a geometric mean foliar DT_{50} of 4.31 days was derived. This value could potentially be used in a refined risk assessment for birds and mammals. However, the risk to birds and mammals was acceptable at Tier 1 for all proposed uses. For the current renewal application, using the available higher tier data in a refined risk assessment was therefore not necessary.

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

No additional studies have been submitted.

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

Cereals (winter/spring) at BBCH 30-69, 1-2 x 90 g a.s./ha (interval 21 days)

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous bird	Acute	15.72	52.1 [1]	10
All	Small omnivorous bird	Long-term	3.71	1.67	5
Tier 1 (Birds)					
BBCH 30-39	Small omnivorous bird “lark”	Long-term	0.309	20.03	5
BBCH ≥ 40	Small omnivorous bird “lark”	Long-term	0.189	32.77	5
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	11.72	48.3 [2]	10
All	Small herbivorous mammal	Long-term	2.76	2.89	5
Tier 1 (Mammals)					
BBCH ≥ 20	Small insectivorous mammal “shrew”	Long-term	0.109	73.56	5

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Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
BBCH ≥ 40	Small herbivorous mammal "vole"	Long-term	1.242	6.44	5
BBCH 30-39	Small omnivorous mammal "mouse"	Long-term	0.223	35.84	5
BBCH ≥ 40	Small omnivorous mammal "mouse"	Long-term	0.131	60.77	5

Risk from bioaccumulation and food chain behaviour[*indicate when not relevant* i.e *if Log kow≤3]*

Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds	Long-term	0.299	20.73	5
Earthworm-eating mammals	Long-term	0.364	21.98	5
Fish-eating birds	Long-term	0.00798	775.6	5
Fish-eating mammals	Long-term	0.00713	1122.4	5

Risk from consumption of contaminated water

Scenarios	**Indicator or focal species**	**Time scale**	**PEC_{dw}xDWR**	**TER**	**Trigger**
Leaf scenario	Birds	acute	Not relevant		5
Puddle scenario, Screening step 1)Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed 2)Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed					
Puddle scenario	Birds	acute	Not needed	Case 2 (0.204)	10
Puddle scenario	Mammals	acute	Not needed	Case 2 (0.295)	10
Puddle scenario	Birds	Long-term	Not needed	Case 2 (26.99)	5
Puddle scenario	Mammals	Long-term	Not needed	Case 2 (20.88)	5

[1] *a geomean LD_{50} of 819 mg a.s./kg bw, calculated from the LD_{50} for Bobwhite quail (Colinus virginianus) from three different studies, was used in the risk assessment to calculate this TER value.*
[2] *a geomean LD50 value of 566.7 mg a.s./kg bw, calculated based on the available and relevant acute toxicity studies on mice (1) and rats (3), was used in the risk assessment to calculate this TER value.*

Winter oilseed rape at BBCH 13-20 (autumn) and 21-71 (spring), 1-2 x 72 g a.s./ha (interval 90 days) (= "autumn application")

Winter oilseed rape at BBEC 21-71), 1-2 x 72 g a.s./ha (interval 14 days) (= "spring application")

For oilseed rape, only the worst case use rate of 2 x 72 g a.s./ha is used for the risk assessment; to cover also the single application in earlier growth stages, worst case scenarios for BBCH 13-20 were included in the calculations

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous bird	Acute	13.72	59.7 [1]	10

List of end points

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Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
All	Small omnivorous bird	Long-term	3.46	1.79	5
Tier 1 (Birds)					
Late-late (with seeds) BBCH 30-90	Small insectivorous bird "dunnock"	Long-term	0.144	42.91	5
Early shoots BBCH	Large herbivorous bird "goose"	Long-term	0.849	7.29	5
BBCH 10-29	Small omnivorous bird "lark"	Long-term	0.582	10.63	5
BBCH 10-39	Small omnivorous bird "lark"	Long-term	0.176	35.11	5
BBCH ≥ 40	Small omnivorous bird "lark"	Long-term	0.144	42.91	5
BBCH 10-19	Medium herbivorous / granivorous bird "pigeon"	Long-term	1.213	5.10	5
BBCH 20-29	Medium herbivorous / granivorous bird "pigeon"	Long-term	0.187	33.10	5
BBCH 30-39	Medium herbivorous / granivorous bird "pigeon"	Long-term	0.059	105.33	5
BBCH ≥ 40	Medium herbivorous / granivorous bird "pigeon"	Long-term	0.048	128.74	5
BBCH 10-19	Small insectivorous bird "wagtail"	Long-term	0.315	19.64	5
BBCH 20-29	Small insectivorous bird "wagtail"	Long-term	0.150	41.38	5
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	10.23	55.4 [2]	10
All	Small herbivorous mammal	Long-term	2.58	3.10	5
Tier 1 (Mammals)					
BBCH 10-19	Small insectivorous mammal "shrew"	Long-term	0.224	35.65	5
BBCH ≥ 20	Small insectivorous mammal "shrew"	Long-term	0.102	78.81	5
BBCH ≥ 40	Small herbivorous mammal "vole"	Long-term	0.967	8.27	5
All season	Largen herbivorous mammal "lagomorph"	Long-term	0.764	10.47	5
BBCH 10-29	Small omnivorous mammal "mouse"	Long-term	0.417	19.20	5
BBCH 30-39	Small omnivorous mammal "mouse"	Long-term	0.123	65.11	5
BBCH ≥ 40	Small omnivorous mammal "mouse"	Long-term	0.102	78.81	5

Risk from bioaccumulation and food chain behaviour[*indicate when not relevant* i.e *if Log kow≤3]*

Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds	Long-term	0.299	20.73	5
Earthworm-eating mammals	Long-term	0.364	21.98	5
Fish-eating birds	Long-term	0.00931	664.8	5

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Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Fish-eating mammals		Long-term	0.00832	962.0	5

Risk from consumption of contaminated water

Scenarios	Indicator or focal species	Time scale	PEC_{dw}xDWR	TER	Trigger
Leaf scenario	Birds	acute	Not relevant		5
Puddle scenario, Screening step 1)Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed 2)Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed					
Puddle scenario	Birds	acute	Not needed	Case 2 (0.167)	10
Puddle scenario	Mammals	acute	Not needed	Case 2 (0.242)	10
Puddle scenario	Birds	Long-term	Not needed	Case 2 (22.12)	5
Puddle scenario	Mammals	Long-term	Not needed	Case 2 (17.11)	5

[1] *a geomean LD_{50} of 819 mg a.s./kg bw, calculated from the LD_{50} for Bobwhite quail (Colinus virginianus) from three different studies, was used in the risk assessment to calculate this TER value.*
[2] *a geomean LD50 value of 566.7 mg a.s./kg bw, calculated based on the available and relevant acute toxicity studies on mice (1) and rats (3), was used in the risk assessment to calculate this TER value.*

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Laboratory tests				
Fish				
Rainbow trout (*Oncorhynchus mykiss*)	Metconazole (87:17 *cis:trans*)	Acute, 72 hr (semi-static)	Mortality, LC_{50}	2.1 mg a.s./L (mm)
Rainbow trout (*Oncorhynchus mykiss*)	Metconazole (95% *cis*)	Acute, 96 hr (semi-static)	Mortality, LC_{50}	4.0 mg a.s./L (nom)
Rainbow trout (*Oncorhynchus mykiss*)	Preparation (BAS 555 01 F)	Acute, 96 hr (static)	Mortality, LC_{50}	10 mg prep./L (0.85 mg a.s./L) (nom)
Fathead minnow (*Pimephales promelas*)	Metconazole (87:17 *cis:trans*)	Acute, 96 hr (semi-static)	Mortality, LC_{50}	3.9 mg a.s./L (mm)
Common carp (*Cyprinus carpio*)	Metconazole (85:15 *cis:trans*)	Acute, 96 hr (flow-through)	Mortality, LC_{50}	3.99 mg a.s./L (mm)
Sheepshead minnow (*Cyprinodon variegatus)*	Metconazole (85:15 *cis:trans*)	Acute, 96 hr (static)	Mortality, LC_{50}	6.3 mg a.s./L (mm)

List of end points

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Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Bluegill sunfish (*Lepomis macrochirus*)	Metconazole (80:20 *cis:trans*)	Acute, 96 hr (static)	Mortality, LC_{50}	4.9 mg a.s./L (nom)
Zebrafish (*Danio rerio*)	Metconazole (80:20 *cis:trans*)	Acute, 96 hr (static)	Mortality, LC_{50}	6.8 mg a.s./L (nom)
Threespine stickleback (*Gasterosteus aculeatus*)	Metconazole (85:15 *cis:trans*)	Acute, 96 hr (static)	Mortality, LC_{50}	4.2 mg a.s./L (nom)
Rainbow trout *(Oncorhynchus mykiss)*	Metconazole (85:15 *cis:trans*)	Chronic, 28 days (flow-through)	Survival, NOEC EC_{20} EC_{10}	 1.14 mg a.s./L (mm) 1.40 mg a.s./L (mm) 1.26 mg a.s./L (mm)
Rainbow trout *(Oncorhynchus mykiss)*	Metconazole (85:15 *cis:trans*)	Chronic, 95 days (flow-through)	Dry weight, NOEC EC_{20} EC_{10}	 0.00291 mg a.s./L (mm) 0.00504 mg a.s./L (mm) 0.00398 mg a.s./L (mm)
Sheepshead minnow (*Cyprinodon variegatus)*	Metconazole (85:15 *cis:trans*)	Chronic, 33 days (flow-through)	Dry weight, total length, NOEC	0.011 mg a.s./L (mm)
Fathead minnow (*Pimephales promelas*)	Metconazole (95% *cis*)	Chronic, 35 days (flow-through)	Dry weight, NOEC EC_{20} EC_{10}	 0.011 mg a.s./L (mm) 0.027 mg a.s./L (mm) 0.021 mg a.s./L (mm)
Fathead minnow (*Pimephales promelas*)	Metconazole (85:15 *cis:trans*)	Chronic, 5 months (flow-through)	Survival, growth, reproduction, NOEC EC_{20} EC_{10}	 0.00358 mg a.s./L (mm) 0.0097 mg a.s./L (mm) 0.0077 mg a.s./L (mm)
Rainbow trout (*Oncorhynchus mykiss*)	Metabolite M555F020 (1,2,4-triazole)	Acute, 96 hr (static)	Mortality, LC_{50}	600 mg/L (mm)
Rainbow trout (*Oncorhynchus mykiss*)	Metabolite M555F020 (1,2,4-triazole)	Chronic, 28 days (semi-static)	Toxic symptoms, NOEC	3.20 mg/L (nom)

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Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Aquatic invertebrates				
Water flea (*Daphnia magna*)	Metconazole (83:17 *cis:trans*)	Acute, 48 h (static)	Mortality, EC_{50}	4.2 mg a.s./L (im)
Water flea (*Daphnia magna*)	Metconazole (95% *cis*)	Acute, 48 h (static)	Mortality, EC_{50}	3.6 mg a.s./L (nom)
Water flea (*Daphnia magna*)	Preparation (BAS 555 01 F)	Acute, 48 h (static)	Mortality, EC_{50}	9.28 mg prep./L (0.82 mg a.s./L) (mm)
Water flea (*Daphnia magna*)	Metconazole (85:15 *cis:trans*)	Chronic, 21 days (semi-static)	Reproduction, NOEC EC_{20} EC_{10}	0.16 mg a.s./L (mm) 0.172 mg a.s./L (mm) 0.149 mg a.s./L (mm)
Water flea (*Daphnia magna*)	Metconazole (95% *cis*)	Chronic, 21 days (semi-static)	Reproduction and decelopment, NOEC EC_{20} EC_{10}	0.21 mg a.s./L (mm) 0.276 mg a.s./L (mm) 0.215 mg a.s./L (mm)
Water flea (*Daphnia magna*)	Metabolite M555F020 (1,2,4-triazole)	Acute, 48 h (static)	Mortality, EC_{50}	> 100 mg/L (nom)
Sediment-dwelling organisms				
Midge (*Chironomus riparius*)	Metconazole (85:15 *cis:trans*)	Chronic, 28 days, spiked water (static)	NOEC EC_{20} EC_{10}	2.12 mg a.s./L (8.23 mg a.s./kg dry sediment) (im) 2.58 mg a.s./L (im) 2.21 mg a.s./L (im)
Algae				
Green microalgae (*Pseudo-kirchnerialla subcapitata*)	Metconazole (83:17 *cis:trans*)	Chronic, 72 h (static)	Growth rate: E_rC_{50} E_rC_{20} E_rC_{10} NOEC Biomass: E_bC_{50} E_bC_{20} E_bC_{10} NOEC	 2.2 mg a.s./L (im) 1.22 mg a.s./L (im) 0.90 mg a.s./L (im) 0.38 mg a.s./L (im) 1.7 mg a.s./L (im) 0.44 mg a.s./L (im) 0.19 mg a.s./L (im) 0.38 mg a.s./L (im)

List of end points

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Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Green microalgae (*Pseudo-kirchnerialla subcapitata*)	Preparation (BAS 555 01 F)	Chronic, 72 h (static)	Growth rate: E_rC_{50} E_rC_{20} E_rC_{10} Biomass: E_bC_{50} E_bC_{20} E_bC_{10}	 >6.91 mg prep/L (>0.609 mg a.s./L) (mm) 4.56 mg prep./L (0.402 mg a.s./L) (mm) 3.31 mg prep./L (0.292 mg a.s./L) (mm) 3.94 mg prep./L (0.347 mg a.s./L) (mm) 2.90 mg prep./L (0.256 mg a.s./L) (mm) 2.14 mg prep./L (0.189 mg a.s./L) (mm)
Green microalgae (*Pseudo-kirchnerialla subcapitata*)	Metabolite M555F020 (1,2,4-triazole)	Chronic, 72 h (static)	Growth rate: E_rC_{50} E_rC_{20} E_rC_{10} NOEC Biomass: E_bC_{50} E_bC_{20} E_bC_{10} NOEC	 > 31 mg/L (mm) 11.33 mg/L (mm) 8.31 mg/L (mm) 3.1 mg/L (mm) 13 mg/L (mm) 7.18 mg/L (mm) 5.95 mg/L (mm) 3.1 mg/L (mm)
Higher plant				
Lemna gibba	Metconazole	Chronic, 7 days (static)	Fronds number, E_rC_{50} E_rC_{20} E_rC_{10} E_yC_{50} E_yC_{20} E_yC_{10} NOEC	 0.527 mg a.s./L (im) 0.022 mg a.s./L (im) 0.004 mg a.s./L (im) 0.077 mg a.s./L (im) 0.008 mg a.s./L (im) 0.004 mg a.s./L (im) 0.003 mg a.s./L (im)

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Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Further testing on aquatic organisms *Acute risk to fish: SSD approach* Based on the available acute toxicity data for seven fish species, a Species Sensitivity Distribution (SSD) was constructed, resulting in an HC_5 value of 2.216 mg a.s./L. Taking into account the assessment factor (AF) of 9 as recommended by the EFSA Guidance Document on aquatic organism (2013), an SSD-$RAC_{SW,ac}$ of 246.2 µg a.s./L was obstained. *Chronic risk to fish: Weight of Evidence Approach* All available acute and chronic toxicity studies for metconazole (acute data for seven fish species, and chronic data for three of these species) were taken into account in a Weight of Evidence (WoE) approach. The available data indicates that the difference in sensitivity between species is limited (no more than a factor 3 to 4 difference among the endpoints). Further, both in the acute and chronic studies, *Oncorhynchus mykiss* was the most sensitive among the tested species. Therefore, it was considered acceptable to lower the assessment factor (AF) for the chronic risk assessment for fish from 10 to 5. By applying this AF of 5 to the lowest chronic EC_{10} for fish (EC10 for rainbow trout of 0.00398), a WoE-$RAC_{SW,ch}$ of 0.796 µg a.s./L was obtained.				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3) A fish full life cycle test with fathead minnow (*Pimephales promelas*) is available, in which parameters reflecting endocrine activity (sex ratio (including histological examination of the gonads of both generations) and vitellogenin levels in the blood plasma) were monitored. Up to the highest tested concentration of 10 µg a.s./L, no effects on sex ratio and vitellogenin levels were observed. In contrast, effects reflecting a general toxicity of metconazole (a reduction of the survival and growth in the F2 generation and fertility in the F1 generation) were found at 10 µg a.s./L. Based on these results, there is no indication of a relevant endocrine potential of metconazole in fish.				

[1] ($_{nom}$) nominal concentration; ($_{mm}$) mean measured concentration; ($_{im}$) initial measured concentration; prep.: preparation; a.s.: active substance

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Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Metconazole	1,2,4-triazole
$logP_{O/W}$	3.85 [1)]	-0.62 to -0.71 (at pH range 5-9)
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	105.1 [3)]	-
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)	97.5	-
Annex VI Trigger for the bioconcentration factor	100	-
Clearance time (days) (CT_{50})	< 1 day	-
(CT_{90})	< 2 days	-
Level and nature of residues (%) in organisms after the 14 day depuration phase	0.4%	-
Higher tier study *Not needed*		

[1)] The study from which this value was derived is no longer considered acceptable (see Volume 3, Section B.2). No other study is available. This value nevertheless indicates that a study on the bioconcentration in fish is necessary;

[2)] No data was available within the metconazole renewal dossier to determine a log P_{OW} for these metabolites. This log P_{OW} value was obtained from the revised Addendum on the confirmatory data for the 'Triazole Derivative Metabolites' (RMS UK, May 2016)

[3)] based on total ^{14}C.

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Regulatory acceptable concentrations used in the risk assessment

Metconazole						
	Species group	**Level of assessment**	**Most sensitive species**	**Endpoint**	**AF**	**RAC**
Acute effect assessment	Fish	Tier 1	*Oncorhynchus mykiss*	LC_{50} = 2.1 mg a.s./L	100	21 µg a.s./L
		Tier 2 (SSD-approach)	Data for 7 fish species	HC_5 = 2.216 mg a.s./L	9	246.2 µg a.s./L
	Aquatic invertebrates	Tier 1	*Daphnia magna*	EC_{50} = 3.6 µg a.s./L	100	36 µg a.s./L
Chronic effect assessment	Fish	Tier 1	*Oncorhynchus mykiss*	EC_{10} = 0.00398 mg a.s./L	10	0.398 µg a.s./L
		Tier 2 (Weight of Evidence approach)	*Oncorhynchus mykiss*	EC_{10} = 0.00398 mg a.s./L	5	0.796 µg a.s./L
	Aquatic invertebrates	Tier 1	*Daphnia magna*	EC_{10} = 0.149 mg a.s./L	10	14.9 µg a.s./L
		Tier 1	*Chironomus riparius*	NOEC = 8.23 mg a.s./kg dry sediment	10	823 µg a.s./kg dry sediment
	Algae	Tier 1	*Pseudo-kirchnerialla subcapitata*	E_rC_{50} = 2.2 mg a.s./L	10	220 µg a.s./L
	Aquatic plants	Tier 1	*Lemna gibba*	E_rC_{50} = 0.527 mg a.s./L	10	52.7 µg a.s./L
Formulation BAS 555 01 F						
Acute effect assessment	Fish	Tier 1	*Oncorhynchus mykiss*	LC_{50} = 10 mg prep./L	100	10 µg prep./L
	Aquatic invertebrates	Tier 1	*Daphnia magna*	EC_{50} = 9.28 mg prep./L	100	92.8 µg prep./L
Chronic effect assessment	Algae	Tier 1	*Pseudokirchneriella subcapitata*	E_rC_{50} > 6.91 mg prep./L	10	> 691 µg prep./L
Metabolite 1,2,4-triazole						
Acute effect assessment	Fish	Tier 1	*Oncorhynchus mykiss*	LC_{50} = 600 mg/L	100	6000 µg/L
	Aquatic invertebrates	Tier 1	*Daphnia magna*	EC_{50} > 100 mg/L	100	> 1000 µg/L
Chronic effect assessment	Fish	Tier 1	*Oncorhynchus mykiss*	NOEC = 3.20 mg/L	10	320 µg/L
	Algae	Tier 1	*Pseudokirchneriella subcapitata*	E_rC_{50} > 31 mg/L	10	> 3100 µg/L

Notes: AF: Assessment Factor

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Comparison of the RAC and endpoint for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

$FOCUS_{sw}$ step 1-3 – Comparison of RACs and global maximum $PEC_{SW/SED}$ for metconazole – Winter cereals at 1-2 x 90 g a.s./ha

Scenario	**fish acute**		**fish chronic**		**Aquatic invertebrates**	**Aquatic invertebrates prolonged**	**Algae**	**Higher plant**	**Sed. dweller prolonged**
	Oncorhynchus mykiss	*SSD approach*	*Oncorhynchus mykiss*	*WoE approach*	*Daphnia magna*	*Daphnia magna*	*Pseudokirchneriella subcapitata*	*Lemna gibba*	*Chironomus riparius*
Level of assessment	Tier 1	Tier 2	Tier 1	Tier 2	Tier 1	Tier 1	Tier 1	Tier 1	Tier 1
RAC	21 µg/L	246.2 µg/L	0.398 µg/L	0.796 µg/L	36 µg/L	14.9 µg/L	220 µg/L	52.7 µg/L	823 µg/kg dry sediment
FOCUS Step 1 PEC values	**26.367**	26.367	**26.367**	**26.367**	26.367	**26.367**	26.367	26.367	271.474
FOCUS Step 2 PEC values									
North Europe	7.855	7.855	**7.855**	**7.855**	7.855	7.855	7.855	7.855	82.437
South Europe	7.855	7.855	**7.855**	**7.855**	7.855	7.855	7.855	7.855	82.437
FOCUS Step 3 PEC values – Tier 2 (values marked with * are Tier 3 values)									
D1 / ditch	-	-	**0.814 ***	**0.814 ***	-	-	-	-	-
D1 / stream	-	-	**0.505**	0.505	-	-	-	-	-
D2 / ditch	-	-	**0.659 ***	0.659 *	-	-	-	-	-
D2 / stream	-	-	**0.535 ***	0.535 *	-	-	-	-	-
D3 / ditch	-	-	**0.570**	0.570	-	-	-	-	-
D4 / pond	-	-	0.039	0.039	-	-	-	-	-
D4 / stream	-	-	**0.475**	0.475	-	-	-	-	-
D5 / pond	-	-	0.060	0.060	-	-	-	-	-
D5 / stream	-	-	**0.460**	0.460	-	-	-	-	-
D6 / ditch	-	-	**0.572**	0.572	-	-	-	-	-
R1 / pond	-	-	0.066	0.066	-	-	-	-	-
R1 / stream	-	-	0.374	0.374	-	-	-	-	-
R3 / stream	-	-	**0.527**	0.527	-	-	-	-	-
R4 / stream	-	-	0.377	0.377	-	-	-	-	-

Notes: PEC values in bold indicate that the $PEC_{SW/SED}$ exceeds the RAC, and thus that further consideration is necessary

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FOCUS$_{sw}$ step 1-3 – Comparison of RACs and global maximum PEC$_{SW/SED}$ for metconazole – Spring cereals at 1-2 x 90 g a.s./ha

Scenario	**fish acute**		**fish chronic**		**Aquatic invertebrates**	**Aquatic invertebrates prolonged**	**Algae**	**Higher plant**	**Sed. dweller prolonged**
	Oncorhynchus mykiss	*SSD approach*	*Oncorhynchus mykiss*	*WoE approach*	*Daphnia magna*	*Daphnia magna*	*Pseudokircherniella subcapitata*	*Lemna gibba*	*Chironomus riparius*
Level of assessment	Tier 1	Tier 2	Tier 1	Tier 2	Tier 1	Tier 1	Tier 1	Tier 1	Tier 1
RAC	21 µg/L	246.2 µg/L	0.398 µg/L	0.796 µg/L	36 µg/L	14.9 µg/L	220 µg/L	52.7 µg/L	823 µg/kg dry sediment
FOCUS Step 1 PEC values	**26.367**	26.367	**26.367**	**26.367**	26.367	**26.367**	26.367	26.367	271.474
FOCUS Step 2 PEC values									
North Europe	7.855	7.855	**7.855**	**7.855**	7.855	7.855	7.855	7.855	82.437
South Europe	7.855	7.855	**7.855**	**7.855**	7.855	7.855	7.855	7.855	82.437
FOCUS Step 3 PEC values – Tier 2 (values marked with * are Tier 3 values)									
D1 / ditch	-	-	**0.811 ***	**0.811 ***	-	-	-	-	-
D1 / stream	-	-	**0.506**	0.506	-	-	-	-	-
D3 / ditch	-	-	**0.570**	0.570	-	-	-	-	-
D4 / pond	-	-	0.057	0.057	-	-	-	-	-
D4 / stream	-	-	**0.466**	0.466	-	-	-	-	-
D5 / pond	-	-	0.042	0.042	-	-	-	-	-
D5 / stream	-	-	**0.479**	0.479	-	-	-	-	-
R4 / stream	-	-	0.377	0.377	-	-	-	-	-

Notes: PEC values in bold indicate that the PEC$_{SW/SED}$ exceeds the RAC, and thus that further consideration is necessary

List of end points

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FOCUS$_{sw}$ step 1-3 – Comparison of RACs and global maximum PEC$_{SW/SED}$ for metconazole – Winter oilseed rape at 1-2 x 72 g a.s./ha (autumn application)

Scenario	**fish acute**		**fish chronic**		**Aquatic invertebrates**	**Aquatic invertebrates prolonged**	**Algae**	**Higher plant**	**Sed. dweller prolonged**
	Oncorhynchus mykiss	*SSD approach*	*Oncorhynchus mykiss*	*WoE approach*	*Daphnia magna*	*Daphnia magna*	*Pseudokircherniella subcapitata*	*Lemna gibba*	*Chironomus riparius*
Level of assessment	Tier 1	Tier 2	Tier 1	Tier 2	Tier 1	Tier 1	Tier 1	Tier 1	Tier 1
RAC	21 µg/L	246.2 µg/L	0.398 µg/L	0.796 µg/L	36 µg/L	14.9 µg/L	220 µg/L	52.7 µg/L	823 µg/kg dry sediment
FOCUS Step 1 PEC values	**21.094**	21.094	**21.094**	**21.094**	21.094	**21.094**	21.094	21.094	217.179
FOCUS Step 2 PEC values									
North Europe	4.352	4.352	**4.352**	**4.352**	4.352	4.352	4.352	4.352	45.420
South Europe	4.352	4.352	**4.352**	**4.352**	4.352	4.352	4.352	4.352	45.420
FOCUS Step 3 PEC values – Tier 2 (values marked with * are Tier 3 values)									
D2 / ditch	-	-	**0.868 ***	**0.868 ***	-	-	-	-	-
D2 / stream	-	-	**0.984**	**0.984**	-	-	-	-	-
D3 / ditch	-	-	**0.458**	0.458	-	-	-	-	-
D4 / pond	-	-	0.057	0.057	-	-	-	-	-
D4 / stream	-	-	0.394	0.394	-	-	-	-	-
D5 / pond	-	-	0.042	0.042	-	-	-	-	-
D5 / stream	-	-	**0.425**	0.425	-	-	-	-	-
R1 / pond	-	-	0.059	0.059	-	-	-	-	-
R1 / stream	-	-	0.397	0.397	-	-	-	-	-
R3 / stream	-	-	**0.553**	0.553	-	-	-	-	-

Notes: PEC values in bold indicate that the PEC$_{SW/SED}$ exceeds the RAC, and thus that further consideration is necessary

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
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FOCUS$_{sw}$ step 1-3 – Comparison of RACs and global maximum PEC$_{SW/SED}$ for metconazole – Winter oilseed rape at 1-2 x 72 g a.s./ha (spring application)

Scenario	**fish acute**		**fish chronic**		**Aquatic invertebrates**	**Aquatic invertebrates prolonged**	**Algae**	**Higher plant**	**Sed. dweller prolonged**
	Oncorhynchus mykiss	*SSD approach*	*Oncorhynchus mykiss*	*WoE approach*	*Daphnia magna*	*Daphnia magna*	*Pseudokircherniella subcapitata*	*Lemna gibba*	*Chironomus riparius*
Level of assessment	Tier 1	Tier 2	Tier 1	Tier 2	Tier 1	Tier 1	Tier 1	Tier 1	Tier 1
RAC	21 µg/L	246.2 µg/L	0.398 µg/L	0.796 µg/L	36 µg/L	14.9 µg/L	220 µg/L	52.7 µg/L	823 µg/kg dry sediment
FOCUS Step 1 PEC values	**21.094**	21.094	**21.094**	**21.094**	21.094	**21.094**	21.094	21.094	217.179
FOCUS Step 2 PEC values									
North Europe	4.352	4.352	**4.352**	**4.352**	4.352	4.352	4.352	4.352	45.420
South Europe	4.352	4.352	**4.352**	**4.352**	4.352	4.352	4.352	4.352	45.420
FOCUS Step 3 PEC values – Tier 2 (values marked with * are Tier 3 values)									
D2 / ditch	-	-	**0.808 ***	**0.808 ***	-	-	-	-	-
D2 / stream	-	-	**0.988**	**0.988**	-	-	-	-	-
D3 / ditch	-	-	**0.455**	0.455	-	-	-	-	-
D4 / pond	-	-	0.047	0.047	-	-	-	-	-
D4 / stream	-	-	0.350	0.350	-	-	-	-	-
D5 / pond	-	-	0.047	0.047	-	-	-	-	-
D5 / stream	-	-	0.314	0.314	-	-	-	-	-
R1 / pond	-	-	0.072	0.072	-	-	-	-	-
R1 / stream	-	-	**0.439**	0.439	-	-	-	-	-
R3 / stream	-	-	**0.425**	0.425	-	-	-	-	-

Notes: PEC values in bold indicate that the PEC$_{SW/SED}$ exceeds the RAC, and thus that further consideration is necessary

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Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Belgium	January 2018	Metconazole

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FOCUS$_{sw}$ step 4 – Comparison of RACs and global maximum PEC$_{SW/SED}$ for metconazole – Winter cereals at 1-2 x 90 g a.s./ha

Scenario	**fish chronic**					
	Oncorhynchus mykiss			*WoE approach*		
Level of assessment	Tier 1			Tier 2		
RAC	0.398 µg/L			0.796 µg/L		
Mitigation options	**5 m D**	**10 m D**	**10 m D+R**	**5 m D**	**10 m D**	**10 m D+R**
FOCUS Step 4 PEC values – Tier 2 (values marked with * are Tier 3 values)						
D1 / ditch	**0.475**	**0.475**	**0.475**	0.475	0.475	0.475
D1 / stream	0.298	0.298	0.298	0.298	0.298	0.298
D2 / ditch	**0.589 ***	**0.589 ***	**0.589 ***	0.589 *	0.589 *	0.589 *
D2 / stream	**0.535 ***	**0.535 ***	**0.535 ***	0.535 *	0.535 *	0.535 *
D3 / ditch	0.154	0.082	0.082	0.154	0.082	0.082
D4 / stream	0.174	0.095	0.095	0.174	0.095	0.095
D5 / stream	0.166	0.101	0.101	0.166	0.101	0.101
D6 / ditch	0.158	0.158	0.158	0.158	0.158	0.158
R3 / stream	0.319	0.319	0.144	0.319	0.319	0.144

D = Drift mitigation using no-spray buffer zones, R = runoff mitigation by vegetated filter strips; PEC values in bold indicate that the PEC$_{SW/SED}$ exceeds the RAC, and thus that further consideration is necessary

FOCUS$_{sw}$ step 4 – Comparison of RACs and global maximum PEC$_{SW/SED}$ for metconazole – Spring cereals at 1-2 x 90 g a.s./ha

Scenario	**fish chronic**					
	Oncorhynchus mykiss			*WoE approach*		
Level of assessment	Tier 1			Tier 2		
RAC	0.398 µg/L			0.796 µg/L		
Mitigation options	**5 m D**	**10 m D**	**10 m D+R**	**5 m D**	**10 m D**	**10 m D+R**
FOCUS Step 4 PEC values – Tier 2 (values marked with * are Tier 3 values)						
D1 / ditch	0.241*	0.193*	-	0.241*	0.193*	-
D1 / stream	**0.485**	**0.485**	**0.485**	0.485	0.485	0.485
D3 / ditch	0.155	0.082	0.082	0.155	0.082	0.082
D4 / stream	0.170	0.137	0.137	0.170	0.137	0.137
D5 / stream	0.175	0.093	0.093	0.175	0.093	0.093

D = Drift mitigation using no-spray buffer zones, R = runoff mitigation by vegetated filter strips; PEC values in bold indicate that the PEC$_{SW/SED}$ exceeds the RAC, and thus that further consideration is necessary

List of end points

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FOCUS$_{sw}$ step 4 – Comparison of RACs and global maximum PEC$_{SW/SED}$ for metconazole – Winter oilseed rape at 1-2 x 72 g a.s./ha (autumn application)

Scenario	**fish chronic**					
	Oncorhynchus mykiss			*WoE approach*		
Level of assessment	Tier 1			Tier 2		
RAC	0.398 µg/L			0.796 µg/L		
Mitigation options	**5 m D**	**10 m D**	**10 m D+R**	**5 m D**	**10 m D**	**10 m D+R**
FOCUS Step 4 PEC values – Tier 2 (values marked with * are Tier 3 values)						
D2 / ditch	**0.868 ***	**0.868 ***	-	**0.868 ***	**0.868 ***	-
D2 / stream	**0.984**	**0.984**	**0.984**	**0.984**	**0.984**	**0.984**
D3 / ditch	0.124	0.066	0.066	0.124	0.066	0.066
D5 / stream	0.155	0.104	0.104	0.155	0.104	0.104
R3 / stream	**0.553**	**0.553**	0.252	0.553	0.553	0.252

D = Drift mitigation using no-spray buffer zones, R = runoff mitigation by vegetated filter strips; PEC values in bold indicate that the PEC$_{SW/SED}$ exceeds the RAC, and thus that further consideration is necessary

FOCUS$_{sw}$ step 4 – Comparison of RACs and global maximum PEC$_{SW/SED}$ for metconazole – Winter oilseed rape at 1-2 x 72 g a.s./ha (spring application)

Scenario	**fish chronic**					
	Oncorhynchus mykiss			*WoE approach*		
Level of assessment	Tier 1			Tier 2		
RAC	0.398 µg/L			0.796 µg/L		
Mitigation options	**5 m D**	**10 m D**	**10 m D+R**	**5 m D**	**10 m D**	**10 m D+R**
FOCUS Step 4 PEC values – Tier 2 (values marked with * are Tier 3 values)						
D2 / ditch	**0.808 ***	**0.808 ***	-	**0.808 ***	**0.808 ***	-
D2 / stream	**0.988**	**0.988**	**0.988**	**0.988**	**0.988**	**0.988**
D3 / ditch	0.123	0.065	0.065	0.123	0.065	0.065
R1 / stream	**0.439**	**0.439**	0.199	0.439	0.439	0.199
R3 / stream	0.363	0.363	0.166	0.363	0.363	0.166

D = Drift mitigation using no-spray buffer zones, R = runoff mitigation by vegetated filter strips; PEC values in bold indicate that the PEC$_{SW/SED}$ exceeds the RAC, and thus that further consideration is necessary

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
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Comparison of RACs and maximum instantaneous $PEC_{SW,ini,drift}$ for BAS 555 01 following aplication in winter/spring cereals (at 1-2 x 90 g a.s./ha) and winter oilseed rape (1-2 x 72 g a.s./ha)

Scenario	**fish acute**	**Aquatic invertebrates**	**Algae**
	Oncorhynchus mykiss	*Daphnia magna*	*Pseudokircherniella subcapitata*
Level of assessment	Tier 1	Tier 1	Tier 1
RAC	100 µg/L	92.8 µg/L	> 691 µg/L
Maximum instantaneous $PEC_{sw,ini,drift}$ (µg/L)	6.729	6.729	6.729

Note: PEC values in bold indicate that the $PEC_{SW/SED}$ exceeds the RAC, and thus that further consideration is necessary

$FOCUS_{sw}$ step 1 and 2 – Comparison of RACs and global maximum $PEC_{SW/SED}$ for the metabolite 1,2,4-triazole – Winter/spring cereals (at 1-2 x 90 g a.s./ha)

Scenario	**fish acute**	**fish chronic**	**Aquatic invertebrates**	**Algae**
	Oncorhynchus mykiss	*Oncorhynchus mykiss*	*Daphnia magna*	*Pseudokircherniella subcapitata*
Level of assessment	Tier 1	Tier 1	Tier 1	Tier 1
RAC	6000 µg/L	320 µg/L	> 1000 µg/L	> 3100 µg/L
FOCUS Step 1 PEC values (µg/L)	1.056	1.056	1.056	1.056
FOCUS Step 2 PEC values (µg/L)				
North Europe	0.288	0.288	0.288	0.288
South Europe	0.288	0.288	0.288	0.288

Note: PEC values in bold indicate that the $PEC_{SW/SED}$ exceeds the RAC, and thus that further consideration is necessary

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FOCUS$_{sw}$ step 1 and 2 – Comparison of RACs and global maximum PEC$_{SW/SED}$ for the metabolite 1,2,4-triazole – Winter oilseed rape (at 1-2 x 72 g a.s./ha)

Scenario	**fish acute**	**fish chronic**	**Aquatic invertebrates**	**Algae**
	Oncorhynchus mykiss	*Oncorhynchus mykiss*	*Daphnia magna*	*Pseudokircherniella subcapitata*
Level of assessment	Tier 1	Tier 1	Tier 1	Tier 1
RAC	6000 µg/L	320 µg/L	> 1000 µg/L	> 3100 µg/L
FOCUS Step 1 PEC values (µg/L)	0.845	0.845	0.845	0.845
FOCUS Step 2 PEC values (µg/L)				
North Europe	0.146	0.146	0.146	0.146
South Europe	0.146	0.146	0.146	0.146

Note: PEC values in bold indicate that the PEC$_{SW/SED}$ exceeds the RAC, and thus that further consideration is necessary

List of end points

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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
Honeybee (*Apis mellifera*)	Metconazole (87:13 *cis:trans*)	Acute, adult toxicity	Oral toxicity (LD_{50})	85 µg a.s./bee
Honeybee (*Apis mellifera*)	Metconazole (87:13 *cis:trans*)	Acute, adult toxicity	Contact toxicity (LD_{50})	> 100 µg a.s./bee
Honeybee (*Apis mellifera*)	Preparation (BAS 555 01 F)	Acute, adult toxicity	Oral toxicity (LD_{50})	208.7 µg prep./bee (17.8 µg a.s./bee)
Honeybee (*Apis mellifera*)	Preparation (BAS 555 01 F)	Acute, adult toxicity	Contact toxicity (LD_{50})	229.8 µg prep./bee (17.8 µg a.s./bee)
Honeybee (*Apis mellifera*)	Preparation (BAS 555 01 F)	Acute, adult toxicity	Oral toxicity (LD_{50})	> 455.44 µg prep./bee (> 39.19 µg a.s./bee)
Honeybee (*Apis mellifera*)	Preparation (BAS 555 01 F)	Acute, adult toxicity	Contact toxicity (LD_{50})	444.46 µg prep./bee (38.24 µg a.s./bee)
Honeybee (*Apis mellifera*)	Metconazole	Chronic (10d), adult toxicity	LDD_{50}	50.0 µg a.s./bee/day
Honeybee (*Apis mellifera*)	Metconazole	Acute (72h), larval toxicity	LD_{50}	49.6 µg a.s./larva
Honeybee (*Apis mellifera*)	Metconazole	Chronic (22d), larval toxicity	NOED	12.5 µg a.s./larva
Bumblebee (*Bombus terrestris*)	Metconazole	Acute, adult toxicity	Oral toxicity (LD_{50})	111.1 µg a.s./bee
Bumblebee (*Bombus terrestris*)	Metconazole	Acute, adult toxicity	Contact toxicity (LD_{50})	> 100 µg a.s./bee

Potential for accumulative toxicity: *not assessed*

Semi-field test (Cage and tunnel test)

One semi-field study (tunnel test) is available, which was performed with the formulation BAS 555 00 F. This formulation has a different composition compared to the representative formulation BAS 555 01 F. Based on a comparable toxicity of both formulations in laboratory toxicity studies with honeybees, this study was considered representative for BAS 555 01 F

Species	Test substance	Type of test	Results
Honeybee (*Apis mellifera*)	BAS 555 00 F	Semi-field test (tunnel test) in *Phacelia tanacetifolia*	No unacceptable lethal or sublethal effects on honeybee colonies exposed to 1500 mL/ha (= 90 g a.s/ha).

List of end points

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Field tests
No field tests have been submitted

Tier 1 Risk assessment according to SANCO/10329/2002 and EPPO (2010)

Risk assessment for Cereals (winter/spring) at BBCH 30-69, 1-2 x 90 g a.s./ha (interval 21 days)

Species	Test substance	Risk quotient	HQ/TER	Trigger
Honeybee (*Apis mellifera*)	Metconazole	HQ_{oral}	1.06	50
Honeybee (*Apis mellifera*)	Metconazole	$HQ_{contact}$	< 0.90	50
Honeybee (*Apis mellifera*)	BAS 555 01 F	HQ_{oral}	5.01	50
Honeybee (*Apis mellifera*)	BAS 555 01 F	$HQ_{contact}$	4.55	50
Honeybee (*Apis mellifera*)	Metconazole	$TER_{CH,adult}$	50.5	1
Honeybee (*Apis mellifera*)	Metconazole	$TER_{CH,larvae}$	256.1	1

Note: HQ and TER values in bold exceed, respectively are below, the trigger, indicating that further consideration is required.

Risk assessment for winter oilseed rape at BBCH 13-20 (autumn) and 21-71 (spring), 1-2 x 72 g a.s./ha (interval 90 days) (= “autumn application”) and winter oilseed rape at BBEC 21-71), 1-2 x 72 g a.s./ha (interval 14 days) (= “spring application”)

Species	Test substance	Risk quotient	HQ/TER	Trigger
Honeybee (*Apis mellifera*)	Metconazole	HQ_{oral}	0.85	50
Honeybee (*Apis mellifera*)	Metconazole	$HQ_{contact}$	< 0.72	50
Honeybee (*Apis mellifera*)	BAS 555 01 F	HQ_{oral}	4.01	50
Honeybee (*Apis mellifera*)	BAS 555 01 F	$HQ_{contact}$	3.64	50
Honeybee (*Apis mellifera*)	Metconazole	$TER_{CH,adult}$	50.5	1
Honeybee (*Apis mellifera*)	Metconazole	$TER_{CH,larvae}$	256.1	1

Note: HQ and TER values in bold exceed, respectively are below, the trigger, indicating that further consideration is required.

Screening Step Risk assessment according to EFSA (2013)

Risk assessment for Cereals (winter/spring) at BBCH 30-69, 1-2 x 90 g a.s./ha (interval 21 days), winter oilseed rape at BBCH 13-20 (autumn) and 21-71 (spring), 1-2 x 72 g a.s./ha (interval 90 days) (= “autumn application”) and winter oilseed rape at BBEC 21-71), 1-2 x 72 g a.s./ha (interval 14 days) (= “spring application”)

Acute contact exposure for adult honeybees – screening step

Test substance	Crop	Application rate (g/ha)	LD_{50} (µg/bee)	HQ	Trigger value
Metconazole	Winter and spring cereals	90	> 100	< 0.90	42
	Winter oilseed rape	72	> 100	< 0.72	42
BAS 555 01 F	Winter and spring cereals	1046 [1)]	229.8	4.55	42
	Winter oilseed rape	836.8 [1)]	229.8	3.64	42

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[1)] maximum application rate in mL/ha multiplied by the product density of 1.046 g/cm³; HQ values shown in bold exceed the trigger.

Acute contact exposure of adult honeybees – Screening step

Type of assessment	Test substance	Crop	Application rate (kg a.s./ha)	SV	Endpoint	ETR	Trigger value
Acute oral exposure adult bees	Metconazole	Winter and spring cereals	0.090	7.6	85 µg a.s./bee	0.008	0.2
		Winter oilseed rape	0.072	7.6		0.006	0.2
	BAS 555 01 F	Winter and spring cereals	1.046 [1)]	7.6	208.7 µg product/bee	0.038	0.2
		Winter oilseed rape	0.8368 [1)]	7.6		0.030	0.2
Chronic oral exposure adult bees	Metconazole	Winter and spring cereals	0.090	7.6	50.0 µg a.s./bee/day	0.014	0.03
		Winter oilseed rape	0.072	7.6		0.011	0.03
Chronic oral exposure larvae	Metconazole	Winter and spring cereals	0.090	4.4	12.5 µg a.s./ larva	0.032	0.2
		Winter oilseed rape	0.072	4.4		0.025	0.2

*[1)] maximum application rate in L/ha multiplied by the product density of 1.046 g/cm³; SV: Shortcut value; **bold** values exceed the trigger, indicating a potential risk.*

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	Preparation (BAS 555 01 F)	Mortality, LR_{50} Reproduction, ER_{50}	95 mL prep./ha (8.47 g a.s./ha) > 56 mL prep./ha (> 5.0 g a.s./ha)
Aphidius rhopalosiphi	Preparation (BAS 555 01 F)	Mortality, LR_{50} Reproduction, ER_{50}	461 mL prep./ha (41.1 g a.s./ha) < 170 mL prep./ha (< 15.2 g a.s./ha)
Additional species			

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Species	Test Substance	End point	Toxicity
Crysoperla carnea	Preparation (BAS 555 01 F)	Mortality, LR_{50} Reproduction, ER_{50}	> 2400 mL prep./ha (> 214.1 g a.s./ha) > 2400 mL prep./ha (> 214.1 g a.s./ha)
Aleochara bilineata	Preparation (BAS 555 01 F)	Reproduction, ER_{50}	> 2000 mL prep./ha (> 5178.4 g a.s./ha)

First tier risk assessment for cereals (winter/spring) at BBCH 30-69, 1-2 x 90 g a.s./ha (interval 21 days), winter oilseed rape at BBCH 13-20 (autumn) and 21-71 (spring), 1-2 x 72 g a.s./ha (interval 90 days) (= "autumn application") and winter oilseed rape at BBEC 21-71), 1-2 x 72 g a.s./ha (interval 14 days) (= "spring application")

Test substance	Species	Effect - LR_{50} (g a.s./ha)	HQ in-field	HQ off-field[1]	Trigger
BAS 555 01 F	*Typhlodromus pyri*	8.47	18.06	0.430	2
BAS 555 01 F	*Aphidius rhopalosiphi*	41.1	3.72	0.089	2

[1]a distance of 1m was assumed to calculate the drift rate

Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (mL prep./ha)	End point	% effect[2]	ER_{50}
Typhlodromus pyri	Nymphs	BAS 555 01 F Natural substrate (bean leaf disks)	7 days	125, 250, 500, 1000, 2000 mL prep./ha, Fresh residues	Mortality Reproduction	81.3% mortality at 250 mL prep./ha and 100% mortality at 500 mL prep./ha and higher. 9.5% reduction in reproduction at 125 mL prep/ha	LR_{50} = 188 mL prep./ha (16.8 g a.s./ha) ER_{50} >125 mL prep./ha (>11.2 g a.s./ha)

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Species	Life stage	Test substance, substrate	Time scale	Dose (mL prep./ha)	End point	% effect[2]	ER_{50}
Typhlodromus pyri	Nymphs	BAS 555 01 F Natural substrate (treated bean leaves)	7 days	1000, 2000 mL prep./ha, Fresh residues and aged residues of 3 and 7 days[1]	Mortality	14.3 to 17.6% mortality	LR_{50} > 2000 mL prep./ha (> 177.8 g a.s./ha)
					Reproduction	-4.6 to 7.6% reduction in reproduction	ER_{50} > 2000 mL prep./ha (> 177.8 g a.s./ha)
Aphidius rhopalosiphi	Adults	BAS 555 01 F Natural substrate (barley seedlings)	48 h	500, 800, 1000, 1600, 2000 mL prep./ha, Fresh residues	Mortality	No mortality observed up to the highest tested dose of 2000 mL prep./ha	LR_{50} > 2000 mL prep./ha (> 178.4 g a.s./ha)
					Reproduction	6.8 to 34.4% reduction in reproduction	ER_{50} >2000 mL prep./ha (> 178.4 g a.s./ha)

[1] only results for fresh residues are reported. Bioassays for 3 and 7 DAT were terminated as no effects were found in the bioassay with fresh residues

[2] a positive value indicates a decrease in reproduction, relative to the control

Risk assessment for cereals (winter/spring) at BBCH 30-69, 1-2 x 90 g a.s./ha (interval 21 days), winter oilseed rape at BBCH 13-20 (autumn) and 21-71 (spring), 1-2 x 72 g a.s./ha (interval 90 days) (= "autumn application") and winter oilseed rape at BBEC 21-71), 1-2 x 72 g a.s./ha (interval 14 days) (= "spring application")

Species	Endpoints	In-field rate	Off-field rate[1]
Typhlodromus pyri	LR_{50} = 16.8 g a.s./ha No unacceptable effects on reproduction up to 11.2 g a.s./ha. (ER_{50} > 11.2 g a.s./ha)	**153 g a.s./ha**	0.36 [2]
Typhlodromus pyri	No unacceptable effects on total mortality and reproduction on DAT 0 for up to 177.8 g a.s./ha	153 g a.s./ha	-
Aphidius rhopalosiphi	LR_{50} > 178.4 g a.s./ha No unacceptable effects on reproduction up to 178.4 g a.s./ha (ER_{50} > 178.4 g a.s./ha)	153 g a.s./ha	3.64 [3]

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[1]a distance of 1m was assumed to calculate the drift rate
[2]off-field rate calculated for 2D exposure
[3]off field rate calculated for 3D exposure

Semi-field tests: No semi-field tests have been submitted
Field studies: No field tests have been submitted
Additional specific test: No additional specific tests have been submitted

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[1]	Time scale	End point	Toxicity
Earthworms					
Earthworm (*Eisenia fetida*)	Metconazole (85:15 *cis:trans*)	Applied to soil surface / 10%	Chronic	Growth, reproduction, behaviour	NOEC ≥ 1.8 mg a.s./kg d.w.soil (1350 g a.s./ha) $NOEC_{CORR}$ ≥ 0.9 mg a.s./kg d.w. soil
Earthworm (*Eisenia fetida*)	Metconazole	Mixed with soil after application to quartz sand / 10%	Chronic	Reproduction	EC_{50} > 40 mg a.s./kg d.w. soil $EC_{50,CORR}$ > 20 mg a.s./kg d.w. soil EC_{20} = 16 mg a.s./kg d.w. soil $EC_{20,CORR}$ = 8 mg a.s./kg d.w. soil EC_{10} = 7.8 mg a.s./kg d.w. soil $EC_{10,CORR}$= 3.9 mg a.s./kg d.w. soil NOEC = 5 mg a.s./kg d.w. soil $NOEC_{CORR}$ = 2.5 mg a.s./kg d.w. soil

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Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Earthworm (*Eisenia fetida*)	Preparation (BAS 555 01 F)	Mixed with soil as a solution / 5%	Chronic	Reproduction	EC_{50} > 406.8 mg prep./kg d.w. soil (> 35.0 mg a.s./kg d.w. soil) $EC_{50,CORR}$ > 203.4 mg prep./kg d.w. soil (> 17.5 mg a.s./kg d.w. soil NOEC = 239.9 mg prep./kg d.w. soil (= 20.6 mg a.s./kg d.w. soil) $NOEC_{CORR}$ = 120 mg prep./kg d.w. soil (= 10.3 mg a.s./kg d.w. soil)
Earthworm (*Eisenia fetida*)	Preparation (BAS 555 00 F)	Mixed with soil as a solution / 5%	Chronic	Reproduction	EC_{50} > 518.6 mg prep./kg d.w. soil (> 35.0 mg a.s./kg d.w. soil) $EC_{50,CORR}$ > 259.3 mg prep./kg d.w. soil (> 17.5 mg a.s./kg d.w. soil NOEC = 305.0 mg prep./kg d.w. soil (= 20.6 mg a.s./kg d.w. soil) $NOEC_{CORR}$ = 152.5 mg prep./kg d.w. soil (= 10.3 mg a.s./kg d.w. soil)
Earthworm (*Eisenia fetida*)	Metabolite M555F020 (1,2,4-triazole)	Mixed with soil as a solution / 10%	Chronic	Reproduction	EC_{50} = 5.7 mg/kg d.w. soil EC_{20} = 3.19 mg/kg d.w. soil EC_{10} = 1.81 mg/kg d.w. soil NOEC = 1.0 mg/kg d.w. soil

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Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Other soil macroorganisms					
Folsomia candida	Metconazole	Mixed with soil after application to quartz sand / 5%	Chronic	Reproduction	EC_{50} > 320 mg a.s./kg d.w. soil $EC_{50,CORR}$ > 160 mg a.s./kg d.w. soil EC_{20} = 102.40 mg a.s./kg d.w. soil $EC_{20,CORR}$ = 51.20 mg a.s./kg d.w. soil EC_{10} = 46.46 mg a.s./kg d.w. soil $EC_{10,CORR}$= 23.23 mg a.s./kg d.w. soil NOEC = 40 mg a.s./kg d.w. soil $NOEC_{CORR}$ = 20 mg a.s./kg d.w. soil
Folsomia candida	Preparation (BAS 555 01 F)	Mixed with soil as a solution / 5%	Chronic	Mortality, Reproduction	EC_{50} > 500 mg prep./kg d.w. soil (> 43.02 mg a.s./kg d.w. soil) $EC_{50,CORR}$ > 250 mg prep./kg d.w. soil (> 21.51 mg a.s./kg d.w. soil) NOEC = 500 mg prep./kg d.w. soil (= 43.02 mg a.s./kg d.w. soil) $NOEC_{CORR}$ = 250 mg prep./kg d.w. soil (= 43.02 mg a.s./kg d.w. soil)
Folsomia candida	Metabolite M555F020 (1,2,4-triazole)	Mixed with soil as a solution / 10%	Chronic	Reproduction	EC_{20} = 1.74 mg a.s./kg d.w. soil EC_{10} = 1.51 mg a.s./kg d.w. soil NOEC = 1.8 mg a.s./kg d.w. soil

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Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Hypoaspis aculeifer	Metconazole	Mixed with soil after application to quartz sand / 5%	Chronic	Reproduction	EC_{50} = 138.2 mg a.s./kg d.w. soil $EC_{50,CORR}$ = 69.1 mg a.s./kg d.w. soil EC_{20} = 90.3 mg a.s./kg d.w. soil $EC_{20,CORR}$ = 45.15 mg a.s./kg d.w. soil EC_{10} = 72.3 mg a.s./kg d.w. soil $EC_{10,CORR}$= 36.15 mg a.s./kg d.w. soil NOEC = 62.5 mg a.s./kg d.w. soil $NOEC_{CORR}$ = 31.25 mg a.s./kg d.w. soil

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Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Hypoaspis aculeifer	Preparation (BAS 555 01 F)	Mixed with soil as a solution / 5%	Chronic	Reproduction	EC_{50} = 613.5 mg prep./kg d.w. soil (= 52.79 mg a.s./kg d.w. soil) $EC_{50,CORR}$ = 306.75 mg prep./kg d.w. soil (= 26.40 mg a.s./kg d.w. soil) EC_{20} = 444.3 mg prep./kg d.w. soil (= 38.23 mg a.s./kg d.w. soil) $EC_{20,CORR}$ = 222.15 mg prep./kg d.w. soil (= 19.12 mg a.s./kg d.w. soil) EC_{10} = 375.4 mg prep./kg d.w. soil (= 32.30 mg a.s./kg d.w. soil) $EC_{10,CORR}$ = 187.7 mg prep./kg d.w. soil (= 16.15 mg a.s./kg d.w. soil) NOEC = 250 mg prep./kg d.w. soil (= 21.51 mg a.s./kg d.w. soil) $NOEC_{CORR}$ = 125 mg prep./kg d.w. soil (= 10.76 mg a.s./kg d.w. soil)
Hypoaspis aculeifer	Metabolite M555F020 (1,2,4-triazole)	Mixed with soil after application to quartz sand / 5%	Chronic	Reproduction	EC_{20} = 241 mg a.s./kg d.w. soil EC_{10} = 190 mg a.s./kg d.w. soil NOEC = 171 mg a.s./kg d.w. soil

[1]To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).

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Higher tier testing (e.g. modelling or field studies)

A field study to test the potential effects and potential recovery of field populations of earthworms after application of BAS 555 00 F at a rate of 3.0 L/ha (equivalent to 180 g a.s./ha) was performed. The application of 180 g metconazole/ha resulted in an initial reduction in earthworm abundance, but recovery to 81.5% of the control was reached within one year. Earthworm biomass did not show a statistically significant reduction at any sampling point. Similarly, no significant effects were seen on the abundance of the three main species, *Aporrectodea caliginosa*, *Allolobophora chlorotica* and *Octolasium tyrtaeum*. The numbers of juveniles were statistically reduced at each sampling date, but at the third sampling (1 year after application) only by 23.6%. However, the ratio between juveniles and adult earthworms was approximately on the same level.

Nitrogen transformation	Preparation (BAS 555 01 F)	Maximum tested rare of 11.16 mg prep./kg d.w. soil (720 g a.s./ha); Loamy sand soil	18.9 % effect at day 28 at 11.16 mg prep./kg d.w.soil (720 g a.s/ha)
	Metabolite M555F020 (1,2,4-triazole)	Maximum tested rare of 0.333 mg/kg d.w. soil; Sandy loam soil	1.5% effect at day 28 at 0.333 mg/kg d.w. soil

Toxicity/exposure ratios for soil organisms

Cereals (winter/spring) at BBCH 30-69, 1-2 x 90 g a.s./ha (interval 21 days), winter oilseed rape at BBCH 13-20 (autumn) and 21-71 (spring), 1-2 x 72 g a.s./ha (interval 90 days) (= "autumn application") and winter oilseed rape at BBEC 21-71), 1-2 x 72 g a.s./ha (interval 14 days) (= "spring application")

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia fetida	Metconazole	Chronic	0.071	35.21	5
	Preparation (BAS 555 01 F)	Chronic	0.071	145.1	5
	Metabolite M555F020 (1,2,4-triazole)	Chronic	0.001	1000	5
Other soil macroorganisms					
Folsomia candida	Metconazole	Chronic	0.071	281.7	5
	Preparation (BAS 555 01 F)	Chronic	0.071	303.0	5
	Metabolite M555F020 (1,2,4-triazole)	Chronic	0.001	1510	5
Hypoaspis aculeifer	Metconazole	Chronic	0.071	440.1	5

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Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
	Preparation (BAS 555 01 F)	Chronic	0.071	151.5	5
	Metabolite M555F020 (1,2,4-triazole)	Chronic	0.001	171000	5

[1]Maximum accumulated PEC values ($PEC_{soil, accu}$) were used

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

Screening data

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

Laboratory dose response tests

Species	Test substance	ER_{50} (g/ha) vegetative vigour	ER_{50} (g/ha) emergence	Exposure[1] (g/ha)	TER	Trigger
Zea mays (corn), *Allium cepa* (onion), *Lollium perenne* (ryegrass), *Triticum aestivum* (wheat), *Phaseolus vulgaris* (bean), *Brassica oleracea* (cabbage), *Lactuca sativa* (lettuce), *Raphanus sativus* (radish), *Glycine max* (soybean), *Lycopersicon esculentum* (tomato)	BAS 555 01 F	>1.24 L prep./ha (> 112 g a.s./ha)	>1.24 L prep./ha (> 112 g a.s./ha)	1) 2.493 g a.s./ha 2) 1.994 g a.s./ha	1) > 44.93 2) > 56.17	5
Extended laboratory studies: *none submitted* Semi-field and field test: *none submitted*						

Note: 1) For the use in winter and spring cereals; 2) for the use in winter oilseed rape

[1] Exposure has been estimated based on Ganzelmeier drift data with a standard drift distance of 1 m for the use in cereals and oilseed rape

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	No acceptable endpoint available
Pseudomonas sp	No data available

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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)

No data available

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

Compartment	
soil	Parent (Metconazole)
water	Parent (Metconazole)
sediment	Parent (Metconazole)
groundwater	Parent (Metconazole)

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

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

Substance	name
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][9]:	H411 M-factor = 1
Peer review proposal[10] for harmonised classification according to Regulation (EC) No 1272/2008:	Category Acute 1 | Endpoint: 0.527 mg a.s./L [7-day E_rC_{50} *Lemna gibba*] H400 (M-factor = 1) Category Chronic 1 | Endpoint: 0.00291 mg a.s./L [Chronic NOEC *Oncorhynchus mykiss*] H410 (M-factor = 10)

[9] 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.

[10] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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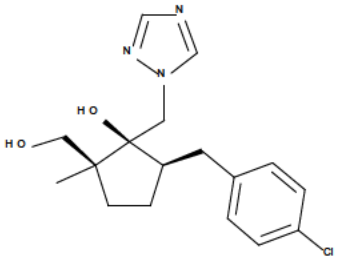
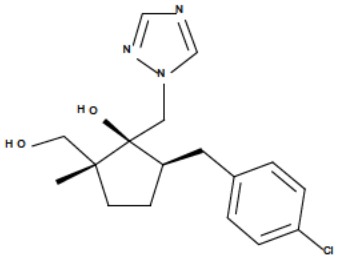
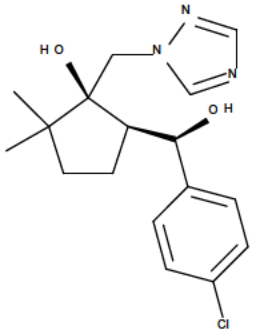
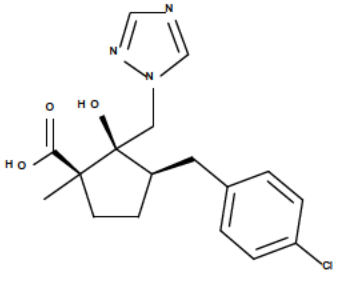
Appendix

Used compounds code(s)

Code/Trivial name*	IUPAC name/SMILES notation	Structural formula
M555F001 cis (**M1**)	(1SR,2SR,5RS)-5-(4-chlorobenzyl)-2-(hydroxymethyl)-2-methyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	
M555F002 cis (**M2**)	(1SR,2RS,5RS)-5-(4-chlorobenzyl)-2-(hydroxymethyl)-2-methyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	
M555F011 cis (**M11**)	(1RS,5SR)5-[(SR)-(4-chlorophenyl)(hydroxy)methyl]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	
M555F012 cis (**M12**)	(1RS,2SR,3RS)-3-(4-chlorobenzyl)-2-hydroxy-1-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanecarboxylic acid	

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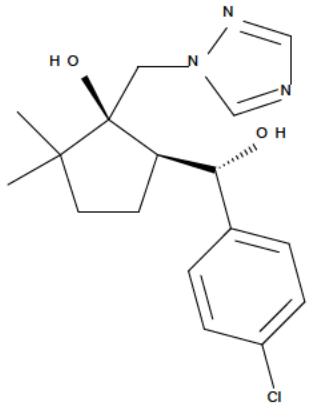
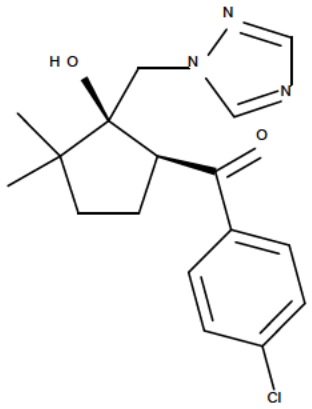
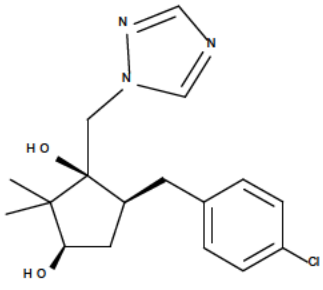
M555F021 cis (**M21**)	(1RS,5SR)-5-[(RS)-(4-chlorophenyl)(hydroxy)methyl]-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	
M555F030 cis (**M30**)	(1RS,5SR)-5-(4-chlorobenzoyl)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	
M555F031 cis (**M31**)	(1RS,3SR,5RS)-5-(4-chlorobenzyl)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentane-1,3-diol	

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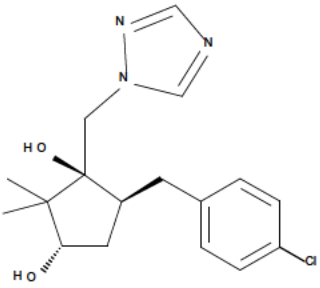
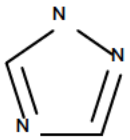
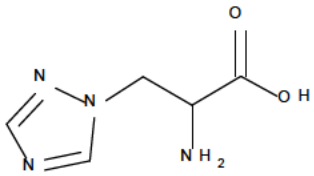
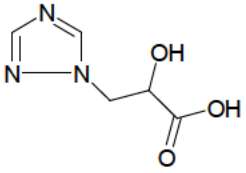
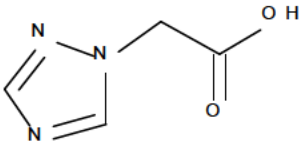
M555F032 cis (**M32**)	(1RS,3RS,5RS)-5-(4-chlorobenzyl)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentane-1,3-diol	
1,2,4-triazole (**T**)	1,2,4-(1H)-triazole	
Triazolyl alanine (**TA**)	2-amino-3-(1H-1,2,4-triazol-1-yl)propionic acid	
Triazolyl lactic acid (**TLA**)	2-hydroxy-3-(1H-1,2,4-triazol-1-yl)-proprionic acid	
Triazolyl acetic acid (**TAA**)	(1H-1,2,4-triazol-1-yl)acetic acid	

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