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TRITICONAZOLE

Volume 3 – B.9 (PPP) – Premis 25 FS

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Version History

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B.9. ECOTOXICOLOGY DATA AND ASSESSMENT OF RISKS FOR NON-TARGET SPECIES

Triticonazole is a fungicidal active substance and was included into Annex I of Directive 91/414/EEC in 2005 (Directive 2006/39/EC, 12th April 2006). Directive 91/414/EEC has been repealed by Regulation (EC) no 1107/2009 of 21 October 2009 concerning the placing of plant protection products on the market. Accordingly triticonazole is deemed to have been approved under Regulation (EC) no 1107/2009, as set out in Part A of the Annex of Commission Implementing Regulation (EC) no 540/2011 as regards the list of approved substances (entry no. 127).

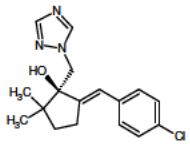
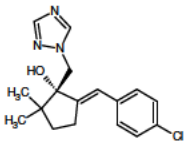
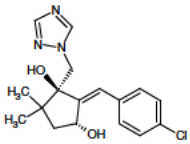
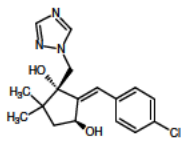
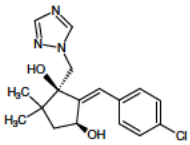
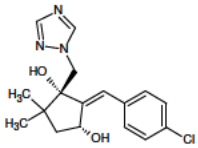
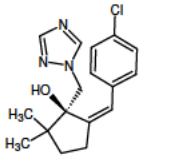
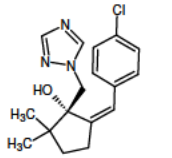
This renewal assessment report (RAR) contains summaries of studies on triticonazole, which were not available at the time of the Annex I inclusion under Directive 91/414/EEC and were, therefore, not evaluated during the first EU review of this compound. In addition, all studies, which were already submitted for the Annex I inclusion under Directive 91/414/EEC, were re-evaluated according to the current valid test guidelines and were summarized in the RAR (study title is greyed out).
Studies which were submitted for the first EU peer-review of the active substance triticonazole but are no longer a data requirement according to the data requirements for active substances (Commission Regulation (EU) 283/2013) and/or plant protection products (Commission Regulation (EU) 284/2013) are briefly summarised (text in *italic*).

In case where reliable and adequate literature was found during the literature search, summaries are integrated in the respective sections of the RAR.

Triticonazole is a racemic mixture of two enantiomers. The fungicidal activity of the two enantiomers has been shown to be equivalent and not different from the racemic mixture. In degradation studies (non-guideline lysimeter study and in a water sediment study) no significant changes in the ratio of the racemate (1:1) were observed, indicating that the degradation and distribution of both enantiomers is the same in the environment. Therefore it was considered adequate that all studies on the active substance where performed using the racemic mixture.

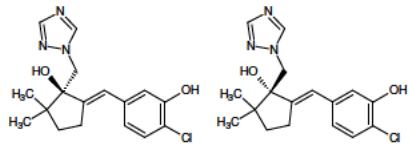
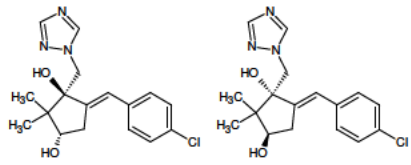
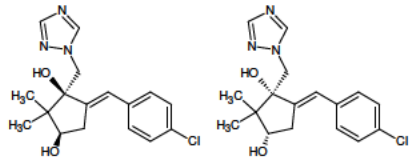
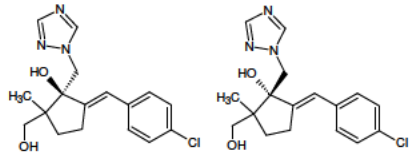
The different synonyms and codes for the active substance triticonazole and its metabolites used in the RAR are summarized in the table B 9 -1.

Table B 9-1: Substances and metabolites (structure, synonyms and codes)

Code number (Synonyms)	Chemical name and molecular formula	Mol weight (g/mol)	Occurrence (% AR)	Structure
Triticonazole E-isomer (BAS 595 F, RPA 400727, M595F000)	(1*RS*, 5*E*)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl) cyclopentanol $C_{17}H_{20}ClN_3O$	317.8	Not applicable (parent)	 *R*-isomer  *S*-isomer
RPA 406341 Trans-diol (Alpha-hydroxy-triticonazole, M595F002, AE 0540093, Reg. No. 5059144)	(1*RS*,2*E*,3*SR*)-2-(4-chlorobenzylidene)-5,5-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)-1,3-cyclopentanediol $C_{17}H_{20}ClN_3O_2$	333.8	**Aerobic soil: 20.2** Anaerobic soil: 1.8 Soil photolysis: 3.5 Aquatic hydrolysis: ni Aquatic photolysis: ni Aerobic surface water: 1.8 Water/sediment: ni	 *RS*-isomer  *SR*-isomer
RPA 404766 Cis-diol (Beta-hydroxy-triticonazole, M595F001, AE 0591653, Reg. No. 5079285)	(1*RS*,2*E*,3*RS*)-2-(4-chlorobenzylidene)-5,5-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)-1,3-cyclopentanediol $C_{17}H_{20}ClN_3O_2$	333.8	**Aerobic soil: 13.9**[a] Anaerobic soil: 2.0 Soil photolysis: 3.3 Aquatic hydrolysis: ni Aquatic photolysis: ns Aerobic surface water: 1.3 Water/sediment: ni	 *RR*-isomer  *SS*-isomer
RPA 406203 Z-isomer (M595F014, Reg. No. 5079359)	(1*RS*, 5*Z*)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl) cyclopentanol $C_{17}H_{20}ClN_3O$	317.8	Aerobic soil: 4.4 Anaerobic soil: - **Soil photolysis: 11.0** Aquatic hydrolysis: 2.6 **Aquatic photolysis: 42.3**[b] Aerobic surface water: 4.2[c] Water/sediment: ni	 *R*-isomer  *S*-isomer

ni denotes not investigated (below 5 % AR)
ns denotes not stated (below 5 % AR)
(a) 10 °C study (max. 9.9 % AR in 20 - 25 °C studies)
(b) Without sensitizer
(c) Arithmetic mean of phenyl and triazole label

Table B 9-2: Other metabolites of triticonazole originally considered as possible metabolites of triticonazole (considered not to occur at significant amounts in environmental compartments following re-evaluation)

Code number (Synonyms)	Chemical name and molecular formula	Mol weight (g/mol)	Occurrence (% AR)	Structure
RPA 407922 (M595F013, Reg. No. 5079288)	2-chloro-5-{(E)-[(2RS)-2-hydroxy-3,3-dimethyl-2-(1H-1,2,4-triazol-1-ylmethyl)cyclopentylidene]methyl}phenol $C_{17}H_{20}ClN_3O_2$	333.8	Unlikely to occur at significant (> 5 % AR) amounts in environmental compartments	 *R*-isomer *S*-isomer
RPA 406780[(a)]	(1SR,3RS,5E)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentane-1,3-diol $C_{17}H_{20}ClN_3O_2$	333.8	Unlikely to occur at significant (> 5 % AR) amounts in environmental compartments	 *RS*-isomer *SR*-isomer  *RR*-isomer *SS*-isomer
RPA 404886 (M595F005, Reg. No. 5079247)	(1*RS*,5*E*)-5-(4-chlorobenzylidene)-2-(hydroxymethyl)-2-methyl-1-(1*H*-1,2,4-triazol-1-ylmethyl) cyclopentanol $C_{17}H_{20}ClN_3O_2$	333.8	Unlikely to occur at significant (> 5 % AR) amounts in environmental compartments	 *R*-isomer *S*-isomer

(a) Isomeric composition not specified further (Trans- vs. Cis-diol)

RPA 406203 is the Z-isomer of triticonazole and can be formed under light conditions from triticonazole (the E-isomer). The applicant provided a separate Document (N5) summarizing all available information about the Z-isomer, its environmental fate, toxicological and ecotoxicological relevance. In order to address the potential of the exposure of granivorous birds to the Z-isomer by eating unburied seeds the applicant additionally provided a study regarding the abundance and density of unburied seeds in freshly drilled cereal fields in Germany and a study for determination of BAS 595 F and M595F014 (RPA 406203) in wheat seed after seed treatment with Bas 595 01 F. A summary of document N5 and the studies as well as their evaluations is presented in B.9.1 Effects on birds and other terrestrial vertebrates.

The formulation is intended for use as a seed treatment fungicide in cereals. The critical use pattern for this formulation is summarised in Table B.9-2.

Table B 9-3: Intended application pattern

Crop	Timing of application	No. of applications	Application interval [days]	Maximum application rate (formulation) [L/ha]	Maximum application rate (active substance) [kg ai/ha]
winter wheat, spring wheat, winter barley, spring barley, rye, triticale, oats	BBCH 00/ spring and autmn	1	365	0.5 L/ha (based on 200 mL/100 kg, 250 kg seed/ha	12.5 g/ha (based on 5 g ai/100 kg seed, 250 kg seed/ha)

B.9.1. EFFECTS ON BIRDS AND OTHER TERRESTRIAL VERTEBRATES

B.9.1.1. Effects on birds

Several acute, dietary and reproductive toxicity studies with triticonazole have been performed with mallard duck and bobwhite quail. Most of the studies were already submitted for the first EU peer-review of the active substance triticonazole. A new one-generation bird toxicity study ([redacted], 2012a) was submitted, for the renewal of the EU peer-review.

The study summaries are provided under point B.9.1.1 of Volume 3 – B.9-CA

A summary of the toxicity of triticonazole to birds is given in Table 9.1-1

Table 9.1-1: Toxicity of triticonazole to birds

Test species	Test design	Ecotoxicological endpoint	Reference
Bobwhite quail *(Colinus virginianus)*	Acute, oral	LD_{50} > 2000 mg ai/kg bw **$LD_{50\ extrapol.}$ = 3776 mg ai/kg bw** [a]	[redacted], 1991a
Mallard duck *(Anas platyrhynchos)*		LD_{50} > 2000 mg ai/kg bw $LD_{50\ extrapol.}$ = 3776 mg ai/kg bw [a]	[redacted], 1991b
Grey partridge *(Perdix perdix)*		LD_{50} > 2000 mg ai/kg bw **$LD_{50\ extrapol.}$ = 3776 mg ai/kg bw** [a]	[redacted], 1992a
Red-legged partridge *(Alectoris rufa)*		LD_{50} > 2000 mg ai/kg bw **$LD_{50\ extrapol.}$ = 3776 mg ai/kg bw** [a]	[redacted], 1992b
Pigeon (*Columba livia*)		LD_{50} > 2000 mg ai/kg bw	[redacted], 1990a
Ring-necked pheasant *(Phasianus colchicus)*		LD_{50} > 2000 mg ai/kg bw	[redacted], 1990b
Bobwhite quail *(Colinus virginianus)*	Short-term, dietary	LC_{50} > 5200 ppm LDD_{50} > 693 mg ai/kg bw/d	[redacted] 1992a
Mallard duck *(Anas platyrhynchos)*		LC_{50} > 5200 ppm LDD_{50} > 1300 mg ai/kg bw/d	[redacted]., 1992b
Bobwhite quail *(Colinus virginianus)*	Reproduction	NOEC = 150 mg/kg diet NOEL = 10.98 mg ai/kg bw/d	[redacted] 2012a
		NOAEL = 12.4 mg/kg bw/d	[redacted] 2007[c]
		NOAEL = 19.5 mg/kg bw/d	[redacted], 1995a
Mallard duck *(Anas*		NOEC = 1000 ppm NOAEL = 108.15 mg ai/kg bw[b]	[redacted], 1998b

Test species	Test design	Ecotoxicological endpoint	Reference
platyrhynchos)			

Bold values were used for the risk assessment
[a]LD_{50} extrapolated according to the EFSA Guidance Document on Birds and Mammals (2009). 10 birds per group were tested without any mortality during the study. An extrapolation factor of 1.888 was used for the calculation of the extrapolated LD_{50}.
[b]conversion based on the mean consumption of 117.98 g/day and an average body weight of 1090, 9 g
[c]reliability of the study is questioned; please refer to Volume 3 – B.9-CA

Table 9.1-2: Toxicity of metabolite RPA 406341 to birds

Test species	Test design	Ecotoxicological endpoint	Reference
Bobwhite quail *(Colinus virginianus)*	Acute, oral	$LD_{50} \geq 2250$	[redacted], 2000a

Acute toxicity endpoint

Seven acute toxicity studies already submitted during the first peer-review process are available. According to the EFSA Guidance Document on Birds and Mammals (2009) the geometric mean can be used if data for more than one species are available. However the study with the pigeon ([redacted], 1990a) and the study with the ring-necked pheasant ([redacted], 1990b) are considered to be used only as additional information. In the study with the mallard duck ([redacted], 1991b) regurgitation occurred and it will therefore not be used for the endpoint estimation. In the studies with bobwhite quail ([redacted], 1991a and [redacted]., 2000a) two different vehicles (1 % methylcellulose and corn oil, respectively) were used and therefore the geometric mean is not applicable for these two studies.

Thus the endpoint used for the risk assessment is 3776 mg ai/kg bw based on the geometric mean of the endpoints from the studies with bobwhite quail ([redacted], 1991a), Grey partridge ([redacted], 1992a) and Red-legged partridge ([redacted], 1992b).

Long-term toxicity endpoint

Three reproductive studies already submitted for the first EU peer-review process are available [redacted], 1995a; [redacted], 1998b; [redacted], 2007) A one-generation bird toxicity study ([redacted], 2012a) was submitted additionally. In the course of the re-evaluation the reliability of the study submitted as confirmatory data ([redacted], 2007) was questioned.

For an overview all available studies are presented in Table 9.1-3 summarising deficiencies and uncertainties regarding study design or choice of the endpoint. For full study summaries and further details please refer to Volume 3, B 9-CA.

Table 9.1-3: Summary of standard bird 1-generation reproductive toxicity studies – deficiencies and uncertainties regarding study design and choice of endpoint

Study reference number, author, year, species tested, concentrations tested	Guidelines	Considerable Deviations from Guidelines	Proposed Endpoint by the notifier	Uncertainties (including comments of the Co-RMS)	Further remarks
BASF DocID 2011/1269059, [redacted] 2012a, Bobwhite quail 50, 150, 400 mg ai/kg diet	OECD 206, US EPA § 71-4, U.S. EPA-OTSPP 850.2300	Not all validity criteria for OCSPP 850.2300 are met, however valid according OECD 206	NOEL= 10.98 mg ai/ kg bw/day (150 mg/kg diet)	There is a potential dose/concentration and treatment related effect on the number of 14-day surviving chicks/female per week. Whilst the effect at 150 ppm isn't statistically significant it is fitting a dose/concentration could be potentially treatment related, therefore, this issue should be discussed further in the assessment of the study. UK has some concerns about the reliability of the study as not all validity criteria of OCSPP 850.2300 (2012) are met	The effect is 13.6% and not statistically significant. All other parameters do not show treatment related effects at this concentration
R013161, [redacted], 1995a, Northern bobwhite, 250, 500, 1000 mg ai/kg diet	FIFRA Subdivision E, Section 71-4, OECD 206	Valid according to OECD 206	NOAEL= 19.5 mg ai/ kg bw/day (250 mg/kg diet)	Whilst there are non-statistically significant effects on the number of 14-day old survivors/egg set, there is a potential dos/concentrations and treatment related effect that warrants further consideration. UK proposes to set the NOEC < 250 ppm	The effect is 10.6% and not statistically significant. All other parameters do not show effects over 10%. It is set as a NOAEL
R000098, [redacted], 1998b,	EPA Guideline No.: 71-4 (b)	Valid according to OCSPP 850.2300 and OECD 206	NOEL= 108.15 mg ai/ kg bw/day (1000 mg/kg diet)	-	-

Mallard duck 125, 250, 500, 1000 mg ai/kg diet	(1982)				
BASF DocID 2006/1026908, [redacted], 2007, Bobwhite quail, 170, 300 mg ai/kg diet	FIFRA Subdivision E, Section 71-4, U.S. EPA-OPPTS 850.2300, OECD 206	Not all validity criteria for OCSPP 850.2300 are met, however valid according OECD 206	NOAEL = 12.4 mg ai/kg bw/day (170 mg/kg diet)	Statistically significant differences compared to the control occurred at the lowest concentration of 170 ppm, and therefore the UK considers that the possible toxicity endpoint is < 170 ppm. The reliability of the study is questionable as only two concentrations were tested and it is not clear which consequences this has on the statistical power.	The hatchability in the next higher concentration shows no statistically significant effect and therefore no dose-response relation seems seems to be given.

According to the EFSA Guidance Document on Birds and Mammals (2009), datasets from more than one study on the same species may be merged. Merging is only possible if the studies are conducted according to a similar protocol or guideline and the key endpoints have been assessed in all studies. The studies have to be similar regarding dose-response, number of animals used and the same conditions have to be applied.

The three data sets from standard bobwhite quail reproduction studies have been merged and then sorted according to their dose rate range from highest to lowest dose rate value. Therefore the NOAEL used in the risk assessment is 19.5 mg ai/kg bw/d. The endpoints which were used for the merging are presented in Table 9.1-4.

The three studies merged were conducted according to the same guideline (OECD 206) and all key endpoints have been assessed. The conditions under which the studies have been conducted are comparable (number of replicates, duration of the study, light regime).

Table 9.1-4: Effects observed in standard 1-generation reproductive toxicity bird bobwhite quail studies – sorted from lowest to highest dose rate for deriving a combined NOAEL for triticonazole

Study author/year/ BASF DocID	[redacted] 2012a 2011/1269059	[redacted], 2012a 2011/1269059	[redacted] 2007 2006/1026908	[redacted] 1995a R013161	[redacted] 2007 2006/1026908	[redacted], 2012a 2011/1269059	[redacted] 1995a R013161	[redacted] 1995a R013161
Concentration **Effects**	50 ppm	150 ppm	170[l] (12.4 mg/kg bw/d)	250 **(19.5 mg/kg bw/d)**	300[l]	450 ppm	500	1000
Number of replicates	16	16	16	14	16	16	13	13
No treatment related mortalities	0	0	0	0	0	0	0	0
Eggs laid per hen/day	0.68[a]	0.66[a]	0.66[a]	0.63	0.51[a]	0.43[a]*	0.44*	0.3*
No. eggs laid per hen/week	4.8	4.6	4.6	4.74[d]	3.6	3.0*	3.28[d]*	2.25[d]*
No. chicks hatched per hen/week	3.0	2.5	2.2	3.51[d]	1.7*	1.8*	2.00[d]*	1.05[d]*
No 14 d survivors/hen/week	2.4	1.9	1.4	2.88[d]	0.7	1.1*	1.19[d]*	0.19[d]*
Mean body weight chicks hatching	6.3	6.1	5.5*[f]	6.9	5.4*	6.0	6.3*	5.8*
Mean eggshell thickness	0.19	0.20	0.21	0.224*[e]	0.2	0.19	0.219*[e]	0.223*[e]
% fertile eggs of eggs set	95.3	92.6	84.8	87.4[b]	78.5*	93.5	85.7[b]	75.9[b]
% 14 day survivors chicks hatched	79.6	73.1	56.2	82	37.8*	55.3*	60*	18*
% hatchlings/eggs set	75.1	65.8	33.8[a]	67	55.24[c]	70.1	42*	10*

[l]The study by [redacted] 2007 was included although its reliability is questioned. The study results seem not to influence the endpoint.
[a] Values estimated by the RMS by derivation from the eggs laid per group divided by the days of egg laying period
[b]Values estimated by the RMS by dividing fertile eggs/group by eggs set/group*100
[c]Values estimated by the RMS by dividing chicks hatched by the eggs set *100
[d] Values provided by the applicant
[e]no dose response
[f]post hatch survival not significantly decreased, body weights after 14 days comparable to control group – no biologically adverse effect
*statistically significant difference to control

As a refinement option of the long-term toxicity endpoint the applicant provided a 1-generation reproduction study on bobwhite quail with shortened exposure duration ([redacted] 2008).
The proposed endpoint of this study is 24.7 mg ai/kg bw. However, after re-evaluation its validity as well as its reliability is considered questionable. Furthermore the usefulness of a study with shortened exposure duration has to be discussed as it is questionable whether all reproductive phases have been assessed and if so whether there were sufficient to detect any effects. For details please refer to Volume 3, B.9-CA.

Toxicity of the formulated product

Due to animal welfare reasons, no additional study with the current formulation was conducted in birds. However, a formulation study is available on rats, indicating that the formulation does not pose additional risk to vertebrates (for further information, reference is made to point 9.1.2). Therefore, the risk assessment will be based on the active substance.

Endocrine disruption

The population relevant effects of triticonazole on birds were studied in reproductive toxicity studies on bobwhite quails and mallard ducks. At the date of submission no formally adopted criteria were available in the EU for what constitutes an endocrine disruptor under Regulation 1107/2009. For birds, there was also no internationally validated regulatory testing guideline available. At the current state a final conclusion on the potential of triticonazole on endocrine disrupting properties is not possible.
To address the issue the applicant provided a statement which is presented in the following (*in italic*):
Effects on avian reproduction are covered by the avian reproduction study, which is part of the standard data package for an active ingredient.

For triticonazole, four standard avian reproduction studies are available, three in bobwhite quail and one in mallard duck (see chapter M-CA 8.1.1.3 above). The standard data requirement for registration in the EU for reproductive bird testing comprises a single study with one bird species. However, for triticonazole, avian reproduction studies are available for two species, hence reducing the uncertainty on potential variations in species sensitivity. All studies were conducted according to OECD 206 and/or OCSPP 850.2300. In addition to these standard studies, one modified 1-generation study in bobwhite quail is available, also following guideline protocols, but with a shortened exposure period. As guideline regulatory studies, the focus of these studies was on the general and reproductive toxicity of triticonazole to birds, but they do include reproductive endpoints that are under endocrine control. With their long-term exposure (≥ 20 weeks) and detailed assessment of fitness and reproductive parameters, and gross necropsy assessment, the standard studies provide adequate information on the overall effect pattern of the active substance triticonazole in birds. Hence, the studies are considered suitable to allow for a full evaluation of the reproductive toxicity, including any endocrine potential of triticonazole that might impact the reproductive performance in birds. This is in line with a recent conclusion of the US EPA in its

Endocrine Disruptor Screening Program (EDSP)1. In June 2015, US EPA released its review2 of the Tier 1 screening assay results for the list 1 chemicals (total of 52 chemicals) in the EDSP. EPA clearly states that data obtained from the "avian reproduction studies (OCSPP 850.2300) are considered sufficient for evaluating potential reproductive effects to birds" and "additional testing is not recommended" (e.g. propiconazole, p. 333).

Many plant protection product actives were among the chemicals screened in the EDSP, including four triazoles, namely myclobutanil, propiconazole, tebuconazole and triadimefon. All these compounds belong to the same chemical group as triticonazole, i.e. the triazoles. For all evaluated triazoles, the US EPA concluded that further bird testing is not recommended and the avian reproduction studies were considered sufficient for the evaluation of potential reproductive effects on birds.

In summary, it can be concluded that the available data from the multiple avian reproduction toxicity studies for triticonazole are suitable to derive a robust NOEL, which also covers the endocrine potential of triticonazole in the avian reproductive risk assessment.

Metabolites of triticonazole

The potential routes of avian or mammal exposures are via direct consumption of treated seeds or emerging cereal shoots. The active substance exhibits at least some systemic behaviour; hence exposure to metabolites is also considered likely to metabolites in emerging shoots.

The main initial metabolic process for triticonazole in plants is hydroxylation, either on the pentane ring (to give rise to RPA 404766, RPA 406341 or RPA 406780) or on one of the methyl groups associated with the pentane ring (to give rise to RPA 404886). The separation/destruction of the triazole group may occur with the parent molecule unchanged or from the hydroxy metabolites. Once it has occurred, the incorporation into natural products is very rapid and such molecules are transported to the grain during its development. The residual molecule (or metabolites derived from it) will form part of the polar residue remaining in straw.

In the plant metabolism and rotational crop studies with triticonazole (BASF DocIDs R000502 [EU reference P91/110], R012989 [EU reference P91/358], C021046 [EU reference CX/01/010], R012993 [EU reference P93/192]) some unidentified non-polar and polar metabolites, and the metabolites RPA 406341, RPA 404766,

[1] The Endocrine Disruptor Screening Program (EDSP) of US EPA is a program to screen chemicals for their potential to affect the estrogen, androgen and thyroid hormone systems using a two-tiered screening and testing process. The results of the screening are evaluated in a weight of evidence (WoE) approach by EPA to determine whether a chemical has the potential to interact with the endocrine system and whether more thorough testing is required. The WoE conclusion on the tier 1 screening assays for list 1 chemicals was published in June 2015.

[2] United States Environmental Protection Agency Washington, D.C. 20460, Memorandum, June 29, 2015, EDSP Weight of Evidence Conclusions on the Tier 1 Screening Assays for the List 1 Chemicals.

[3] United States Environmental Protection Agency. EDSP: Weight of Evidence Analysis of Potential Interaction with Estrogen, Androgen or Thyroid Pathways. Chemical: Propiconazole. Washington, D.C. 20460, Memorandum, June 29, 2015.

RPA 406780, and RPA 404886 approached or exceeded 10% TRR. In green plant material at BBCH 24 / 30, a potential feed item for herbivorous birds, only polar unidentified metabolites and metabolite RPA 406780 were shown to be major. These metabolites were also found at BBCH 65 / 62-65. However, most metabolites approaching or exceeding 10% TRR were found in cereal chaff, grain or straw (polar unidentified metabolites, RPA 406341, RPA 404766, RPA 406780, RPA 404886), which are not considered to be feed items of herbivorous birds.

Due to their significant relative quantities, the metabolites mentioned above will be evaluated as to their potential relevance for birds:

- The unidentified non-polar and the identified metabolites (RPA 406341, RPA 404766, RPA 406780, RPA 404886) are more polar than the parent molecule triticonazole, and therefore would be rapidly excreted when consumed by animals via the food. Based on this it can be concluded that these metabolites are of lower concern than the parent molecule.
- Toxicological limit tests in quails (BASF DocID B002787) and rats (BASF DocID R000206) with RPA 406341 indicate no mortality up to the highest concentration tested (> 2250 mg ai/kg b.w. in quails and > 2000 mg ai/kg b.w. in rats), hence no increased toxicity compared to the parent.
- RPA 406780 and RPA 404886 evolve from triticonazole via hydroxylation, and due to the lower lipophilicity would be excreted more rapidly than the parent molecule.
- The identified major metabolites mentioned so far (RPA 406341, RPA 404766, RPA 406780 and RPA 404886) were also found in rats (BASF DocID R013078 and C018956). This indicates that potential toxicity of these metabolites is covered by the toxicity testing of the parent compound.

Based on these findings for the metabolites approaching or exceeding 10% TRR in the plant metabolism and rotational crop studies, it is assumed that the risk assessments for the parent molecule triticonazole, as provided in the following chapters, addresses the potential risk from the major plant metabolites.

Higher tier studies:

During the first EU-approval of triticonazole, confirmatory data were required to address the long term risk for birds. In 2009 a one-generation reproduction study on bobwhite quail with shortened exposure duration to 4 weeks was submitted as confirmatory data [redacted], 2008) to derive a refined endpoint (NOEL = 24.7 mg ai/kg bw/day). The study report summary and the re-evaluation are presented in Volume 3 – B.9-CA. However, during the re-evaluation of the review process, the reliability and the usefulness of the study in the risk assessment was questioned and the RMS requests for expert consultation (Please refer to Volume 3 – B.9-CA).

Furthermore two degradation studies (Scrimshaw, 2006 and Moreno 2008) were provided as confirmatory data. The results were used for the risk assessment. For the current application the applicant submitted two additional studies addressing residues in spring wheat seeds (Plier, 2016) and winter wheat seeds (Plier & Elze, 2017) and separate reports reviewing the degradation kinetics for the calculation of DT_{50} dissipation times (Szegedi, 2017a & b). Furthermore studies to determine the focal species and to refine PD and PT values respectively of skylark, yellowhammer and chaffinch (Moosmayer, 2008a; Barfknecht; 2006a; Sadowski *et al.*; 2014a; Dittrich &

Benito; 2017a; Erni *et al.*; 2017a) were submitted. The study report summaries, the evaluations and re-evaluations, respectively, are presented in the following:

Reference:	**Rate of degradation of prochloraz and triticonazole under field conditions on spring wheat seed exposed on the soil surface following treatment with Kinto (BAS 591 01 F) seed treatment in UK**
Author(s), year:	Scrimshaw O., 2006
Report/Doc. number:	BASF DocID 2006/1015760
Guideline(s):	None
GLP:	Yes
Deviations:	Please refer to the commenting box below
Validity:	Acceptable

Material and methods:

Test substance:	BAS 5901F (Kinto) FS Triticonazole (BAS 959 F) 20 g ai/L Batch No.:84096 Prochloraz copper chloride complex (5050913) 60 g ai/L
Type of the test:	Residue/degradation study with treated seed
Treatments:	Nominal application rate: 4 g triticonazole, 12 g prochloraz copper chloride complex/100 kg seed Actual application rate: 3.96 g triticonazole, 11.99 g prochloraz copper chloride complex/100 kg seed
Experimental procedure:	Three field trials were conducted with spring wheat seeds in England and Scotland in February and March. The trials consisted of one variant with one plot at each testing site. Field preparations, pre-sowing activities and the sowing were carried out according to GAP. The treated seed was applied to the soil surface using commercial drilling machinery and immediately after application specimen of seeds were collected and again 1, 3, 7, 14 and 21 days after application. The seeds were covered with netting to prevent the grains being eaten by birds and mammals. In addition agricultural fleece was placed over the netting to offer protection against heavy rainfall preventing excessive wash, but without having impact on normal temperature at ground level. At each sampling event, two separate seed samples were collected (in total 225 seeds) by means of tweezers into plastic vessels. Non-germinated seeds were preferred. Specimens were frozen until analysis (for a maximum of 36 days). Data from the official weather service station were obtained for the relevant time period.
Test parameters, observations:	The samples were analysed for triticonazole content with BASF method no. 526/0 (HPLC-MS/MS), which quantifies the residues; the LOQ was 0.01 mg/kg. Procedural recoveries obtained averaged 94 % for triticonazole at fortification levels of 0.01 and 0.1 mg/kg. Analyses for prochloraz were also conducted. These and their results are not reported in this summary.

Results:

Germination: Seeds collected from day 0 to day 3: not germinated.
On day 7: 0-10% showed signs of germination.
On day 14: 15-20% germinated
On day 21: 90-100% germinated

Residues:

Table 9.1-5: Initial residues of triticonazole on spring wheat seeds exposed onto the soil surface at day 0 after sowing in UK

Crop, country		Loading before sowing	Initial loading after sowing				Reference (BASF DocID)
			Trial 1 (Code)	Trial 2 (Code)	Trial 3 (Code)	Arithmetic mean (trials 1-3)	
Spring wheat, UK			BA/1	BA/2	BA/3	BA/1-3	2006/1015760
	Measured residues [mg ai/kg seed]	39.6	27.64	22.53	29.22	26.46	
	[%] [1)]	100	69.80	56.89	73.79	66.83	

[1)]The measured residue levels before sowing were put to 100%. The remaining measured values are related to these 100%-values.

Conclusion: Directly after broadcasting of the spring wheat seeds, the total residue of triticonazole ranged between 22.529 and 29.217 mg/kg. These residues were degraded to values between 2.236 and 7.180 mg/kg within 3 weeks.

Comment RMS: This study was submitted as confirmatory data in 2009.
The nominal rate of triticonazole was 4 g/100 kg seeds, which is less than the intended application rate of 5 g ai/100 kg seeds.
Please note, that the three trials were conducted in only one site (field) each with two seed samplings per field and sampling event.
Acceptability of the analytical methods used in the test:
Evaluation of the analytical methods (water/sediment/soil) according to the Guidance Document SANCO/3029/99 rev. 4.
Method: LC/MS/MS (BASF method No. 562/0)
Linearity: number of duplicates not stated and not possible to identify via the calibration curve.
calibration range: not possible to identify via calibration curve; r^2 0.9997
Accuracy: two fortification levels (0.01 and 0.1), 2 measurements; mean recovery for each level: 88.8 and 99.8 %, respectively
Precision: The relative standard deviation per fortification level is 1.27 and 2.07%, respectively
LOQ: 1.01mg/kg ai

	LOD: not reported The analytical method fulfils the requirements of guideline SANCO/3029/99 rev. 4. **Endpoints:** Initial residues: 22.529 - 29.217 mg ai/kg Residues after 3 weeks: 2.236 - 7.180 mg ai/kg **Conclusion of the RMS:** The RMS considers the study acceptable.

Reference:	**Rate of degradation of triticonazole under field conditions on spring wheat seeds treated with Premis 25 FS (BAS 59501 F) exposed on the soil surface after sowing in Spain (2007)**
Author(s), year:	Moreno S., 2008
Report/Doc. number:	BASF DocID 2007/1016397
Guideline(s):	None
GLP:	Yes
Deviations:	At trial 07/S/13, an application of the insecticide Dursban 48 EC at a rate of 1.5l/ha was conducted to avoid the loss of seeds due to seed predation by ants on March 27th, 2007. On May 7th, 2007 at trial No. 07/S/15 no specimen could be collected due to > 95% of the seeds were at BBCH growth stages ≥ 09 Please also refer to the commenting box below
Validity:	Acceptable

Material and methods:

Test substance:	BAS 5901F (Premis 25 FS) Triticonazole 25g ai/L Batch No.:84002
Type of the test:	Residue/degradation study with treated seed
Treatments:	Nominal application rate: 5 g triticonazole/100 kg seed Actual application rate: 5.6 g triticonazole/100 kg seed
Experimental procedure:	Three field trials were conducted with spring wheat seeds in Spain in March and April. The trials consisted of one variant with one plot at each testing site. Field preparations, pre-sowing activities and the sowing were carried out according to GAP. The treated seed was applied to the soil surface using commercial drilling machinery and immediately after application specimen of seeds were collected and again 1, 3, 7, 14 and 21 days after application. The plot was fenced and protective cover (net) was used to prevent the grains being eaten by birds and mammals. At each sampling event, two separate seed samples were collected (in total 576 seeds) by means of forceps into plastic vessels. Non-germinated seeds were preferred.

Specimen were frozen until analysis. Weather data were recorded with a portable meteorological station during sowing.

Test parameters, observations: The samples were analysed for triticonazole content with BASF method no. 526/0 (HPLC-MS/MS), which quantifies the residues; the LOQ was 0.01 mg/kg. Procedural recoveries were about 102 % for triticonazole at fortification levels of 0.01 and 0.1 mg/kg.

Results:

Germination: Previous to all samplings of seeds an estimation of the amount of germinated seeds was carried out at the same day. Non-germinated seeds or seeds germinated up to BBCH 09 were sampled. At one plot at the last sampling date, May 7th, 2007 more than 95% of the seeds were already in BBCH growth stages ≥ 09. Therefore, no specimen was collected in this plot.

Residues:

Table 9.1-6: Initial residues of triticonazole on spring wheat seeds exposed onto the soil surface at day 0 after sowing in Spain

Crop, country		Loading before sowing	Initial loading after sowing				Reference (BASF DocID)
			Trial 1 (Code)	Trial 2 (Code)	Trial 3 (Code)	Arithmetic mean (trials 1-3)	
Spring wheat, Spain			07/S/13	07/S/14	07/S/15	07/S/13-15	2007/1016397
	Measured residues [mg ai/kg seed]	56.0	41.705	26.516	39.753	35.99	
	[%] [1)]	100	74.47	47.35	70.99	64.27	

[1)]The measured residue levels before sowing were put to 100%. The remaining measured values are related to these 100%-values.

Conclusion: At sowing the total residue of BAS 595 F in spring wheat seeds ranged between 26.516 and 41.705 mg/kg.

The spring wheat seeds sampled at the end of the study (21 days) contained total BAS 595 F between 0.508 and 2.675 mg/kg.

Comment RMS: This study was submitted as confirmatory data in 2009.

Please note, that the three trials were conducted in only one site (field) each with two seed samplings per field and sampling event.

Acceptability of the analytical methods used in the test:

Evaluation of the analytical methods (water/sediment/soil) according to the Guidance Document SANCO/3029/99 rev. 4.

Method: LC/MS/MS (BASF method No. 562/0)

Linearity: number of duplicates not stated and not possible to identify via the calibration curve.

	calibration range: not possible to identify via calibration curve; r^2 0.9952 Accuracy: two fortification levels (0.01 and 0.1), 2 measurements; mean recovery for each level is 106.75 and 96.9% respectively Precision: The relative standard deviation per fortification level is 3.78 and 5.67%, respectively LOQ: 0.01mg/kg ai LOD: not reported The analytical method fulfils the requirements of guideline SANCO/3029/99 rev. 4. **Endpoints:** Initial residues: 26.516 - 41.705 mg ai/kg Residues after 3 weeks: 0.508 - 2.675 mg ai/kg **Conclusion of the RMS:** The RMS considers the study acceptable.

Reference:	**Determination of residues of BAS 595 F (Triticonazole) in spring wheat seeds treated with BAS 728 00 F exposed on the soil surface in Germany and the Netherlands, 2016 and amendment No. 1**
Author(s), year:	Plier, S., 2016
Report/Doc. number:	BASF Study ID: 783269/ BASF DocID: 2017/1000581 and BAS DocID: 2016/1321103 (amendment No. 1)
Guideline(s):	None
GLP:	Yes
Deviations:	Amendment No. 1 presents the details of the weather data. Please also refer to the commenting box below
Validity:	Acceptable

Material and methods:

Test substance:	BAS 728 00 F (FS); including Metabolite M595F014 (RPA406203) Batch No.: FD-140805-0031; density 1.104 g/cm^3 Triticonazole 33.5g ai/L (analysed) Fluxapyroxad 34.0 g ai/L (analysed) Fludioxonil 33.7 g ai/L (analysed)
Type of the test:	Magnitude and dissipation of triticonazole residues in treated seeds
Treatments:	Application rate: 12.5 g triticonazole/ha (250 kg seeds/ha), 5.2 g triticonazole/100 kg seeds
Experimental procedure:	Two field trials were conducted with spring wheat seeds in Germany and one in The Netherlands in March and April. Each trial consisted of one treated plot. The sowing was carried out according to GAP. The treated seeds were drilled directly

on the soil surface. Treated spring wheat seeds for analysis were sampled on the day of the application as well as 1, 3, 5, 7, 10, 14-15, 17 and 21 days after application (DAA). Specimens were collected from at least 24 spots evenly and randomly cross the entire plot using forceps. Additionally, before application two single specimens were taken: one untreated specimen was taken directly from the bag of the untreated seeds, which were afterwards treated with the formulation. One treated specimen was taken directly from the bag of the treated seeds.

General the specimens were frozen within 12 hours of being taken and remained frozen at or below -18°C, including during transportation, until analysis. Weather data is reported.

Test parameters, observations: The specimens were analysed for BAS 595 F and M595F014 using BASF analytical method no. L0106/03. The LOQ was 0.01 mg/kg for all analytes. Procedural recoveries were about 101% for triticonazole and 98.9% for M595F014 at fortification levels of 0.01, 0.1, 1, 10 and 100 mg/kg.

Results:

Residues:

Residues in the untreated specimen were below the limit of quantitation (< 0.010 mg/kg) for BAS 595 F and M595F014.

Table 9.1-7: Residues of triticonazole and M595F014 on spring wheat seeds exposed onto the soil surface

Portion analysed	DAT[1)]	Growth stage	n	Residues of BAS595 F [mg/kg]	Residues of M595F014 [mg/kg]
Wheat (seeds)	0	00	3	39-50	> 0.010
	1	00	3	35-41	0.64-1.4
	3	00-01	3	20-31	0.89-1.3
	5	00-03	3	4.7-27	0.45-1.7
	7	01-05	3	5.5-24	0.54-0.99
	10	03-05	3	5.3-24	0.48-0.97
	14-15	03-05	3	4.2-6.8	0.41-0.62
	17	03-07	3	1.8-3.9	0.14-0.38
	21	03-07	3	1.5-3.8	0.08-0.4

[1)]Days after treatment

Conclusion: Residues of Triticonazole in wheat seeds specimens taken 0 days after treatment (BBCH 00) ranges between 39 mg/kg and 50 mg/kg and decreased to levels between 1.5 mg/kg and 3.8 mg/kg at 21 days after treatment (BBCH 03-07).

Residues of the metabolite M595F014 (Reg. No. 5079359) in specimens taken 0 days after treatment (BBCH 00) were < 0.01 mg/kg, increased to levels between 0.45 mg/kg and 1.7 mg/kg at 5 days after treatment (BBCH 00/01- 01/03) and decreased to levels between 0.080 mg/kg and 0.40 mg/kg at 21 days after treatment.

Comment RMS:	Please note, that the three trials were conducted in only one field each with 24 specimens per field and sampling event. **Acceptability of the analytical methods used in the test:** Evaluation of the analytical methods (water/sediment/soil) according to the Guidance Document SANCO/3029/99 rev. 4. Method: HPLC-MS/MS (BASF method No.L0106/03) Linearity: number of duplicates not stated and not possible to identify via the calibration curve. It may be assumed that there were five concentrations with three measurements each. calibration range: not possible to identify via calibration curve; $r^2 = 0.9981$ for the ai and $r^2 = 0.9984$ for the metabolite M595F014 (RPA 406203) Accuracy: five fortification levels (0.01, 0.10, 1, 10 and 100), one measurement for the ai mean recovery for each level is 98.6, 100, 103.3, 99.3 and 108% respectively for the metabolite M595F014 (RPA 406203) recovery for each level is 97.9, 96.7, 99.6, 97.6 and 104.5% respectively Precision: The relative standard deviation per fortification level is 11.3, 8.5, 3.1, 4.8 and 1.3%, respectively for the ai The relative standard deviation per fortification level is 8.9, 7.3, 2.5, 2.9 and 2.1%, respectively for the M595F014 (RPA 406203) LOQ: 0.01mg/kg ai LOD: 0.002 mg/kg The analytical method fulfils the requirements of guideline SANCO/3029/99 rev. 4. **Endpoints:** Active substance: Initial residues: 39 - 50 mg ai/kg Residues after 3 weeks: 1.5 - 3.8 mg ai/kg Metabolite RPA 406203: Initial residues: < 0.01 mg/kg Residues after 5 days: 0.45 - 1.7 mg mg/kg Residues after 3 weeks: 0.080 - 0.40 mg mg/kg **Conclusion fo the RMS:** In general the RMS considers the study acceptable.

Reference:	**Determination of residues of BAS 595 F (Triticonazole) in winter wheat seeds treated with BAS 728 00 F exposed on the soil surface in Germany, France (North), Poland and United Kingdom**
Author(s), year:	Plier, S., Elze M., 2017a
Report/Doc. number:	BASF DocID: 2017/1000582
Guideline(s):	None
GLP:	Yes
Deviations:	Please refer to the commenting box below
Validity:	Acceptable

Material and methods:

Test substance:	BAS 728 00 F (FS), including Metabolite M595F014 (RPA 406203) Batch No.: FD-141104-0024; density 1.103 g/cm^3 Triticonazole 33.0 g ai/L (analysed) Fluxapyroxad 33.3 g ai/L (analysed) Fludioxonil 33.0 g ai/L (analysed)
Type of the test:	Magnitude and dissipation of triticonazole residues in treated seeds
Treatments:	Application rate: 12.5 g triticonazole/ha (250 kg seeds/ha), 5.05 g triticonazole/100 kg seeds
Experimental procedure:	Two field trials were conducted with winter wheat seeds in Germany, one in France, one in Poland and one in UK in September and October. Each trial consisted of one treated plot. The sowing was carried out according to GAP. The treated seeds were drilled directly on the soil surface. Treated winter wheat seeds for analysis were sampled on the day of the application as well as 1, 3, 5, 7, 10, 14-15, 17-18 and 20-21 days after application (DAA). Specimens were collected from at least 24 spots evenly and randomly cross the entire plot using forceps. On the day of the application, the seeds were taken directly out of the seeding equipment after running through the seeding machinery using a fine net for collecting. Additionally, before application one single specimen was taken: one untreated specimen was taken directly from the bag of the untreated seeds, which were afterwards treated with the formulation. Generally the specimens were frozen within 12 hours of being taken and remained frozen at or below -18°C, including during transportation, until analysis. Weather data is reported.
Test parameters, observations:	The specimens were analysed for BAS 595 F and M595F014 using BASF analytical method no. L0106/03 The LOQ was 0.01 mg/kg for all analytes. Procedural recoveries were about 106% for triticonazole and 102% for M595F014 at fortification levels between 0.01and 100 mg/kg.

Results:

Residues: Residues in the untreated specimen were below the limit of quantitation (< 0.010 mg/kg) for BAS 595 F and M595F014.

Table 9.1-8:Residues of triticonazole and M595F014 on winter wheat seeds exposed onto the soil surface

Test system/ Matrix	DAT[1)]	Growth stage	n	Residues of BAS595 F [mg/kg]	Residues of M595F014 [mg/kg]
Wheat (seeds)	0	00	5	43-49	< 0.010-0.047
	1	00	5	35-45	0.31-1.8
	3	00-01	5	29-36	0.72-2.1
	5	00-03	5	16-31	0.80-2.1
	7	00-03	5	8.8-28	0.77-2.1
	10	00-05	5	4.6-29	0.53-2.1
	14-15	00/03-05	5	2.3-12	0.19-1.0
	17-18	00/05-03/06	5	1.2-12	0.076-0.84
	20-21	03/05-07/09	4	1.1-2.5	0.063-0.27

[1)]Days after treatment
n number of specimens

Conclusion: Residues of Triticonazole in wheat seeds specimens taken 0 days after treatment (BBCH 00) ranges between 43 mg/kg and 49 mg/kg and decreased to levels between 1.1 mg/kg and 2.5 mg/kg at 20-21 days after treatment (BBCH 03/05-07/09).

Residues of the metabolite M595F014 (Reg. No. 5079359) in specimens taken 0 days after treatment (BBCH 00) ranged between < 0.01 mg/kg and 0.047 mg/kg, increased to levels between 0.72 mg/kg and 2.1 mg/kg at 3 to 5 days after treatment (BBCH 00-03) and decreased to levels between 0.063 mg/kg and 0.27 mg/kg at 20-21 days after treatment (BBCH 03/05-07/09).

Comment RMS: Please note, that the five trials were conducted in only one field each with 24 specimens per field and sampling event.

Acceptability of the analytical methods used in the test:

Evaluation of the analytical methods (water/sediment/soil) according to the Guidance Document SANCO/3029/99 rev. 4.

Method: HPLC-MS/MS (BASF method No.L0106/03)

Linearity: number of duplicates not stated and not possible to identify via the calibration curve. It may be assumed that there were five concentrations with three measurements each.

calibration range: not possible to identify via calibration curve; $r^2 = 0.9989$ for the ai and $r^2 = 0.9991$ for the metabolite M595F014 (RPA 406203)

Accuracy: five fortification levels, five measurements for the fortification levels 0.01 and 0.1mg/kg, four measurements for the fortification levels 10 and 100 mg/kg and one measurement for the fortification level 1.0 mg/kg for the ai mean recovery for each level is 110.4, 102.1, 106, 103.25 and 105.5% respectively

three fortification levels (0.01, 0.1 and 10), five measurements per fortification level

	mean recovery for each level is 103.2, 101.3 and 101.5% respectively for the metabolite M595F014 (RPA 406203) Precision: The relative standard deviation per fortification level is 4.1, 2.2, 2.4, and 3.1%, respectively for the ai The relative standard deviation per fortification level is 5.1, 6.2, and 4.2%, respectively for the M595F014 (RPA 406203) LOQ: 0.01mg/kg ai LOD: 0.002 mg/kg The analytical method fulfils the requirements of guideline SANCO/3029/99 rev. 4. **Endpoints:** Active substance: Initial residues: 43 - 49 mg ai/kg Residues after 3 weeks: 1.1 - 2.5 mg ai/kg Metabolite RPA 406203: Initial residues: < 0.01 - 0.047 mg/kg Residues after 3 to 5 days: 0.72 - 2.1 mg mg/kg Residues after 3 weeks: 0.063 - 0.27 mg/kg **Conclusion of the RMS:** In general the RMS considers the study acceptable.

Reference:	**Additional information regarding the initial residue values of triticonazole on treated seeds – Position Paper**
Author(s), year:	Not reported
Report/Doc. number:	BASF DocID: 2018/1011232
Guideline(s):	None

Background:	In degradation studies (DocIDs 2006/1015760, 2007/1016397) it was shown that only 67% of the active substance remained on the seeds. The RMS questioned if this decline might be related to stability issues. Thus, asked for more information related to stability and storage conditions from treatment to drilling during the studies. In the following document, the notifier addresses this question in detail including the discussion of the methodology and results of two recent seed residue dissipation studies conducted with triticonazole under field conditions (DocIDs 2017/1000581 and 2017/1000582), submitted to AGES with the updated dossier
Stability and storage of treated seeds:	No certificates of analyses were included in the study reports DocIDs 2007/1016397, 2017/1000581. These are provided in Appendix 1 to of this additional information document. The table below shows a summary of parameters regarding preparation and storage

Table 9.1-9:Optimal and actual storage conditions as well as preparation, expiry and drilling dates of all kinds of treated seeds used in the four residue decline studies

BASF DocID (Formulation Code)	Batch treated seeds	Storage conditions stated on CoA	Actual storage temperature [°C]	Preparation date	Expiration date	Drilling date
2006/1015760 (BAS 591 01 F)	ST-06-W010_1	Ambient temperature (+5 to +30°C)	6 to 12	15-Feb-06	24-Feb-07	24 to 28 Feb 2006
2007/1016397 (BAS 595 01 F)	ST-07-W-012c_3	Ambient temperature (+5 to +30°C)	11 to 20	22-Feb-07	32-Oct-07	20 Mar to 17 Apr 2007
2017/1000581 (BAS 728 00 F)	2016-US-017-TRZAS	room temperature (typically <= 25°C), keep away from humidity	15 to 29*	25-Feb-16	1-Nov-16	14 Mar to 11 Apr 2016
2017/1000582 (BAS 728 00 F)	2016-US-021-TRZAW	room temperature (typically <= 25°C), keep away from humidity	13.5 to 25.4	8-Jul-16	1-Feb-17	19 Sept to 10 Oct 2016

*25 °C was exceeded in only one trial

These data show that drilling took place at latest 2.5 months after production, thus, well before the expiry date

Storage stability studies:

In the following a summary of the three stability studies for triticonazole formulations, BASF DocID C038422, C035126 and 2017/1015632, is presented. The studies can be provided by the applicant upon request.

BAS 591 01 F was used in one of the older residue decline studies (BASF DocIDs 2006/1015760) conducted in 2006. The storage stability study with treated wheat seeds using this formulation was run from early 2002 until the end of 2003 (BASF DocID C038422). This study shows that related to the nominal triticonazole loading 80.5% and 80.0% are remaining on the seeds after 3 or 18 months, respectively. Related to the analytically measured initial loading, 96.4% and 95.8% remained. Thus, the HPLC analysis confirmed that the ai loading rate after 18 months under ambient conditions was within the required specifications.

Table 9.1-10:Screenshot study report BASF DocID C038422

Tests	Methods	Results	
Initial seed loading (based on active ingredients)	P-1077-04-02	prochloraz $CuCl_2$	nominal loading: 120 mg/kg loading found: 102.8 mg/kg % loading found: 85.7 %
		triticonazole	nominal loading: 40 mg/kg loading found: 33.4 mg/kg % loading found: 83.5 %
Loading after 3 month storage		prochloraz $CuCl_2$	loading found: 94.7 mg/kg % loading found: 78.9 %
		triticonazole	loading found: 32.2 mg/kg % loading found: 80.5 %
Loading after 18 month storage		prochloraz $CuCl_2$	loading found: 90.0 mg/kg % loading found: 75.0 %
		triticonazole	loading found: 32.0 mg/kg % loading found: 80.0 %

BAS 595 01 F was used in the second older residue decline study (BASF DocID 2007/1016397) conducted in 2007. The storage stability study with treated wheat seeds using this formulation was run from end of 2001 until mid of 2003 (BASF DocID C035126). This study shows that related to the nominal triticonazole loading 76.4% and 76.6% are remaining on the seeds after 3 or 18 months, respectively. Related to the analytically measured initial loading 96.2% and 96.5% remained. Thus, the HPLC analysis confirmed that the ai loading rate after 18 months under ambient conditions was within the required specifications.

Table 9.1-11:Screenshot study report BASF DocID C035126

Tests	Methods	Results
Initial seed loading (based on triticonazole)	T-864-01-01	nominal loading: 50 mg/kg loading found: 39.7 mg/kg % loading found: 79.4 %
Loading after 3 month storage		loading found: 38.2 mg/kg % loading found: 76.4 %
Loading after 18 month storage		loading found: 38.3 mg/kg % loading found: 76.6 %

BAS 728 00 F was used in the two newer residue decline studies (BASF DocIDs 2017/1000581 and 2017/1000582) conducted in 2016. The storage stability study with treated wheat seeds using this formulation was run from mid July 2015 until the beginning of 2017 (BASF DocID 2017/1015632). This study shows that related to the nominal triticonazole loading 86.4% are remaining on the seeds after 78 weeks. Related to the analytically measured initial loading 85% remained. Thus, the HPLC analysis confirmed that the ai loading rate after 18 months under ambient conditions was within the required specifications.

Table 9.1-12:Screenshot study report BASF DocID 2017/1015632

Active Ingredient	Target rate [g/100 kg]	Initial [g/100kg]	%	After storage 78 weeks [g/100kg]	%
Triticonazole	5.0	5.08	101.5	4.32	86.4
Fludioxonil	5.0	5.14	102.8	4.27	85.3
Fluxapyroxad	5.0	5.37	107.4	5.42	108.3

Overall, these studies confirm that the ai content on treated seeds is stable over 18 months, if stored under ambient conditions or temperatures.

Storage of treated seeds within the residue studies:

Since no details are stated in the study reports, the notifier requested from all study directors the raw data to track this information. An overview of the actual storage conditions is also given in Table B.9.1.1-7.

For **BASF DocID 2006/1015760** the applicant received the following feedback from the study director (Agrisearch UK Ltd, Slade lane, Wilson, Derbyshire):

"The seeds were stored at ambient temperature prior to use in our seed store here at Wilson with a minimum temperature of 6°C and Max of 10°C."

"I can confirm that all the seed samples would have been kept at the same location in Wilson prior to application, as we only had the one facility in the UK at the time, and we operated just from here (even the one in Scotland)."

"For the facility temperature records for storage, these were from an excel spreadsheet." In this file – which can be provided by the notifier upon request – temperatures in all rooms of the test facility were tracked.

For **BASF DocID 2007/1016397** the notifier got the following feedback by the study director:

"To place you in situation, once the seeds were received in our facilities, they were managed as any other test item; they were placed in our GLP store for substances under dark conditions and with temperature controlled. First trial 07/S/13 was performed close to our facilities so the seeds were directly extracted for the sowing (temperature range 11-18 ºC); but the other two trials 07/S/14 and 07/S/15 (temperature range 11 – 20 ºC) were performed in the North of Spain, so there was a timelapse between the exit of our store and the sowing date. For this period the seeds were also stored controlled in darkness and appropriate temperature conditions, as can be seen on the attached documentation."

Screenshots of the raw data files are listed in Appendix 2 of the additional information document. Please note the raw data are given in Spanish. However, it is traceable that the seeds were stored under the proposed conditions for all three trials.

For **BASF DocID 2017/1000581** and **2017/1000582** the raw data concerning the storage conditions of the seeds is given in Appendices 3 and 4, of the additional

information document, respectively. In DocID 2017/1000581, considering all trials, the seeds were stored between 15 and 29°C; the level of 25°C was exceeded in only one of the trials; in DocID 2017/1000582 between 13.5 and 25.4°C. Please note some parts of the raw data are given in German. However, it is traceable that the seeds were stored under the proposed conditions.

Conclusion on stability: Overall the study raw data confirm that the treated seeds were stored under the required conditions that ensure stability of triticonazole on treated seeds. In general, stability was shown for a period of 18 months for all kind of treated seeds used in the residue studies. The seeds were drilled the latest 2.5 months after production. Comparing production dates, drilling times, stability and actual storage conditions, it can be concluded that stability, storage and handling of the seeds used in these studies were appropriate. Therefore, the lower initial residue values measured in the field studies cannot be attributed to stability or storage issues.

Correction factor as refinement option for the revised birds and mammals risk assessment: The Tier 1 risk assessment in the submitted dossier is based on the nominal triticonazole loading rate of 50 mg ai/kg cereal seeds. However, there is good evidence from data for several pesticides used as seed treatments that the actual level of residues on treated seeds at the day of sowing is lower than the nominal loading itself (e.g. Pascual & Hart 1997, McKay et al. 1999).

For the purpose of a wild bird risk assessment, consideration of the actual residues on seeds after sowing is justified as agronomic practice is only reflected by the residue levels on seeds collected in the field subsequent to sowing. Furthermore, only the sown seeds present on the soil surface are actually the ones available for wild birds and mammals.

Available field data: Two field studies were conducted to support this hypothesis. One in Spain, BASF DocID 2007/1016397 and one in UK BASF DocID 2006/1015760, evaluated by the RMS in the Confirmatory Data Addendum, July 2009.

Additionally with the update of the dossier, two recently conducted studies, BASF DocID 2017/1000581 and 2017/1000582 were submitted. These two new studies were carried out to increase the sample size of the database with a targeted focus on residue decline, not on initial residues. As described below, the methodology of these two studies is not as suitable as the one in the older studies to measure realistic initial residues on soil-exposed seeds. In the two newer studies, the day 0 sample was taken directly after running through the seeding machinery using a fine net in contrast to the older studies were the initial samples on day 0 were taken directly from the field.

Initial residue values of triticonazole:

Table 9.1-13: Basic study set up of available field residue decline studies

DocID	Test item	Crop and country	Nominal seed load triticonazole	Actual seed load triticonazole (according to CoAs)
2006/1015760 BAS 591 01 F	BAS 591 01 F (Kinto Duo)	wheat spring seeds, UK	4 g/100 kg seed	3.96 g/100 kg seed
2007/1016397	BAS 595 01 F (Premis)	wheat spring seeds, SP	5 g/100 kg seed	5.6 g/100 kg seed
2017/1000581	BAS 728 00 F	wheat spring seeds DE, NL	5 g/100 kg seed	5.2 g/100 kg seed
2017/1000582	BAS 728 00 F	wheat autumn seeds DE, FR, PL, UK	5 g/100 kg seed	5.05 g/100 kg seed

Table 9.1-14: Residue levels in the seeds collected in the field in relation to the actual seed load measured in the four field studies (please notice the different sampling methods)

DocID	Sampling method	Residue level day 0 [%] – single trials					Residue level day 0 – mean single study [%]
2006/1015760	With forceps from soil surface	69.8	56.89	73.79			66.83
2007/1016397		74.47	47.35	70.99			64.27
2017/1000581	Net behind drilling machinery	80.77	96.15	90.38			89.10
2017/1000582		97.03	85.15	93.07	89.11	95.05	91.88

The day 0 samples in the two newer studies (run in 2016) seeds were sampled directly after running through the drilling machinery. The seeds were collected in a fine net that was placed behind the machinery. This means, the seeds collected on day 0 were never in contact with the soil surface. On average, the measured seed load reduction in these two studies was about 10% (remaining seed load of 89.1 % and 91.88 % in DocID 2017/1000581 and 2017/1000582, respectively). Such reduction could be explained by some degree of abrasion during the handling and broadcast of seeds with the drilling machine.

In contrast, in the two older studies (run in 2006 & 2007), the sampled seed specimens were taken directly from the soil surface with forceps, shortly (i.e., within less than 2 hours) after drilling. According to the raw data, in DocID 2006/1015760 sampling took place within the first 65 min after drilling. In DocID 2007/1016397 sampling took place within the first 85 min after drilling. Screenshots from the raw data are included as Appendix 6 and 7 of the additional information document, respectively.

Comparing the results using these two sampling techniques it can be concluded that abrasion is not the only driving process leading to a reduction of the seed load in seeds available to birds and mammals on the soil surface. Reduction based on the handling and drilling processes was about 10% in the studies of 2017. Yet, in the older studies of 2006/2007, where the seeds were collected on the soil surface, remaining residues

	were down to 67% on the day of drilling for triticonazole. Even though the underlying mechanisms are not fully clear, one likely explanation is dilution via water uptake by the seed. That this can happen relatively fast, already within a few hours, is reported in the literature. This topic is discussed in more detail with literature data in the position paper itself. In general, independent of how the residues were reduced in the field situation, this set-up for the studies in UK and Spain resembles more closely the exposure to birds and mammals. The animals would roam the field for food after the tractor with the drilling machine has left the field and feed on the seeds that are available on the soil surface. Thus, the two older studies are considered most relevant to conclude on a refined initial residue value. In conclusion, the applicant still considers a correction factor of 67% reasonable for the refined birds and mammals risk assessment for triticonazole.
Literature data:	To set the observed data into context, the applicant searched for additional information in the literature. This literature is partly general information about the dissipation of residues on seeds as well as substance specific literature concerning several active substances. All cited references can be provided by the applicant upon request.
Conclusion on correction factor:	Considering all the data given above, the stability of the seed load under maintained storage conditions, the reduction of seed load during the drilling process and the further reduction of seed load on the field surface, likely explainable by moistening the seed, the two older BASF studies, namely DocID 2006/1015760 and 2007/1016397 are considered the relevant studies to derive a realistic initial residue value in freshly drilled wheat seeds to which birds and mammals are exposed to. The main reason is that in the older studies of 2006/2007 seeds were collected from the soil surface after being in contact with soil (realistic exposure to birds and mammals) while in the most recent studies (2017) the seeds were not collected after being into contact with soil but directly from the drilling machine. Thus, the originally proposed correction factor of 67% from the 2006/2007 studies is still considered as the most appropriate for the refined birds and mammals risk assessment for triticonazole.
Comment RMS:	The storage condition seemed to be acceptable, the time between treating of the seeds and sowing was 9 days to 2.5 months. The RMS acknowledges the possibility that moistening processes in soil count responsible for the residue decline after sowing. It is not known if the methods and machineries to treat and sow the seeds were the same in the old and the new studies. The difference of initial residues between these studies could for example also be caused due to the use of different glues for the seed treatment. Therefore several uncertainties remain, for the definition of the initial residue values.

	The literature provided by the applicant in general supports the theory that a decrease in residues occurs from the date of treated seed production to the possible uptake by birds. However, the study by Malkell 1986, for example, reports residues from 40%-102% not guaranteeing a residue decline. The study of Wiwart 2006 reports an average weight increase of triticale kernels placed between two filter layers of 10% after 2 hours. However, it is also stated that water absorption differs between different wheat varieties. The argumentation in general is accepted, however, due to the remaining uncertainties a worst-case correction factor of 0.92 (91.88%) will be used for the risk assessment.

Reference:	**Calculation of DT_{50} dissipation times for BAS 595 F - Triticonazole in treated spring wheat seeds from field trials conducted in Europe**
Author(s), year:	Szegedi K, 2017a
Report/Doc. number:	BASF DocID: 2017/1070086
Guideline(s):	None
GLP:	No
Validity:	Acceptable

Material and methods:

Kinetic analysis was performed in order to derive dissipation parameters (DT_{50} values) for the residues of triticonazole in wheat seeds. Since no specific recommendation is available how to carry out the kinetic evaluation for plant dissipation experiments, guidance of the FOCUS workgroup on degradation kinetics was followed to derive degradation parameters for modeling purposes.

The recommended kinetic models, i.e. the single first order kinetics (SFO) and the Gustafson-Holden model (FOMC) were tested in order to identify the best-fit model for derivation of DT_{50} values. The goodness-of-fit of the kinetic models was assessed by visual inspection and statistical measures, as recommended by the FOCUS guidance (FOCUS, 2006) on degradation kinetics.

According to FOCUS, a SFO kinetic model is considered appropriate, if the fit is visually acceptable and passes the $\chi 2$-test at an error level of 15% or less and the estimated degradation parameters are significantly different from zero, i.e. the t-test for the degradation parameters is passed at 5% error level. Furthermore, the error term required to pass the $\chi 2$-test may be larger if there is a large scatter in the data like for field studies. In this case, a decision should be based on visual assessment. If the overall pattern of decline in pesticide concentrations is represented adequately by the model and the distribution of the residuals is random, the half-life from the SFO model may be used for modelling.

Results: The choice of the SFO model resulted in the most appropriate fit for all trials and provided reliable DT_{50} values for all trials. The derived DT_{50} values are given in Table 8.1-6. All degradation rate constants of the different fits were significantly different from zero as indicated by low p values (t-test). The $\chi 2$ error values were below or slightly above 15. Trials with $\chi 2$ error values above 15 are considered acceptable as the visual fits were acceptable, the observations generally well described by the fitted curves and the residuals randomly scattered around the zero line.

Table 9.1-15:Calculated DT_{50} values for triticonazole in spring wheat seeds and statistical indices of 3 different sites in Europe

Plant	Trial	Country	Kinetic model	$\chi 2$ error [%]	DT_{50} [d]	P (t-test)
Wheat seeds	L160002	Germany	SFO	16.34	7.15	< 0.001
Wheat seeds	L160003	Netherlands	SFO	14.01	2.08	< 0.001
Wheat seeds	L160004	Germany	SFO	16.35	4.02	< 0.001

Conclusion: Kinetic evaluation of triticonazole residues obtained in field studies was performed according to the current guidance of the FOCUS workgroup on dissipation kinetics in order to derive dissipation parameters (DT_{50} values). The choice of the SFO model resulted in the best fit and provided reliable DT_{50} values for all trials.

Comment RMS:	According to the expert for environmental fate the calculations are considered acceptable.

Reference:	**Calculation of DT_{50} dissipation times for BAS 595 F - Triticonazole in treated winter wheat seeds from field trials conducted in Europe**
Author(s), year:	Szegedi K, 2017b
Report/Doc. number:	BASF DocID: 2017/1134017
Guideline(s):	None
GLP:	No
Validity:	Acceptable

Material and methods: Kinetic analysis was performed in order to derive dissipation parameters (DT_{50} values) for the residues of triticonazole in wheat seeds. Since no specific recommendation is available how to carry out the kinetic evaluation for plant dissipation experiments, guidance of the FOCUS workgroup on degradation kinetics was followed to derive degradation parameters for modelling purposes.

The recommended kinetic models, i.e. the single first order kinetics (SFO) and the Gustafson-Holden model (FOMC) were tested in order to identify the best-fit model for derivation of DT_{50} values. The goodness-of-fit of the kinetic models was assessed by visual inspection and statistical measures, as recommended by the FOCUS guidance (FOCUS, 2006) on degradation kinetics.

According to FOCUS, a SFO kinetic model is considered appropriate, if the fit is visually acceptable and passes the χ2-test at an error level of 15% or less and the estimated degradation parameters are significantly different from zero, i.e. the t-test for the degradation parameters is passed at 5% error level. Furthermore, the error term required to pass the χ2-test may be larger if there is a large scatter in the data like for field studies. In this case, a decision should be based on visual assessment. If the overall pattern of decline in pesticide concentrations is represented adequately by the model and the distribution of the residuals is random, the half-life from the SFO model may be used for modelling.

Results:

Table 9.1-16: Residues of triticonazole and M595F014 on winter wheat seeds exposed onto the soil surface

Plant	Trial	Country	Kinetic model	χ2 error [%]	DT_{50} [d]	P (t-test)
Wheat seeds	L160005	Germany	SFO	20.85	6.1	0.001
Wheat seeds	L160006	France	SFO	9.083	7.9	< 0.001
Wheat seeds	L160007	Germany	SFO	13.64	8.6	< 0.001
Wheat seeds	L160008	Poland	SFO	18.14	6.4	< 0.001
Wheat seeds	L160009	UK	SFO	15.50	3.5	< 0.001

Conclusion: Kinetic evaluation of triticonazole residues obtained in field studies was performed according to the current guidance of the FOCUS workgroup on dissipation kinetics in order to derive dissipation parameters (DT_{50} values). The choice of the SFO model resulted in the best fit and provided reliable DT_{50} values for all trials.

Comment RMS:	According to the expert for environmental fate the calculations are considered acceptable.

Reference:	**Exposure of birds in cereals in Germany in spring – attractiveness of cereal fields, portion of time and diet composition**
Author(s), year:	Moosmayer, P., 2008a
Report/Doc. number:	BASF DocID 2008/1097311
Guideline(s):	No official guideline available
GLP:	Yes
Deviations:	Please refer to the commenting box below
Validity:	Acceptable

Material and methods:

Study area

The study was conducted in a typical agrarian landscape in the Hunsrueck region, Germany, where cultivation of winter and spring cereals is dominant and the skylark is prevalent. At the time the study was conducted, the majority of the winter cereal fields was in tillering stages up to early stem elongation (BBCH 21-32) whilst the spring cereals were freshly sown (BBCH 00-10).

Method and parameters

The following parameters were assessed:

- the portion of time radio-tracked skylarks spent potentially foraging (PT) in cereal fields in early spring
- the habitat preference of skylarks as shown by radiotracking
- the diet of skylarks in cereal fields
- the abundance of different bird species in cereal fields as shown by transect counts
- the frequency of occurrence of different bird species in cereal fields

Based on information gained from the ornithological literature the skylark (Alauda arvensis) was selected as focal species. This species was expected to be at potential risk of exposure to plant protection products sprayed in winter cereal fields or used as seed treatment in spring cereal fields.

In order to assess the exposure of skylarks to plant protection products in these winter or spring cereal fields, the portion of time spent 'potentially foraging' in the crop (PT) was obtained by radio tracking of 11 different individuals, which were trapped in or near cereal fields and tagged with radio transmitters. Radio tracking was conducted during early spring (tracking period 14.03. – 24.03.2006). Each individual was continuously radio tracked for one or two daylight periods.

To assess the relevance of cereal fields as foraging habitat for birds compared to other habitats, transect counts were conducted along three different transects, representing all main agrarian habitat types within the study area. These transects were surveyed seven times each to attain a full overview of the avifauna.

In 20 defined cereal fields (10 winter cereals, 10 spring cereals) a scan sampling procedure was conducted, where any bird activity was monitored from dawn until dusk, to support data for 'potential foraging times'. Samples of faeces and stomach contents were analysed quantitatively for their composition to quantify remains of plant and animal material ingested by skylarks in cereal fields.

Results:

Portion of time (PT) for skylarks in cereal fields:

Table 9.1-17: Portion of time radio-tracked skylarks spent potentially foraging (PT) in cereal fields in early spring

Crop	Potential foraging time[1)]		Tracking sessions (individuals)
	Mean [%]	90th%ile	
Winter cereals (BBCH 21-32)	44.9	88.2	18 (11)
Spring cereals (BBCH 00 – 10, freshly sown)	17.4	41.8	8 (5)

1) sum of behaviour categories 'foraging', 'active, possibly foraging' and 'unknown'

Habitat preference of skylarks

The following table displays the preference of cereal fields by skylarks as foraging habitat as shown by radio-tracking (expressed as Jacobs index [D], possible range: -1 to +1; Minimum convex polygon home range (MCP) [100%]).

Table 9.1-18: Preference of cereal fields by skylarks as foraging habitat (radiotracking)

Crop	Jacobs Index
Winter cereals (BBCH 21-32)	0.00
Spring cereals (BBCH 00 – 10, freshly sown)	-0.22

Diet of skylarks in cereal fields

The following table summarizes the pooled volume portion of food items [%] after the analysis of faeces (n = 13) and stomach flushing (n = 9). The birds and their faeces, respectively, were gathered in or near cereal fields.

Table 9.1-19: Diet composition of skylarks in cereal in cereal fields (radiotracking)

Food item	Mean volume portion of food item [%]	
	Only winter cereals available	Winter and spring cereals available
Poaceae / cereal seeds	0.9	26.9
Poaceae / cereal leaf remains	65.7	31.3
Other seeds	12.7	5.6
Other plant material	17.5	23.5
Animal matter	3.1	12.8

Bird abundance in cereal

In the following the abundance of selected species in winter and spring cereals is

fields (transect counts) shown. The data was gained from three transect counts covering 576 ha. One transect count is defined as one transect, surveyed seven times.

Table 9.1-20: Abundance of different bird species in cereal fields determined via transect counts

Species	Winter cereals		Spring cereals	
	Abundance [ind./count/ha]	n	Abundance [ind./count/ha]	n
Skylark	1.36	251	1.33	56
Yellowhammer	0.02	3	0.54	23
Chaffinch	0.32	58	0.31	13
Carrion crow	0.11	21	0.17	7
Grey partridge	0.07	12	0.00	--

Bird frequency of occurrence in cereal fileds

The following table displays the frequency of occurrence of selected bird species per scan. The results of ten winter and ten spring cereal fields are expressed as mean of the results for each session.

Table 9.1-21: Frequency of occurrence of selected bird species on winter and spring cereal fields

Species	Frequency of occurrence (FO) [%]	
	Winter cereals	Spring cereals
Skylark	13.2	43.6
Yellowhammer	5.0	42.5
Chaffinch	2.7	19.7
Song thrush	1.3	0.6
Carrion crow	1.2	15.3
Common buzzard	0.6	0.1
Blackbird	0.5	2.2
Mistle thrush	0.4	0.9
Robin	0.5	0.2
Wood pigeon	0.3	6.3
Linnet	0.3	2.3
White wagtail	0.2	8.3

Conclusions: This study investigated the relevance of cereal fields as foraging habitat for birds in spring. It was conducted in an agrarian landscape with a high proportion of cereal fields in the Hunsrueck region of western Germany. Ornithological observations (transect counts, scan sampling) confirmed that the skylark is the most abundant species on winter cereal fields in spring and also uses freshly drilled spring cereal fields as a foraging habitat. Eleven individually radio tracked skylarks showed no particular preference to, or avoidance of, cereal fields compared to other crops but spent a significant amount of their 'potential foraging time' in winter cereal (BBCH 21 - 32) and in freshly sown spring cereal fields (BBCH 10). According to volume

proportion analysis their diet mainly consisted of grass material and cereals, before spring cereals were drilled. Thereafter other plant material i.e. grass or cereal seeds and leaf remains made up the majority of the diet. Consumption of animal matter increased slightly during spring.

For risk assessment purposes a value for portion of time (PT) spent potentially foraging in cereal fields for skylarks was calculated. For winter cereal fields in spring the mean PT value was 0.449 (44.9%), for freshly sown spring cereal fields 0.174 (17.4%).

Comment RMS:	The study is in general considered acceptable. Results account for spring cereals. For individuals with more than one tracking session the mean PT of all tracking sessions should be used. Considering this, only four individuals were available to calculate a PT for consumers only. The RMS recalculated therefore a maximum PT for skylarks in pre-emergence spring sown cereals fields of 0.31.

Reference:	**Generic field study on portion of time (PT), diet (PD) and feeding rates of Yellowhammers, Chaffinches and Skylarks on freshly drilled spring cereal fields**
Author(s), year:	Hahne, J., Sadowski, J., 2014a
Report/Doc. number:	BASF DocID 2014/1263159
Guideline(s):	No official guideline available
GLP:	Yes
Deviations:	Please refer to the commenting box below
Validity:	Acceptable

Material and methods:

Study area

The study was conducted on commercially managed spring cereal fields in the region of Rheinhessen (Rhineland-Palatine), an area with a very high abundance of spring cereal fields in Germany. Furthermore, the relatively small fields in this area with a high frequency of hedges meant that the area was particularly suitable for Chaffinch and Yellowhammer. Hence, the selection of the study area also biased the results towards a high potential exposure of pre-emergence spring cereal seeds (worst case scenario). In the period between the beginning of March and the beginning of April 2013, 11 Skylarks, 18 Chaffinches and 20 Yellowhammers were trapped, individually marked with an aluminium and colour rings, equipped with a radio transmitter and tracked continuously over a whole activity period from dawn till dusk, trying to keep the tracked birds under continuous visual observation. Every change in behaviour and location was accurately recorded to the minute. The location of the bird was recorded by using a tablet computer, which contained aerial

pictures of the study site. The position of the bird was marked by touching the screen at the respective location on the aerial picture. The geographic coordinates of the marked location were recorded.

After each tracking session the habitats within the home range of the respective bird were mapped and entered into a computer-based geographical information system (Quantum GIS) in order to analyse habitat preferences (see below). To calculate the home range sizes, the minimum convex polygon method (MCP, Mohr 1947) was used.

The proportion of diet obtained by an individual bird on a pre-emergence spring cereal field (PT) was calculated as the proportion of time the bird spent potentially foraging in that habitat (sum of the time intervals in which the bird was active or foraging) excluding all instances when the bird was definitely performing non-foraging activities. For each tracking session, the time potentially foraging on the pre-emergence cereal fields was compared to the total time potentially foraging in all habitats. In order to compare the utilisation of pre-emergence cereal fields by the tracked bird with the relative area of this habitat within its home range, the Jacob's preference Index [D] was calculated for each tracking session. A positive Jacobs' index (>0 to +1) indicates preference for pre-emergence spring cereal fields; a negative Jacobs' index (<0 to -1) represents avoidance of this habitat type. In addition, to gather information about the bird´s dietary composition (PD) faecal sampling was conducted. Therefore birds occurring on freshly drilled cereal fields were observed and in case of defecating, the faeces samples were collected. Furthermore, faecal samples were gathered from birds handled during the radio tagging procedure. The collected faecal samples were analysed and correction factors derived from the literature were applied to estimate the proportion of dry weight of each food type in the diet originally ingested by the birds. By the application of food type specific conversion factors (EFSA, 2009) the fresh weight proportions were calculated.

Results:

Portion of time (PT) and Jacob's Index (D)

Radio-tracking combined with visual observations and the trapping scheme as presented here, allowed an accurate and representative assessment of potential foraging times in given home ranges in order to calculate reliable PT values. The average "efficient tracking time" of the performed "entire tracking duration" was 98.17% for skylarks, 91.47% for chaffinches and 91.41% for yellowhammers, respectively. All birds were closely associated with pre-emergence spring cereal fields and had the opportunity to use these fields as foraging habitat.

The results can be considered a worst case in terms of potential exposure. PT data is presented using 3 different approaches.

"All birds"-approach

All tracking sessions were considered to determine a PT estimate. This approach gives an indication of the risk to the wider farmland population that was in the vicinity of pre-emergence spring cereal fields but did not necessarily happen to visit any of these fields during the tracking session.

"Home range"-approach

For each tracking session the home range used by the bird was determined (see 4.4.2). Within the "home range"-approach, sessions were considered in the PT calculation if pre-emergence spring cereal fields were part of this home range, irrespective of whether these fields were used by the birds or not i.e. sessions with PT = 0 were included providing that a pre-emergence spring cereal field was available within the home range of the tracked individual during the tracking session. This approach considers risk for the local population that is closely associated with pre-emergence spring cereal i.e. with these fields in home range.

"Consumer"-approach

PT was estimated from only those radio-tracked individuals, which have used pre-emergence spring cereal fields as a foraging habitat, i.e. PT > 0. The consumer approach has been proposed elsewhere for birds which have been trapped in the general agricultural landscape. If the home range is established through radio tracking, as in this study, then any bird where pre-emergence spring cereal fields appear in the home range can justifiably be included in the PT sample. Exclusion of a bird because it did not visit the crop in question during a single days tracking, ignores the fact that some birds may choose to avoid the crop, and so may represent a significant bias in the estimation of PT.

The calculation of the Jacobs' index provided additional information on habitat preferences of the tracked focal species.

Table 9.1-22: Overview of PT and Jacobs' index for the focal species Skylark, Chaffinch and Yellowhammer in pre-emergence spring cereal fields

Proportion of diet obtained in freshly drilled summer cereal fields (PT) and preference for this habitat for foraging (Jacobs' index)					
Species	**Value**	**PT approach**			**Jacobs' index (H)**
		All birds[1)]	Home range[2)]	Consumer[3)]	
Skylark Individuals : 11 Sessions : 14[1)], 13[2)], 13[3)]	Median	0.53	0.59	0.59	0.07
	90%tile	0.89	0.90	0.90	0.73
	Mean	0.56	0.60	0.60	0.16
Chaffinch Individuals : 18 Sessions : 18[1)], 16[2)], 15[3)]	Median	0.23	0.32	0.36	-0.10
	90%tile	0.54	0.55	0.55	0.64
	Mean	0.25	0.29	0.31	-0.52
Yellowhammer	Median	0.08	0.08	0.08	-0.52

Individuals : 20 Sessions : 20[1)], 20[2)], 19[3)]	90%tile	0.17	0.17	0.18	0.16
	Mean	0.09	0.09	0.10	-0.38

[1)]All sessions were included in this approach
[3)]Sessions with pre-emergence spring cereal fields as part of the home range, irrespective of whether these fields were used by the birds or not.
[3)]PT was estimated including only those individuals, shown by radio tracking to have used pre-emergence spring cereal fields as a foraging habitat, i.e. PT > 0.

Table 9.1-23: Overview of PD for the focal species Skylark, Chaffinch and Yellowhammer in pre-emergence spring cereal fields

Proportions of different food types obtained in pre-emergence spring cereal fields (PD)[1]						
Species	Value	Fresh weight proportions of food types [%][1]				
		Invertebrates	Cereal grain	Weed and grass seeds	Dicot. plant material	Moncot. Plant material
Skylark (based on 17 faeces / 29 observations)	Mean	14.2	58.4	3.0	17.5	6.9
	SEM	5.2	7.1	0.7	6.7	3.7
Chaffinch (based on 18 faeces / 44 observations)	Mean	20.3	58.7	21.0	-	-
	SEM	4.8	8.5	7.7	-	-
Yellowhammer	Mean	15.2	83.6	1.2	-	-
	SEM	8.0	7.9	0.4	-	-

Conclusion: The PT of skylarks, Chaffinches and Yellowhammers in freshly drilled spring cereals fields was successfully determined.

Comment RMS: In the text of the study report it says for chaffinches that only one individual did not use pre-emergence spring cereal fields for foraging. However, in the respective table, three individuals are reported with 00:00 (hrs:min) potential foraging time.
No information is given about vegetation composition of the study sites which was not identified as pre-emergence spring cereal fields.
The study is in general considered acceptable. For individuals with more than one tracking session the mean PT of all tracking sessions should be used. The RMS therefore recalculated the 90th percentile PT for consumers only to be 0.88 for skylarks, in spring sown cereals. The RMS also recalculated the 90th percentile for chaffinches to 0.63 and for yellowhammers to be 0.2 in spring sown cereals according to Excel 2010.

Reference:	**Generic GLP field study on skylark PT in freshly-drilled spring cereals in Central Europe (Germany)**
Author(s), year:	Erni, M. *et. al.*, 2017a
Report/Doc. number:	BASF DocID 2017/1121782
Guideline(s):	No official guideline available
GLP:	Yes
Deviations:	Please refer to the commenting box below
Validity:	Acceptable

Material and methods:

Study area

The study was conducted on freshly drilled spring cereals fields (up to 14 days after drilling) and in fields that were planned to be drilled within the next days near the communities Hochscheid and Sohrschied in the Hunsrück region, Rheinland-Pfalz, Germany. The study area consisted mainly of spring cereal, winter cereal and oilseed rape fields, however, based on the outcome of pre-study searches (Non-GLP) for skylarks, spring cereal fields were selected as study fields for skylark trapping. This represents preferred skylark habitats with sufficient foraging areas and resting/roosting places as well as good locations for nesting. The experimental phase of the study started on March 15th and was completed on April the 10th, 2016.

Mist netting was the applied method for trapping and individuals were marked with an aluminium ring on the tarsus. Each transmitter had a unique frequency which was used for individual recognition of the tagged birds.

To calculate the overall PT three different approaches were applied: 'consumer'-approach, 'home range'-approach and 'all individuals'-approach. The home range sizes were estimated by plotting a Minimum Convex Polygon around the outermost locations recorded for a bird during one tracking session.

To quantify the proportion of potential foraging time (PT), the birds were successfully tracked for the entire activity period of the individual from dawn till dusk. The radio-tracking of the bird was conducted from March 25th to the 10th of April. Tracking sessions performed before drilling of spring cereals were excluded from the calculations of spring cereal PTs. During each session the respective bird was tracked continuously i.e. it was constantly followed by car or on foot. Every change in behavior or location (habitat) and the time of this change was recorded. The "Potential foraging time" was determined as the sum of the time intervals during which a bird showed any of the behavior categories "active" or "foraging". For each tracking session the PT of an individual bird in target crop fields was calculated as the proportion of time the bird spent foraging and potentially foraging in these fields. All time intervals recorded as non-foraging behavior (e.g.

reproductive behavior, other behavior) or when it was considered to be inactive (e.g. not moving) were excluded from the PT calculations.

Results:

In total, nine individuals were radio-tracked (six of them several times). The tracked individuals comprised seven males and two females. The tracking sessions took place within the three weeks from 23th March 2016 to 10th April 2016. This time period corresponded to the early breeding season and end of migration of skylarks.
Six out of nine tracked individuals could still be located (five during single checks and one during tracking session) in the study area on the 10th April 2016.
Pre-emergence fields were available for the whole duration of the study. Thus, each radio-tracked individual had a realistic chance to enter drilled cereal fields.

From 25th March to the 10th of April 33 complete radio-tracking sessions were successfully performed on 8 individual skylarks. The outcome of the 33 radio-tracking sessions conducted with skylarks are summarized below. Overall, PT values per session ranged from 0 to 0.98.

Table 9.1-24: Overview of PT for the Skylark in pre-emergence spring cereal fields

Bird number	Time potentially foraging in spring cerals fields [mi]	PT per session	Mean PT per Individual		
			All birds[1]	Home range[2]	Consumer[3]
3	0	0.000	0.000	-	
	0	0.000			
	0	0.000			
8	755	0.975	0.747		
	717	0.943			
	671	0.967			
	710	0.959			
	681	0.937			
	208	0.261			
	138	0.186			
10	535	0.696	0.500		
	469	0.585			
	295	0.363			
	228	0.299			
	446	0.558			
11	0	0.000	0.022		
	77	0.095			
	10	0.013			
	0	0.000			
	0	0.000			
12	0	0.000	0.000	-	
13	37	0.049	0.021		
	10	0.014			
	0	0.000			
	32	0.041			
	0	0.000			
14	0	0.000	0.000	-	

15	189	0.237	0.418	
	352	0.448		
	554	0.755		
	244	0.345		
	341	0.449		
	213	0.276		
Mean PT			0.213	0.342
SEM			0.105	0.142
90th percentile			0.574	0.648

[1]All birds considered (8 individuals, 33 sessions)
[2]Individuals with drilled spring cereal fields inside the home range (5 individuals, 23 sessions)
[3]Birds that used spring cereal fields for potentially foraging within tracking session (5 individuals, 23 sessions)

Conclusion: PT of skylarks in freshly drilled spring cereals fields of eight different individuals was successfully determined. It was shown that individual PT values vary considerably between and within individuals (0 to 0.98).

Comment RMS:	The study is in general considered acceptable. For individuals with more than one tracking session the mean PT of all tracking sessions should be used leaving only five individuals for consumers only PT calculation. Because of the low number of tracked individuals, the RMS used the maximum consumer only PT for skylarks in pre-emergence spring sown cereal fields of 0.75 instead of the 90th percentile as a worst case approach.

Reference:	**PT of the skylark (*Alauda arvensis*) in pre-emergence winter cereal fields in autumn in Germany**
Author(s), year:	Dittrich R., Benito M., 2017a
Report/Doc. number:	BASF DocID 2016/1234467
Guideline(s):	No official guideline available
GLP:	Yes
Deviations:	Please refer to the commenting box below
Validity:	Acceptable

Material and methods:

Study area

The study was conducted on 11 winter cereal fields and their surroundings, with field sizes ranging from 3.1 ha to 23 ha (average: 9.2 ha) and located in the departments of Lower and Middle Franconia in the south of Germany. The study area was located in the surroundings of Ochsenfurt. The area is representative for the cultivation of winter cereals and for the presence of the focal species during the drilling period. The experimental phase of the study started in September 28th and was completed in October the 27th, 2016.

In order to estimate and document the presence/availability of freshly drilled cereal fields in the study area, five crop monitoring plots were established. Within these plots, in total 84 winter cereal fields were regularly checked for their status of field

preparation, drilling activities and the development of the crop (i.e. BBCH growth stages).

All skylark individuals were caught in pre-emergence winter cereal fields before (-2 to 0 days: 12 birds, 31.6%) or shortly after the drilling of winter cereals (within 1-2 days: 24 birds, 63.2%; within 3-4 days, 2 birds, 5.3%). Mist netting was the applied method for trapping. All captured individuals were fitted with an aluminium ring on the right leg (tarsus), which had an engraved unique number to identify each individual bird. Radio-tags were attached to the birds. In order to exclude any bias during the initial adaptation process, birds were not tracked on the day of trapping.

To quantify the proportion of potential foraging time (PT), the birds were successfully tracked for one daylight period. The radio-tracking of the bird was conducted from 7th to 25th of October right after the drilling of the trapping fields, at pre-emergence, i.e. when the growth stages for cereal fields were BBCH < 10. During each session the birds were tracked continuously from dawn till dusk (around 12h) so that location, habitat and behaviour could be recorded in order to get information on the proportion of diet, home range and habitat selection of individuals living in a cereal cultivation area. The "Potential foraging time" was determined as the sum of the time intervals during which a bird showed any of the behaviour categories "active" or "foraging". All instances when the animal was definitely known to be performing non-foraging activities (e.g. preening) or when it was considered to be inactive (e.g. resting) were excluded from the "potential foraging time".

Additionally, the radio tracking results enabled the calculation of the size and shape of the individuals´ home range (during each session), using the minimum convex polygon method (MCP). Moreover, the Jacob´s preference index was calculated for each tracking session, which indicates if an individual bird prefers or avoids pre-emergence winter cereals fields as feeding habitat. In addition, the trapping location for each individual bird is presented.

Results:

The outcome of the crop monitoring shows the high availability of pre-emergence cereal fields (BBCH <10) during the telemetry time. Pre-emergence fields were available for the whole duration of the study. Thus, each radio-tracked individual had a realistic chance to enter drilled cereal fields.

From 7th to 25th October 41 complete radio-tracking sessions were successfully performed on 21 individual skylarks. The outcome of the 41 radio-tracking sessions conducted with skylarks are summarized below. Overall, PT values per session ranged from 0 to 0.74. The variability of PT values was moderate between and within individuals. The home range size ranged from 0.17 ha to 129.39 ha for the individual sessions.

Table 9.1-25: Summary of complete radio tracking sessions

Session	n Birds	n Sessions
Single session (S)	21	21
4 repetitions (in total 5 sessions)	3	12
2 repetitions (in total 3 sessions)	3	6
1 repetition (in total 2 sessions)	2	2
Total	**21**	**41**

Table 9.1-26: PT in pre-emergence winter cereal fields for 21 skylarks during 41 sessions and their home range size

Bird ID	Session	% Time potentially foraging		PT drilled cereal fields	Mean PT drilled cereal fields	Home range [ha]
		All habitats	Drilled cereal fields*			
A2	S	89.27	20.53	0.23	0.54	38.26
	R1	83.91	57.90	0.69		47.57
	R2	94.36	69.68	0.74		4.67
	R3	78.47	35.00	0.45		65.04
	R4	83.22	47.67	0.57		6.74
A3	S	92.07	0.00	0.00	0.00	31.93
A4	S	88.98	0.00	0.00	0.00	0.83
A5	S	93.92	0.00	0.00	0.00	30.54
A7	S	93.22	40.98	0.44	0.44	8.09
A8	S	88.00	57.78	0.66	0.66	26.27
A9	S	66.82	2.08	0.03	0.03	71.03
A10	S	72.30	15.33	0.21	0.21	104.23
A12	S	91.10	0.00	0.00	0.00	1.79
A13	S	95.15	0.00	0.00	0.00	1.33
	R1	91.22	0.00	0.00		7.62
B1	S	89.81	0.00	0.00	0.11	78.83
	R1	93.49	0.00	0.00		1.89
	R2	94.76	30.17	0.32		6.90
B6	S	90.90	0.00	0.00	0.00	3.32
B7	S	88.84	14.58	0.16	0.16	37.33
C1	S	92.60	0.00	0.00	0.26	59.52
	R1	89.64	20.87	0.23		129.39
	R2	84.94	22.45	0.26		16.53
	R3	69.55	40.93	0.59		27.74
	R4	88.61	19.85	0.22		13.95
C3	S	91.81	0.00	0.00	0.00	54.62
C4	S	92.22	0.00	0.00	0.03	1.23
	R1	87.43	4.39	0.05		7.05
C5	S	91.92	24.09	0.26	0.26	2.70
D1	S	88.20	0.00	0.00	0.14	5.22
	R1	95.24	17.18	0.18		29.75

	R2	96.60	19.29	0.20		6.03
	R3	92.50	27.64	0.30		16.81
	R4	90.09	0.00	0.00		9.44
D3	S	88.06	2.78	0.03	0.01	0.17
	R1	94.17	0.00	0.00		4.37
	R2	90.42	0.00	0.00		1.04
E2	S	83.93	11.26	0.13	0.25	76.51
	R1	89.44	28.96	0.32		12.47
	R2	79.41	22.27	0.28		21.62
E4	S	49.44	0.00	0.00	0.00	3.71

Descriptive statistics[4]	All individuals approach[1]	Consumer approach[2]	Home range approach[3]
Mean**	0.15	0.24	0.18
Median**	0.03	0.21	0.14
90%ile**	0.44	0.52	0.48
SEM	0.04	0.06	0.05
SD	0.19	0.20	0.20

* as fraction of "foraging behavior in all habitats"
**calculated over all sessions
[1]all birds considered (21 individuals)
[2]birds that used drilled cereal fields within at least one tracking session (13 individuals)
[3]consumers plus individuals with drilled cereal fields inside the home range (17 individuals)
[4]calculated over mean of individuals (all sessions included)
S…Single tracking session; R…repeated tracking session
SEM…Standard error of the mean; SD…Standard deviation

Conclusion: This study demonstrated that overall, pre-emergence winter cereal fields are not a preferred foraging habitat for skylarks. The chosen method (radio-tracking coupled and monitoring of the crop availability in the region) successfully documented the presence of skylarks in the study area and the abundance of freshly drilled winter cereal available to the bird individuals.

Comment RMS: The study is in general considered acceptable. The RMS recalculated the 90th percentile PT consumer only for skylarks to be 0.61 in autumn sown cereals according to Excel 2010.

Reference:	**Generic field monitoring of birds in freshly drilled winter cereal fields in autumn in Germany**
Author(s), year:	Barfknecht, R., 2006a
Report/Doc. number:	BASF DocID 2006/1047473
Guideline(s):	No official guideline available
GLP:	Yes
Deviations:	Please refer to the commenting box below
Validity:	Acceptable

Material and methods:

Study area

The study was conducted in and around different freshly drilled winter cereal fields in the "Nördliches Harzvorland" region in the district of the towns Blankenburg and Quedlinburg in the federal state of Sachsen-Anhalt, Germany. This region is a typical area for cereal cultivation in Europe. The study fields and adjacent areas were typical sites for cereal cultivation in an open landscape, occasionally interrupted by orchards (mostly cherries) and small areas of pine-forests. The experimental phase of the study started on 15.09.2005 and was completed on 31.12.2005.

From the literature (Bauer et al. 2005, Crocker & Irving 1999) the three main focal species were deduced: the Skylark, the Chaffinch and the Yellowhammer. In order to obtain a reliable indicator for exposure of these species to treated seeds, the portion of time spent 'potentially foraging' on freshly drilled fields was acquired by radio tracking.

In total 13 Skylarks were trapped in winter cereal and adjacent habitats and tagged with radio transmitters; eight Skylarks were tracked for one (N = 5) or two (N = 3) daylight periods each. The respective number of trapped and radio tagged Chaffinches was 12. Telemetry sessions comprehended one (N = 6) or two (N = 1) daylight periods each. Eleven Yellowhammers were trapped and radio tagged. Eight individuals were tracked for one and three individuals for two daylight periods. In order to assess the general relevance of winter cereal fields and other habitats as feeding locations for birds, 7 census counts each were carried out along five different transects, representing all main agrarian habitat types within the study area. These transects were walked once a week to acquire a full overview of bird life.

Additionally on six defined subareas of freshly drilled winter cereal fields (2 winter barley, 4 winter wheat) - including a small adjacent 'outside-area' - a scan sampling procedure was conducted. Here all bird activities were observed from dawn till dusk.

This procedure was conducted once before drilling and two times after

drilling to quantify any changes of bird activities possibly caused by the availability of treated cereal seeds. For each session the portion of scans a given species could be observed was calculated (frequency of occurrence = FO).

In order to gain information about food items selected by the focal species, 48 samples of faeces or stomach flushings were analysed quantitatively for their composition: taxonomic orders of plants, in particular components of winter cereals and arthropods or other identifiable items were recorded. Faeces and stomach flushing samples were taken during the handling of individual birds after mist netting and as well if defecating was observed during the telemetry session of tagged individuals.

To quantify the availability of winter cereal seeds to small and medium sized granivorous bird species, the initial exposure of the seeds was measured. Within 24 hours after the termination of drilling visible seeds were counted on the six different study plots when there was no scan sampling conducted.

Results:

Table 9.1-27: PT, habitat preference, diet, abundance and frequency of occurrence of bird species in pre-emergence winter cereal fields

Portion of time potentially foraging (PT in cereal fields by radio tracked species					
Potential foraging time radio tracked birds spent in freshly drilled winter cereals fields (wheat + barley)	**Species**	**Mean [%]**	**90th %ile [%]**	**Tracking sessions (individuals)**	
	Yellowhammer	6.41	23.63	14 (11)	
	Skylark	16.97	95.73	11 (8)	
	Chaffinch	8.54	22.05	8 (7)	
Habitat preference of species according to radio tracking					
Preference of winter cereals as a feeding habitat (D: Jacobs' Index, range: -1 to +1; MCP [100%])	**Species**	**D**			
	Yellowhammer	-0.79			
	Skylark	-0.29			
	Chaffince	-0.89			
Diet of species in cereal fields					
Portion of samples [%] containing each food item after the analysis of faeces (19) and samples of stomach flushing (29) gathered in cereals fields (N: no. of faeces/flushings)	**Food items**	**Yellowhammer (N = 8/16)**	**Skylark (N = 6/3)**	**Chaffinch (N = 5/10)**	
	Wheat seeds	75.00	60	80.00	
	Other cereals seeds	4.17	-	-	
	Other seeds	12.50	50	53.33	
	Other plant material	33.33	30	53.33	
	Coleoptera	29.17	10	53.33	

	Diptera	25.00	20	73.33
	Hymenoptera	8.33	10	13.33
	Dermaptera	4.17	-	20.00
	Rhynchota	12.50	10	26.67
	Araneae	12.50	-	26.67
	Other animal material	4.17	10	20.00
	Unidentified objects	16.67	-	-
Bird abundance in winter cereals according to transect counts (based on population)				
Abundance of focal species and four other abundant species after seven transect counts covering 310.35 hectare	**Species**	**[Ind./ha]**		
	Skylark	1.321		
	Starling	1.266		
	Chaffinch	1.260		
	Linnet	0.319		
	Yellowhammer	0.313		
	Wood Pigeon	0.213		
	Mistle Trush	0.113		
Bird frequency of occurrence according to scan sampling				
Frequency of occurrence (mean of the results for each session; n = 12) of focal species and five other prevalent species on six fields	Species	[%]		
	Yellowhammer	5.83		
	Black Redstart	5.54		
	Chaffinch	5.35		
	Jay	3.56		
	Blackbird	2.92		
	Brambling	2.90		
	Greenfinch	2.39		
	Skylark	0.16		

Conclusion: For risk assessment purposes a value for portion of diet obtained in treated area (PT - estimated from the time spent potentially foraging) can be derived for Yellowhammer, Skylark and Chaffinch from the study results: Yellowhammers spent on average 6.41 % of their potentially foraging time in winter cereal fields (90^{th} percentile = 23.63 %); Skylarks spent 16.97 % of their potentially foraging time in winter cereal fields (90^{th} percentile = 95.73 %) and Chaffinches spent 8.54 % of their potentially foraging time in winter cereals (90^{th} percentile = 22.05 %).

Comment RMS:	The study is in general considered acceptable. For individuals with more than one tracking session the mean PT of all tracking sessions should be used. Considering this, only three individuals were available to calculate a consumers only PT for

	skylarks, four for chaffinches and eight for yellowhammers. The RMS recalculated therefore a maximum consumer only PT in pre-emergence autumn sown cereals fields of 1.0 for skylarks, 0.06 for chaffinches and 0.35 for yellowhammers. As the study was used for PT refinement, PD estimation was not further considered. However the Co-RMS provided an evaluation conducted for the resubmission of triazoxide which is presented in the following: *Dietary composition based on a faecal or stomach contents analysis of the yellowhammer, skylark and chaffinch were estimated in Barfknecht (2006). Details of the results of these analyses are presented in the study in terms of the percentage of individual samples containing cereal seed and other foods items.* *The way the data have been presented is not considered to be suitable to estimate the proportion of food types in the diet obtained from the treated area (or 'PD').* *Data based on numbers will tend to over-estimate the contribution of small items to the total quantity of diet consumed, therefore, for risk assessment purposes, dietary composition should be based on weight. Assuming a similar bulk density for all food types, the dietary weight percentage for each can be based on dietary volume percentages. This has been used with the following (very approximate) assumptions:* *i) the volume of each consumed seed or invertebrate body is approximately equal to its length x width x 'height'* *ii) In the absence of data, seed or invertebrate body width and 'height' is approximately one third (0.33) of its length.* *Based on these assumptions, the dietary composition data given in terms of 'number of food items' have been converted to '% by volume'* *Based on the converted data, the PD for the skylark was 0.42, for the yellowhammer 0.58 and for the chaffinch 0.32.*

Reference:	**Triticonazole Document N5 – Consideration of isomeric composition on the risk assessment**
Author(s), year:	[redacted] 2014
Report/Doc. number:	BASF DocID 2014/1092400

The Z-isomer can be formed under light conditions from triticonazole (E-isomer). There is data available from water and soil photolysis studies on the extent of photoisomerisation in aqueous and soil conditions. (For details refer to Section B8).

Table 9.1-28: List of studies and endpoints for the Z-isomer of triticonazole/photo-metabolite: RPA 406203 (Reg. No. 5079359)

Organism	Endpoint	Value	Reference (BASF DocID)
Terrestrial vertebrates (mammals)			

Rat	Acute oral LD_{50}	> 2000 mg/kg b.w.	R000127
Aquatic invertebrates			
Daphnia magna	48 h EC_{50}	3.4 mg/L	C044320
Daphnia magna	48 h EC_{50}	> 10 mg/L	2009/1075083
Algae			
Pseudokirchneriella subcapitata	72 h E_rC_{50} 72 h E_yC_{50}	73.32 mg/L 9.29 mg/L	2009/1050280

The endpoints of the available studies generally indicate that RPA 406203(Z-isomer) is not more toxic than triticonazole (E-isomer).

Further data (non-GLP trials with seeds)

A non-GLP study (BASF DocID 2015/1189076) was conducted to determine the extent of conversion of the E-isomer of Triticonazole to its Z-isomer on wheat seeds after seed treatment with BAS 595 01 F and subsequent irridation with UV light during a time period of 10 days. After irridation of BAS 595 01 F treated seeds in the laboratory, the overall amount of Z-isomer formed in these trials is very low, and the large majority of residues is made up by the E-isomer (for details refer to the summary and evaluation of the study)

Exposure to seeds on the soil surface

For animals feeding on treated seeds the aspects of availability of treated seeds and formation rate of the Z-isomer on this food source should be taken into account. As the Z-isomer is only formed in the presence of light only seeds on the surface need to be considered. From these seeds parts of the seed surface will not be directly exposed to sunlight as they are located on the ground and will be partly covered from the soil.

Data from a specific field study (BASF docID 2012/1126440) show that the 90th percentile of seeds being exposed on the soil surface is 57 seeds/m^2 in the headlands and 24 seeds/m^2 in the midfield. Based on a thousand grain weight of 46 g for winter wheat taken from the DAR (September 2003) and a maximum seeding rate of 250 kg/ha, this leads to the conclusion that under the abovementioned conditions only 5 to 10% of the total amount of sown seeds could be theoretically exposed to sunlight. Together with the low formation rate of the Z-isomer after irradiation of treated seeds it leads to the conclusion that exposure of granivorous birds and mammals to the Z-isomer should be very limited and thus covered by the risk assessment for the E-isomer.

Comment RMS:	The document provides extensive information regarding the Z-isomer of triticonazole, its properties, its behaviour in the environment and its toxicity to organisms. Furthermore the document provides argumentation that the exposure to the Z-isomer is limited due to the number of treated cereal seeds exposed on the soil surface, e.g. seeds being readily available for consumption by granivorous birds or mammals and the low formation rate of the Z-isomer after irradiation of treated seeds. Together with the information that the toxicity of the Z-isomer for other organisms than birds and mammals is not more toxic than the E-isomer, this argumentation is considered acceptable.

Reference:	**Determination of BAS 595 F and M595F014 in wheat seed after seed treatment with BAS 595 01 F – non-GLP data**
Author(s), year:	Spangler, Ch., Guedez Orozco, A. A., Fleischer, G., Rabe, U., 2015
Report/Doc. number:	BASF DocID 2015/1189076
Guideline(s):	None
GLP:	No

The objective of the study was to determine the extent of conversion of the E-isomer of Triticonazole (BAS 595 F) to its Z-isomer (M595F014) on wheat seeds after seed treatment with BAS 595 01 F and subsequent irradiaton with UV light during a time period of 10 days.

Material and methods:

Five gram of seeds (winter wheat) were weighed in and placed on a sheet of pulp in a petri dish. Three petri dishes for each sampling timepoint were incubated on a table in a climatic chamber for 0, 1, 3, 4, 7 and 10 days. The program for the climatic conditions in the chamber mimic a period beginning of April in the palatinate area of Germany. The light system in the chambers consists of 6 metal halide lamp (Osram HMI) with a filter (cut at 280 nm). After irradiation, samples were stored between 0 and 4 days in the freezer (≤ -18°C) before start of analysis.

For analysis BASF methods no. L0106/01 and L0106/02 were used which determine the analytes by means of HPLC-MS/MS. Storage stability of BAS 595 F in different matrices was investigated in studies mentioned in the reference section of the report.

Results:

Table 9.1-29: Residues of E-isomer and Z-isomer of triticonazole after irradiation with UV light under laboratory conditions

Time period of radiation [d]	Sample no.	E-isomer BAS 595 F [mg/kg]	Z-isomer M595F014 [mg/kg]	Ratio BAS 595 F / M595F014 [%]*
0	L1504060001	40	< 0.01	100 / < 0.03**
	L1504060002	36	< 0.01	100 / < 0.03**
	L1504060003	39	< 0.01	100 / < 0.03**
1	L1504120001	37	0.35	99.1 / 0.9
	L1504120002	37	0.15***	99.6 / 0.4
	L1504120003	36	0.37	99.0 / 1.0
3	L1504070001	37	0.63	98.3 / 1.7
	L1504070002	37	0.61	98.4 / 1.6
	L1504070003	37	0.57	98.5 / 1.5
4	L1504080007	32	0.65	98.0 / 2.0
	L1504080008	31	0.66	97.9 / 2.1
	L1504080009	29	0.66	97.8 / 2.2
7	L1504090004	28	0.69	97.6 / 2.4
	L1504090005	27	0.64	97.6 / 2.4

	L1504090006	28	0.66	97.7 / 2.3
10	L1504100001	32	0.78	97.6 / 2.4
	L1504100002	32	0.78	97.7 / 2.3
	L1504100003	33	0.76	97.8 / 2.2

* percentage is calculated by dividing residue of BAS 595 F or M595F014 by the sum of residues of BAS 595 F and M595F014
** for the calculation of the ratio BAS 595 F/M595F014 the result <0.01 mg/kg for M595F014 ws set to 0.01 mg/kg
*** mean of two results (0.14 and 0.15 mg/kg)

Conclusion:

BAS 595 F is partly converted to M595F014 during the 10 day irradiation period after seed treatment. Residues of M595F014 were in the range of 0.76 to 0.78 mg/kg after 10 days of irradiation, which corresponds to a ratio of BAS 595 F / M595F014 in the range of 97.8 / 2.2 % to 97.6 / 2.4 %

Comment RMS:	The study is a non-GLP study. However it is considered acceptable to be used as supportive information.

Reference:	**Abundance and density of unburied seeds in freshly drilled cereal fields in Germany**
Author(s), year:	Laucht, S., 2013
Report/Doc. number:	BASF DocID 2012/1126440
Guideline(s):	No official guideline available
GLP:	Yes

The aim of this study was to quantify the presence and to estimate the abundance of freshly drilled cereal seeds visible on the soil surface on headland and midfield parts in commercial spring cereal fields in Germany over a period of 10 days.

Material and methods:

Test item	Spring cereal seeds treated with BAS 590 05 F containing the active substance Prochloraz (20 g/100 kg seed nominal; 21.2 g/100 kg seed analysed)
Crop	Barley
Thousand grain weight	49.7 g
Germination rate	98%
Study site	The study was conducted on six freshly sown spring cereal fields located in Rhineland-Palatinate (three close to the city of Limburgerhof and three close to the city of Gösenroth), Germany, that had been sown with spring cereal seeds treated with BAS 590 05 F in spring 2012.
Seed drilling	Non GLP- application with Integra 3000 drilling rate: 180 kg/ha (270 kg; 1.5 ha); weather during drilling: sunny, dry

Seed exposure	The seed exposure was assessed three times: once shortly after sowing (count 1), approximately five days after the first count (count 2) and approximately five days after the second count (count 3). The assessment was performed by counting visible seeds on the soil surface in two different areas of the study fields: one in the headland (H) and one in the midfield (M). Ten points each were assessed at 5m distances along one diagonal transect, or along two diagonal transects where necessary. Each point consisted of an area of 0.5 m x 0.5m (= 0.25 m2) that was established by placing a frame on the ground parallel to the transect. All seeds visible on the soil surface within this frame were counted and recorded. In addition, GPS coordinates of the start and end point of each transect were recorded. The total number of surface seeds and the seed density (per m2) per count were calculated for each of the two sections (i.e. headland and midfield) as well as for totals of each of the study fields. For the overall evaluation average density across all study fields and the standard error of the mean (SE) were calculated, and minimum (min) and maximum (max) values of seed densities per count are given.
Results:	Six study fields were investigated during three counts. On each study field 20 points were assessed (and hence an area of 5 m^2 was examined) leading to a total of 120 points per count (correlating to an area of 30 m^2). During all three counts, exposed seeds were found on both areas, but more on the headlands. In addition, there was considerable variation between the six study fields (count 1: 5 – 146 seeds, count 2: 0 – 68 seeds, count 3: 0 – 152 seeds). Taking all six study fields into account, count 1 resulted in a total of 479 seeds for both sections and an average density of 15.97 + 4.15 (SE) seeds/m^2, count 2 in 273 seeds and a density of 9.10 + 2.22 (SE) seeds/m^2, and count 3 in 240 seeds and a density of 8.00 + 5.22 (SE) seeds/m^2.
Conclusion:	To conclude, this study demonstrates that the exposure of treated seeds on the soil surface after cereal drilling can be variable for a period of 10 days after drilling: including a very high variation between study fields, seed densities ranged between 15.97 + 4.15 (SE) seeds/m^2 and 8.00 + 5.22 (SE) seeds/m^2 for the three counts.
Comment RMS:	The study is a non-GLP study. It gives an indication of how the variation of the number of seeds available on the soil surface after drilling. Depending on the drilling method the numbers may be even more variable. The study may be accepted as supportive information.

Two bird studies on the avoidance of seeds treated with triticonazole were provided for the first EU-approval. The studies have not been re-evaluated. The references and are given below

Reference:	**Trials to evaluate the consumption of fungicide-coated wheat seeds by Grey partridges (*Perdix perdix*) in captivity,**
Author(s), year:	[redacted] 1992a
Report/Doc. number:	R013096
Guideline(s):	INRA methodology
GLP:	No

Reference:	**A test for avoidance of treated barley seed with the northern bobwhite (*Colinus virginianus*)**
Author(s), year:	[redacted], J.B., 2001a
Report/Doc. number:	C017903
Guideline(s):	Partly based upon BBA Guideline VI25-1, OECD draft proposal
GLP:	Yes

B.9.1.2. Effects on terrestrial vertebrates other than birds

A summary of the toxicity of triticonazole to mammals is given in the Table 9.1-30.

No additional studies were submitted for the renewal of the active substance triticonazole. Hence, the risk assessment is based on the EU peer review acute and long-term endpoints identified for the first EU approval of the active substance.

Table 9.1-30: Toxicity of triticonazole to mammals

Test design	Test species	Ecotoxicological endpoint	Effects the Endpoint is based on	Reference
Oral acute	Rat	**LD_{50} > 2000 mg ai/kg bw**	decreased motor activity and ataxia	[redacted] 1990
Oral toxicity 28 days		NOAEL = 500 ppm corresponding to 52.4 mg ai/kg bw/d	↓absolute uterus weight	[redacted] 1991
Oral toxicity 90 days		NOAEL = 250 ppm corresponding to 19.8 mg ai/kg bw/d (males) and 22.3 mg ai/kg/bw/d (females)	↓Body weight gain, ↓food consumption, ↑absolute and relative liver weight, ↑absolute and relative ovary weight, necropsy findings in adrenals	[redacted] 1991
2-generation reproduction		NOAEL = 750 ppm corresponding to 48.41 mg ai/ kg bw	<u>Parental:</u> maternal mortality, ↓body weight, necropsy findings in adrenals, liver and ovaries ↓mating and fertility index in F1 generation <u>Offspring:</u> reduced survival and growth consistently observed across both generations	[redacted] 1993
Developmental toxicity		NOAEL = 200 mg ai/kg bw/d	↓maternal body weight gain, <u>Foetal:</u> ↑incidence of additional 13th and 14th rib	[redacted], 1991
	Rabbit	**NOAEL = 25 mg ai/kg bw/d**	<u>Paternal:</u> maternal mortality, abortions, ↓food consumption, ↓body weight gain <u>Foetal:</u> Increased incidences of different skeletal findings	[redacted], 1991

Bold values are used for the risk assessment

Table 9.1-31: Toxicity of RPA 406341 to mammals

Test design	Test species	Ecotoxicological endpoint	Effects the Endpoint is based on	Reference
Oral acute	Rat	LD_{50} > 2000 mg/kg bw	decreased activity, reduced defacation	[redacted], 1999

Long-term toxicity endpoint

The long-term toxicity endpoint identified in Section B6 is the lowest NOAEL of 5 mg ai/kg b.w./d from the developmental study in rabbits ([redacted], 1991).
With regards to maternal toxicity in rabbits there were dose related incidences of mortality and statistically significant transient weight loss and statistically significant reduced food intake during gestation in the two highest treatment groups at 50 mg ai/kg b.w./d and 75 mg ai/kg b.w./d.
No mortality occurred at the lower dose groups of 5 or 25 mg ai/kg b.w./d and no significant effects > 10% on bodyweight performance or food intake occurred at 5 or 25 mg ai/kg b.w./d. At 25 mg ai/kg b.w./d a bodyweight loss occurred during the first two days of pregnancy only and bodyweight gain thereafter was essentially similar to control groups in all dose groups. Food intake was reduced only to a marginal extend at 25 mg ai/kg b.w./d (for details please refer to Volume 3 B6-AS). Triticonazole caused increased incidences of precocious ossification of the acromion process (= elongation of acromion process) in the scapula of rabbit fetuses at doses of ≥ 25 mg ai/kg b.w./d. This variation had no impact on survival or development of the offspring, as the acromion process (which is the muscle attachment site of the scapula) will ossify later in development (for details please refer to Volume 3 B6-AS). Therefore, these incidences will highly likely have no impact on the viability and reproduction potential of pups when they reach the reproducing age. Since this was the only finding seen in fetuses at 25 mg ai/kg b.w./d. no impact on the population level of wild mammals is expected and the ecologically relevant NOAEL for pup effects and development for wild mammals is set to 25 mg ai/kg b.w./d.

In summary for the rabbit development study, the marginal effects on maternal toxicity with a route of exposure unrealistic for wild mammals and the ecologically non-relevant developmental effects on pups lead to the conclusion that the population-relevant ecotoxicological endpoint for wild mammals from the developmental study in rabbits is NOAEL= 25 mg ai/kg b.w./d. To further support this conclusion the notifier provided a statement by Exponent, Inc. “Assessment of Acromion Processes Elongated in Rabbit Developmental Toxicity Study of Triticonazole” (September 2016). A short summary of the statement is presented in Volume 3 B6-CA.

The 90 days oral toxicity study in rats results in an NOAEL of 19.8 mg ai/kg bw/d for males and 22.3 mg ai/kg bw/d for females. The observed effects are not considered population relevant for wild mammals, and the ecotoxicological relevance for an increase in ovary weight is questionable and no histopathological effects were observed. Furthermore the choice of dose spacing with concentrations of 25, 250, 12500 and 25000 ppm is very unfavourable having a factor of 50 between the 250 and the 12500 ppm treatment.

A two - generation study in rat results in an NOAEL of 48.41mg ai/kg bw/day showing reduced survival and growth consistently observed across both generations.

For precautionary reasons the endpoint of 25 mg ai/kg bw/d from the developmental study is chosen for the risk assessment. However, this is considered very conservative as the two-generation study in rat is considered more relevant regarding the species tested as well as regarding the methodology used. Furthermore effects besides the

elongated acromion process are mainly shown at 75 mg ai/kg bw/d and are considered more related to maternal toxicity than to developmental toxicity.
An alternative endpoint could therefore be the NOAEL of 48.41 mg ai/kg bw/day from the two-generation study in the rat.

Toxicity of the formulated product:

The acute oral toxicity of the product EXP 80472 was determined in a study with rats. Based on the results of the study, the toxicity of the formulation and the active substance triticonazole is considered to be comparable.

Table 9.1-32: Toxicity of the formulated product to mammals

Test species	Test design	Ecotoxicological endpoint	Reference
Rat	Acute, oral	LD_{50} > 2000 mg prod./kg bw	Clouzeau, 1994

Endocrine disruption:

According to the toxicology section following conclusion can be driven (for details please refer to Volume 3 B6-CA):
"In summary, based on the results of in vivo tests conducted with triticonazole, there is no evidence of a specific effect on the endocrine system or on any endocrine organ, with a demonstrated endocrine MoA. Triticonazole has been shown to inhibit the aromatase enzyme in vitro like other members of the azole class of fungicides, with 20-times lower IC for rat than for human aromatase. However, in vitro activity did not translate into any specific endocrine-related effect in vivo. This observation is supported by the lack of treatment-related carcinogenic effects in two lifetime cancer bioassays conducted in rats and mice, as well as the absence of specific reproductive or developmental toxicity in a 2-generation reproduction study and two developmental toxicity studies. The observed morphological changes in adrenals in all species and almost all studies, always accompanied by marked general toxicity, did not prove to impair the functional capacity of adrenals since corticosterone was successfully excreted after ACTH challenge. It is concluded that no evidence is available that effects observed in studies with triticonazole have an endocrine MoA."

Relevance and toxicity of the metabolites:

The potential routes of avian or mammal exposures are via direct consumption of treated seeds or emerging cereal shoots. The active substance exhibits at least some systemic behaviour; hence exposure is also considered likely to metabolites in emerging shoots.

The main initial metabolic process for triticonazole in plants is hydroxylation, either on the pentane ring (to give rise to RPA 404766, RPA 406341 or RPA 406780) or on one of the methyl groups associated with the pentane ring (to give rise to RPA 404886). The separation/ destruction of the triazole group may occur with the parent molecule unchanged or from the hydroxy metabolites. Once it has occurred, the incorporation into natural products is very rapid and such molecules are transported to the grain during its development. The residual

molecule (or metabolites derived from it) will form part of the polar residue remaining in straw.

In the plant metabolism and rotational crop studies with triticonazole (BASF DocIDs R000502 [EU reference P91/110], R012989 [EU reference P91/358], C021046 [EU reference CX/01/010], R012993 [EU reference P93/192] some unidentified non-polar and polar metabolites, and the metabolites RPA 406341, RPA 404766, RPA 406780, and RPA 404886 approached or exceeded 10% TRR. In green plant material at BBCH 24 / 30, a potential feed item for herbivorous birds, only polar unidentified metabolites and metabolite RPA 406780 showed to be major. These metabolites were also found at BBCH 65 / 62-65. However, most metabolites approaching or exceeding 10% TRR were found in cereal chaff, grain or straw (polar unidentified metabolites, RPA 406341, RPA 404766, RPA 406780, RPA 404886), which are not considered to be feed items of herbivorous birds.

Due to their significant relative quantities, the metabolites mentioned before will be evaluated as to their potential relevance for birds:

The unidentified non-polar and the identified metabolites (RPA 406341, RPA 404766, RPA 406780, RPA 404886) are more polar than the parent molecule triticonazole, and therefore would be rapidly excreted when consumed by animals via the food. Based on this it can be concluded that these metabolites are of lower concern than the parent molecule.
Toxicological limit tests in quails (BASF DocID B002787) and rats (BASF DocID R000206) with RPA 406341 indicate no mortality up to the highest concentration tested (> 2250 mg ai/kg b.w. in quails and > 2000 mg ai/kg b.w. in rats), hence no increased toxicity compared to the parent.

RPA 406203 is the Z-isomer of triticonazole and can be formed under light conditions from triticonazole (the E-isomer). The applicant provided a separate Document (N5) summarizing all available information about the Z-isomer, its environmental fate, toxicological and ecotoxicological relevance.

Higher tier studies:

Two degradation studies were provided as confirmatory data (Scrimshaw, 2006 and Moreno, 2008). The results were used for the risk assessment. For the current application the applicant submitted two additional studies addressing residues in spring wheat seeds (Plier, 2016) and winter wheat seeds (Plier & Elze, 2017) and separate reports reviewing the degradation kinetics for the calculation of DT_{50} dissipation times (Szegedi, 2017 a & b). The study report summaries are provided in Section B.9.1.1 of this document.
Furthermore studies to refine PT values of wood mice were submitted. Two studies performed in spring cereal fields (Fülling & Miersch, 2016; Barfknecht, 2008a) and two studies performed in winter cereals (Fülling & Sainz-Elipe, 2017; Barfknecht, 2006) were submitted. The study report summaries, the evaluations and re-evaluations, respectively for the degradation studies are already presented in chapter 9.1.1 Effects on birds. The studies for the PT are summarised in the following.

Reference:	**Generic Field Study on PT of Wood Mice in freshly drilled Spring Cereal Fields (Germany)**
Author(s), year:	Fülling, O., Miersch, Ch., 2016
Report/Doc. number:	BASF DocID: 2016/1326919
Guideline(s):	EFSA Guidance Document: Risk assessment for birds and mammals (2009)
GLP:	Yes
Deviations:	The study aimed to radio track 16 different individual wood mice within the first 3 days after drilling. Three additional radio tracking sessions should be conducted for a selection of five animals out of those 16. Only 13 individuals were tracked and only the sessions of 11 wood mice were long enough for further analysis. Four wood mice were tracked for three more nights before the spring cereal plants emerged. Two individuals were tracked for two nights each.
Validity:	acceptable

Material and methods:

Study area	The study was conducted on 6 commercially managed spring cereal fields sized from 0.9 ha to 2.8 ha (average: 1.68 ha) and located near the research Centre Neu-Ulrichstein in Hesse, Germany. Selected study fields were representative for commercially managed spring cereal fields and were bordered by off-crop habitats known to be favourable for wood mice (e.g. hedges or forest). Four fields were finally used for radio tracking
Live trapping	Live trapping was conducted prior to the drilling of the spring cereal fields from March 17th to April 20th 2016. Live trapping was begun before drilling to select suitable animals for radio tracking, with the latter only conducted after the study fields were drilled. At each study site 50-60 "Ugglan" multiple capture live traps were set inside the study field and in addition 40-50 traps were set in suitable off-crop habitat in the close vicinity of the field. At least 50% of the traps were always placed inside the study field. The traps in the field were set in a grid whereas the traps along the field margins and in forests were set in suitable places depending on the habitat structure, the trapping success and shape of the corresponding study field.
Radio-tracking	Radio-tracking was used to assess the proportion of time that individual wood mice spend foraging in the crop (PT). The following three selection criteria were applied whenever feasible for equipping wood mice with radio transmitters: first, animals equipped with radio tags had a body weight of 20 g or more. Second, individuals frequently recaptured in or close to the spring cereal fields were preferred. Third, individuals caught in the spring cereal fields were preferred to those only caught close to the fields. For the selection of individuals that were radio tracked repeatedly, animals that were already known as consumers (i.e. were radio tracked

in the spring cereal fields) were preferred for consecutive sessions to ensure a conservative worst-case scenario.

Selected individuals were equipped with light weight radio tags (collars; 0.9 g), allowing to track the animals position. During the tracking sessions, mammals were tracked from dusk till dawn (for approximately 10 to 12 night hours), i.e. an animal was followed nonstop in order to determine its location (habitat used) and any behavioural changes. Every change in behaviour and location (GPS position) was accurately recorded to the minute. Behavioural categories were: "active" (i.e. potentially foraging), "foraging (i.e. visually observed foraging), "inactive" and "travelling" (i.e. moving fast through habitat without foraging). Radio-tracking was conducted from April 13th - 30th 2016.

Additionally, the home range was estimated via the Minimum Convex Polygon (MCP) method and the Jacobs preference index was calculated. The Jacobs preference index compares the habitat use (here the time a wood mouse spent potentially foraging in a habitat) with its availability within the animal's home range (here the area of MCP). The index was also calculated for each radio tracked wood mouse and every tracking session. However, as home ranges and Jacob preference indexes are not used for the refined risk assessment, the results are not provided in more detail in this study summary.

Results: From March 17th to April 20th 2016, 443 captures of small mammals were made at 6 different study sites (study fields and their vicinity). 124 of these captures were identified as wood mice. The 124 captures were first and re- captures of 35 individually marked wood mice. 21 wood mice were equipped with radio collars and released. 13 out of the 21 radio-tagged wood mice could be successfully radio tracked at 4 different fields in 30 night sessions. All radio tracking sessions were made after drilling the spring cereal fields but before the emergence of the crop plants. Three of the 30 radio tracking sessions lasted less than 5 hours. They were regarded as possibly biased and were, therefore, excluded from all further analyses. This slightly reduced the number of tracked individuals to 11 and the number of tracking sessions to 27. Overall, PT values were found to be low: PT values per session ranged from 0 to 0.302 (Table 9.1-33).

Table 9.1-33: PT of 11 tracked wood mice potentially foraging in freshly drilled spring cereal fields

Field	Individual No.	Radio-tracking sessions	Total time potentially foraging observed [hh:mm]	Time potentially foraging in spring cereal fields [hh:mm]	PT in spring cereal fields
1	1/1	1	05:20	00:00	0.000*
1	1/2	1	08:12	00:02	0.004***
1	1/2	2	07:44	00:00	0.000*
1	1/2	3	06:24	00:00	0.000*
1	1/3	1	07:41	00:00	0.000**
1	1/4	1	07:40	00:01	0.002***

1	1/4	2	07:27	00:02	0.004***
1	1/4	3	07:09	00:00	0.000*
1	1/4	4	04:20	00:00	0.000*
1	1/5	1	06:28	00:03	0.008***
1	1/5	2	08:09	00:00	0.000*
1	1/5	3	08:04	00:02	0.004***
2	2/4	2	07:13	00:04	0.009***
2	2/4	3	07:21	00:00	0.000**
2	2/4	4	07:06	00:00	0.000*
2	2/4	5	09:13	00:09	0.016***
4	4/3	1	06:02	01:03	0.174***
4	4/3	2	07:24:50[a]	01:16:20[a]	0.172***
4	4/3	3	06:13	01:40	0.268***
4	4/3	4	07:29	02:15:30[a]	0.302***
4	4/7	1	07:02	00:36	0.085***
4	4/7	2	07:51	01:38	0.208***
4	4/7	3	06:43:30[a]	00:56:30[a]	0.140***
4	4/7	4	08:04	01:46:30[a]	0.220***
6	6/1	1	08:41	00:00	0.000**
6	6/2	1	05:06	00:00	0.000*
6	6/3	1	05:41	00:00	0.000**
All session approach (N = 27 sessions)	mean				0.060
	median				0.004
	90th percentile				0.213
Home range approach (N = 19 sessions)	mean				0.085
	median				0.009
	90th percentile				0.230
Consumers only approach (N = 15 sessions)	mean				0.108
	median				0.085
	90th percentile				0.249

*PT value was only used to calculate the "all sessions" approach
**PT value was used for the calculations of the "all sessions" and the "home range" approach
***value was used for the calculations of all three approaches
[a] time indication [hh:mm:ss]

Conclusion: In the present study freshly drilled spring cereal fields were not very attractive for wood mice. Overall, PT values were found to be low.

Comment RMS: The study is in general considered acceptable. Results account for spring sown cereals. For individuals with more than one tracking session the mean PT of all tracking sessions should be used leaving only six individuals for consumers only PT calculation resulting in a 90th percentile PT of 0.196. Because of the low number of tracked individuals, the maximum consumer only PT for wood mice in pre-emergence spring sown cereal fields of 0.229 instead of the 90th percentile of should be used as a worst case approach. However, the use of these study results in the current risk assessment was considered not necessary. The evaluation and the results are provided as supplemental information.

Reference: **Generic field monitoring of mammals in freshly drilled summer cereals in Hunsrueck, Germany**

Author(s), year:	Barfknecht, R., 2008a
Report/Doc. number:	BASF DocID: 2008/1097310
Guideline(s):	OECD 187 (1997)
GLP:	Yes
Validity:	acceptable

Material and methods:

Study area	The study was conducted on four commercially managed spring cereal fields sized from 1.68 ha to 6.13 ha and located in the region of Sohren, Hunsruck, Germany. Selected study fields were representative for commercially managed spring cereal fields and were bordered by off-crop habitats known to be favourable for wood mice (e.g. hedges or forest). The experimental field study was initiated on March 13th, 2006, and continued until the April 27th, 2006.
Scan sampling	Scan sampling from March 14th to April 10th 2006. To quantify the occurrence of small mammals in the prospective summer barley fields, 'scan sampling' observations were carried out using a thermal image IR camera. Scans were carried out prior to drilling on all fields and also in the immediate days before drilling, where all fields were scanned continuously for 1.5 hours.
Live trapping	Live trapping was conducted before and after drilling of the spring cereal fields from March 16th to April 25th 2006. At each study site 48“Ugglan” multiple capture live traps were set inside the study field and in addition 16 traps were set in suitable off-crop habitat in the close vicinity of the field. On each study field a square trapping grid covered 0.64 ha. Traps were placed in a 8 x 8 arrangement within both the field itself and in areas expected to inhabit small mammals, such as a woodland or shrubbery. One quarter of the grid (2 rows of 8 traps) was therefore positioned within the adjacent woodland of each of the study fields. The first row was situated at approximately 15 m distance and parallel to the field edge, whilst the second row was situated at approximately 5 m distance from the field edge and 10 m distance form the first trapping row. Row 3 lay within the study field parallel to row 2 with an interspaced distance of 10 m. Rows 4 to 8 were set up in the exact same fashion each having the interspaced distance of 10 m.
Radio-tracking	Radio-tracking was used to assess the proportion of time that individual wood mice spend foraging in the crop (PT). Since the actual behavior of the tracked mammal can only rarely be defined, the PT values refer to the potential foraging time i.e. the time when an individual is active and the behaviour "foraging" cannot be excluded. *A. sylvaticus* "candidates for radio-tracking" were defined as adult and healthy individuals, and weighing 22 g or more. These individuals were retained at trapping

events and tagged with radio collars (PIP3-Ag 317, weight 1 g, manufactured by Biotrack Ltd, UK). It was intended to select individuals for radio-tracking only after they were captured at least twice and preferably in traps on the open field. However, the number of suitable candidates was low since most individuals preferred not to enter the open fields. Therefore, also wood mouse individuals which had not been captured on the field before were selected for radio-tracking.

During the tracking sessions, mammals were tracked from dusk till dawn (for approximately 9.5 night hours), and each change of location, habitat and behaviour together with time and GPS position were recorded manually on corresponding data sheets. In addition, GPS position was taken every 15 to 20 minutes, even if no change was observed. Mice were also recorded as being active or inactive. The movement of the mouse distinguished the activity. Active mice were distinguished as those who expressed any type of movement. Since direct observation of the behaviour was impossible, the potential foraging time calculation was based on the total time the mice spent over night outside of the nest. In two cases where the tagged animal was already active before tracking started, the PT-calculation was based on the observed active period only. Radio-tracking was conducted from April 12th – 22nd 2006.

Home Range

Additionally, the home range was estimated via the Minimum Convex Polygon (MCP) method and the Jacobs preference index was calculated. The Jacobs preference index compares the habitat use (here the time a wood mouse spent potentially foraging in a habitat) with its availability within the animal's home range (here the area of MCP). The index was also calculated for each radio tracked wood mouse and every tracking session. However, as home ranges and Jacob preference indexes are not used for the refined risk assessment, the results are not provided in more detail in this study summary.

Results:

From April 12th – 22nd 2006 a total of 44 individuals of 5 species were captured and marked at 5 different study sites (study fields and their vicinity). Although the capture rates on the cereal fields were much lower than in the surrounding habitats for the wood mouse, the wood mouse was the only granivorous species with significant abundance on the fields. For the wood mice, the trapping efficiency in the surrounding was nearly eight times as high as in the field (no. of captures per 100 trap nights: field: 0.3, surrounding: 2.2).

In total, 4 individuals of *A. sylvaticus* were tracked for the full extent of their nocturnal movements. Three mice were caught on the study fields. Each of these mice were tracked twice. The fourth *A. sylvaticus* (ID: 175570) was captured

during another nearby field study on Field X5). Due to unexpected mortality, the second radio tracking night could not be completed for this additional mouse (ID: 175570 field 5) and was therefore not analysed for PT values. The radio tracking data of 4 wood mice (males) result in PT values per session ranging from 0% to 30% (Table 9.1-34). Overall, PT values were found to be low for all individual wood mice.

Table 9.1-34: PT of 4 tracked wood mice potentially foraging in freshly drilled spring cereal fields

Field	Individual No.	Radio-tracking sessions	Total time tracked [hh:mm]	Time spent in spring cereal fields [hh:mm]	PT in spring cereal fields [%]
3	631152	1	09:30	01:21	14.21
3	631152	2	09:20	00:00	0.00
1	620651	1	08:40	02:38	30.38
1	620651	2	09:40	02:28	25.52
3	619817	1	09:45	01:04	10.94
3	619817	2	09:50	00:48	8.14
X5	175570	1	09:55	01:08	11.43

Conclusion: In the present study, freshly drilled spring cereal fields were not very attractive for wood mice because they were only used to a limited extent as potentially foraging sites. Overall, PT values were found to be low.

Comment RMS:	Although the study is considered acceptable in general, no PT value can be derived from this study as only 4 mice were tracked. It may be considered in a weight of evidence approach. Results account for spring sown cereals.

Reference:	**Generic field study on PT of woold mice in freshly drilled winter cereal fields (Germany)**
Author(s), year:	Fülling, O., Sainz-Elipe, S., 2017
Report/Doc. number:	BASF DocID: 2017/1025731
Guideline(s):	EFSA Guidance Document: Risk assessment for birds and mammals (2009)
GLP:	Yes
Validity:	acceptable

The objective of this study was to obtain information on the crop use of the wood mouse (*Apodemus sylvaticus*) in winter cereal fields at pre-emergence (BBCH < 10) in Germany.

Material and methods:

Study area: The study was conducted on 11 commercially managed winter cereal fields sized from 0.68 ha to 3.02 ha (average: 1.69 ha) and located near the research Centre Neu-Ulrichstein in Hesse, Germany. Selected study fields were representative for

	commercially managed winter cereal fields and were bordered by off-crop habitats known to be favorable for wood mice (forest, hedges, meadows, water associated vegetation).
Drilling	Drilling was done by local farmers according to good agricultural practice. Drilling density was between 470 seeds/m^2 and 350 kg/ha depending on the field. On all fields visible seed exposure was identified.
Live trapping	Live trapping was conducted prior to the drilling of the winter cereal fields from September 24th to October 28th 2016. Life trapping was performed before drilling to select suitable animals for radio tracking which was only conducted after the study fields were drilled. At each study site 60-80 "Ugglan" multiple capture live traps were set inside the study field and in addition 20-50 traps were set in suitable off-crop habitat in the close vicinity of the field. At least 50% of the traps were always placed inside the study field. The traps in the field were set in a grid whereas the traps along the adjacent off-crop habitats were set in suitable places depending on the habitat structure, the trapping success and shape of the corresponding study field.
Radio-tracking	Radio-tracking was used to assess the proportion of time that individual wood mice spend foraging in the crop (PT). The following three selection criteria were applied whenever feasible for equipping wood mice with radio transmitters: first, animals equipped with radio tags had a body weight of 20 g or more. Second, individuals frequently recaptured in or close to the winter cereal fields were preferred. Third, individuals caught in the winter cereal fields were preferred to those only caught close to the fields. For the selection of individuals that were radio tracked repeatedly, animals that were already known as consumers (i.e. were radio tracked in the winter cereal fields) were preferred for consecutive sessions to ensure a conservative worst-case scenario. Selected individuals were equipped with light weight radio tags (collars; 0.9g), allowing to track the animals position. During the tracking sessions mammals were tracked from dusk till dawn (for approximately 12 night hours), i.e. an animal was followed nonstop in order to determine its location (habitat used) and any behavioural changes. Every change in behaviour and location (GPS position) was accurately recorded to the minute. Behavioural categories were: "active" (i.e. potentially foraging), "foraging (i.e. visually observed foraging), "inactive", "in the burrow" (i.e. active or resting but for sure not foraging outside) and "travelling" (i.e. moving fast through habitat without foraging). Radio-tracking was conducted from October 10th to November 6th 2016.
Home Range	Additionally, the home range was estimated via the Minimum Convex Polygon (MCP) method and the Jacobs preference index was calculated. The Jacobs

preference index compares the habitat use (here the time a wood mouse spent potentially foraging in a habitat) with its availability within the animal's home range (here the area of MCP). The index was also calculated for each radio tracked wood mouse and every tracking session. However, as home ranges and Jacob preference indexes are not used for the refined risk assessment, the results are not provided in more detail in this study summary.

Results: From September 24th to October 28th 2016, 1606 captures of small mammals were made at 11 different study sites (study fields and their vicinity). 401 of these captures were identified as wood mice. The 401 captures were first and re- captures of 175 individual marked wood mice. 24 wood mice were equipped with radio collars and released. 16 out of the 24 radio-tagged wood mice could be successfully radio tracked at 7 different fields in 38 night sessions. All radio tracking sessions were made after drilling the winter cereal fields but before the emergence of the crop plants. Two out of these 16 wood mice were caught two and three times in a winter cereal field, respectively. Overall, PT values per session ranged from 0 to 1 (Table 9.1-35), albeit PT values were found to be low for the vast majority of individual wood mice.

Table 9.1-35: PT of 16 tracked wood mice potentially foraging in freshly drilled spring cereal fields

Field	Individual No.	Radio-tracking sessions	Status	Time observed potentially foraging in all habitats [hh:mm]	Time observed potentially foraging in winter cereal fields [hh:mm]	PT in winter cereal fields
2	2-1	1	all	08:00	00:00	0.000
2	2-3	1	consumer	03:92	01:04	0.306
2	2-3	2	consumer	05:11:30*	00:57:30[a]	0.185
2	2-3	3	consumer	00:58	00:58	1.000
2	2-3	4	consumer	06:10	05:05	0.824
2	2-3	5	consumer	04:29	03:21	0.747
2	2-4	1	consumer	09:12	00:04	0.007
3	3-1	1	all	10:11	00:00	0.000
3	3-1	2	home range	09:07	00:00	0.000
3	3-1	3	home range	07:55	00:00	0.000
3	3-1	4	home range	07:00	00:00	0.000
3	3-1	5	all	05:50	00:00	0.000
4	4-1	1	consumer	09:42	00:00:20[a]	0.001
4	4-1	2	consumer	09:19	00:00:30[a]	0.001
4	4-1	3	all	08:49	00:00	0.000
4	4-1	4	all	06:53	00:00	0.000
4	4-1	5	all	09:01	00:00	0.000
8	8-1	1	all	09:11	00:00	0.000
8	8-2	1	consumer	09:09	00:00:30[a]	0.001
8	8-2	2	home range	08:23	00:00	0.000
8	8-3	1	all	08:57	00:00	0.000
8	8-3	2	consumer	10:59	00:02:30[a]	0.004
8	8-3	3	all	10:38	00:00	0.000
8	8-3	4	consumer	09:08	00:01	0.002
8	8-3	5	all	10:01	00:00	0.000
8	8-4	1	all	06:29	00:00	0.000
9	9-1	1	all	07:30	00:00	0.000

9	9-2	1	all	09:36	00:00	0.000
9	9-2	2	consumer	10:22	00:16	0.026
9	9-2	3	all	09:30	00:00	0.000
9	9-2	4	all	10:49	00:00	0.000
9	9-2	5	all	08:57	00:00	0.000
10	10-1	1	consumer	08:53	00:01:30[a]	0.003
10	10-1	2	all	07:46	00:00	0.000
10	10-2	1	all	07:41	00:00	0.000
13	13-3	1	home range	10:12	00:00	0.000
13	13-5	1	all	09:44	00:00	0.000
13	13-6	1	all	09:31	00:00	0.000
All individual approach* (N = 16 individuals)	mean					0.039
	median					0.000
	90%tile					0.006
Home range approach (N = 9 individuals)	mean					0.070
	median					0.001
	90%tile					0.128
Consumers approach (N = 7 individuals)	mean					0.090
	median					0.001
	90%tile					0.249

*This approach considered all individuals including those with a "home range" or "consumer" status
[a] time indication [hh:mm:ss]

Conclusion: Observations by the means of radio tracking revealed that wood mice occasionally used freshly drilled winter cereal fields for foraging. In the present study an average of about 15% of the home range area were freshly drilled winter cereal fields. Just a single individual obtained PT values up to 1 per night but all other wood spent less than 3% of their foraging time in winter cereal fields. A second indicator of attractiveness, the Jacobs index, showed that the winter cereal fields were avoided, i.e. they were less frequently used than a random use of all available habitats would suggest. It can be concluded that freshly drilled winter cereal fields were occasionally entered by wood mice but the majority of individuals avoided them as foraging habitats.

Comment RMS: The study is considered acceptable in general. Results account for winter sown cereals. For individuals with more than one tracking session the mean PT of all tracking sessions should be used leaving only seven individuals for consumers only PT calculation resulting in a 90th percentile PT of 0.26 when re-calculated by the RMS (90th Quantile inclusive). Because of the low number of tracked individuals, the maximum consumer only PT for wood mice in pre-emergence winter sown cereal fields of 0.612 instead of the 90th percentile should be used as a worst case approach. However, the use of these study results in the current risk assessment was considered not necessary. The evaluation and the results are provided as supplemental information.

Reference:	**Generic field monitoring of mammals in freshly drilled winter cereal fields in autumn in Germany**
Author(s), year:	Barfknecht, R., 2006b
Report/Doc. number:	BASF DocID: 2016/1047474
Guideline(s):	OECD 187 (1997)
GLP:	Yes
Validity:	acceptable

One objective of this study was to obtain information on the crop use of the wood mouse (*Apodemus sylvaticus*) in winter cereal fields at pre-emergence (BBCH < 10) in Germany.

Material and methods:

Study area

The study was conducted on 5 commercially managed winter cereal fields sized from 30.28 ha to 75.24 ha and located in the region of Thale, Saxony-Anhalt, Germany. Selected study fields were representative for commercially managed winter cereal fields and were bordered by off-crop habitats known to be favorable for wood mice (e.g. hedges or forest). The study was conducted on agricultural fields with minimum soil-cultivation (e.g., no ploughing, limited grubbing and harrowing) resulting in worst-case study conditions. The field part of the study was conducted from September 15th to October 28th 2005.

Drilling

The initial exposure of treated seeds within 24 hours after drilling was measured on 40 randomly chosen locations on the five study plots. The mean number of freshly drilled seeds was calculated to be 39.04 seeds/m^2.

Scan sampling

To quantify the occurrence of small mammals in winter cereal fields 'scan sampling' observations were carried out on the five study plots by means of a thermal image camera. Scans were carried out once before and three times after the drilling of winter cereals. Live trapping was conducted prior to or shortly after the drilling of the winter cereal fields from September 21th to October 28th 2005.

Live trapping

Live trapping began before drilling to select suitable animals for radio tracking which was only conducted after the study fields were drilled. The traps were set in a grid. At each study site 48 “Ugglan” multiple capture live traps were set inside the study field and in addition 16 traps were set in suitable off-crop habitat in the close vicinity of the field. One quarter of the grid covered the surrounding habitat (rows 1 and 2 with 8 traps each, running at 15 m and 5 m distance along the field border). Rows 3 to 8 were set up in the field, with row 3 starting 5 m from the field border. The total area of the grid was 0.64 ha with an inter-trap spacing of 10 m and a margin of 5 m around the outermost traps.

It was aspired to tag mainly individuals that were caught in the cereal field with a

weight of at least 20 g, preferring animals which had already been trapped and marked in the cereal field before. It turned out to be very difficult to get suitable animals since the trapping efficiency in the field was very low and the weight of most individuals was not high enough. Additionally, captures of marked individuals in the field were scarce. This leads to the conclusion that individuals did not often enter the field repeatedly, (perhaps among others due to migration). Therefore, also individuals caught in the surrounding and not marked were tagged.

Radio-tracking

Radio-tracking was used to assess the proportion of time that the species spend foraging in the crop (PT) of individual wood mice and common voles. During the study, suitable adult individuals of the relevant species (wood mouse and common voles) caught in the live traps were equipped with radio collars (PIP3-Ag 317, weight 1g and PIP3-Ag 376, weight 2 g, manufactured by Biotrack Ltd, UK). Animals were regarded as suitable if the weight of the collar did not exceed 10 % of the animal's body mass. During the tracking session each change of location, habitat and behaviour together with time and GPS position was recorded. In addition, GPS position was taken every 15 to 20 minutes, even if no change was noticed. These data allowed to calculate the portion of time an animal spent in a specific habitat type (e.g. winter cereal field) and furthermore to calculate the size and shape of the total home range at that day. In case a tagged animal was already active before tracking started, the PT-calculation was based on the observed active period only. However, as only the data relevant for wood mice are used for the refined risk assessment, the results for common voles are not provided in more detail in this study summary.

During the tracking sessions, wood mice were tracked from dusk till dawn, i.e. an animal was followed nonstop in order to determine its location (habitat used) and any behavioural changes. Every change in behaviour and location (GPS position) were accurately recorded to the minute. Since the actual behaviour of the tracked animal can only rarely be defined, the PT values refer to the potential foraging time i.e. the time when an individual is active and the behavior "foraging" cannot be excluded. Radio-tracking of wood mice was conducted from September 23th to October 23th 2005.

Home range

In addition, the home range was estimated via the Minimum Convex Polygon (MCP) method and the Jacobs preference index was calculated. The Jacobs preference index compares the habitat use (here the time a wood mouse spent potentially foraging in a habitat) with its availability within the animal’s home range (here the area of MCP). The index was also calculated for each radio tracked wood mouse and every tracking session. However, as home ranges and Jacob preference indexes are not used for the refined risk assessment, the results are not

provided in more detail in this study summary.

Food choice

Furthermore, the actual food choice of *Apodemus sylvaticus* on freshly drilled winter cereal fields was determined, based on observations of feeding behaviour with a thermal image camera and investigations of the faeces and the stomach contents of individuals foraging on the winter cereal field. Additionally, an exposure assessment of seeds on the surface of freshly drilled winter cereal fields was conducted to quantify the availability of winter cereal seeds to small mammals in which the initial exposure of the red-coloured, treated seeds after drilling was measured. However, as these data are not used for the refined risk assessment, the results are not provided in more detail in this study summary.

Results:

From September 21st to October 28th 2005 a total of 284 marked individuals of 6 species were captured at 5 different study sites (study fields and their vicinity). Wood mice were more often captured in the surrounding traps than in the field traps. For the wood mice, the trapping efficiency in the surrounding was nearly three times as high as in the field (no. of captures per 100 trap nights: field: 4.84, surrounding: 13.42).

The radio tracking data of 9 wood mice (2 females, 7 males) result in PT values per session ranging from 0 to 100% (Table 9.1-36), albeit PT values were found to be rather low for the majority of individual wood mice.

Table 9.1-36: PT of 9 tracked wood mice potentially foraging in freshly drilled spring cereal fields

Field	Date of tracking [1)]	Individual No.	Radio-tracking sessions	Time active in all habitats [hh:mm]	Time observed potentially foraging in winter cereal fields [hh:mm]	PT in winter cereal fields [%]
1	2005-09-23/24	7200498942	1	9:28	0:07	1.23
1	2005-09-28/29	7200500188	1	6:50	1:31	22.20
1	2005-10-04/05	72000000057041	1	11:03	0:55	8.30
3	2005-10-11-12	no ID	1	10:58	4:17	39.06
2	2005-10-13/14	7200367190	1	5:09	5:09	100.00
4	2005-10-16/17	no ID	1	7:25	-	0.00
2	2005-10-18/19	no ID	1	3:03	-	0.00
3	2005-10-19/20 & 2005-10-20/21	72000000184582	1	10:30	0:29	4.60
4	2005-10-22/23	72000000063816	1	4:40	3:33	76.07

[1)]Date of tracking included to better distinguish the wood mice individuals without Individual number (ID).

Conclusion:

In the present study freshly drilled winter cereal fields were visited, but the foraging time spent in this habitat was generally low. Freshly drilled winter cereals fields were less attractive than the surrounding habitats for most individual wood mice.

Comment RMS:	The study is considered acceptable in general. Results account for winter sown cereals. Only 7 consumer mice were tracked.

B.9.2. RISK ASSESSMENT FOR BIRDS AND OTHER TERRESTRIAL VERTEBRATES

Birds and other terrestrial vertebrates may be exposed to triticonazole by eating contaminated seeds and crop seedlings or via secondary poisoning.
The risk assessment for birds and mammals was conducted according to the EFSA Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009;7(12):1438).

Premis 25 FS is intended to be applied as a fungicidal seed treatment in cereals at a maximum single application rate of 12.5 g ai/ha.

B.9.2.1. Risk assessment for birds

With regard to the relevant scenarios small granivorous and small omnivorous birds (see Table B.9.1.2-1) are considered as the relevant generic focal species for risk assessment in the category cereals.

Table 9.2-1: Relevant generic avian focal species for the Tier 1 risk assessment

Crop	Growth stage (BBCH)	Generic focal species	FIR/bw or shortcut value
Cereals	BBCH 00/spring and autumn	Small granivorous bird	0.3
	seedlings	Small omnivorous bird	0.5 x NAR[1]/5

[1]NAR = Nominal loading/application rate of active substance in mg/kg seed.

Acute risk assessment for birds:

The acute risk assessment is based on the endpoints derived from acute toxicity studies with bobwhite quail ([redacted], 1991a), mallard duck ([redacted], 1991b), grey partridge ([redacted], 1992a) and red-legged partridge ([redacted], 1992b). The LD_{50} for all species was determined to be > 2000 mg ai/kg bw. In all acute toxicity tests no mortality was observed. Hence, the LD_{50} value for risk assessment was extrapolated taking into account an extrapolation factor (see table B.9.1.1-1). The acute risk assessment is based on a $LD_{50extrapolated}$ of 3776 mg ai/kg bw.
For the metabolites RPA 406341 an acute oral toxicity study with the northern bobwhite is available ([redacted] 2000a) providing an $LD_{50} \geq 2250$ mg/kg bw.

Table 9.2-2: Tier 1 acute risk assessment for granivorous birds eating cereal seeds

Generic focal species	Growth stage (BBCH)	FIR/bw	NAR[1]	DDD_A	LD_{50} [mg ai/kg bw]	TER_A
Small granivorous bird	BBCH 00/ spring and autumn	0.3	50	15	3776	252

[1]NAR = Nominal loading/application rate of active substance in mg/kg seed.

Table 9.2-3: Tier 1 acute risk assessment for omnivorous birds eating cereal seedlings

Generic focal species	Growth stage (BBCH)	Shortcut value	LD_{50} [mg ai/kg bw]	TER_A
Small omnivorous bird	seedlings	5[1]	3776	755.2
Large herbivorous bird[a]		3[2]		1259

[1]0.5 x NAR/5
[2]0.3 x NAR/5
NAR = Nominal loading/application rate of active substance in mg/kg seed.
[a]Large herbivorous birds are referred to in the text but not in the table of the EFSA GD. Therefore large herbivorous bird is added here with DDD value used for goose.

All TER_A values are above the trigger of 10 for acute exposure, indicating an acceptable risk to birds from the use of the product.

Long-term risk assessment for birds:

The long-term endpoint is based on the merging of three studies on bobwhite quail [redacted] 2012a; [redacted] 2007 and Taliaferro & Brewer 1995a).

The acute oral LD_{50} value used in the acute avian assessment ($LD_{50\ extrapoated}$ = 3776 mg ai/kg bw) divided by 10 to obtain LD_{50}/10 was compared with the lowest NOAEL from the reproduction study ignoring purely parental effects (e.g. changes in parental body weight and food consumption).
However, as a conservative approach, the lower endpoint from the reproduction study (NOAEL = 19.5 mg ai/kg bw/d) will be used in avian reproductive risk assessment.

Table 9.2-4: Tier 1 long-term risk assessment for granivorous birds eating cereals seeds

Generic focal species	Growth stage (BBCH)	FIR/bw	NAR[1]	f_{twa}[2]	DDD_{LT}	NOAEL [mg ai/kg bw]	TER_{LT}
Small granivorous bird	BBCH 00/ spring and autumn	0.3	50	0.72	10.8	19.5	**1.80**
				0.64	9.6		**2.03**
				0.53	7.95		**2.45**

[1]NAR = Nominal loading/application rate of active substance in mg/kg seed.
[2]The averaging time of 21 days is under debate for seed treatments as the time from sowing to germination usually is shorter, for cereals 10 to 14 days can be assumed. To enable expert discussion, the risk assessment is presented with a worst case germination time of 10 days, with a more realistic value of 14 days and with 21 days as used for spray applications.
Bold values do not meet the trigger.

The RMS is of the opinion that the value used for the averaging time should be discussed in an expert round as it is not fully clear which averaging time should be used for seed treatments in general.

Table 9.2-5: Tier 1 long-term risk assessment for omnivorous birds eating cereal seedlings

Generic focal species	Growth stage (BBCH)	Shortcut value	f_{twa}	DDD_{LT}	NOAEL [mg ai/kg bw]	TER_{LT}

Generic focal species	Growth stage (BBCH)	Shortcut value	f_{twa}	DDD_{LT}	NOAEL [mg ai/kg bw]	TER_{LT}
Small omnivorous bird	seedlings	5[1]	0.53	2.65	19.5	7.36
Large herbivorous bird[3]		3[2]		1.59		12.26

[1]0.5 x NAR/5
[2]0.3 x NAR/5
NAR = Nominal loading/application rate of active substance in mg/kg seed.
[3]Large herbivorous birds are referred to in the text but not in the table of the EFSA GD. Therefore large herbivorous bird is added here with DDD value used for goose.
Bold values do not meet the trigger.

The TER_{LT} values for large herbivorous and small granivorous birds eating seedlings are above the trigger of 5, indicating a low risk for birds. However, the TER_{LT} values for small granivorous birds eating seeds are below the trigger of 5 for long-term exposure, indicating a high risk for birds from the use of the product. Therefore further refinement is required.

Higher tier long-term risk assessment for birds

Two degradation studies were provided as confirmatory data in 2009. These studies were conducted to measure initial triticonazole residue levels on seeds exposed onto the soil surface and to also measure the residue decline on these seeds. For the current application two further degradation studies were provided, measuring the residues of the seeds directly from the sowing machinery.

Initial residues on cereal seeds on the soil surface

During the first approval, the worst case figure obtained from the two studies of rounded 67% was used as a correction factor in the risk assessment to cover the Northern and the Southern region of the EU. The RMS asked the applicant for justification and further information regarding the loss of active substance between treatment of the seeds and sowing. The applicant provided an additional data package. Along with two additional studies measuring the residues on the seeds direct from the sowing machinery, the applicant provided literature data indicating that increase of moisture content in the seeds leads to a residue decline (or rather dilution) during the first hours of sowing when the residue content is related to fresh weight. Based on all available data and information and considering several uncertainties, the RMS decided to use the worst case value of all submitted studies being 91.88% as correction factor in the risk assessment.

Decline of residues on cereal seeds on the soil surface

The RMS reanalysed the data set from the confirmatory data using the KinGUI v.2 model in order to check the DT_{50} values and noted that in 3 out of 6 trials the fit to single first order decline was borderline or bad.

The applicant provided two additional new studies and additionally two documents (Szegedi, 2017a and Szegedi 2017b) re-calculating the DT_{50} values based on all the available data, excluding values with bad fit. The applicant summarized all values as there was no statistically significant difference between the degradation in winter or spring cereal seeds ($p = 0.63$). The resulting DT_{50} values are listed in Table 9.2-6.

The trials were conducted in UK (England, Scotland), Spain, Germany, Netherlands, Northern France and Poland with one Plot at each testing site. Field preparations, pre-sowing activities and the sowing were carried out according to GAP. The treated seed was applied to the soil surface using commercial drilling machinery and immediately after application specimen of seeds were collected and again 1, 3, 7, 14 and 21 days after application. The RMS considers the methods and the study designs comparable and the geographical distribution of the trials sufficient to cover the EU.

Table 9.2-6: Dissipation half live of triticonazole on cereal seeds exposed onto the soil surface

BASF DocID [1)]	Season	Trial	Country	Kinetic model	DT_{50} [days]
2006/1015760	Spring	BA/1	UK	SFO	9.7 [2)]
		BA/2	UK	SFO	10.6
		BA/3	UK	SFO	4.2
2007/1016397	Spring	07/S/13	Spain	SFO	6.0
		07/S/14	Spain	SFO	7.8 [2)]
		07/S/15	Spain	SFO	7.9 [2)]
2017/1000581	Spring	L160002	Germany	SFO	7.2
		L160003	Netherlands	SFO	2.1
		L160004	Germany	SFO	4.0
2017/1000582	Autumn/Winter	L160005	Germany	SFO	6.1
		L160006	France (North)	SFO	7.9
		L160007	Germany	SFO	8.6
		L160008	Poland	SFO	6.4
		L160009	UK	SFO	3.5
Geometric mean (n, sample size)					**5.5 (11)**

[1]Field residue study
[2]Values excluded from the geometric mean calculation because of bad fit or borderline fit.

With this DT_{50} of 5.5 and an averaging time of 21 days an f_{twa} of 0.351 is derived. However, the averaging time of 21 days is under debate for seed treatments as the time from sowing to germination usually is shorter, for cereals 10 to 14 days can be assumed. Therefore the refined f_{twa} by using a worst case averaging time of 10 days is 0.568 and with an averaging time of 14 days it is 0.470.

Table 9.2-7: Refined long-term risk assessment for granivorous birds eating cereals seeds*

Generic focal species	Growth stage (BBCH)	FIR/bw	NAR	Correction factor	ftwa	DDD_{LT}	NOAEL [mg ai/kg bw]	TER_{LT}
Small granivorous bird	BBCH 00/ spring and autmn	0.3	50	0.92	0.568	7.84	19.5	**2.49**
					0.470	6.486		**3.01**
					0.351	4.84		**4.03**

NAR = Nominal loading/application rate of active substance in mg/kg seed.
*The averaging time of 21 days is under debate for seed treatments as the time from sowing to germination usually is shorter, for cereals 10 to 14 days can be assumed. To enable expert discussion, the risk assessment is presented with using the f_{twa} based on DT_{50} of 5.5 days and a worst case germination time of 10 days, with a more realistic value of 14 days and with 21 days as used for spray applications.

Focal species

The study by Moosmayer (2008a) indicates Skylark, Yellowhammer and Chaffinch as focal species from literature. The list of focal species can be extended considering the results of a DEFRA study from 2009

[4](PS2328). In this study birds occurring in newly-drilled arable crop fields (spring and winter barley, winter wheat) were observed. In this study the species were ranked in order of abundance and prevalence combined.

Based on all information, the relevant focal species are concluded to be Skylark (*Alauda arvensis*), Yellowhammer (*Emberiza citrinella*), Chaffinch (*Frignilla coelebs*), Woodpigeon (*Columba palumbus*), Rook (*Corvus frugilegus*)/Carrion Crow (*Corvus corone*) and Pheasant (*Phasanius colchicus*). During the EU peer-review of the Annex I approval, the house sparrow was agreed as a relevant focal species. Nevertheless, it is considered to be covered by the Chaffinch, which was also identified as a focal species. The FIR/bw of both species is comparable (0.33 for the house sparrow and 0.32 for the chaffinch). However, the linnet as a smaller bird was also observed in these studies.

The applicant provided following argumentation to justify that the linnet should not be considered as relevant focal species (highlighted in *italic*):

However, in the preliminary risk assessment, the RMS questioned the relevance of the linnet as focal species. Based on the following aspects, the applicant does not consider the linnet a relevant focal species: although in both studies linnets were observed on freshly drilled cereals fields, their mean frequency of occurrence was much lower compared to skylark, yellowhammer and chaffinch. In the study by Moosmayer (2008a) the FO_{scan} of the linnet was only 2.3% and the dominance value only 0.8%. As stated in Appendix M of EFSA/2009/1438, those species with a frequency of occurrence >20% might be considered as focal species, especially if they have high dominance. Skylark, yellowhammer and chaffinch had respective mean FO_{scan} values of 43.6%, 42.5% and 19.7%, while the dominance values were 88.1%, 82.1% and 88.5%. In the DEFRA study (2009) skylark, yellowhammer and chaffinch were the most important small granivorous species as well and linnets were of much less importance. Furthermore, it is known that linnets feed on a wide variety of weed seeds (e.g Eber 1956; Newton, 1967; Clarke et al., 2003; Holland et al., 2006), while the relatively larger cereal seeds are a typical diet of chaffinch (e.g Eber 1956; Newton, 1967; Clarke et al., 2003; Holland et al., 2006). These differences for different seed types between species can be explained by differences in the size and shape of their bills and subsequent handling of food items, with linnet having relatively shorter and broader bills than chaffinch relative to their body sizes (Newton, 1967, Table 11), facilitating handling of weed seeds over cereal seeds.

Comment RMS:	The applicant argues that linnets are not relevant because their FO values are low. However, the literature cited by the applicant indicates that linnets, together with greenfinch and goldfinch were most closely associated with farmland. (Newton, 1976). Furthermore they are known to build flocks with high number of individuals on the field, especially in October (Eber, 1956). According to Newton (1979), linnets also frequently pick up fallen seeds from the ground and they are considered to be mediate in bill-size and in the size of seeds they prefer. According to Barfknecht (2006a) the linnet with 0.139 individuals/ha was ranked fourth regarding abundance even before the yellowhammer with 0.013 individuals/ha in freshly winter cereal fields using transect count. With scan sampling it was the most abundant with 0.360 individuals/ha. The applicant argues that linnets only feed on weed seeds much smaller than cereal seeds. However, in

[4] Research Project Final Report PS2328, Objective 3: Prevalence and abundance of birds in newly-drilled arable crops

	the study from Schleswig-Holstein by Eber (1956), which the applicant refers to, it is stated, that cereal grain was the most frequent food item in April and in autumn. Additionally in the study by Newton (1979) it is reported that seeds in weight from 0.05 mg to 50 mg were eaten. This size range would also include several seeds of cereal crops. The study by Clarke *et al.* (2003) was based on raptor pellet analyses and states that cereal grain was predominant with yellowhammer remains, but because of its vulnerability to early digestion cereal grain could be more important to other species than those data show. Comment Co-RMS: The UK considers that it is unlikely that linnet will seek out and consume treated cereals, and therefore this species should not be selected as a focal species. It would be highly appreciated to discuss the relevance of linnets as a focal species for cereal fields during peer review or in an expert meeting to derive a final and general accepted decision.

The FIR/bw values for the focal bird species were calculated according to EFSA/2009/1438 and are summarized in Table 9.2-8.

Table 9.2-8: Calculation of FIR/bw values for focal granivorous bird species in cereals

Focal species	Skylark	Yellow-hammer	Chaffinch	Wood-pigeon	Rook	Carrion Crow	Pheasant	Linnet
Body weight [g][1]	37.2	26.5	20.9	490	418	570	953	15.3
Energy content of cereal seeds [kJ/ g dry wt]	18.4	18.4	18.4	18.4	18.4	18.4	18.4	18.4
% H2O	14.7	14.7	14.7	14.7	14.7	14.7	14.7	14.7
Energy content of cereal seeds [kJ/g wet wt]	15.7	15.7	15.7	15.7	15.7	15.7	15.7	15.7
Assimilation efficiency [%]	0.80	0.80	0.80	0.76	0.80	0.80	0.65	0.80
Energy content of cereal seeds [kJ/g wet wt] corrected for ass. Eff.	12.56	12.56	12.56	11.93	12.56	12.56	10.21	12.56
DEE [kJ]	124.08	98.65	84.03	435.25	636.67	785.18	679.22	68.05
Fresh weight of food required [g]	9.88	7.85	6.69	36.48	50.69	62.51	66.52	5.42
FIR/b.w.	0.266	0.296	0.320	0.074	0.121	0.110	0.070	0.354

[1]The applicant provided body weights according to Dunning (2008). The RMS compared the values with those stated in the Bird Bible (1998 Update CONTRACT PN0919 MILESTONE REPORT Birds and farming: information for risk assessment J.M. Buxton, D.R. Crocker & J. A. Pascual
In case the two values diverged, the worst case value was used.

Table 9.2-9: Higher tier long-term risk assessment for granivorous focal species in cereals*

Focal species	Growth stage (BBCH)	FIR/bw	NAR	Correction factor	ftwa	DDD_{LT}	NOAEL [mg ai/kg bw]	TER_{LT}
Skylark	BBCH 00/ spring and autumn	0.266	50	0.92	0.568	6.95	19.5	**2.81**
					0.470	5.75		**3.39**
					0.351	4.29		**4.55**
Yellowhammer		0.296			0.568	7.73		**2.52**
					0.470	6.40		**3.05**
					0.351	4.78		**4.08**
Chaffinch		0.320			0.568	8.36		**2.33**
					0.470	6.92		**2.82**
					0.351	5.17		**3.77**
Woodpigeon		0.074			0.568	1.93		10.1
					0.470	1.60		12.2
					0.351	1.19		16.4
Rook		0.121			0.568	3.16		6.17
					0.470	2.62		7.44
					0.351	1.95		10.0
Carrion Crow		0.110			0.568	2.87		6.80
					0.470	2.38		8.19
					0.351	1.78		11.0
Pheasant		0.070			0.568	1.83		10.7
					0.470	1.51		12.9
					0.351	1.13		17.3
Linnet		0.354			0.568	9.25		**2.11**
					0.470	7.65		**2.55**
					0.351	5.72		**3.41**

NAR = Nominal loading/application rate of active substance in mg/kg seed.
*The averaging time of 21 days is under debate for seed treatments as the time from sowing to germination usually is shorter, for cereals 10 to 14 days can be assumed. To enable expert discussion, the risk assessment is presented with using the f_{twa} based on DT_{50} of 5.5 days and a worst case germination time of 10 days, with a more realistic value of 14 days and with 21 days as used for spray applications.

PT-refinement

The RMS considers the PT values for spring sown cereals and for autumn sown cereals separately. For three of the seven identified focal species, skylark, chaffinch and yellowhammer, refined PT values are available. For Skylarks in spring sown cereals data from three studies are available (Moosmayer, 2008a, Sadowski *et al.*, 2014a and Erni *et al*., 2017a). All three studies are combined to derive a PT and the data is shown in Table 9.2-10.

For Yellowhammer and Chaffinch in spring sown cereals data from one study is available (Sadowski et al., 2014a). The PT for Yellowhammer in spring sown cereals is 0.2.

For Skylarks in autumn sown cereals data from two studies are available (Barfknecht 2006a and Dittrich & Benito 2017a). Both studies are combined to derive a PT and the data is shown in Table 9.2-11. For Chaffinch and Yellowhammer in autumn sown cereals data of one study is available (Barfknecht 2006a). For PT calculation the consumer only approach is used.

All studies available were conducted in Germany indicating that the estimated PT values are applicable for the

central zone. Please note that the conditions in the northern and southern zone may be different and the refined PT may be of limited relevance for those zones.

Table 9.2-10: PT data for the skylark in freshly drilled spring cereal fields (combined data from Moosmayer, 2008a BASF DocID 2008/1097311, Sadowski *et al*., 2014a BASF DocID 2014/1263159 and Erni *et al*., 2017a BASF DocID 2017/1121782)

BASF DocID	Individual bird no.	Tracking session	PT session (n=65)	PT individual bird (n=30)	PT individual – 'birds caught in/by target crop' (n=21)	PT relevant for 'consumer' approach (n=19)	Home range of individual bird [ha]
2008/1097311	1	1	0.0	0.0	-- [1)]	--	9.2
2008/1097311	1	2	0.0				
2008/1097311	2	1	0.0	0.0	-- [1)]	--	5.9
2008/1097311	2	2	0.0				
2008/1097311	4	1	0.0	0.0	-- [1)]	--	28.3
2008/1097311	6	1	0.0	0.0	-- [1)]	--	17.9
2008/1097311	7	1	0.0	0.0	-- [1)]	--	5.8
2008/1097311	8	1	0.086	0.211	0.211	0.211	28.4
2008/1097311	8	2	0.336				
2008/1097311	9	1	0.0	0.0	-- [1)]	--	6.7
2008/1097311	9	2	0.0				
2008/1097311	10	1	0.0	0.0	-- [1)]	--	4.7
2008/1097311	10	2	0.0				
2008/1097311	11	1	0.0	0.306	0.306	0.306	5.1
2008/1097311	11	2	0.611				
2008/1097311	12	1	0.283	0.283	0.283	0.283	10.6
2008/1097311	13	1	0.052	0.036	0.036	0.036	5.3
2008/1097311	13	2	0.020				
2014/1263159	43	1	0.0	0.0	0.0 [2)]	-	8.61
2014/1263159	44	1	0.65	0.65	0.65	0.65	10.48
2014/1263159	61	1	0.46	0.46	0.46	0.46	7.07
2014/1263159	62	1	0.41	0.43	0.43	0.43	6.84
2014/1263159	62	2	0.45				

2014/1263159	63	1	0.26	0.26	0.26	0.26	8.55
2014/1263159	64	1	0.30	0.30	0.30	0.30	4.33
2014/1263159	65	1	0.83	0.89	0.89	0.89	5.35
2014/1263159	65	2	0.95				
2014/1263159	66	1	0.73	0.73	0.73	0.73	2.28
2014/1263159	67	1	0.92	0.83	0.83	0.83	37.64
2014/1263159	67	2	0.74				
2014/1263159	68	1	0.59	0.59	0.59	0.59	3.15
2014/1263159	70	1	0.47	0.47	0.47	0.47	18.84
2017/1121782	3	1	0.0	0.0	0.0 [3)]	-	5.7
2017/1121782	3	2	0.0				
2017/1121782	3	3	0.0				
2017/1121782	8	1	0.975	0.747	0.747	0.747	8.8
2017/1121782	8	2	0.943				
2017/1121782	8	3	0.967				
2017/1121782	8	4	0.959				
2017/1121782	8	5	0.937				
2017/1121782	8	6	0.261				
2017/1121782	8	7	0.186				
2017/1121782	10	1	0.696	0.500	0.500	0.500	27.5
2017/1121782	10	2	0.585				
2017/1121782	10	3	0.363				
2017/1121782	10	4	0.299				
2017/1121782	10	5	0.558				
2017/1121782	11	1	0.0	0.021	0.021	0.021	10.1
2017/1121782	11	2	0.095				
2017/1121782	11	3	0.013				
2017/1121782	11	4	0.0				
2017/1121782	11	5	0.0				
2017/1121782	12	1	0.0	0.0	-- [4)]	--	2.0
2017/1121782	13	1	0.049	0.021	0.021	0.021	10.9

2017/1121782	13	2	0.014				
2017/1121782	13	3	0.0				
2017/1121782	13	4	0.041				
2017/1121782	13	5	0.0				
2017/1121782	14	1	0.0	0.0	-- [5)]	--	1.0
2017/1121782	15	1	0.237	0.419	0.419	0.419	23.3
2017/1121782	15	2	0.448				
2017/1121782	15	3	0.755				
2017/1121782	15	4	0.345				
2017/1121782	15	5	0.449				
2017/1121782	15	6	0.276				
				PT 'all birds'	**PT 'birds caught in/by target crop'**	**PT 'consumer' birds**	
N (sample size)				**30**	**21**	**19**	
Arithmetic mean PT				**0.27**	**0.39**	**0.43**	
90th percentile PT				**0.73**	**0.75**	**0.83**	

[1]The PT value from all birds with PT=0 were excluded from the data set used to derive the PT for the 'birds caught in/by target crop' because this study (Moosmayer 2008a) was not clearly targeted on newly-sown cereal fields (the target crop) and the location of capture was not closely associated to the target crop

[2]The PT value from this bird was included in the data set used to derive the PT for the 'birds caught in/by target crop' because this study focused on the target crop and this individual was captured within 65 meters of the nearest newly-drilled field and therefore well within the foraging distance taking account its home range of 8.6 ha.

[3]The PT value from this bird was included in the data set used to derive the PT for the 'birds caught in/by target crop' because in this study focused on the target crop and this individual was captured inside a field of the target crop.

[4]The PT value from this bird was excluded from the data set used to derive the PT for the 'birds caught in/by target crop' because this individual was captured rather far (c. 335 m) from the nearest newly-sown cereal field and due to the relatively small size of its territory (2.0 ha), it is unlikely that newly-drilled cereal fields were within its normal foraging area.

[5]The PT value from this bird was excluded from the data set used to derive the PT for the 'birds caught in/by target crop' because this individual was captured rather far (c. 338 m) from the nearest newly-sown cereal field and due to the relatively small size of its territory (1.0 ha), it is unlikely that newly-drilled cereal fields were within its normal foraging area.

Table 9.2-11: PT data for the skylark in freshly drilled winter cereal fields and its home range size [(combined data from Barfknecht (2006a, BASF DocID 2006/1047473) and Dittrich and Benito (2017a, BASF DocID 2016/1234467)]

BASF DocID	Individual bird no.	Tracking session	PT session (n=52)	PT individual bird (n=29)	PT individual – 'birds caught in/by target crop' (n=29)	PT relevant for 'consumer' approach (n=16)	Home range of individual bird [ha]
2006/1047473	2	1	0.0	0.0	0.0 [1)]	--	32.00

2006/1047473	2	2	0.0				
2006/1047473	4	1	0.0	0.0	0.0 [1)]	--	16.25
2006/1047473	5	1	0.79	0.39	0.39	0.39	201.00
2006/1047473	5	2	0.0				
2006/1047473	7	1	0.0	0.0	0.0 [1)]	--	15.00
2006/1047473	8	1	0.0	0.0	0.0 [1)]	--	5.75
2006/1047473	9	1	0.0	0.0	0.0 [1)]	--	7.19
2006/1047473	9	2	0.0				
2006/1047473	11	1	0.08	0.08	0.08	0.08	10.13
2006/1047473	13	1	1.0	1.0	1.0	1.0	182.50
2016/1234467	A2	S	0.23	0.54	0.54	0.54	32.46
2016/1234467	A2	R1	0.69				
2016/1234467	A2	R2	0.74				
2016/1234467	A2	R3	0.45				
2016/1234467	A2	R4	0.57				
2016/1234467	A3	S	0.0	0.0	0.0 [2)]	--	31.93
2016/1234467	A4	S	0.0	0.0	0.0 [2)]	--	0.83
2016/1234467	A5	S	0.0	0.0	0.0 [2)]	--	30.54
2016/1234467	A7	S	0.44	0.44	0.44	0.44	8.09
2016/1234467	A8	S	0.66	0.66	0.66	0.66	26.27
2016/1234467	A9	S	0.03	0.03	0.03	0.03	71.03
2016/1234467	A10	S	0.21	0.21	0.21	0.21	104.23
2016/1234467	A12	S	0.0	0.0	0.0 [2)]	--	1.79
2016/1234467	A13	S	0.0	0.0	0.0 [2)]	--	4.48
2016/1234467	A13	R1	0.0				
2016/1234467	B1	S	0.0	0.18	0.18	0.18	29.21
2016/1234467	B1	R1	0.0				
2016/1234467	B1	R2	0.32				
2016/1234467	B6	S	0.0	0.0	0.0 [2)]	--	3.32
2016/1234467	B7	S	0.16	0.16	0.16	0.16	37.33
2016/1234467	C1	S	0.0	0.26	0.26	0.26	49.43

2016/1234467	C1	R1	0.23				
2016/1234467	C1	R2	0.26				
2016/1234467	C1	R3	0.59				
2016/1234467	C1	R4	0.22				
2016/1234467	C3	S	0.0	0.0	0.0 [2)]	--	54.62
2016/1234467	C4	S	0.0	0.03	0.03	0.03	4.14
2016/1234467	C4	R1	0.05				
2016/1234467	C5	S	0.26	0.26	0.26	0.26	2.70
2016/1234467	D1	S	0.0	0.14	0.14	0.14	13.45
2016/1234467	D1	R1	0.18				
2016/1234467	D1	R2	0.20				
2016/1234467	D1	R3	0.30				
2016/1234467	D1	R4	0.0				
2016/1234467	D3	S	0.03	0.01	0.01	0.01	1.86
2016/1234467	D3	R1	0.0				
2016/1234467	D3	R2	0.0				
2016/1234467	E2	S	0.13	0.24	0.24	0.24	36.87
2016/1234467	E2	R1	0.32				
2016/1234467	E2	R2	0.28				
2016/1234467	E4	S	0.0	0.0	0.0 [2)]	--	3.71
				PT 'all birds'	**PT 'birds caught in/by target crop'**	**PT 'consumer' birds**	
N (sample size)				**29**	**29**	**16**	
Arithmetic mean PT				**0.16**	**0.16**	**0.28**	
90th percentile PT				**0.54**	**0.54**	**0.76**	

[1]The PT value from this bird was included in the data set used to derive the PT for the 'birds caught in/by target crop' because this study focused on the target crop and this individual was captured within 10 meters of the nearest newly-drilled field and therefore well within the foraging distance taking account its home range.

[2]The PT value from this bird was included in the data set used to derive the PT for the 'birds caught in/by target crop' because in this study focused on the target crop and this individual was captured inside a field of the target crop.

Table 9.2-12: Higher tier long-term risk assessment for granivorous focal species in spring cereals including PT refinement*

Focal species	Growth stage (BBCH)	FIR/bw	NAR	Correction factor	PT	ftwa	DDD_{LT}	NOAEL [mg ai/kg bw]	TER_{LT}
Skylark	BBCH 00/ spring and autumn	0.266	50	0.92	0.83	0.568	5.769	19.5	**3.4**
						0.470	4.773		**4.1**
						0.351	3.822		5.1
Yellowhammer		0.296			0.20	0.568	1.547		12.6
						0.470	1.280		15.2
						0.351	0.956		20.4
Chaffinch		0.320			0.63	0.568	5.267		**3.7**
						0.470	4.359		**4.5**
						0.351	3.255		5.9
Linnet		0.354			1	0.568	9.250		**2.11**
						0.470	7.653		**2.55**
						0.351	5.716		**3.41**

NAR = Nominal loading/application rate of active substance in mg/kg seed.
*The averaging time of 21 days is under debate for seed treatments as the time from sowing to germination usually is shorter, for cereals 10 to 14 days can be assumed. To enable expert discussion, the risk assessment is presented with using the f_{twa} based on DT_{50} of 5.5 days and a worst case germination time of 10 days, with a more realistic value of 14 days and with 21 days as used for spray applications.

Table 9.2-13: Higher tier long-term risk assessment for granivorous focal species in winter cereals with PT refinement*

Focal species	Growth stage (BBCH)	FIR/bw	NAR	Correction factor	PT	ftwa	DDD_{LT}	NOAEL [mg ai/kg bw]	TER_{LT}
Skylark	BBCH 00/ spring and autumn	0.266	50	0.92	0.76	0.568	5.282	19.5	**3.7**
						0.470	4.371		**4.5**
						0.351	3.264		6.0
Yellowhammer		0.296			0.35	0.568	2.707		7.2
						0.470	2.240		8.7
						0.351	1.673		11.7
Chaffinch		0.320			0.06	0.568	0.502		38.8
						0.470	0.415		47
						0.351	0.310		62.9
Linnet		0.354			1	0.568	9.25		**2.11**
						0.470	7.65		**2.55**
						0.351	5.72		**3.41**

NAR = Nominal loading/application rate of active substance in mg/kg seed.
*The averaging time of 21 days is under debate for seed treatments as the time from sowing to germination usually is shorter, for cereals 10 to 14 days can be assumed. To enable expert discussion, the risk assessment is presented with using the f_{twa} based on DT_{50} of 5.5 days and a worst case germination time of 10 days, with a more realistic value of 14 days and with 21 days as used for spray applications.

Further refinement options and supportive information

To further support the risk assessment for birds in freshly drilled cereals fields, the applicant summarized information which was not used in the current quantitative risk assessment but is provided as qualitative additional information below (*in italic*).

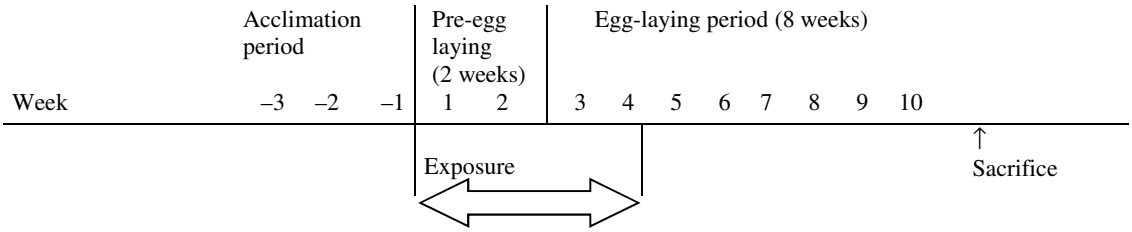
Reproductive toxicity endpoint

*The chronic toxicity endpoints being used for deriving a combined NOAEL (*Table 9.1-1: Toxicity of triticonazole to birds*Table 9.1-1) relevant for the initial (Tier 1) risk assessment are derived from avian reproduction tests conducted according to OECD guideline 206 "Avian Reproduction Test". During such standard tests, birds are exposed to the test substance for a period of not less than 20 weeks. The resulting toxicity endpoint (NOEC) is thus derived from long-term exposure. As exposure through treated spring-sown cereal seeds would only last a few weeks, such an endpoint seems less appropriate for use in a higher tier risk assessment.*

Therefore, based on OECD guideline 206, a modified higher tier avian reproduction test was performed (BASF DocID 2008/1023059, evaluated by RMS in the Confirmatory Data Addendum, July 2009, p. 15). The study was designed to determine the effect of triticonazole offered via food on the reproduction of the bobwhite quail (Colinus virginianus) following an exposure scheme reflecting more closely the realistic exposure pattern of treated cereals seeds sown in spring (Figure 9.2-1).

The test design comprised an acclimation period of 3 weeks, followed by a pre-egg laying period of 2 weeks, and an egg-laying period of 8 weeks (test layout in diagram below). During the pre-egg laying period and the first 2 weeks of the egg-laying period, i.e. for 4 subsequent weeks, the birds were offered diet with the test substance ad libitum at dose levels of 0 (control), 300 and 500 mg ai/kg diet.

Figure 9.2-1: Exposure scheme reflecting more closely the realistic exposure pattern of treated cereals seeds sown in spring



Laid eggs were collected, incubated and hatched. The offspring (F1-generation) were raised for 2 weeks during all 8 weeks of the egg-laying period.

As a result, in the parent generation, no test substance-related effects on mortality and birds' health could be detected. The food consumption of the 500 mg ai/kg group was slightly reduced during the exposure period (-11%). However, this did not result in a marked effect on the body weight development.

The findings for effects on reproduction were the following:
In the 300 mg ai/kg diet group, no biologically relevant test substance-related effects were observed.
In the 500 mg ai/kg diet group, the number of the 14-day surviving chicks hatched was statistically significantly reduced during the egg-laying weeks of the exposure period. The number of 14-day surviving chicks per hen was

6% lower than in the control group but was not statistically significant. No treatment-related effects on the number of eggs per female or on the fertility rate were observed in any of the treatment groups.

Thus, in the modified avian reproduction test with bobwhite quails, the NOEC / NOEL and LOEC / LOEL for triticonazole were determined at 300 mg ai/kg diet (24.7 mg ai/kg b.w./day) and 500 mg ai/kg diet (38.0 mg ai/kg b.w./day), respectively. The NOEL of 24.7 mg ai/kg b.w./day is assumed more realistic for exposure to cereal seeds treatments.
The refined NOEL was accepted by the RMS Austria commenting in the Confirmatory Data Addendum (July 2009, p. 15): "Hence the refined NOEL of 24.7 mg/kg bw, reflecting a more appropriate exposure scenario with regard to seed treatment uses, is used in the refined risk assessment."

However, in the current EU review process RMS Austria questioned the validity of this study due to the lower number of dose levels tested (2) compared to the recommended number (3) according to the respective guidelines (OECD 206 and EPA OPPTS 850-2300). Despite this deviation, the applicant considers the study valid due to the following reasons. The study is not meant to be a standard study. It was rather a modified study using an adapted protocol that was based on the aforementioned guidelines. The main purpose was to reflect a more realistic exposure scenario via treated seeds (as explained above). However, as in standard studies a solid NOEC/NOEL should be derived. Statistically, two dose levels are sufficient to determine a NOEC/NOEL. Following OECD 206 and OPPTS 850.2300 a pairwise comparison of the treatment groups to the control group is recommended. Thus, three treatment levels are not necessary to statistically derive a solid endpoint. Considering the purpose of the study, providing additional information to the standard studies and for animal welfare reasons, two dose levels were considered sufficient to run this study.

However, despite the position of the applicant that the study is valid and that the NOAEL of 24.7 mg/kg bw/d is a realistic estimate and suitable endpoint for a risk assessment for seed treatments, particularly for short exposure periods (21 days standard or even shorter of 10 days), the value was not included quantitatively in the refined risk assessment, but as supportive information only.

Comment RMS:	As already mentioned before, the RMS would highly appreciate a general discussion and decision about the usability of studies with modified exposure. For a detailed evaluation of this study please refer to Volume 3, B9-CA (B.9.1.1.3 [redacted] 2008).

PD data for the skylark in freshly drilled spring and winter cereals

Considering the fact that skylark was the bird species with the lowest TER_{LT} values in the current risk assessment, a further potential refinement is introduced here. For the skylark, PD data in freshly-drilled spring and winter cereals are available. The data presented in the table below are derived from two industry field studies (Sadowski et al., 2014a, BASF DocID 2014/1263159 and Moosmayer, 2008a, BASF DocID 2008/1097311) for spring cereals and one industry study (Barfknecht, 2006a, BASF DocID 2006/1047473) for winter cereals.

In addition, PD data from Green (1978) cited in the Nordic zone document on higher tier "Pesticide risk assessment for birds and mammals" (Northern Zone, 2017, p. 36, Tab. 5.19) are presented. Please note, the data presented by the Northern Zone (2017) are specifically compiled for the use in long-term risk assessments for seed treatments.

The skylark is an omnivorous bird (e.g. Bauer et al. (eds.), 2005), i.e. its diet is a mix of e.g. plant remains, animal remains and seeds. The PD values for the food item 'cereal seeds' in the diet of the skylark as presented in Table 9.2-14 *are below 1 and therefore show that a PD of 1, as used in the higher tier TER calculations for the skylark in freshly drilled spring and winter cereals (*Table 9.2-7*and* Table 9.2-9*, respectively), is overly conservative.*

Table 9.2-14: ***PD data for the food item cereal seeds as consumed by skylarks in freshly-drilled spring and winter cereal fields***

Study	***PD value***
Spring cereals	
Sadowski et al. (2014a)	*0.58*
Moosmayer (2008a)	*0.27*
Northern Zone (2017)	*0.46*
Winter cereals	
Barfknecht (2006a)	*0.98*
Northern Zone (2017)	*0.74*

To summarize, PD data for skylarks are not included in the current higher tier risk assessment quantitatively, but confirm the conservativeness of the calculations and the low risk to birds from BAS 595 01 F used as cereal seed treatment at the proposed label rate.

Comment RMS:	The provided data is considered acceptable as supportive information.

De-husking behaviour

As a further line of evidence and supportive information highlighting the conservatism of the quantitative risk assessment presented above, information about potential de-husking behaviour of birds is discussed in the following section.

The foraging technique of 'de-husking' enables small granivorous bird species of the seed-eating families Fringilidae (finches), Emberizidae (buntings) and Passeridae (sparrows) to remove the husk of seeds prior to ingestion. Consequently, as residues of seed treatment products are largely bound to the seed husk, these bird species can substantially reduce their exposure by means of 'de-husking'.

The specialisation on seeds as feed results in functional and anatomic adaptations in seed-eating birds. One of them is the structure of the bill, which allows the bird to crack open the husk of the seeds they feed on. The elements of cracking the husk and de-husking itself are characteristic elements of the foraging behaviour of

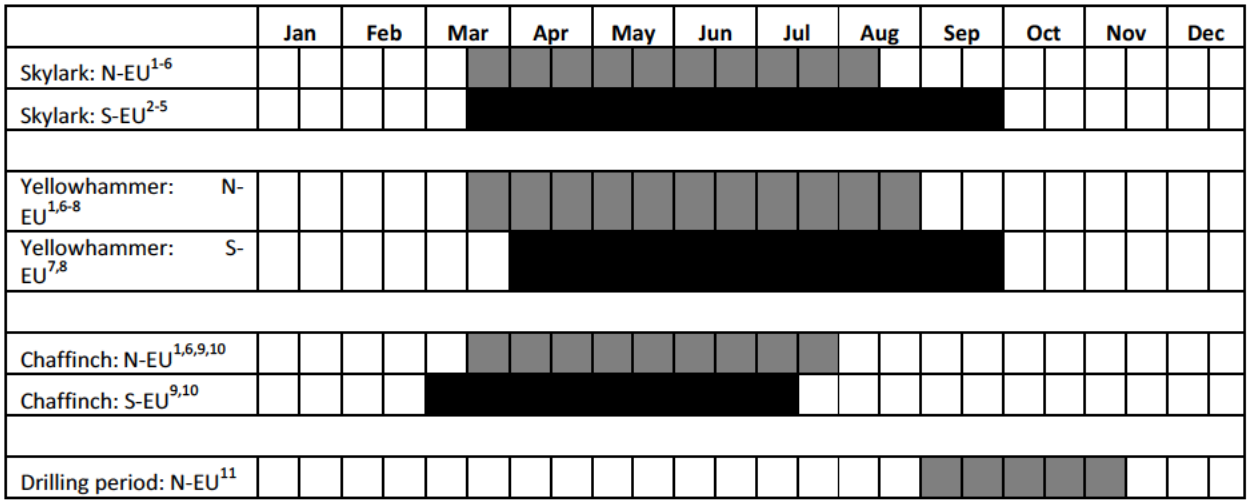
finches, sparrows and buntings. This is confirmed by observations in the study of Prosser (2001). One major aim of the field study conducted by Prosser (2001) was to quantify de-husking in seed-eating birds. Prosser found out that chaffinchs de-husked 90% of the wheat seeds and 48% of the barley seeds, clearly indicating that the chaffinch de-husks the bulk of cereal seeds it feeds on. In general, the very exact exposure reduction via de-husking is hard to quantify. According to the work by Edwards et al. (1998) the exposure reduction by de-husking could be as high as 85%. However, in the trials by Edwards et al. the seeds were de-husked manually, hence the results may not reflect completely the situation in the field.

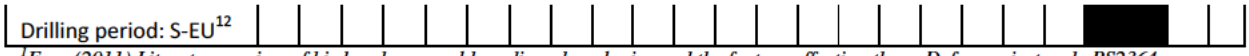
The TER_{LT} calculations for the chaffinch and the yellowhammer as presented above are therefore conservative given that these birds would possibly de-husk as routine behaviour, a large amount of the seeds prior to feeding and would therefore further reduce the exposure to the active substances.

Comment RMS:	It is acknowledged that de-husking is likely to affect the exposure of some bird species. However, as the applicant mentions as well, the extent of exposure reduction is not known and the information may be used as qualitative support for some species like the chaffinch.

Relevance of exposure outside breeding season (winter use)

This section provides a weight-of-evidence justification supporting that the reproductive risks to birds from the proposed seed treatment use of triticonazole in autumn is negligible. The three bird focal species of primary interest (skylark, yellowhammer and chaffinch) do not breed during autumn/winter, and spring breeding periods for these species do not overlap with the autumn drilling period, either in terms of late breeding in spring coinciding with early autumn drilling or early spring breeding coinciding with late autumn drilling, as illustrated in the Gant diagram below. Although the breeding periods and drilling periods do not overlap, it is noted that in some instances, there is little interval between them as presented in the Gant diagram. It should be borne in mind when interpreting these data that breeding activity will not be uniform during the breeding period, with the majority of birds breeding earlier in the season, with some achieving multiple broods. Therefore, fewer birds will be breeding at the end of the breeding period indicated in the Gant diagram.





[1]*Fera (2011) Literature review of bird and mammal breeding phenologies and the factors affecting them. Defra project code PS2364*
[2]*EC (2007) Management plan for skylark (Alauda arvensis) 2007-2009. Directive 79/409/EEC on the conservation of wild birds. ec.europa.eu/environment/nature/conservation/wildbirds/hunting/docs/skylark.pdf*
[3]*EU Wildlife and Sustainable Farming project (2009) Skylark, Alauda arvensis factsheet. http://ec.europa.eu/environment/nature/natura2000/management/docs/Alauda%20arvensis%20factsheet%20-%20SWIFI.pdf*
[4]*MNHN (2012) http://www.uipp.org/content/download/316/2054/version/6/file/CAO_Final_mai2013.pdf*
[5]*Donald P.F (2004) The Skylark. T&AD Poyser, London. e-PDF ISBN 978-1-4081-3334-7*
[6]*Košice (2010) Focal bird species for refined exposure assessment in accordance with the Guidance document (EFSA) under Directive 91/414/EEC. National Reference Laboratory for Pesticides UVLF.*
[7]*BTO bird facts: yellowhammer. https://app.bto.org/birdfacts/results/bob18570.htm*
[8]*BirdLife International (2016) Emberiza citrinella. The IUCN Red List of Threatened Species 2016: e.T22720878A89289181. http://dx.doi.org/10.2305/IUCN.UK.2016-3.RLTS.T22720878A89289181.en*
[9]*BTO bird facts: chaffinch. https://blx1.bto.org/birdfacts/results/bob16360.htm*
[10]*BirdLife International (2017) Species factsheet: Fringilla coelebs. Downloaded from http://datazone.birdlife.org/species/factsheet/common-chaffinch-fringilla-coelebs on 24/07/2017.*
[11]*Drilling dates based on FOCUS$_{gw}$ (FOCUS (2000) FOCUS groundwater scenarios in the EU review of active substances. Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000 rev.2, 202pp) and FOCUS$_{sw}$ (FOCUS (2001) Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev2) model inputs. The earliest drilling date corresponds to the FOCUS$_{sw}$ D4 scenario in Scandinavia. The latest drilling date corresponds to the FOCUS$_{sw}$ R1 scenario in Germany.*
[12]*Drilling dates based on FOCUS$_{gw}$ and FOCUS$_{sw}$ model inputs. The earliest drilling dates corresponds to the FOCUS$_{sw}$ D6 and R4 scenarios in Greece and Southern France, respectively. The latest drilling date corresponds to the FOCUS$_{gw}$ Piacenza scenario in Italy.*

*In addition to the breeding periods of critical focal bird species not overlapping with drilling periods, negligible exposure of breeding birds in the following spring is also predicted. According to available field studies undertaken in six Member States across N- and S-EU, the DT$_{50}$ for residues on treated seeds is 5.5 (*see also section 9.2.1, Decline of residues on cereal seeds on the soil surface*). Furthermore, residues in subsequent germinated seedlings will also be very low, with maximum residues resulting from seeds containing 50 mg ai/kg being maximum just 0.37 mg ai/kg 7-14 days after emergence, BBCH 11-13 (*see also section 9.2.2, Triticonazole residues in cereal shoots emerging from treated seeds*). Therefore, the exposure of breeding birds in spring feeding on seeds or germinated seedlings planted in the previous autumn will be negligible, with the shortest interval between spring breeding starting and autumn drilling ending being 3.5 months (>100 days; see Gant diagram above).*

Birds breeding in spring are not expected to be impacted by delayed effects occurring following exposure to triticonazole in the previous autumn. Triticonazole residues are not expected to accumulate within birds, being rapidly excreted from the body according to the available mammalian studies on rats and goats (please refer to chapter MCA 5.1.1 and MCA 6.2.3); therefore, residues are not expected to be accumulated in autumn and later metabolised in spring or transferred to unlaid eggs.

Non-breeding adult birds potentially exposed to triticonazole in autumn are not expected to experience adverse effects that could impact their ability to overwinter and therefore breed successfully the following spring, with no biologically significant effects on body weight or food consumption observed in the available avian reproduction studies. No effects on pre-mating behaviour (pair formation, site selection, nest building i.e. those behaviours not covered by the avian reproductive toxicity study design) are expected following potential exposure of adult birds in autumn; according to Appendix J of EFSA (2009), this can be estimated using 1/10th LD$_{50}$, which would be >200 mg/kg bw for triticonazole, corresponding to a Tier 1 TER$_{repro}$ of 25.2.

No adverse effects with a suspected androgenic/anti-androgenic or estrogenic/anti-estrogenic mode of action have been observed in any of the chronic vertebrate toxicity studies (e.g. mammals or fish). Triticonazole has

been extensively studied for endocrine activity in ToxCast and in further publications (see Chapter MCA 5.8.3). No evidence for any estrogenicity/anti-estrogenicity was seen in none of the mechanistic studies. The data for androgenicity/anti-androgenicity were less clear and indicated in some studies, but not in others, in vitro properties of triticonazole to bind to the human and rat androgen receptor (see Chapter MCA 5.8.3). There was however no correlating adverse finding in the in vivo rat (e.g. 2-Generation toxicity study, chronic study) studies, dosed up to 5000 ppm. This gives some further confidence, that in vitro effects are not translated to the in vivo situation in rats. For the human situation, it was concluded that triticonazole does not fulfil the criteria for an endocrine disrupting compound (see Chapter MCA 5.8.3). For birds no specific data addressing endocrine activity are available. However, considering all the information given above, no delayed effects on reproductive output in birds breeding in spring are expected following potential exposure in autumn.

Additional evidence is available in the avian modified exposure reproductive toxicity study (BASF DocID 2008/1023059). Birds were exposed for 4 weeks instead of the usual c.22 weeks, with less effects resulting from this reduced exposure period. Given that residue decline will be rapid in the environment, even a 4-week continuous exposure duration represents a worst case. Therefore, effects resulting from even a short overlap of breeding with drilling would be negligible. Furthermore, the modified exposure study provided evidence that no delayed effects occurred after ceasing the exposure.

In summary, the reproductive risk to the focal bird species of interest from the proposed seed treatment application of triticonazole in autumn should be considered as acceptable and a quantitative risk assessment is not relevant because:
these species do not reproduce in the wild during autumn drilling
birds breeding in spring are not predicted to be exposed to significant triticonazole residues in their diet
birds breeding in spring are not predicted to experience delayed effects from autumn exposure

Comment RMS:	The information presented by the applicant appears to be plausible. However the cited references were not checked. The information may be used by member states as a weight of evidence in a case by case decision.

Drinking water risk assessment:

According to the EFSA Guidance Document on Birds and Mammals (2009) significant contamination of drinking water after the use of a pesticide as seed treatment seems very unlikely to be a critical route or to lead to TER values greater than direct dietary consumption. A drinking water risk assessment therefore is not considered necessary.

Secondary poisoning:

Substances with a high potential to bioaccumulate in the food chain could theoretically bear a risk of secondary poisoning for birds if feeding on contaminated prey like fish or earthworms. For organic chemicals, a log P_{OW} > 3 is used to trigger an in-depth evaluation of the potential for bioaccumulation.

The log P_{OW} value of the active substance triticonazole is 3.3 (*Chabassol* et *al*, 1991) and for the metabolite RPA

406203 it is 3.5 (*Cowlyn*, 2014e). Therefore a risk assessment for earthworm to earthworm-eating birds and from fish to fish-eating birds is required. For all other metabolites the log P_{ow} is < 3 (For details please also refer to B.9 - CA).

Food chain from earthworm to earthworm-eating birds

The risk to earthworm-eating birds from bioaccumulation of triticonazole is calculated with the following
The risk to earthworm-eating birds from bioaccumulation of triticonazole is calculated with the following equations in accordance with the EFSA Guidance (2009).
The risk of RPA 406203 can be considered low as the Z-isomer only is formed under irradiation. Therefore earthworms are not likely to be exposed to RPA 406203.

Calculation of the PEC_{worm} for earthworm-eating birds:

$BCF = (0.84 + 0.012 * K_{OW}) / (f_{OC} * K_{OC})$

$PEC_{worm} = PEC_{soil} * BCF$

Where:

PEC_{worm}	Predicted concentration in earthworms [mg/kg]
PEC_{soil}	Initial PEC_{soil} in soil [mg/kg soil dw]
BCF	Bioconcentration factor in earthworms
K_{OW}	Octanol/water partition coefficient
F_{OC}	Organic carbon content of soil, default = 0.02
K_{OC}	Organic carbon adsorption coefficient

The factor of 1.05 is used to convert the residues in worms to a daily dose based on a bird of 100 g eating 104.6 g worms per day, according to EFSA.
The risk assessment was performed for the single application of 12.5 kg ai/ha.

Table 9.2-15: Parameters and calculations for the assessment of the long-term risk to earthworm-eating birds

Parameter	Triticonazole/cereal seeds
$NOAEL_{long\text{-}term}$ [mg ai/kg bw/d]	19.5
K_{oc} (Organic carbon adsorption coefficient)	290*
K_{ow} (Octanol water partition coefficient)	1995
f_{oc} (Organic carbon content of soil)	default value: 0.02
$PEC_{soil\ 21d\ twa\ accu}$ [mg ai/kg]	0.1863
BCF_{worm}	4.27
PEC_{worm} [mg ai/kg]	0.796
Daily dose [mg ai/kg bw/d]	0.836
TER	23
Trigger	**5**

*As the adsorption is pH-dependent no geomean was calculated and the worst case K_{oc} was used.

The TER-value following use according to the GAP is above the trigger of 5 for long-term risk, indicating that the use of triticonazole poses a low risk to earthworm-eating birds.

Food chain from fish to fish-eating birds

The risk to fish-eating birds from bioaccumulation of triticonazole is calculated with the following equations in accordance with EFSA Guidance (2009):
No toxicological endpoint for RPA 406203 is available therefore as a worst case a 10-fold higher toxicity than the parent is assumed.
Calculation of the Daily Dietary Dose (DDD) for fish-eating birds:
$PEC_{fish} = PEC_{sw} * BCF$

Where:

PEC_{fish}	Predicted concentration in fish [mg/kg]
PEC_{sw}	PEC in surface water [mg/L]
BCF	Bioconcentration factor in fish

The factor of 0.159 is used to convert the residues in fish to a daily dose based on a bird of 1000 g eating 159 g per day, according to EFSA.
The risk assessment is based on the use according to GAP for which the highest initial PEC_{sw} at FOCUS Step 1 was calculated as 0.0031 mg ai/L for triticonazole and 0.002 mg/L for RPA 406203. The initial PEC was used instead of the 21 days twa as it represents a worst-case.

Table 9.2-16: Parameters and calculations for the assessment of the long-term risk to fish-eating birds

Parameter	Triticonazole/ cereal seeds	RPA 406203
$NOEL_{long\text{-}term}$ [mg ai/kg bw/d]	19.5	1.95
PEC_{water} (initial, FOCUS step 1) [mg ai/L]	0.0031	0.002
BCF_{fish}	72.55	72.55
PEC_{fish} [mg ai/kg]	0.226	0.145
Daily dose [mg ai/kg bw/d]	0.036	0.023
TER	542	84.78
Trigger	**5**	**5**

The TER-value following use according to the GAP is above the long-term trigger of 5, indicating that the use of triticonazole poses a low risk to fish-eating birds.

Biomagnification in terrestrial food chains

Based on the results of the livestock metabolism study in lactating goat (radioactivity associated with edible portions, milk and tissues, accounted for ≤ 1% of the administered dose), the ADME studies with rats and a

bioaccumulation study in fish demonstrate that triticonazole has a low potential to bioaccumulate and biomagnify in vertebrates (please also refer to sections B6 and B7).

Proportion of active substance LD_{50} per 100 items and per gram of items

Table 9.2-17: Proportion of the LD_{50} birds are ingesting via uptake of one gram cereal seeds treated with triticonazole

Species	LD_{50} [mg ai/kg b.w.]	Bird weight [1)] [g/bird]	LD_{50} [mg ai/bird]	Proportion of LD_{50} per 100 treated kernels [3)] [% of LD_{50}]	Proportion of LD_{50} per 1 g seed [4)] [% of LD_{50}]
Bobwhite quail (*Colinus virginianus*)	3776	202	763	0.014 – 0.042	0.007
Grey partridge (*Perdix perdix*)	3776	381	1439	0.007 – 0.022	0.003
Red-legged partridge (*Alectoris rufa*)	3776	468	1767	0.006 – 0.018	0.003

[1)]Mean initial body weight at the start of the pre-treatment period as reported in the respective acute toxicity study.
[3)]Proportion of $LD_{50\ Bird}$ consumed per 100 treated particles = 100* (Amount of ai per 1 seed * 100 seeds / $LD_{50\ Bird}$); based on an amount of 0.00105 – 0.0032 mg ai / 1 cereal seed. Thousand grain weight (TGW) of 21-64 g for winter wheat weight was used to calculate the amount of ai for one seed.
[4)]Proportion of $LD_{50\ Bird}$ consumed per 1 g seed = 100* (Nominal Seed Load per 1 g seeds / LD_{50}); based on a nominal seed load of 0.05 mg / 1 g cereal seeds

Acceptance of treated seeds (palatability testing)

Two studies on avoidance of seeds treated with triticonazole were evaluated in the first approval process. One study with Grey partridges in captivity feeding on wheat seeds treated with a formulation containing 200 g tritconazle/L and a study with Norther bobwhite feeding on barley seeds treated with EXP80472B, which is identical to BAS 595 01 F, containing 25 g/l triticonazole. The results were not fully unambiguous. The studies were not re-evaluated, the references are given above.

Overall conclusion for the risk assessment for birds

The acute risk for birds due to exposure of triticonazole in spring and winter cereal fields was assessed as low at tier 1. For long-term exposure no low risk can be concluded at a tier 1 for granivorous birds feeding on freshly drilled treated seeds and a refined risk assessment is required. Seven focal species were identified for pre-emergence cereal fields. These are skylark, yellowhammer, chaffinch, wood pigeon, rook, carrion crow and pheasant. Additionally the linnet is discussed as a potential focal species representing small granivorous birds (for detailed information, please refer to B.9.2.1 Risk assessment for birds - Focal species). For this species no refinement is available but an argumentation by the applicant why it should not be considered as a focal species (Subject to peer review). For the bigger of the focal species, wood pigeon, rook, carrion crow and pheasant, a low long-term risk is indicated. Refined residues on seeds and PT-refinement lead to a low risk for the yellowhammer in spring and winter cereals and for the chaffinch in winter cereals. For the chaffinch a low risk in spring cereals is only possible by using a best case germination time of 21 days. For the skylark a low risk in both, spring and winter cereals, is only possible by using a best case germination time of 21 days.

Further refinement options and supportive additional information was provided by the applicant. Taking into account that the long-term toxicity endpoint for birds may be conservative and using the endpoint estimated in the modified exposure study would lead to a low risk (to be discussed during the peer review or an expert-meeting). Furthermore a refined PD for skylarks is available, which could be used in a weight of evidence approach considering that the TER_{LT} without PD refinement is between 3.2 and 5.1 (depending on the germination time used) in spring cereals and between 3.7 and 6.0 (depending on the germination time used) in winter cereals. For chaffinches a de-husking behaviour can be assumed in a weight of evidence approach considering that the TER_{LT} without de-husking is between 3.7 and 5.9 (depending on the germination time used). It should be noted, that the studies for PD and PT refinement have all been conducted in Germany. Therefore it is not ascertained that these refinement options account for other than the central zones. The risk for secondary poisoning and biomagnification is low.

B.9.2.2. Risk assessment for mammals

With regard to the relevant scenarios small omnivorous mammals (see Table B.9.1.3-1) is considered as the relevant generic focal species for risk assessment in the category cereals.

Table 9.2-18: Relevant generic mammalian focal species for the Tier 1 risk assessment

Crop	Growth stage (BBCH)	Generic focal species	FIR/bw or shortcut value
Cereals	BBCH 00/spring and autumn	Small omnivorous mammal	0.24
	seedlings	Small omnivorous mammal	0.24 x NAR[1]/5

[1]NAR = Nominal loading/application rate of active substance in mg/kg seed.

Acute risk assessment for mammals:

The acute risk assessment is based on the endpoint derived from an acute toxicity study with rat ([redacted], 1990). The LD_{50} was determined to be > 2000 mg ai/kg bw. No mortality was observed at this dose.

Table 9.2-19: Tier 1 acute risk assessment for omnivorous mammals eating cereals seeds

Generic focal species	Growth stage (BBCH)	FIR/bw	NAR[1]	DDD_A	LD_{50} [mg ai/kg bw]	TER_A
Small omnivorous mammal	BBCH 00/ spring and autmn	0.24	50	12	> 2000	> 167

[1]NAR = Nominal loading/application rate of active substance in mg/kg seed.

Table 9.2-20: Tier 1 acute risk assessment for omnivorous mammals eating cereal seedlings

Generic focal species	Growth stage (BBCH)	Shortcut value	LD_{50} [mg ai/kg bw]	TER_A
Small omnivorous mammal	seedlings	2.4[1]	> 2000	> 834

Generic focal species	Growth stage (BBCH)	Shortcut value	LD_{50} [mg ai/kg bw]	TER_A
Large herbivorous mammal[a]		4[2]		> 500

[1]0.24 x NAR/5
[2]0.4 x NAR/5
NAR = Nominal loading/application rate of active substance in mg/kg seed.
[a]Large herbivorous mammals are referred to in the text but not in the table of the EFSA GD. Therefore large herbivorous mammal is added here with DDD value used for rabbit.

All TER_A values are above the trigger of 10 for acute exposure, indicating low risk to mammals from the use of the product.

Long-term risk assessment for mammals:

Table 9.2-21: Tier 1 long-term risk assessment for omnivorous mammals eating cereals seeds

Generic focal species	Growth stage (BBCH)	FIR/bw	NAR	f_{twa}[2]	DDD_{LT}	NOAEL [mg ai/kg bw]	TER_{LT}
Small omnivorous mammal	BBCH 00/ spring and autumn	0.24	50	0.72	8.64	25	**2.89**
				0.64	7.68		**3.26**
				0.53	6.36		**3.93**

[1]0.24 x NAR/5
NAR = Nominal loading/application rate of active substance in mg/kg seed.
[2]The averaging time of 21 days is under debate for seed treatments as the time from sowing to germination usually is shorter, for cereals 10 to 14 days can be assumed. To enable expert discussion, the risk assessment is presented with a worst case of 10 days, with a more realistic value of 14 days and with 21 days as used for spray applications.

The RMS is of the opinion that the value used for the averaging time should be subject to peer-review as it is not fully clear which averaging time should be used for seed treatments in general.

Table 9.2-22: Tier 1 long-term risk assessment for omnivorous mammals eating cereal seedlings

Generic focal species	Growth stage (BBCH)	Shortcut value[1]	f_{twa}	DDD_{LT}	NOAEL [mg ai/kg bw]	TER_{LT}
Small omnivorous mammal	seedlings	2.4	0.53	1.27	25	19.7
Large herbivorous mammal		4		2.12		11.7

[1]0.24 x NAR/5
[2]0.4 x NAR/5
NAR = Nominal loading/application rate of active substance in mg/kg seed.

The TER_{LT} values for small omnivorous and large herbivorous mammals eating seedlings are above the trigger of 5 for long-term exposure, indicating a low risk to mammals. However, the TER_{LT} values for small omnivorous mammals eating seeds are below the trigger of 5 for long-term exposure, indicating high risk to

mammals from the use of the product. Therefore further refinement is required.

Higher tier long-term risk assessment for mammals eating seeds

Two degradation studies were provided as confirmatory data in 2009. These studies were conducted to measure initial triticonazole residue levels on seeds exposed onto the soil surface and to also measure the residue decline on these seeds. For the current application two further degradation studies were provided, measuring the residues of the seeds directly from the sowing machinery.

Initial residues on cereal seeds on the soil surface

During the first approval, the worst case figure obtained from the two studies of rounded 67% was used as a correction factor in the risk assessment to cover the Northern and the Southern region of the EU. The RMS asked the applicant for justification and further information regarding the loss of active substance between treatment of the seeds and sowing. The applicant provided an additional data package. Along with two additional studies measuring the residues on the seeds direct from the sowing machinery, the applicant provided literature data indicating that increase of moisture content in the seeds leads to a residue decline (or rather dilution) during the first hours of sowing when the residue content is related to fresh weight. Based on all available data and information and considering several uncertainties, the RMS decided to use the worst case value of all submitted studies being 91.88% as correction factor in the risk assessment.

Decline of residues on cereal seeds on the soil surface

The RMS reanalysed the data set from the confirmatory data using the KinGUI v.2 model in order to check the DT_{50} values and noted that in 3 out of 6 trials the fit to single first order decline was borderline or bad.

The applicant provided two additional new studies and additionally two documents (Szegedi, 2017a and Szegedi 2017b) re-calculating the DT_{50} values based on all the available data, excluding values with bad fit. The applicant summarized all values as there was no statistically significant difference between the degradation in winter or spring cereal seeds ($p = 0.63$). The resulting DT_{50} values are listed in Table 9.2-23.

The trials were conducted in UK (England, Scotland), Spain, Germany, Netherlands, Northern France and Poland with one Plot at each testing site. Field preparations, pre-sowing activities and the sowing were carried out according to GAP. The treated seed was applied to the soil surface using commercial drilling machinery and immediately after application specimen of seeds were collected and again 1, 3, 7, 14 and 21 days after application. The RMS considers the methods and the study designs comparable and the geographical distribution of the trials sufficient to cover the EU.

Table 9.2-23: Dissipation half live of triticonazole on cereal seeds exposed onto the soil surface

BASF DocID [1)]	Season	Trial	Country	Kinetic model	DT_{50} [days]
2006/1015760	Spring	BA/1	UK	SFO	9.7 [2)]
		BA/2	UK	SFO	10.6
		BA/3	UK	SFO	4.2
2007/1016397	Spring	07/S/13	Spain	SFO	6.0
		07/S/14	Spain	SFO	7.8 [2)]
		07/S/15	Spain	SFO	7.9 [2)]
2017/1000581	Spring	L160002	Germany	SFO	7.2
		L160003	Netherlands	SFO	2.1

		L160004	Germany	SFO	4.0
2017/1000582	Autumn/Winter	L160005	Germany	SFO	6.1
		L160006	France (North)	SFO	7.9
		L160007	Germany	SFO	8.6
		L160008	Poland	SFO	6.4
		L160009	UK	SFO	3.5
Geometric mean (n, sample size)					**5.5 (11)**

[1]Field residue study
[2]Values excluded from the geometric mean calculation because of bad fit and borderline fit, respectively.

With this DT_{50} and an averaging time of 21 days an f_{twa} of 0.351 can be derived. However, the averaging time of 21 days is under debate for seed treatments as the time from sowing to germination usually is shorter, for cereals 10 to 14 days can be assumed. Therefore the refined f_{twa} by using a worst case averaging time of 10 days is 0.568 and with an averaging time of 14 days it is 0.470.

Table 9.2-24: Higher tier long-term risk assessment for omnivorous mammals eating cereals seeds*

Generic focal species	Growth stage (BBCH)	FIR/bw	NAR	Correction factor	ftwa	DDD_{LT}	NOAEL [mg ai/kg bw]	TER_{LT}
Small omnivorous mammal	BBCH 00/ spring and autumn	0.24	50	0.92	0.568	6.271	25	**3.99**
					0.470	5.189		**4.82**
					0.351	3.875		6.45

NAR = Nominal loading/application rate of active substance in mg/kg seed.
*The averaging time of 21 days is under debate for seed treatments as the time from sowing to germination usually is shorter, for cereals 10 to 14 days can be assumed. To enable expert discussion, the risk assessment is presented with using the f_{twa} based on DT_{50} of 5.5 days and a worst case germination time of 10 days, with a more realistic value of 14 days and with 21 days as used for spray applications.

Focal species

In the Tier 1 risk assessment for treated seeds according to EFSA/2009/1438 the omnivorous mouse scenario is considered as mammalian generic indicator species for seed treatment uses. The representative species for this scenario, the wood mouse (*Apodemus sylvaticus*), is in fact a typical small mammal species, widespread in Europe and common in agricultural land and will be considered for the refined risk assessment as well.

PD-refinement

Data sources for refinement of PD from open scientific literature on wood mouse diet composition in arable land, i.e. the work from Pelz (1989) and Green (1979) are considered.

According to the work by Pelz (1989) and Green (1979), arable land-dwelling wood mice can be clearly characterized as omnivorous animals. Hence, although cereal seeds may form an important part of the diet, other feed items like arthropods, plant leaves, earthworms and weed seeds always contribute significantly to the diet of the wood mouse. Consequently, regarding the refined long-term risk assessment, the assumption of PD = 1 (exclusive feeding on treated cereal seeds over a prolonged period of time) is considered as an over conservative approach.

The Notifier proposed to estimate the diet composition of wood mice in arable land based on the two publications by Pelz (1989) and Green (1979) at the time of cereals sowings in spring (February - April) and

autumn (September - November).

The RMS agrees to use results from these two studies but emphasises the following uncertainties:

- In both studies only winter cereal fields were observed, spring cereal fields were not considered
- According to the Birds and Mammals GD EFSA/2009/1438 the conservative assumption of taking only treated seed should be retained unless there is specific data on the foods taken on relevant fields as the intake of crop seed for animals feeding on newly drilled fields may be underestimated when assumed that food obtained on treated fields follows the same dietary composition as measured for the general population in all habitats. The study of Pelz (1989) intended to estimate aspects of damage to sugar beet seeds by *Apodemus sylvaticus*. The publication does not clearly state how many mice were caught in the cereal fields of the region.
- The provided publication by Pelz (1989) does not contain tables or raw data. It only provides a figure representing the diet of wood mice on arable farmland via analysis of stomach contents (pooled data for several years). Therefore the numbers taken from this publication may be inexact.
-The studies were conducted in Germany and UK, respectively; therefore it is unclear if the values are suitable for other regions of Europe as well.

To cover all these uncertainties the mean PD of the worst-case values of both studies over the whole year is used in the risk assessment. Therefore the PD is 0.5.

Table 9.2-25: Diet composition of the wood mouse in arable land in Germany according to Pelz (1989)

Month	Habitat / Country	Food item	% diet [vol%]	Reference
January	Arable land (sugar beet, wheat, barley) DE	Cereal grain	53[3]	Pelz 1989
February			28 [1]	
March			23 [1]	
April			5 [2]	
September			33 [2]	
October			30 [1]	
November			40 [1]	
December			40[3]	

[1]Values estimated from Figure 3.3 in Pelz (1989) by the notifier
[2]Values estimated from Figure 3.3 in Pelz (1989) by Swedish competent authorities (KEMI) (Anonymous 2006)
[3]Values estimated from Figure 3.3 in Pelz (1989) by the RMS

Table 9.2-26: Diet composition of the wood mouse in arable land in the UK according to Green (1979)

Time period	Habitat / Country	Food item	% diet [vol%]	Reference
Sep-Dec	Winter wheat (UK)	Cereal endosperm	60	Green 1979
Jan-Mar			55	

Time period	Habitat / Country	Food item	% diet [vol%]	Reference
Apr-Jun			6	

Table 9.2-27: Higher tier long-term risk assessment with refined PD for the wood mouse in cereals *

Focal species	Growth stage (BBCH)	FIR/bw	NAR	Correction factor	ftwa	PD	DDD_{LT}	NOAEL [mg ai/kg bw]	TER_{LT}
Wood mouse	BBCH 00/ spring and autumn	0.24	50	0.92	0.568	0.5	3.135	25	7.97
					0.470		2.594		9.64
					0.351		1.938		12.90

NAR = Nominal loading/application rate of active substance in mg/kg seed.
*The averaging time of 21 days is under debate for seed treatments as the time from sowing to germination usually is shorter, for cereals 10 to 14 days can be assumed. To enable expert discussion, the risk assessment is presented with using the f_{twa} based on DT_{50} of 5.5 days and a worst case germination time of 10 days, with a more realistic value of 14 days and with 21 days as used for spray applications.

Based on refined residues on seeds and a refined PD for the wood mouse, the risk for omnivorous mammals eating seeds is considered low.

Further refinement options and supportive information

To further support the risk assessment for birds in freshly drilled cereals fields, the applicant summarized information which was not used in the current quantitative risk assessment but is provided as qualitative additional information below (*in italic*).

PT data for wood mouse in freshly drilled spring and winter cereals

For the possible refinement of the proportion of the diet obtained in cereal fields (i.e. PT values) by wood mice, the applicant provides data from four industry radiotracking studies conducted in areas with freshly drilled cereals seeds. There are two studies available in freshly drilled spring cereal fields (Barfknecht, 2008a, BASF DocID 2008/1097310 and Fülling and Miersch, 2016, 2016/1326919) and two studies in autumn-drilled cereals (Barfknecht, 2006b, BASF DocID 2006/1047474 and Fülling and Sainz-Elipe, 2017, 2017/1025731). The summary of the combined PT values is given in the Table below. For a detailed evaluation of the study data please refer to Appendix 2 to chapter 10.1.2.2.

Table 9.2-28: Summary of PT values for the wood mouse in freshly sown cereal fields in spring (spring cereals) and autumn (winter cereals).

		Spring cereals	*Winter cereals*
All animals	*N*[1]	*15*	*25*
	Mean PT	*0.06*	*0.13*
	90th percentile PT	*0.20*	*0.52*
Consumer animals	*N*[1]	*10*	*14*
	Mean PT	*0.10*	*0.22*
	90th percentile PT	*0.23*	*0.72*

[1] *Sample size (number of individual animals)*

PT data for the wood mouse in freshly drilled spring and winter cereals are included in the current dossier as supportive information only. Currently, the information is not used quantitatively in the refined risk assessment. However, the data shows that the realistic PT is clearly below 1 and thus, the current higher tier risk assessment is conservative in this respect.

Comment RMS:	The provided approach is considered acceptable as supportive information

De-husking behaviour

There is evidence that the foraging technique of de-husking can reduce significantly the exposure to active substances used as seed treatments. For example, Barber et al. (2003) found in the stomachs of wood mice during the winter wheat sowing period in autumn (arable land in Yorkshire, UK) not only low amounts of cereal seeds (90% of all animals caught on the field had consumed less than 20% seeds/by stomach volume), but also that the residues of the fungicide (seed treatment) in stomach, intestine, and liver were lower than would be expected for the amount of seed consumed. The authors suggested that the reason for the findings were the de-husking of the seeds by mice.

Recently, laboratory experiments with wild-caught wood mice (Apodemus sylvaticus) showed that this species de-husks fungicide-treated seed of wheat and barley (Brühl et al. 2011). In a study performed by Brühl et al. (2011), a reduction of ai intake via de-husking for mammals consuming different types of seeds was determined by exposing 20 wood mice (Apodemus sylvaticus) to treated seeds under laboratory conditions. Four seed types were used in the experiment, winter wheat, summer barley, maize seeds and sunflower seeds which were treated with a formulated suspension of a triazole fungicide or a blank formulation (without active substances) which contained a colouring pigment. The de-husking factor was determined by residue analysis of the remaining seeds, and of the husks and sand collected in the cage after 24 hours of exposure. The results show that de-husking and handling of the seeds reduced the actual intake of residues of the fungicide seed treatment. The reduction of fungicide via de-husking behaviour by wood mice was observed in the study by Brühl for wheat (n=13) with 61% and for barley (n=14) by 79% reduction. For pigment load reductions observed were 58% for wheat (n=12) and 84% for barley (n=11).

Comment RMS:	The RMS did not evaluate the studies referred to. However, it is general knowledge that wood mice partially de-husk and therefore de-husking may be used in a weight of evidence approach.

Triticonazole residues in cereal shoots emerging from treated seeds

After sowing of the seeds, the active substance distributes in the surrounding soil but would also be partly transferred from the seed into the emerging shoot. Due to this dilution process, the potential exposure via emerging shoots would be inferior compared to the direct exposure via treated seeds. This is confirmed by results of BASF-own residue trials (BASF DocIDs C015362, C015364, R003472 and R003473). The studies were evaluated in the DAR (September 2003, Volume 3, B.7 Residue data).

*After cereal seed treatment with triticonazole, the highest residue level measured in seedlings (BBCH 11-13) was 0.37 mg/kg at a loading of 50 mg ai/kg cereal seeds (*Table 9.2-29*), corresponding to the intended seed load.*

Table 9.2-29: Residues of triticonazole (BAS 595 F) in cereal shoots emerging from treated seeds

Crop	Seed loading[1)] [mg ai/kg]	Sampling			Residues	Reference
		Matrix	Days after emergence	Growth stage (BBCH code)	[mg ai/kg]	(BASF DocID)
Spring barley	50	Young shoots	7	11-12	< 0.05	C015362
					0.066	
			7	11-12	0.13	C015364
					< 0.05	
Winter wheat	50	Young shoots	7	12	0.22	R003472
			14	13	0.35	
			7	12	0.2	
			14	13	0.31	
Winter rye	50	Young shoots	7	12	0.32	R003473
			14	13	0.25	
			7	12	0.37	
			14	13	0.35	
Range (n = 12)					< 0.05 - 0.37	
Arithmetic mean (n = 12)					0.22	

1) Nominal seed treatment rate

Comment RMS:	This approach is considered acceptable. However the risk for mammals eating cereal shoots is considered low without refinement.

Drinking water risk assessment:

According to the EFSA Guidance Document on Birds and Mammals (2009) significant contamination of drinking water after the use of a pesticide as seed treatment seems very unlikely to be a critical route or to lead to TER values greater than direct dietary consumption. A drinking water risk assessment therefore is not considered necessary.

Secondary poisoning:

Substances with a high potential to bioaccumulate in the food chain could theoretically bear a risk of secondary poisoning for mammals if feeding on contaminated prey like fish or earthworms. For organic chemicals, a log P_{OW} > 3 is used to trigger an in-depth evaluation of the potential for bioaccumulation.

The log P_{OW} value of the active substance triticonazole is 3.3 (Chabassol et al, 1991) and for the Z-isomer RPA 406203 it is 3.5 (Cowlyn, 2014e). Therefore a risk assessment for earthworm to earthworm-eating mammals and from fish to fish-eating mammals is required. For all other metabolites no risk assessment is required as the log P_{ow} is < 3 (for details pleas also refer to B.9 – CA).

Food chain from earthworm to earthworm-eating mammals

The risk to earthworm-eating mammals from bioaccumulation of triticonazole is calculated with the following

equations in accordance with the EFSA Guidance (2009).

The risk of RPA 406203 can be considered low as the Z-isomer only is formed under irradiation. Therefore earthworms are not likely to be exposed to RPA 406203.

Calculation of the PEC_{worm} for earthworm-eating mammals:

$BCF = (0.84 + 0.012 * K_{OW}) / (f_{OC} * K_{OC})$

$PEC_{worm} = PEC_{soil} * BCF$

Where:

PEC_{worm}	Predicted concentration in earthworms [mg/kg]
PEC_{soil}	Initial PEC_{soil} in soil [mg/kg soil dw]
BCF	Bioconcentration factor in earthworms
K_{OW}	Octanol/water partition coefficient
F_{OC}	Organic carbon content of soil, default = 0.02
K_{OC}	Organic carbon adsorption coefficient

The factor of 1.28 is used to convert the residues in worms to a daily dose based on a mammal of 10 g eating 12.8 g worms per day, according to EFSA.

The risk assessment was performed for the single application of 12.5 kg ai/ha.

Table 9.2-30: Parameters and calculations for the assessment of the long-term risk to earthworm-eating mammals

Parameter	Triticonazole/cereal seeds
$NOAEL_{long-term}$ [mg ai/kg bw/d]	25
K_{oc} (Organic carbon adsorption coefficient)	290*
K_{ow} (Octanol water partition coefficient)	1995
f_{oc} (Organic carbon content of soil)	default value: 0.02
$PEC_{soil\ 21d\ twa\ accu}$ [mg ai/kg]	0.1863
BCF_{worm}	4.27
PEC_{worm} [mg ai/kg]	0.796
Daily dose [mg ai/kg bw/d]	1.019
TER	24
Trigger	**5**

*As the adsorption is pH-dependent no geomean was calculated and the worst case K_{oc} was used.

The TER-value following use according to the GAP is above the trigger of 5 for long-term risk, indicating that the use of triticonazole poses a low risk to earthworm-eating mammals.

Food chain from fish to fish-eating mammals

The risk to fish-eating mammals from bioaccumulation of triticonazole is calculated with the following equations in accordance with EFSA Guidance (2009):

No toxicological endpoint for RPA 406203 is available therefore as a worst case a 10-fold higher toxicity than the parent is assumed.

Calculation of the Daily Dietary Dose (DDD) for fish-eating mammals:

$PEC_{fish} = PEC_{sw} * BCF$

Where:

PEC_{fish}	Predicted concentration in fish [mg/kg]
PEC_{sw}	PEC in surface water [mg/L]
BCF	Bioconcentration factor in fish

The factor of 0.142 is used to convert the residues in fish to a daily dose based on a mammal of 3000 g eating 425 g per day, according to EFSA.

The risk assessment is based on the use according to GAP for which the highest initial PEC_{sw} at FOCUS Step 1 was calculated as 0.0031 mg ai/L for triticonazole and 0.002 mg/L for RPA 406203. The initial PEC was used instead of the 21 days twa as it represents a worst-case. The initial PEC was used instead of the 21 days twa as it represents a worst-case.

Table 9.2-31: Parameters and calculations for the assessment of the long-term risk to fish-eating mammals

Parameter	Triticonazole/ cereal seeds	RPA
$NOEL_{long\text{-}term}$ [mg ai/kg bw/d]	25	2.5
PEC_{water} (initial, FOCUS step 1) [mg ai/L]	0.0031	0.002
BCF_{fish}	72.55	72.55
PEC_{fish} [mg ai/kg]	0.226	0.145
Daily dose [mg ai/kg bw/d]	0.032	0.021
TER	781	119
Trigger	**5**	**5**

The TER-value following use according to the GAP is above the long-term trigger of 5, indicating that the use of triticonazole poses a low risk to fish-eating mammals.

Biomagnification in terrestrial food chains

Based on the results of the livestock metabolism study in lactating goat (radioactivity associated with edible portions, milk and tissues, accounted for ≤ 1% of the administered dose), the ADME studies with rats and a bioaccumulation study in fish demonstrate that triticonazole has a low potential to bioaccumulate and biomagnify in vertebrates (please also refer to sections B6 and B7).

Overall conclusion for the risk assessment for mammals

The acute risk for mammals due to exposure of triticonazole in spring and winter cereal fields was assessed as low at tier 1. For long-term exposure no low risk could be concluded at a tier 1 for small omnivorous mammals feeding on freshly drilled treated seeds and a refined risk assessment is required. The wood mouse is considered to be the focal species for pre-emergence cereal fields. Risk assessment with refined residues on the seed and a refined PD for the wood mouse indicate an acceptable long-term risk. Further refinement options and supportive additional information was provided by the applicant. A refined PT for wood mice is available as supporting information.

It has to be noted, that the studies for PD (a worst case value was used for the refinement, which may cover all zones) and PT refinement have all been conducted in Germany. Therefore it is not ascertained that these refinement options account for other than the central zones. The risk for secondary poisoning and biomagnification is low.

B.9.3. EFFECTS ON AQUATIC ORGANISMS

In addition to the acute toxicity studies with the active substance triticonazole and its metabolites (see RAR, Volume 3, B.9-CA) studies with the EU representative formulation BAS 595 01 F (other name: Premis 25 FS) were conducted with aquatic invertebrates and algae. The study summaries are given below.

B.9.3.1. Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

Reference:	**Acute toxicity of BAS 595 01 F to *Daphnia magna* Straus in a 48 hour static test**
Author(s), year:	Janson, G.M., 2009a
Report/Doc. number:	BASF DocID 2009/1072605
Guideline(s):	OECD 202 and OPPTS 850.1010, draft (1996)
GLP:	Yes
Deviations:	Please refer to commenting box below
Validity:	Acceptable

Material and methods:	
Test substance:	BAS 595 01 F, batch no.: FRE-000660, purity: 25.7 g ai/L (analysed)
Test species:	Water flea, *Daphnia magna*, in house culture
Number of organisms:	4 replicates per treatment and control, each replicate containing 5 daphnids
Age:	neonates, > 2 < 24 h old
Type of test, duration:	Static test, 48 hours
Applied concentrations:	
Nominal:	0 (control), 6.25, 12.5, 25, 50 and 100 mg prod./L
Mean measured:	Not given
Solvent:	None
Reference item	Potassium dichromate
Test conditions:	
Water quality:	Daphnia synthetic medium M4 according to Elendt, total hardness: 2.42 mmol/L (measured at test initiation)
Temperature:	20.0 – 20.9 °C
pH:	7.99 – 8.3
O_2 content:	8.8 – 9.0 mg/L corresponding to 101.3 – 102.5% of air saturation
Light regime:	16 hours light / 8 hours darkness
Feeding:	During the exposure the daphnids were not fed.
Test parameters:	Immobility and sublethal effects were assessed after 24 and 48 hours. Measurements of pH, temperature and dissolved oxygen concentrations were made at the start (0 h), and in one replicate of each concentration at the end of the test

(48 h).

Samples (from all treatments were taken for analytical verification of the test concentrations at test start and test end.

Statistics: No statistical analyses were performed because no effects were observed.

Findings:

Analytical measurements: The measured concentrations were within a range of 99.2 - 111.5% of the nominal test concentrations at the start of the test and within a range of 99.7 – 115% of the nominal test concentration at the end of the test. Hence, the results should be based on nominal concentrations.

Table 9.3-1: Effects on daphnids (*D. magna*) exposed to BAS 959 01 F

BAS 959 01 F [mg prod./L] (nominal)	Mean cumulative immobilized organisms [%]	
	24 hours	48 hours
Control	0	0
6.25	0	0
12.5	0	0
25	0	0
50	0	0
50	0	0
100	0	0

The sensitivity of the test system was verified by testing the reference item potassium dichromate. The 24 hour-EC_{50} value was determined to be 1.29 mg/L and the 24-hour EC_{100} was > 1.8 mg/L.

Conclusion: The acute toxicity of formulated triticonazole to *Daphnia magna* has been investigated. The 48-hour EC_{50} was calculated as > 100 mg prod./L based on nominal concentrations. The 48-hour NOEC is 100 mg product/L.

Comment RMS: The study was evaluated following the recommendations of the currently valid test guidelines OECD 202 (2004)

Check of validity criteria:

- In the control, including the control containing the solubilizing agent, not more than 10 per cent of the daphnids should have been immobilized or show other signs of disease or stress (e.g. discoloration or unusual behavior). During the study no immobilization in the control occurred.
- The dissolved oxygen concentration at the end of the test should be ≥ 3 mg/L in control and test vessels. The dissolved oxygen concentration was between 8.9 and 9.0 mg/L after 48 hours.

Acceptability of the analytical methods used in the test: The evaluation of the analytical methods was conducted according to the Guidance Document

	SANCO/3029/99 rev. 4. Based on the evaluation (see Volume 3 B.5-CA, B.5.1.2.6) it could be demonstrated that the method fulfils the requirements with regard to linearity, specificity, accuracy, repeatability, and limit of quantification. LOQ: 0.001 mg ai/L. **Endpoints:** The RMS agrees on the endpoints given in the study report. EC_{50} > 100 mg product/L nominal concentration corresponding to 2.5 mg ai/L NOEC = 100 mg product/L nominal concentration corresponding to 2.5 mg ai/L **Conclusion of the RMS:** Based on the evaluation of the study the daphnid acute toxicity test is considered valid.

Reference:	**Effect of BAS 595 01 F on the Growth of the Green Alga *Pseudokirchneriella subcapitata***
Author(s), year:	Hoffmann, F., 2009a
Report/Doc. number:	BASF DocID 2009/1072606
Guideline(s):	OECD 201
GLP:	Yes
Deviations:	Please refer to commenting box below
Validity:	Acceptable

Material and methods:

Test substance:	BASF 595 01 F, batch no.: FRE-000660, purity: 25.7 g ai/L
Test species:	Green algae *Pseudokirchneriella subcapitata,* in-house culture, originally obtained from Sammlung von Algenkulturen Göttingen
Number of organisms:	1 x 10^4 cells/mL; 5 replicates per treatment group and 10 replicates for the control group
Type of test, duration:	Static test, 72 hours
Applied concentrations:	
Nominal:	0 (control), 1.56, 3,13, 6.25, 12.5, 25, 50 and 100 mg prod./L
Mean measured:	Not given
Solvent:	None
Toxic reference:	Potassium dichromate
Test conditions:	
Water quality:	Nutrient medium according to the OECD guideline
Temperature:	22 ± 1°C
pH:	7.70 – 7.96
Illumination:	uniform lightning, approx. 8000 lux
Test parameters:	Cells concentration in each flask was determined 24, 48 and 72 hours after the

start of the test with a spectrophotometer (623 nm, 5 cm glass cuvettes). For the control and the nominal test concentration algal medium without algae were used as a blank. To obtain the actual number of cells/ML a linear correlation (calibration curve) was calculated from the cell numbers (counted under a microscope) versus extinction values.

The pH was measured at the last sampling interval of analytical sampling. No information is given about the measurement of temperature and illumination.

At the beginning and at the end of the test samples were taken for verification of the test item concentrations.

Statistical analysis: The mathematical determination of the EC_x was done by probit analysis. The calculations were conducted with ToxRat Professional 2.10 (ToxRat Solutions GmbH, Alsdorf, Germany).

Findings:

Analytical data: The mean measured concentrations of triticonazole are in a range of 94.5 – 102.3% of nominal test concentrations at test start and 95.2-101.5% of nominal test concentrations at test termination. Hence, the results are based on nominal test concentrations.

Table 9.3-2: Effects of BASF 595 01 F on the green alga *Pseudokirchneriella subcapitata*

[mg /L] (nominal)	Growth rate (standard deviation)	% inhibition relative to control	Yield (standard deviation)	% inhibition relative to the control
Control	1.560 (0.0125)	-	106.7	-
1.56	1.571(0.0094)	-0.7	110.5	-3.5
3.13	1.564 (0.0201)	-0.3	108.1	-1.3
6.25	1.465 (0.0203)	6.1	80.1	24.9
12.5	1.396 (0.0090)	10.5	64.9	39.2
25	1.331 (0.0194)	14.7	53.2	50.1
50	1.065 (0.0420)	31.7	23.6	77.9
100	0.619 (0.0636)	60.3	5.5	94.8

The sensitivity of the test system was verified by testing the reference item potassium dichromate. The EC_{50} values for the growth rate and yield were determined to be 0.85 mg/L (growth rate) and 0.39 mg/L (yield).

Conclusion: 72 h E_rC_{50} = 79.4 mg prod./L (95 % C.I. = 74.0-85.9 mg/L)
72 h E_rC_{10} = 17 mg prod./L (95 % C.I. = 14.6-19.3 mg/L)
72 h E_yC_{50} = 19.5 mg prod./L (95 % C.I. = 17.8-21.4 mg/L)
72 h E_yC_{10} = 3.9 mg prod./L (95 % C.I. = 3.1-4.6 mg/L)
based on nominal concentrations

Comment RMS:	The study was evaluated following the recommendations of the currently valid test

guideline OECD 201 (2006)

Check of validity criteria:

- The biomass in the control cultures should have increased exponentially by a factor of at least 16 within the 72-hour test period. In the test the cell concentration of the control culture increased by a factor of 108 after a 72 h period.
- The mean coefficient of variation for section-by-section specific growth rates (day 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures must not exceed 35%. The coefficient of variation derived in the current study is 19.4%.
- The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures must not exceed 7% in tests with *Pseudokirchneriella subcapitata*. The coefficient of variation derived in the current study is 0.8%.

In addition, the following points deviated from the test guideline or were not reported in detail:

The study report does not provide detailed information about the measurements of temperature and illumination.

Acceptability of the analytical methods used in the test: The evaluation of the analytical methods was conducted according to the Guidance Document SANCO/3029/99 rev. 4. Based on the evaluation (see Volume 3 B.5-CA, B.5.1.2.6) it could be demonstrated that the method fulfils the requirements with regard to linearity, specificity, accuracy, repeatability, and limit of quantification.

LOQ: 0.001 mg ai/L.

Endpoints: The cell densities were estimated by spectrophotometer. No detailed information was provided about the conditions of this method and about the calibration. No raw data was given. The notifier provided some data afterwards. Based on these data the endpoints were recalculated by the RMS via ToxRatPro® 3.2. The endpoints provided in the study could be confirmed.

72 h E_rC_{10} = 16.98 mg prod./L (95 % C.I. = 15.48-18.44 mg/L)

reliability based on normalised width of C.I. = excellent

72 h E_rC_{20} = 28.84 mg prod./L (95 % C.I. = 27.11-30.50 mg/L)

72 h E_rC_{50} = 79.4 mg prod./L (95 % C.I. = 75.9-83.34 mg/L)

72 h E_yC_{10} = 3.8 mg prod./L (95 % C.I. = 2.92-4.96 mg/L)

reliability based on normalised width of C.I. = fair

72 h E_yC_{20} = 6.60 mg prod./L (95 % C.I. = 5.07-8.58 mg/L)

72 h E_yC_{50} = 19.02 mg prod./L (95 % C.I. = 13.84-26.08 mg/L)

NOEC = 3.13 mg prod./L (yield and growth rate)

based on nominal concentrations

Conclusion of the RMS: Based on the evaluation of the study the long-term *Pseudokirchneriella subcapitata* toxicity test is considered valid.

During the first approval of triticonazole studies were conducted with different formulations than the representative one. As studies with the representative formulation are considered more relevant, the other studies have not been re-evaluated.

The study summaries given in the DAR for the first EU approval are given below as additional information.

[redacted] ***2001 – CRLD 001002: Acute toxicity to rainbow trout (Oncorhynchus mykiss)***

Document number: C020487

Test guideline: OECD 203, EU 92/69/EEC C1

GLP: yes

Material and methods:

After a preliminary range finding study fish were exposed in groups of ten to an aqueous solution of the formulation CRLD 001002 (nominal concentrations of 5, 11, 24, 53 and 117 mg/l) under static test conditions for 96 h. The test substance CRLD 001002 contained 10.1 g ai/l. Test conditions: Temperature, 14 – 15 °C; pH, 7.6 – 8; dissolved O2, 8.7 – 9.5 mg/l, hardness as CaCO3, 100 mg/l

Findings:

The concentration of the ai at 0 and 96 h was in the range of 93 % to 109 % of nominal. Results and calculations of LC50 values were based on nominal concentrations of CRLD 001002. No dead fish were observed in control and at test concentrations up to 53 mg/l. All fish died at the test concentration of 117 mg/l. Sublethal effects like increased pigmentation and swimming at the bottom of the vessel were only observed at a concentration of 117 mg/l.

Assessment: The 96 h LC50 value of CRLD 001002 was 79 mg/l with 95 % confidence limits of 53 – 117 mg/l. The NOEC was 53 mg/l.

Comment: The composition of the tested formulation was not identical to the formulation EXP80472B (Premis 25 FS)

Wetton P.M., Mullee D.M., 1999b – EXP 10642A: Acute toxicity to Daphnia magna

Document number: C020490

Test guideline: OECD 202; EEC 92/69, C2

GLP: yes

Material and methods:

Following a preliminary range finding study, the definitive test was performed with 20 daphnids (2 replicates of 10 animals) per nominal concentrations of 1, 1.8, 3.2, 5.6, 10, 18, 32, 56 and 100 mg EXP 10642A/l. The test substance EXP 10642A contained 10 g ai/l. The daphnids were kept under static conditions for 48 h and the number of immobilised animals was recorded after 24 and 48 h. Test conditions: Temperature, 21 °C; pH, 7.8 ± 0.2; photoperiod, 16 h light / 8 h dark; dissolved O2, 8 – 8.4 mg/l; total hardness as CaCO3, 250 mg/l.

Findings:

The measured concentrations of EXP 10642A at 0 and 48 h were in the range of 93 – 104 % of nominal

concentrations. Results and the calculation of LC50 values were based on nominal concentrations. No immobilised animals were observed in the control and at concentrations up to 32 mg/l. All animals were immobilised at a concentration of 100 mg/l after 48 h. The concentrations of 32, 56 and 100 mg/l appeared as cloudy white dispersions and oily slick was observed at the surface of the test media. As the measured test concentrations of EXP 10642A were based on the detection of ai (triticonazole) and the deviation of measured concentrations from nominal concentrations was moderate after 48 h, it can be concluded that the ai was not trapped in the oily slick. No daphnids were observed to be caught in this oily fraction.

Assessment: The 48 h EC_{50} of EXP 10642A was 69 mg/l (95 % confidence limits were 63 – 76 mg/l) and the 48 h NOEC was 32 mg/l. The composition of the tested formulation was not identical to the formulation EXP80472B (Premis 25 FS).

Mead C., Mullee D.M., 1999a – EXP 10642A: Alfal inhibition test

Document no.: C020489

Test guideline: OECD 201/ EEC, C3

GLP: yes

Material and methods:

Following a preliminary range finding study, Scenedesmus subspicatus was exposed to an aqueous dispersion of EXP 10642A at concentrations of 6.25, 12.5, 25, 50 and 100 mg/l for 72 h under static conditions. The content of ai in the formulation was 9.95 g/l. At initiation of the study the cell density was 4.68 x 105 cells per ml. Samples were taken at 0, 24, 48 and 72 h and the cell densities determined by using a haemocytometer and a light microscope. Three replicates per concentration and control were incubated at 24 ± 1 °C under continuous illumination at 7000 lux and constantly shaken at 100 rpm for 72 hours.

Findings:

Measured concentrations were 95 to 100 % of nominal at the beginning of test and ranged between 75 and 102 % of nominal concentrations after 72 h. Two measured test concentrations were below 80 % of the respective nominal concentrations. Nevertheless calculations and results were based on nominal concentrations because the authors explained the two low values with analytical/sampling variation, as it was shown that the active ingredient was stable over 72 h. The pH value rose from 7.4 at test initiation to 8.9 after 72 h. The rise in pH can be attributed to the photosynthetic activity of the algae. The cell density in the control rose from 9.45 x 103 at test initiation to 4.8 x 105 after 72 h. Both, the growth and biomass of Scenedesmus subspicatus were affected by the presence of EXP 10642A. After 72 h the mean cell density was 2.94 x 105 at a concentration of 50 mg/l and 4.45 x 103at a concentration of 100 mg/l. The corresponding inhibition of growth (area under curve) was 44 and 100 %, respectively, compared to the control. At nominal concentrations of 12.5 and 25 mg/l the inhibition of growth was 4 and 12 %, respectively. The test concentration of 6.25 mg/l led to no inhibition of growth.

Assessment: The EbC50 (72 h) = 57 mg EXP 10642A/l (95 % confidence limits = 49 – 67 mg/l), ErC50 = 86 mg EXP 10642A /l

Comment: Other than stated by the authors of the study, the rise in pH values was higher than indicated in the OECD guideline 201, which suggests a deviation of pH values of less than one unit during the test. However, the rise in pH is assumed to have no influence on the results of the study because the ai was hydrolytically stable up

to pH 9. The composition of the tested formulation was not identical to the formulation EXP80472B (Premis 25 FS).

B.9.3.2. Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

No long-term studies with the formulation were provided.

B.9.3.3. Further testing on aquatic organisms

In view of the risk assessment indicating acceptable risk to aquatic organisms, further testing on aquatic organisms is not required.

B.9.4. RISK ASSESSMENT FOR AQUATIC ORGANISMS

The aquatic risk assessment includes triticonazole (as active substance and formulated in the EU representative product) and the environmentally relevant metabolites RPA 404766, RPA 406341 and RPA 406203 (see Table B 9.1-1). The risk assessment was conducted according to the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters, EFSA Journal 2013;11(7):3290.

A summary of the toxicity studies conducted with the active substance, the representative formulation and its metabolites are provided in the following tables.

Table 9.4-1: Endpoints: Toxicity of triticonazole to aquatic organisms

Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg/L]	EC_x/LC_x [mg/L]	Reference
Fish							
Oncorhynchus mykiss Rainbow trout	Semi-static	96 h	Mortality	n	10	LC_{50} > 10	[redacted] M.T., 1990a
Oncorhynchus mykiss Rainbow trout	Flow-through	96 h	Mortality	mm	1.4	**LC_{50} > 3.6**	[redacted] M., 1998a
Oncorhynchus mykiss Rainbow trout	Static	96 h	Mortality	mm	2.62	LC_{50} > 12.4	[redacted] 2006a
Lepomis macrochirus Bluegill sunfish	Flow-through	96 h	Mortality	mm	8.9	LC_{50} > 8.9	[redacted] M.W., 1998b
Lepomis macrochirus Bluegill sunfish	Static	96 h	Mortality	mm	10.1	LC_{50} > 10.1	[redacted] 2006b
Cyprinodon variegatus Sheepshead minnow	Flow-through	96 h	Mortality	mm	5.7	LC_{50} > 9.1	[redacted] 1998a
Cyprinus carpio Common carp	Static	96 h	Mortality	mm	9.1	LC_{50} > 18	[redacted] 2014a
Pimephales promelas	Flow-	FFLC	Reproductio	mm	**0.0114**	-	[redacted] 2008a

Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg/L]	EC_x/LC_x [mg/L]	Reference
Fathead minnow	through		n/Growth				
Pimephales promelas Fathead minnow	Flow-through	FFLC	Reproduction/ Growth	mm	0.0473	-	[redacted] 2012a
Pimephales promelas Fathead minnow	Flow-through	ELS (34 d)	Mortality/ Growth	n	< 0.024	$EC_{10\ length}$ = 0.156 $EC_{20\ length}$ = 0.282 $EC_{50\ length}$ = 0.777 $EC_{10\ dry\ weight}$ = 0.037 $EC_{20\ dry\ weight}$ = 0.077 $EC_{50\ dry\ weight}$ = 0.239	[redacted] 1998b
Pimephales promelas Fathead minnow	Flow-through	ELS (34 d)	Mortality/ Growth	n	0.021	-	[redacted] 1998c
Cyprinodon variegatus Sheepshead minnow	Flow-through	ELS (34 d)	Mortality/ Growth	mm	0.12	-	[redacted] M.A., 2006a
Aquatic invertebrates							
Daphnia magna Waterflea	Static	48 h	Immobility	n	1.8	**EC_{50} = 7.85**	Douglas, M.T., Halls, R.W.S., Macdonald, I.A. 1990b
Mysidopsis bahia (Americamysis bahia) Mysid shrimp	Flow-through	96 h	Immobility	mm	1	**LC_{50} =1.9**	Sousa, J.V., 1998d
Crassostrea virginica Eastern oyster	Flow-through	96 h	Mortality/ Shell growth	mm	1.4	**LC_{50} = 8.9**	Dionne, E, 1998a
Daphnia magna Waterflea	Semi-static	21 d	Survival Reproduction	mm	NOAEC = 0.19	EC_{50} > 3	Putt, E., 2006a
Daphnia magna Waterflea	Semi-static	21 d	Survival/ Reproduction/Growth	mm	**0.11**	EC_{50} > 3.5	Urann, K, 2012a
Americamysis bahia Mysid shrimp	Flow-through	28 d	Survival Reproduction	mm	**0.041**	LC_{50} > 0.32	Putt, E., 2006b
Sediment dwelling organisms							
Chironomus riparius Midge	Static	26 d	Emergence/ Development	imm	0.777	EC_{50} > 0.777	Van der Kolk, J., 1998[a]

Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg/L]	EC_x/LC_x [mg/L]	Reference
Algae							
Pseudokirchneriella subcapitata Green algae	Static	72 h	Growth rate Yield	n	NOEC = 1.0	E_rC_{50} > 10 E_yC_{50} > 10	Seeland-Fremer, A., Wydra, V., 2014a
Skeletonema costatum Saltwater diatom	Static	72 h	Growth rate Biomass	n	-	E_rC_{10} = 0.25 E_rC_{20} = 0.31 **E_rC_{50} = 0.46** E_yC_{10} = 0.23 E_yC_{20} = 0.33 E_yC_{50} = 0.22	Hoberg, J.R., 1998e[b]
		120 h	Growth rate Biomass	n	0.031	E_rC_{10} = 0.24 E_rC_{20} = 0.33 E_rC_{50} = 0.58 E_yC_{10} = 0.25 E_yC_{20} = 0.28 E_yC_{50} = 0.34	
Aquatic macrophytes							
No valid studies provided							
Bioconcentration fish[c]							
Lepomis macrochirus Bluegill sunfish	**BCF_{Kwhole} fish**				72.55		
	$BCF_{Kinedible}$ fish				114.86		
	$BCF_{Kedible}$ fish				9.2		

Bold values are used for the risk assessment

n…nominal, mm…mean measured, imm…initially mean measured

[a]validity of the study is questionable, for details please refer to the commenting box of the study summary.

[b]not valid according to OECD 201 as coefficient of variation for section-by-section specific growth rates is 60%, but valid according OCSPP 850.4500.

[c]the results of the study indicate some uncertainties as the bioconcentration factor seems to first decrease and than increase again. Furthermore some information is missing in the study report (lipid content of fish, TOC, testing of a second concentration). However, even if the validity of the study is questionable, the results have been used to be able to do a risk assessment.

Effects to aquatic organisms from exposure to the metabolites RPA 404766, RPA 406341 and RPA 406203 were tested for the aquatic invertebrates. RPA 406203 was also tested for algae. No studies were conducted with fish and aquatic macrophytes.

Table 9.4-2: Endpoints: Acute toxicity of metabolites to aquatic organisms

Test substance	Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg/L]	EC_x/LC_x [mg/L]	Reference
Aquatic invertebrates								
Metabolite RPA 404766	*Daphnia magna* Waterflea	Semi-static	48 h	Immobility	n	100	**EC_{50} > 100**	Sewell, I.G., Mulle, D.M., 2001b
Metabolite RPA 407922	*Daphnia magna* Waterflea	Semi-Static	48 h	Immobility	n	100	**EC_{50} > 100**	Sewell, I.G., Mulle, D.M., 2001a
Metabolite RPA 406341	*Daphnia magna* Waterflea	Semi-static	48 h	Immobility	n	32	EC_{10} = 34.7 EC_{20} = 40.7 EC_{50} = **51.78**	Sewell, I.G., Mulle, D.M., 2002a
Metabolite RPA 406203	*Daphnia magna* Waterflea	Flow-through	48 h	Immobility	mm	1.8	**EC_{50} = 3.4**	Putt, E., 1998a
Metabolite RPA 406203 (Reg. No. 5079359)	*Daphnia magna* Waterflea	Static	48 h	Immobility	n	10	EC_{50} > 10	Janson, G.-M., 2009a
Algae								
Metabolite RPA 406203 (Reg. No. 5079359)	*P. subcapitata* Green algae	Static	72 h	Growth rate Yield	mm	**1.4** (yield)	E_rC_{10} = 3.51 E_rC_{20} = 9.55 E_rC_{50} = **64.83** E_yC_{10} = 1.84 E_yC_{20} = 3.12 E_yC_{50} = 8.57	Hoffmann, F., 2009a

n…nominal, mm…mean measured

Table 9.4-3: Endpoints: Acute toxicity of Premis 25 FS to aquatic organisms

Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg ai/L]	EC_{50}/LC_{50} [mg ai/L]	Reference
Fish							
No studies provided							
Aquatic invertebrates							
Daphnia magna Waterflea	Static	48 h	Immobility	n	2.5 (100 prod.)	> 2.5 (> 100 prod.)	Janson, G.M., 2009
Algae							
Pseudokirchneriella subcapitata Green algae	Static	72 h	Growth rate Biomass	n	0.08 (3.13 prod.)	E_rC_{10} = 0.44 (16.98 prod.) E_rC_{20} = 0.74 (28.84 prod.) E_rC_{50} = 2.04 (79.4 prod.) E_yC_{10} = 0.095 (3.8 prod.) E_yC_{20} = 0.169 (6.6 prod.)	Hoffmann, F. 2009

Test organism	Test condition	Time	Endpoint	Test conc.	NOEC [mg ai/L]	EC_{50}/LC_{50} [mg ai/L]	Reference
						E_yC_{50} = 0.49 (19.02 prod.)	
Aquatic macrophytes							
No studies provided							

For the Metabolite RPA 407922 no PEC_{SW} values are available as after re-evaluation in the e-fate section it is considered not to occur at significant amounts in environmental compartments. Two unknown fractions were discovered during the re-evaluation process. For these unknown metabolites Met 6 (MWT 333) and Met 7 (MWT 315) no toxicity studies are available.

Long-term toxicity endpoint for fish:

An ELS study with *Pimephales promelas* [redacted] 1998b) is available resulting in an endpoint < 0.024 mg ai/L. As this endpoint is an < value, it comprises some uncertainties. However, a second early life stage test with *Pimephales promelas* was conducted ([redacted] 1998c) resulting in a NOEC of 0.021 mg/L showing that the endpoint for early life stages is in this range.

Furthermore a fish full life cycle test with the same species is available resulting in a NOEC of 0.0114 mg/L. It can therefore be assumed that the early life stage toxicity is covered with this full life cycle study and the endpoint is determined to be 0.0114 mg/L.

The risk assessment for aquatic organisms is based on the recommendations of the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013;11(7):3290).

Table 9.4-4: Summary of maximum observed PEC_{SW} values of triticonazole and metabolites, FOCUS Step 1, 2 and 3

Substance	Winter Cereals (Oct.-Feb.), Application rate: 1 x 12.5 g ai/ha		
	FOCUS Step 1 [µg/L]	FOCUS Step 2 [µg/L]	
		Northern EU	Southern EU
Triticonazole	3.07	1.52	1.23
RPA 406341	0.74	0.35	0.28
RPA 404766	0.55	0.27	0.21
RPA 406203	1.99	0.99	0.80
Met 6 (MWT 333)	0.41	0.20	0.16
Met 7 (MWT 315)	0.19	0.09	0.07
	FOCUS Step 3 [µg/L]		
Triticonazole	D1	Ditch	0.600
		Stream	0.375
	D2	Ditch	0.915
		Stream	0.571
	D3	Ditch	< 0.001
	D4	Pond	0.098
		Stream	0.100
	D5	Pond	0.082
		Stream	0.101
	D6	Ditch	0.326
	R1	Pond	0.009
		Stream	0.208
	R3	Stream	0.272
	R4	Stream	0.188
	Spring Cereals (March-May), Application rate: 1 x 12.5 g ai/ha		
	FOCUS Step 1 [µg/L]	FOCUS Step 2 [µg/L]	
		Northern EU	Southern EU
Triticonazole	3.07	0.66	1.23
RPA 406341	0.74	0.14	0.28
RPA 404766	0.55	0.11	0.21
RPA 406203	1.99	0.43	0.80
Met 6 (MWT 333)	0.41	0.08	0.16
Met 7 (MWT 315)	0.19	0.04	0.07
	FOCUS Step 3 [µg/L]		
Triticonazole	D1	Ditch	0.235
		Stream	0.147
	D3	Ditch	< 0.001
	D4	Pond	0.037
		Stream	0.037
	D5	Pond	0.012
		Stream	0.014
	R4	Stream	0.066

For a detailed summary of the FOCUS PEC_{SW} values please refer to section B.8.

B.9.4.1. Acute risk

Acute risk to fish

The Tier 1 LC_{50} for fish was determined to be 3.6 mg ai/L, resulting in a $RAC_{fish\ acute}$ of 360 µg ai/L.

No acute fish study was conducted with the EU representative formulation BAS 59501 F as aquatic invertebrates and algae showed to be more sensitive.

No metabolites were tested with fish, therefore a 10 - fold toxicity from the parent is assumed as a worst case scenario.

Table 9.4-5: Tier 1acute risk assessment for fish – FOCUS PEC_{SW} Step 1- Cereals, 1 x 12.5 g ai/ha

Crop	Species	Test substance	96-h LC_{50} (µg ai/L)	PEC_{SW} (µg/L)	Tier 1 $RAC_{sw:ac}$ (µg/L)
FOCUS Step 1					
Winter Cereals/Spring Cereals	*Oncorhynchus mykiss*	Triticonazole	3600	3.07	36
	Calculated value[a]	RPA 406341	378	0.74	3.78
	Calculated value[a]	RPA 404766	378	0.55	3.78
	Calculated value[b]	RPA 406203	360	1.99	3.60
	Calculated value[c]	Met 6 (MWT 333)	377	0.41	3.77
	Calculated value[d]	Met 7 (MWT 315)	357	0.19	3.57

Values in **bold** are below PECsw, thus indicating an unacceptable risk

[a]calculated by considering the molecular weight of the metabolite of 333.8 g/mol and assuming 10-times more toxicity than the parent

[b]calculated by considering the molecular weight of the metabolite of 317.8 g/mol and assuming 10-times more toxicity than the parent

[c]calculated by considering the molecular weight of the metabolite of 333 g/mol and assuming 10-times more toxicity than the parent

[d]calculated by considering the molecular weight of the metabolite of 315 g/mol and assuming 10-times more toxicity than the parent

Based on a Tier 1 risk assessment considering FOCUS Step 1 values the acute risk to fish from exposure to the active substance triticonazole can be considered acceptable. The risk considering the RPA 406203, RPA 406341, RPA 404766 and RPA 407922 was identified to be acceptable taking into account FOCUS Step 1 PEC_{sw} values and the assumption that the metabolites are 10-fold more toxic than the parent.

Acute risk to aquatic invertebrates

The Tier 1 EC_{50} for *Daphnia magna* was determined to be 7.85 mg ai/L, resulting in a $RAC_{daphnid\ acute}$ of 78.5 µg ai/L. The Tier 1 LC_{50} for *Americamysis bahia* was determined to be 1.9 mg ai/L, resulting in a $RAC_{mysidopsis\ acute}$ of 19 µg ai/L. In addition, a daphnid study with the EU representative formulation was submitted resulting in an EC_{50} of > 2.5 mg ai/L based on nominal concentrations. As the mysid seems to be more sensitive, but the endpoint is a greater as value, the following risk assessment is based on *Mysidopsis bahia* and *Daphnia magna*. The metabolites RPA 406203, RPA 406341, RPA 404766 and RPA 407922 were also tested on *Daphnia magna*.

Table 9.4-6: Tier 1 acute risk assessment for aquatic invertebrates – FOCUS PEC_{SW} Step 1 - Cereals, 1 x 12.5 g ai/ha

Crop	Species	Test substance	48 h EC_{50} (µg ai/L)	PEC_{SW} (µg/L)	Tier 1 $RAC_{sw;ac}$ (µg/L)
FOCUS Step 1					
Winter Cereals/Spring Cereals	*Daphnia magna*	triticonazole	7850	3.07	78.5
		Premis 25 FS	2500	3.07	25
		RPA 406341	51780	0.74	517.8
		RPA 404766	100000	0.55	1000
		RPA 406203	3400	1.99	34
	Calculated value[a]	Met 6 (MWT 333)	823	0.41	8.23
	Calculated value[b]	Met 7 (MWT 315)	778	0.19	7.78
	Mysidopsis bahia	triticonazole	1900	3.07	19

Values in **bold** are below PECsw, thus indicating an unacceptable risk
[a]calculated by considering the molecular weight of the metabolite of 333 g/mol and assuming 10-times more toxicity than the parent
[b]calculated by considering the molecular weight of the metabolite of 315 g/mol and assuming 10-times more toxicity than the parent

Based on a Tier 1 risk assessment considering FOCUS Step 1 PEC_{sw} values an acceptable acute risk to aquatic invertebrates from exposure to the active substance triticonazole was identified. The risk considering the RPA 406203, RPA 406341, RPA 404766 and RPA 407922 was identified to be acceptable taking into account FOCUS Step 1 PEC_{sw} values, respectively.

Risk to algae

The Tier 1 E_rC_{50} for algae (*Skeletonema costatum*) was determined to be greater than 0.53 mg ai/L, resulting in a RAC_{algae} of 53 µg ai/L. A study with the representative formulation was conducted on *Pseudokirchneriella subcapitata*, resulting in an E_rC_{50} of E_rC_{50} = 2.04 mg ai/L.

Additionally a study with the metabolite RPA 406203 on *Pseudokirchneriella subcapitata* is available. For the other metabolites a 10 - fold toxicity from the parent is assumed as a worst case scenario.

Table 9.4-7: Tier 1 risk assessment for algae – FOCUS PECSW Step 1 - Cereals, 1 x 12.5 g ai/ha

Crop	Species	Test substance	72- h E_rC_{50} (µg ai/L)	PEC_{SW} (µg/L)	Tier 1 $RAC_{sw;chr}$ (µg/L)
FOCUS Step 1					
Winter Cereals/Spring Cereals	*Skeletonema costatum*	Triticonazole	530 (96 h)	3.07	53
	Pseudokirchneriella subcapitata	Premis 25 FS	2040	3.07	204
	Calculated value[a]	RPA 406341	55.7	0.74	5.57
	Calculated value[a]	RPA 404766	55.7	0.55	5.57
	Pseudokirchneriella subcapitata	RPA 406203	64830	1.99	6483

Crop	Species	Test substance	72- h E_rC_{50} (µg ai/L)	PEC_{SW} (µg/L)	Tier 1 $RAC_{sw;chr}$ (µg/L)
	Calculated value[b]	Met 6 (MWT 333)	55.5	0.41	5.55
	Calculated value[c]	Met 7 (MWT 315)	52.5	0.19	5.25

Values in **bold** are below PECsw, thus indicating an unacceptable risk
[a]calculated by considering the molecular weight of the metabolite of 333.8 g/mol and assuming 10-times more toxicity than the parent
[b]calculated by considering the molecular weight of the metabolite of 333 g/mol and assuming 10-times more toxicity than the parent
[c]alculated by considering the molecular weight of the metabolite of 315 g/mol and assuming 10-times more toxicity than the parent

Based on a Tier 1 risk assessment considering FOCUS Step values an acceptable risk to algae from exposure to the active substance triticonazole was identified. The risk considering the RPA 406203, RPA 406341, RPA 404766 and RPA 407922 was identified to be acceptable taking into account FOCUS Step 1 PEC_{sw} values,

B.9.4.2. Chronic risk

Chronic risk to fish

The Tier 1 risk assessment was conducted based on the results of the 6-month FFLC study ([redacted] 2008) with *Pimephales promelas* providing a NOEC of 0.0114 mg ai/L resulting in a $RAC_{fish\ chronic}$ of 1.14 µg ai/L.

Table 9.4-8: Tier 1 chronic risk assessment for fish– FOCUS PEC_{SW} Step 1, Step 2 and Step 3 - Cereals, 1 x 12.5 g ai/ha

Crop	Species	Test substance	190-d NOEC (µg/L)	FOCUS Scenario	PEC_{SW} (µg/L)	Tier 1 $RAC_{sw;chr}$ (µg/L)
FOCUS Step 1						
Winter Cereals/Spring Cereals	*Pimephales promelas*	Triticonazole	11.4	n/a	3.07	**1.14**
FOCUS Step 2						
Winter Cereals	*Pimephales promelas*	Triticonazole	11.4	Northern	1.52	**1.14**
				Southern	1.23	**1.14**
Spring Cereals	*Pimephales promelas*	Triticonazole	11.4	Northern	0.66	1.14
				Southern	1.23	**1.14**
FOCUS Step 3						
Winter Cereals	*Pimephales promelas*	Triticonazole	11.4	D1 Ditch	0.600	1.14
				D1 Stream	0.375	1.14
				D2 Ditch	0.915	1.14
				D2 Stream	0.571	1.14
				D3 Ditch	< 0.001	1.14
				D4 Pond	0.098	1.14
				D4 Stream	0.100	1.14

Crop	Species	Test substance	190-d NOEC (µg/L)	FOCUS Scenario	PEC_{SW} (µg/L)	Tier 1 $RAC_{sw;chr}$ (µg/L)
				D5 Pond	0.082	1.14
				D5 Stream	0.101	1.14
				D6 Ditch	0.326	1.14
				R1 Pond	0.009	1.14
				R1 Stream	0.208	1.14
				R3 Stream	0.272	1.14
				R4 Stream	0.188	1.14
Spring Cereals	*Pimephales promelas*	Triticonazole	11.4	D1 Ditch	0.235	1.14
				D1 Stream	0.147	1.14
				D3 Ditch	< 0.001	1.14
				D4 Pond	0.037	1.14
				D4 Stream	0.037	1.14
				D5 Pond	0.012	1.14
				D5 Stream	0.014	1.14
				R4 Stream	0.066	1.14

Values in **bold** are below PECsw, thus indicating an unacceptable risk

Based on a Tier 1 risk assessment considering FOCUS Step 1, Step 2 and Step 3 PEC_{sw} values an acceptable chronic risk to fish from exposure to the active substance triticonazole was identified.

Chronic risk to aquatic invertebrates

The lowest NOEC for daphnids was determined to be 0.11 mg ai/L based on mean measured concentrations resulting in a $RAC_{daphnids\ chronic}$ of 11 µg ai/L. Additionally a chronic study with *Americamysis bahia* was conducted, providing a 28-d NOEC of 0.041 mg ai/L, resulting in a $RAC_{mysid\ chronic}$ of 4.1 µg ai/L.

Table 9.4-9: Tier 1 chronic risk assessment for aquatic invertebrates– FOCUS PEC_{SW} Step 1 - Cereals, 1 x 12.5 g ai/ha

Crop	Species	Test substance	21-d NOEC (µg/L)	PEC_{SW} (µg/L)	Tier 1 $RAC_{sw;chr}$ (µg/L)
FOCUS Step 1					
Winter Cereals/Spring Cereals	*Daphnia magna*	Triticonazole	110	3.07	11
	Americamysis bahia		41	3.07	4.1

Values in **bold** are below PECsw, thus indicating an unacceptable risk

Based on a Tier 1 risk assessment considering FOCUS Step 1 PEC_{sw} values an acceptable chronic risk to aquatic invertebrates from exposure to the active substance triticonazole was identified.

Sediment dwelling organisms

A study on *Chironomus riparius* was conducted with triticonazole. The reliability of the study is considered questionable. For further details please refer to B-9 AS of the RAR. However a risk assessment with the NOEC of 0.777 mg ai/L is presented in the following:

Table 9.4-10: Tier 1chronic risk assessment for sediment dwelling organisms– FOCUS PEC_{SW} Step 1 and Step 2 - Cereals, 1 x 12.5 g ai/ha

Crop	Species	Test substance	26-d NOEC (µg/L)	PEC_{SW} (µg/L)	Tier 1 $RAC_{sw;chr}$ (µg/L)
FOCUS Step 1					
Winter Cereals/Spring Cereals	*Chironomus riparius*	Triticonazole	77.7	3.07	7.77

Values in **bold** are below PECsw, thus indicating an unacceptable risk

Based on a Tier 1 risk assessment considering FOCUS Step 1 PEC_{sw} values an acceptable chronic risk to sediment dwelling organisms from exposure to the active substance triticonazole was identified, provided that the study on *Chironomus riparius* can be considered valid.

B.9.4.3. Bioaccumulation

The accumulation and elimination of triticonazole has been determined in two fish bioaccumulation studies.
The kinetic bioconcentration factor (BCF_K) of triticonazole was determined to be 72.55 in whole fish. The bioconcentration factor for edible and non-edible tissues was 9.2 and 114.86, respectively. Depuration was very rapid with a calculated elimination half-life of < 1 day.

According to the EFSA Aquatic Guidance Document (EFSA, 2013) a risk assessment addressing biomagnification is not considered necessary as the BCF is below the trigger of 1000 and the elimination of during the 14-day depuration phase is > 95%.
However, the validity of the study used for the derivation of the BCF is questionable as the results of the study indicate uncertainties and some information is missing in the study report (lipid content of fish, TOC, testing of a second concentration). However, even if the validity of the study is questionable, the results have been used to be able to do a risk assessment.
Comment Co-RMS: The BCF studies with triticonazole were evaluated as not acceptable. In addition, no bioaccumulation study was submitted for metabolite RPA 406203 (log Kow =3.5). This should be discussed in this section.
The UK suggests predicting the BCF for triticonazole and metabolite RPA 406203 using EPI Suite. For triticonazole, the predicted BCF value could be compared with the experimental value (although value evaluated as not valid) to provide further weight of evidence of the low bioaccumulation of the active substance in fish.
The RMS agrees that both studies seem not to be valid but is of the opinion that rather a valid Bioconcentration study should be available than using calculated assumptions. It is highly appreciated to receive the opinions from the other member states regarding this issue.

Overall conclusion for the risk assessment for aquatic organisms

For all aquatic organism groups a low risk could be identified due to exposure to the active substance triticonazole and its metabolites at FOCUS step 1-3 for the intended use as a seed treatment. A study with the sediment dwelling organism *Chironomus riparius* was provided, however its validity and reliability, respectively is questionable. The applicant argues that a study with a sediment dwelling organism is not triggered. However, the RMS disagrees and is of the opinion that based on the data situation testing of a sediment dwelling organism is required.

B.9.5. EFFECTS ON ARTHROPODS

B.9.5.1. Effects on bees

Regarding the toxicity data on the technical triticonazole please refer to Volume 3, B.9-CA.

In addition studies with the representative formulation BAS 595 01 F were submitted by the notifier.

B.9.5.1.1. Acute toxicity to bees

Reference:	**Effects of BAS 595 01 F (acute contact and oral) on honey bees (*Apis mellifera* L.)**
Author(s), year:	Hernádi, D., 2007a
Report/Doc. number:	BASF Doc ID: 2007/1052765
Guideline(s):	OECD 213 and 214 (1998)
GLP:	Yes
Deviations:	Please refer to the commenting box below
Validity:	Acceptable

Material and Methods:

Test substance:	BAS 595 01 F, Batch no.: 84108
Active Ingredient:	Triticonazole (BAS 595 F)
Content:	Nominal: 25.0 g/L; analysed: 25.2 g/L
Certificate of Analysis Ref. Code/Date:	173902_8; 06.08.2007
Reference:	BAS 152 11 I; nominal: 400 g dimethoate/L, analysed: 414.4 g dimethoate/L EC
Control:	Oral test: sucrose solution (50 w/v %) with deionized water Contact test: deionized water control with anaesthetization and solvent control with anaesthetization
Solvent:	Acetone solution (50 v/v %)
Test species:	*Apis mellifera* L., adult worker honeybees, approx. 6 week old female bees; honey bee colonies, disease-free and queen-right, bred by Györgyi Purger Pordánné
Type of test:	Acute oral and contact toxicity test
Number of organisms:	Three replicates with 10 bees for the controls and the test item treatment groups
Food:	50 w/v % sucrose solution
Oral toxicity test:	
Applied concentrations:	Sucrose solution control Test item nominal: 6.25, 12.5, 25.0, 50.0, 100.0 and 200.0 µg ai/bee (corresponding to 267.75, 535.5, 1071, 2142, 4284 and 8568 µg formulated product/bee). Test item actual intake: 6.06, 12.02, 24.0, 44.34, 81.17 and 156.96 µg ai/bee (corresponding to 259.61, 514.94, 1028.16, 1899.53, 3477.32 and 6724.17 µg

formulated product/bee).

Toxic reference nominal : 0.07,0.12, 0.19 and 0.30 µg dimethoate/bee

Toxic reference actual intake : 0.07,0.12, 0.18 and 0.29 µg dimethoate/bee

Exposure route: The test item was dispersed in 50% w/v sucrose solution in appropriate concentration and was administered as a single dose of 0.2 ml in the feeders, which were weighed before and after introduction into the cages (after maximum 6 hours the test item treated food was replaced by fresh, untreated food).

Test conditions: Temperature: 25.1-25.4 °C, relative humidity: 52 - 66 %, darkness (except during observations), ventilation to avoid possible accumulation of pesticide vapour

Test parameter: Mortality: number of dead bees after 4 hours (first day); 24 and 48 hours.

Behavioural abnormalities (vomiting, apathy, intensive cleaning): after 4 hours (first day); 24 and 48 hours.

Contact toxicity test:

Applied concentrations: CO_2/water treated control and CO_2/acetone treated control

Test item: 1.25, 2.5, 5.0, 10.0 and 20 µg ai/bee (corresponding to 53.55, 107.1, 214.2, 428.4 and 856.8 µg formulated product/bee)

Toxic reference nominal : 0.07,0.12, 0.19 and 0.30 µg dimethoate/bee

Exposure route: Bees were lightly anaesthetised with CO_2 and 2 µL/bee volume of the test item solution and 1 µl/bee volume of the toxic standards solution were applied to the thorax of each bee.

Test conditions: Temperature: 25.1-25.4 °C, relative humidity: 52 - 66 %, darkness (except during observations), ventilation to avoid possible accumulation of pesticide vapour

Test parameter: Mortality: number of dead bees after 4 hours (first day); 24 and 48 hours.

Behavioural abnormalities (vomiting, apathy, intensive cleaning): after 4 hours (first day); 24 and 48 hours.

Findings:

Oral toxicity test: Mortalities were observed in all treatment groups. No mortality was observed in the control group. Adverse effects on behaviour (partial paralysis, total paralysis, decreased activity) were observed in all treatment groups.

Table 9.5-1: Mortalities and behavioural abnormalities of the bees in the oral toxicity test

Nominal dosage [µg ai/bee]	Time after ingestion					
	4 hours		24 hours		48 hours	
	Mortality mean [%]	Behavioural abnormalities mean [%]	Mortality [mean%]	Behavioural abnormalities mean [%]	Mortality [mean%]	Behavioural abnormalities mean [%]
Water/ sugar control	0.0	0.0	0.0	0.0	0.0	0.0
6.25	6.7	0.0	13.3	0.0	13.3	8.3
12.5	3.3	3.7	16.7	0.0	16.7	12.5
25	3.3	0.0	16.7	0.0	23.3	23.1
50	16.7	11.1	36.7	0.0	40.0	33.3

Nominal dosage	Time after ingestion					
	4 hours		24 hours		48 hours	
100	13.3	4.2	46.7	22.2	50.0	55.6
200	10.0	0.0	60.0	0.0	66.7	80.0
Reference item						
0.07	0.0	0.0	13.3	0.0	13.3	0.0
0.12	26.7	13.9	40.0	32.1	40.0	51.1
0.19	53.3	36.1	96.7	0.0	96.7	0.0
0.30	70.0	11.1	96.7	100.0	96.7	100.0

Table 9.5-2: Mortalities and behavioural abnormalities of the bees in the contact toxicity test

Nominal dosage [µg ai/bee]	Time after ingestion					
	4 hours		24 hours		48 hours	
	Mortality mean [%]	Behavioural abnormalities mean [%]	Mortality [mean%]	Behavioural abnormalities mean [%]	Mortality [mean%]	Behavioural abnormalities mean [%]
CO_2/water control	0.0	0.0	0.0	0.0	3.3	0.0
CO_2/solvent control	0.0	0.0	3.3	0.0	3.3	0.0
1.25	0.0	0.0	0.0	0.0	0.0	0.0
2.5	0.0	0.0	0.0	0.0	6.7	0.0
5	0.0	0.0	3.3	0.0	3.3	0.0
10	0.0	0.0	0.0	0.0	3.3	0.0
20	0.0	0.0	3.3	0.0	6.7	0.0
Reference item						
0.07	0.0	0.0	6.7	0.0	13.3	12.5
0.12	20.0	0.0	50.0	42.2	53.3	52.8
0.19	33.3	15.9	83.3	100.0	83.3	100.0
0.30	36.7	8.3	100.0	-	100	-

Conclusions:

48 h LD_{50} = 76.74 µg ai/bee (oral toxicity)

48 h LD_{50} > 20 µg ai/bee (contact toxicity)

Reference item: 24h LD_{50} = 0.12 µg/bee

Comment RMS:	The study was evaluated following the recommendations of the currently valid test guideline OECD 213 (1998) for oral toxicity and OECD 214 (1998) for contact toxicity Please note that no certificate of analysis was provided along with the study report and only a reference code and date is given. **Check of validity criteria:** - The average mortality for the total number of controls must not exceed 10% at

	the end of the test. In the current test 3.3% mortality was observed in the controls of the contact toxicity test. Fulfilled. - The LD_{50} of the toxic standard meets the specified range (0.10-0.35 µg dimethoate/bee for the oral test and 0.1-0.3 µg dimethoate/bee for contact test). In the current study the LD_{50} for the toxic standard was 0.12 µg dimethoate/bee for oral and contact testing. Fulfilled. **In addition, the following points deviated from the test guideline or were not reported in detail:** - According to OECD 214 a volume of 1 µl of solution containing the test substance at the suitable concentration should be applied. In the current study, 2µl of the test substance in solvent was applied. **Acceptability of the analytical methods used in the test:** No information regarding the analytical methods was reported. **Endpoints:** The RMS agrees on the endpoints given in the study report. 48 h LD_{50} = 76.74 µg ai/bee (oral toxicity), corresponding to 3287.54 µg formulated product/bee 48 h LD_{50} > 20 µg ai/bee (contact toxicity), corresponding to 856.8 µg formulated product/bee **Conclusion of the RMS:** Based on the evaluation of the study the acute oral and contact honey bee toxicity test is considered valid.

B.9.5.1.2. Chronic toxicity to bees

According to the data requirements for active substances (Commission Regulation (EU) 283/2013) and/or plant protection products (Commission Regulation (EU) 284/2013) the chronic risk to adult honeybees has to be evaluated.

The applicant addressed the chronic toxicity with a formulation study only. This is considered acceptable by the RMS.

Reference:	**Chronic oral toxicity test of BAS 595 01 F on the honey bee (*Apis mellifera* L.) in the laboratory**
Author(s), year:	Schmitzer, S., 2014a
Report/Doc. number:	BASF DocID: 2014/1000023
Guideline(s):	OECD 213 (1998) and CEP No.: 230 with modifications
GLP:	Yes
Deviations:	Please refer to the commenting box below
Validity:	Acceptable

Material and Methods:

Test substance:	BAS 595 01 F, Batch no.: 84210
Active Ingredient:	Triticonazole (BAS 595 F)
Content:	Nominal: 25 g/L; analytical: 26.1 g/L (according to certificate of analysis)
Certificate of Analysis Study Code:	432805_2
Reference:	BAS 15211 I (Perfekthion EC); nominal: 400 g dimethoate/L; analytical: 411.7 g dimethoate/L
Control:	Control: 50% aqueous water/sugar syrup solution, blanc control corresponding to the highest test item rate of the blanc formulation and 50% syrup
Test species:	*Apis mellifera* L., adult worker honeybees (1 day old)
Type of test:	10 days chronic oral feeding test (dose-response test)
Number of organisms:	Three replicates with 10 bees each for controls and the test item treatment groups
Applied concentrations:	Control, Blanc control Test item: 156.3, 312.5, 625, 1250 and 2500 mg ai/kg food (ppm) Target Dose level: 6.3, 12.5, 25, 50 and 100 µg ai/bee/day Toxic reference nominal: 0.04 µg dimethoate/bee/day Toxic reference actual intake: 0.19 µg dimethoate/bee/day
Exposure route:	Over a period of 10 days, honeybees were fed continuously *ad libitum* with 50 % (w/v) aqueous solution of commercial ready-to-use syrup, containing either a respective concentration of the test and reference item or the blanc formulation at the highest test item rate (blanc control). Every day the feeder was replaced by a new one with fresh treated or untreated food.

Test conditions: Temperature: 32-34 °C, short term deviations (< 2 hours) are not reported, relative humidity: 41 – 79 %, average: 72% darkness (except during observation); ventilation to avoid possible accumulation of pesticide vapour.

Test parameter: Mortality counts and checks for behavioural abnormalities (e.g. apathy, intensive cleaning, vomiting, movement coordination problems, cramping) were made every 24 hour (approx. at the same time of day) during the 10 days test period.
Food uptake was recorded daily at approx. the same day time.

Statistics: The LC_{50} and LD_{50} values of the test item were estimated with Probit Analysis (according to Finney 1971).
The NOEC as well as the NOED (daily) and NOED (overall) of the test item were determined using Fisher's Exact Test (pairwise comparison, one-sided greater, $\alpha = 0.05$).
Statistical analysis were performed by using ToxRat Professional, Version 2.10.05, ® ToxRat Solutions GmbH.

Findings:

The actual mean dose levels based on daily actual intake were 4.47, 8.00, 12.2, 20.2 and 25.8 µg ai/bee/day after 10 days corresponding to overall doses of 44.7, 80.0, 122, 202 and 258 µg ai/bee. At test end, 3.3, 6.7, 40.0, 86.7 and 100.0 % mortality occurred dose dependent.

In the blanc control group 96.7% mortality occurred on day 10.

No mortality occurred in the untreated water control with 50 % aqueous sugar syrup solution. The reference item at a concentration of 0.019 µg dimethoate/bee/day caused 100% mortality at day 5.

On day 3 and 5 some bees in the 25.8 µg ai/bee/day group showed movement coordination problems or apathy. At a dose of 20.2 µg ai/bee/day some bees had movement coordination problems or were apathetic on days 6, 8 and 9. In the 4.47 µg ai/bee/day dose level, one bee showed a discoordinated movement on day 4.

Several bees in the blanc formulation group had movement coordination problems from day 2 until day 9 (with exception of day 5).

Table 9.5-3: Uptake of BAS 59501 F by bees during 10 days oral exposure in a chronic toxicity test

Nominal dose of active ingredient [mg ai/kg]	Mean consumed feeding solution per bee/day over the test period [mg]	Mean actual dose of active ingredient per bee/day [µg ai/kg]	Accumulated uptake of active ingredient over the test period [µg ai/kg]
Water/sugar control	27.7	0.0	0.0
Blanc control 2500	21.8	21.8	0.0
2500.0	11.2	25.8	206.6
1250.0	16.2	20.2	201.9
625.0	19.6	12.2	122.5
312.5	25.6	8.00	80.0
156.3	28.6	4.47	44.7
Reference item 1.0 mg /kg	19.4	0.019	0.097

Table 9.5-4: Effects of BAS 59501 F on *Apis mellifera* following 10 days oral exposure in a chronic toxicity test

Nominal dose [mg ai/kg]	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
Cumulative mortality [%]										
Water/sugar control	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Blanc control 2500	0.0	0.0	16.7	43.3	46.7	50.0	66.7	83.3	96.7	96.7
2500.0	0.0	0.0	0.0	13.3	50.0	86.7	86.7	100.0	100.0	100.0
1250.0	0.0	0.0	0.0	0.0	0.0	10.0	13.3	43.3	73.7	86.7
625.0	0.0	0.0	0.0	3.3	3.3	3.3	3.3	10.0	26.7	40.0
312.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	6.7	6.7	6.7
156.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.3	3.3
Reference item	0.0	0.0	0.0	30.0	100.0	100.0	100.0	100.0	100.0	100.0
Mean consumption of feeding solution per bee [mg/bee]										
Water/sugar control	4.33	18.0	35.4	37.4	36.8	30.0	31.4	29.8	24.6	29.3
Blanc control	3.77	6.87	17.0	17.2	24.0	17.6	22.9	19.5	30.4	59.0
2500.0	3.50	4.20	10.8	16.3	17.3	15.5	11.8	10.3	-	-
1250.0	5.73	5.57	14.6	21.2	23.4	16.0	16.6	14.0	14.1	30.4
625.0	3.30	11.8	25.3	29.6	25.5	22.4	19.9	21.9	15.4	20.8
312.5	3.63	12.3	34.3	40.8	28.9	32.7	26.5	28.8	22.2	25.7
156.3	3.37	18.7	34.4	39.9	41.6	22.7	32.7	39.3	26.8	26.5
Reference item	3.07	13.2	34.7	27.1	18.8	-	-	-	-	-
Mean nominal intake of active substance per bee [µg ai/bee]										
Water/sugar control	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Blanc control	-	-	-	-	-	-	-	-	-	-
2500.0	8.75	10.5	26.9	40.8	43.2	38.6	29.4	8.54	-	-
1250.0	7.17	6.96	18.3	26.5	29.3	20.0	20.7	17.5	17.6	38.0
625.0	2.06	7.35	15.8	18.5	16.0	14.0	12.4	13.7	9.65	13.0
312.5	1.14	3.83	10.7	12.8	9.0	10.2	8.27	9.01	6.95	8.02
156.3	0.53	2.92	5.38	6.24	6.50	3.54	5.11	6.14	4.18	4.15
Reference item	0.003	0.013	0.035	0.027	0.019	-	-	-	-	-
Mean behavioural abnormalities [%]										
Water/sugar control	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Blanc control	0.0	3.3	10.0	0.0	0.0	20.0	16.7	10.0	3.3	0.0
2500.0	0.0	0.0	6.7	0.0	23.3	0.0	0.0	0.0	0.0	0.0
1250.0	0.0	0.0	0.0	0.0	0.0	3.3	0.0	16.7	3.3	0.0
625.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
312.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
156.3	0.0	0.0	0.0	3.3	0.0	0.0	0.0	0.0	0.0	0.0
Reference item	0.0	0.0	3.3	40.0	-	-	-	-	-	-

D…Day

Conclusions:

10 days LC_{50} = 674.2 mg ai/kg food (95 % C.I. = 565.0 – 805.0 mg/kg)

10 days $LD_{50(daily)}$ = 12.9 µg ai/bee/day (95 % C.I. = 7.34 – 20.3 µg/bee/day)

10 days $LD_{50(overall)}$ = 129 µg ai/bee (95 % C.I. = 73.4 – 203 µg /bee)

10 days NOEC = 312.5 mg ai/kg food

10 days $NOED_{(daily)}$ = 8.0 µg ai/bee/day

10 days $NOED_{(overall)}$ = 80.0 µg ai/bee

Comment RMS:	The study was evaluated following the recommendations of the currently valid test guideline OECD 245 (2017) **Check of validity criteria:** - The average mortality across replicates for the untreated control and solvent control groups is ≤ 15 % at the end of the test (10 days following start of exposure). In the current study no mortality occurred in the water control. Fulfilled. - The average mortality in the reference substance treated group is ≥ 50 % at the end of the test (10 days following start of exposure). In the current study 100% mortality (on day 5) occurred in the reference item group. Fulfilled. **In addition, the following points deviated from the test guideline or were not reported in detail:** - According to OECD 245 the bees should be kept at a relative humidity of 50-70%. In the current study the relative humidity was 41-79%; average: 72% - According to OECD 245 sampling for analytical determination of the feeding solution is required. In the current study no information about sampling or analytical determination is reported. - According to OECD 245 it is necessary to adjust for possible evaporation of test solutions from the feeders with additional test cages which are set up at the main test. In the current study consideration of possible evaporation is not reported. **Acceptability of the analytical methods used in the test:** No information regarding the analytical methods was reported. **Endpoints:** The RMS agrees on the endpoints given in the study report. 10 days LC_{50} = 674.2 mg ai/kg food (95 % C.I. = 565.0 – 805.0 mg/kg) 10 days $LD_{50(daily)}$ = 12.9 µg ai/bee/day (95 % C.I. = 7.34 – 20.3 µg/bee/day) 10 days $LD_{50(overall)}$ = 129 µg ai/bee (95 % C.I. = 73.4 – 203 µg /bee) 10 days NOEC = 312.5 mg ai/kg food 10 days $NOED_{(daily)}$ = 8.0 µg ai/bee/day 10 days $NOED_{(overall)}$ = 80.0 µg ai/bee **Conclusion of the RMS:** Based on the evaluation of the study chronic adult honey

	bee toxicity test is considered valid.

B.9.5.1.3. Effects on honeybee development and other honeybee life stages

A honeybee brood study with the solo formulation BAS 595 01 F was conducted to address the risk on the bee brood.

Reference:	**Acute toxicity of BAS 595 01 F to honeybee larvae (*Apis mellifera* L.) under laboratory conditions (in vitro)**
Author(s), year:	Kleebaum, K., 2014b
Report/Doc. number:	BASF Doc ID: 2014/1000024
Guideline(s):	OECD 237 (2013)
GLP:	Yes
Deviations:	Please refer to the commenting box below
Validity:	Acceptable

Material and Methods:

Test substance:	BAS 595 01 F, batch no.: 84210
Active Ingredient:	Triticonazole (BAS 595 F)
Content:	Nominal: 25 g/L; analytical: 26.1 g/L
Reference:	Dimethoate tech.; 99.8 % analysed purity
Control:	Untreated diet C (50% aqueous sugar solution with 50% royal jelly)
Test species:	*Apis mellifera* L., worker honeybee larvae, first instar stage (one day old) during grafting; larvae from healthy, disease free and queen-right bee colonies; Bienenfarm Kern GmbH
Type of test:	Feeding test
Number of organisms:	12 larvae per replicate; 3 replicates per treatment group, control and toxic reference
Range finder test (non-GLP)	A preliminary rangefinder test was performed under non-GLP conditions to determine the definitive dosages.
Applied concentrations:	Control: Diet C Treatment: 99.1, 49.6, 24.8, 12.4, and 6.2 µg ai/larva (corresponding to 4238.7, 2119.3, 1059.7, 529.8 and 264.9 µg product/larva) Toxic reference: 8.8, 4.4, 2.2 and 1.1 µg dimethoate/larva
Test conditions:	Climatic chamber (Type: Binder KBF 720); temperature: 34.0-34.5 °C; relative humidity: 93-97% with two short periods of lower humidity; constant darkness (diffuse artificial light only during handling and assessments); conditions continuously recorded.
Test parameter:	Number of dead larvae after 24, 48, 72 and 96 hours, notification of larger

amounts of unconsumed food on D7 and D8 or substantially undersized larvae (in comparison to control treatment)

Statistics: For statistical calculation of the mortality results and for determination NOEC/NOED the Fisher's Exact Binomial test (with Bonferroni Correction) was used ($p \leq 0.05$ one-sided greater).

Findings: On D7 deviations to the normal food consuming behaviour and correspondingly to developing into an average sized larva occurred in the treatment groups 99.1, 49.6 and 24.8 µg ai

The concentration of active substance in the test item stock solution A was 100% of the nominal concentration and therefore within acceptable parameters as defined in the study plan.

Table 9.5-5: Effects of BAS 595 01 F on *Apis mellifera* following exposure to larvae

Dosage [µg a.s/larva]	Mortality				Other observations
	Cumulative mortality [number of larvae] after			% mortality after D7/corrected mortality	Number/% of larvae with food left or small size after D7
	D5	D6	D7		
Control	0	0	1	2.8	1/3
99.1	0	10	19	52.8/51.4	17/100
49.6	0	9	13	36.1/34.3	9/39.7
24.8	0	0	3	8.3/5.7	3/9.4
12.4	0	0	0	0.0/0.0	0/0.0
6.2	0	1	1	2.8/0.0	1/2.8
Reference Item:					
8.8	0	12	22	61.1/60.0	10/76.7
4.4	0	7	16	44.4/42.9	12/59.9
2.2	0	6	17	47.2/45.7	2/8.3
1.1	0	5	9	25.0/22.9	2/7

Conclusions:

72 hour LC_{50} = 2.526 g ai/kg food (95% C.I.: 1.917-3.328 a.s/kg)

72 hour LD_{50} = 85.6 µg ai/larva (95% C.I. = 65.0-112.8 µg/larva)

72 hour NOEC = 0.731 g a.s/kg food

72 hour NOED = 24.8 µg ai/larva

Comment RMS: The study was evaluated following the recommendations of the currently valid test guideline OECD 237 (2013)

Check of validity criteria:

- In the control plate(s), cumulative larval mortality from D4 to D7 should be ≦ 15% across replicates. In the current study the mortality was 2.8% on D7. Fulfilled.
- In the reference chemical treatment, larval mortality (after adjustment, see

	paragraph 33) should be ≧ 50% at D7. In the current study the mortality for the reference item was 61.1 at 8.8 µg dimethoate/larva on D7. Fulfilled. **In addition, the following points deviated from the test guideline or were not reported in detail:** - According to OECD 237 the diet should be stored in a fridge at ≦ +5°C. In the current test the diet was stored at 8-10°C. **Acceptability of the analytical methods used in the test:** The evaluation of the analytical methods was conducted according to the Guidance Document SANCO/3029/99 rev. 4. Based on the evaluation (see Volume 3 B.5-CA, B.5.1.2.6) it could be demonstrated that the analytical method was sufficiently validated for determination of triticonazole in sugar solution. LOQ: 3489 mg ai/L. **Endpoints:** The RMS agrees in on the endpoints given in the study report 72 hour LC_{50} = 2.526 g ai/kg food (95% C.I.: 1.917-3.328 a.s/kg) 72 hour LD_{50} = 85.6 µg ai/larva (95% C.I. = 65.0-112.8 µg/larva) 72 hour NOEC = 0.731 g ai/kg food 72 hour NOED = 24.8 µg ai/larva **Conclusion of the RMS:** Based on the evaluation of the study acute larval honey bee toxicity test is considered valid.

B.9.5.1.4. Cage and tunnel tests

Based on the results reported in the available laboratory studies (acute oral and contact toxicity to honey-bees, chronic toxicity to adult honey-bees and effects on larvae of honey-bees), no further studies are required addressing the risk to honey-bees.

B.9.5.1.5. Field tests

Based on the results reported in the available laboratory studies (acute oral and contact toxicity to honey-bees, chronic toxicity to adult honey-bees and effects on larvae of honey-bees), no further studies are required addressing the risk to honey-bees.

B.9.5.2. Effects on non-target arthropods other than bees

The applicant provided studies on *Poecilus cupreus* and *Aleochara bilineata* with the representative formulation BAS 595 F 01. The study reports are summarised below. During the first approval of triticonazole, several laboratory studies with formulated triticonazole have been performed with the arthropod species *Aphidius rhopalosiphi, Typhlodromus pyri*, *Poecilus cupreus* and *Aleochara bilineata*. As the current submission is a seed treatment the studies with *Aphidius rhopalosiphi* and *Typhlodromus pyri* are not considered relevant. Furthermore the studies with *Poecilus cupreus* and *Aleochara bilineata* were conducted with formulations

containing two active substances. These studies were therefore not re-evaluated and only references are given below.

Mead-Briggs M., 1998b - A laboratory evaluation of the effects of EXP 80523A on the parasitic wasp, Aphidius rhopalosiphi

Document number: R005707

Moll M.G., Bützler R., 2002 - Effects of EXP80472B on the parasitoid Aphidius rhopalosiphi in the laboratory – dose response test

Document number: C020491

Vinall S., 1998 - A laboratory evaluation of the effects of EXP 80523A on the phytoseiid mite Tyhplodromus pyri

Document number: R005711

Vinall S., 1998 – Toxicity to the predatory mite Tyhplodromus pyri SCHEUTEN (Acari, Phytoseeidae) in the labaratory EXP80472B

Document number: C02379

Kühner Ch., 1996a– EXP 80560B: Acute toxicity to the ground beetle, Poecilus cupreus L. (Coleoptera, Carabidae) in the Laboratory

Document number: R005429

Kühner Ch., 1996b– EXP 80527B: Acute toxicity to the ground beetle, Poecilus cupreus L. (Coleoptera, Carabidae) in the Laboratory

Document number: R005451

Kühner Ch., 1996c– EXP 80560B: Acute toxicity to the rove beetle, Aleochara bilineata Gyll. (Coleoptera, Staphilinidae)) in the Laboratory and Addendum

Document number: R005432 and C018900

Kühner Ch., 1996d– EXP 80527B: Acute toxicity to the rove beetle, Aleochara bilineata Gyll. (Coleoptera, Staphilinidae) in the Laboratory

Document number: R005447

Reference:	**Effects of BAS 595 01 F applied as a seed treatment of wheat seeds on larvae of the ground dwelling arthropod *Poecilus cupreus* (Coleoptera, Carabidae) in an extended laboratory trial**
Author(s), year:	Drexler, A., 2004a
Report/Doc. number:	BASF DocID 2004/1025180
Guideline(s):	Heimbach, *et al.* (2002) – draft guideline
GLP:	Yes
Deviations:	Please refer to the commenting box below
Validity:	Acceptable

Material and Methods:

Test substance:	BAS 590 01 F, batch no.: 84002-1; triticonazole content nominal: 2.50 g/100 kg coated seeds, analysed: 2.23 g/kg coated seeds
Control:	Wheat seeds ISENGRAIN, untreated
Toxic reference:	BAS 152 11 I; dimethoate content nominal: 400 g/L, analysed: 401.2 g/L
Test species:	*Poecilus cupreus*, maximum 45:25 hours old larvae at start of exposure, BTL Bio Test Labor GmbH Sagerheide
Type of test:	Extended laboratory test, 70 days
Number of organisms:	40 replicates for treatment, reference and control, 1 beetle larva each
Test substrate:	LUFA 2.1-soil; adjusted 19 days before treatment to 20% of its maximum water holding capacity. One day before the treatment, the actual water content of the soil was measured and adjusted to 35% of its maximum water holding capacity. On the day of treatment the water content was measured again. Until start of the bioassay, the soil was stored under test conditions in a climatic room.
Treatments:	Control: 290 kg seeds/ha untreated wheat seeds. Test item: 290 kg coated seeds/ha, equivalent to 7.25 g/ha triticonazole, equivalent to 5 seeds per test unit. Worst-case exposure as intended application rate was 250 kg coated seeds/ha (4.31 seeds per test unit). Toxic reference: 500 mL/ha BAS 152 11 I
Exposure route:	Round glass beakers (inner dimensions: 9.1 cm diameter, height 5.5 cm) were used as test units. The test units (surface area 65 cm^2) were filled with 60 g moistened LUFA 2.1 soil (1 cm fill height). Then, 5 wheat seeds were laid in two rows with similar distance between each other on the soil surface. Afterwards, the remaining soil was filled in the glass beaker (total fill height of 4 cm), which concluded in a sowing depth of 3 cm. The larvae were introduced into the test units within about two hours after application.
Feeding:	Fly pupae (*Calliphora* sp.) obtained from commercial supplier. Beetles were fed in the first 2 weeks 3 x per week, then, from the 3rd to the 6th week 2 x per week and afterwards until end of the bioassay 1 y per week.

Test conditions: Acclimation: temperature: 19.7-19.8°C; relative humidity: 65.7-73.0 %, darkness
Exposure: temperature: 17.6-22.8°C; humidity: 55.6-83.2%; 24 hours darkness

Test parameter: Development time: Daily check of beetles hatch, by the beginning of the 6th week of exposure. Weight of beetles already seen with dark colour; determination of sex.
Mortality: Determination if hatched beetles were alive or dead, weighing of beetles already seen with dark colour

Statistics: Fisher's Exact test (α = 0.05) for mortality; 2 sample t-test (α = 0.05) for weight and Wilcoxon's Rank Sum test (α = 0.05) for development time.
For statistical analysis Toxstat 3.5 (Western EcoSystems Technology) was used.

Findings:

Table 9.5-6: Mortality of *Poecilus cupreus* larvae following exposure of BAS 590 01 F under extended laboratory conditions

Nominal application rate	Mortality after 70 days (out of 40 individuals/treatment)	Corrected mortality[a]
Control - untreated	10% (4/40)	-
BASF 595 01 F (100 mL/100 kg wheat seeds)	5% (2/40)	-5.6 %
Toxic reference,BAS 152 11 I (500 mL/ha)	97.5% (39/40)*	97.2

[a]According to Schneider-Orelli, negative value means decreased mortality compared to the control.
*Statistically significant compared to the control (Fisher Exact Test; α = 0.05)

Table 9.5-7: Effects on development time and hatching weight of *Poecilus cupreus* larvae following exposure of BAS 590 01 F under extended laboratory conditions

	Sowing rate of seeds [kg/ha]	Rate [g ai/ha]	Mean hatching weight [mg]	Effect on mean hatching weight [%]	Mean development time [days]	Delay in mean development time [days]
Control	290	-	61.4	-	48.4	-
BAS 595 01 F	290	7.25	57.7	6.0	48.6	0.2
Reference Item	-	200	50.0	18.6	80.0	31.6

Conclusion: No effects on survival and the sublethal parameters hatching weight and development time of the larvae were observed when exposed to wheat seeds coated with 100 mL BAS 595 01 F per 100 kg seeds and sown at a rate of 290 kg seeds/ha.

Comment RMS: The study was evaluated following the recommendations of the currently valid test guideline IOBC (2000), Heimbach et. al., A method for testing effects of plant protection products on the carabid beetle *Poecilus cupreus* (Coleoptera, Carabidae) under laboratory and semi-field conditions.

	It has to be noted that the study design was adapted to an extended laboratory test with larvae of *Poecilus cupreus* tested instead of the adult beetles and duration of 70 days. Therefore for the evaluation of the study *Heimbach, U. et al 2002; First ring test results of a laboratory method to evaluate effects of plant protection products on larvae of Poecilus cupreus (Coleoptera: Carabidae),* has also been considered. **Check of validity criteria (derived from Heimbach, U. *et.al*., 2002)** - Control Mortality should not be more than 10%. In the current study the mortality was 10% after 70 days. Fulfilled. - The application of the reference item (approx. 45 g dimethoate/ha) should result in a mortality rate of 36 to 100% after 28 days. In the current study the mortality for the reference item was 97.2% after 70 days at an application rate of 200 g dimethoate/ha. Fulfilled. **In addition, the RMS would like to point out the following uncertainty:** - According to Heimbach, 2002 the temperature should be 20 ± 2 °C. Result of the ring testing shows that already small differences in temperature may influence the development time of the larvae. In the current test the temperature ranged between17.6 and 22.8 °C. No detailed information is reported about the temperature measurement method and no temperature curves are given. **Acceptability of the analytical methods used in the test:** No information regarding the analytical methods was reported. **Endpoints:** The RMS agrees on the endpoints given in the study report No statistically significant effects at an application rate of 7.25 g ai/ha after 70 days were observed. 70 day ER_{50} > 7.25 g ai/ha **Conclusion of the RMS:** The test application rate was lower than the application rate for the intended use. However, the endpoint is a greater than value and only marginal effects < 10% were observed. Based on the evaluation of the study the chronic toxicity test with *Poecilus cupreus* is considered valid.

Reference:	**Effects of BAS 595 01 F applied as a seed treatment of wheat seeds on larvae of the ground dwelling arthropod *Poecilus cupreus* (Coleoptera, Carabidae) in an extended laboratory trial**
Author(s), year:	Sattler, F., 2009a
Report/Doc. number:	BASF DocID 2009/1098729
Guideline(s):	Heimbach *et al.* (2002) – draft guideline
GLP:	Yes
Deviations:	Please refer to the commenting box below
Validity:	Acceptable

Material and Methods:

Test substance:	BAS 595 01 F (200 mL/ 100 kg seeds), batch no.: FRE-000660; triticonazole content nominal: 5.0 g/100 kg, analysed: 5.1 g/100 kg
Crop, Variety:	Wheat seeds, winter DEKAN
Control:	Wheat seeds, winter DEKAN untreated
Toxic reference:	BAS 152 11 I; dimethoate content nominal: 400.0 g/L, analysed: 422.4 g/L
Test species:	*Poecilus cupreus*; 22-39 hours old larvae; BTL Bio Test Labor GmbH Sagerheide
Type of test:	Extended laboratory test, 70 days
Number of organisms:	40 replicates for treatment, reference and control, 1 beetle larva each
Test substrate:	LUFA 2.1-soil; adjusted 19 days before treatment to 20% of its maximum water holding capacity. One day before the treatment, the actual water content of the soil was measured and adjusted to 35% of its maximum water holding capacity. On the day of treatment the water content was measured again. Until start of the bioassay, the soil was stored under test conditions in a climatic room.
Treatments:	Control: 233 kg seeds/ha untreated wheat seeds Test item: 233 kg coated seeds/ha, equivalent to 11.65 g/ha triticonazole, equivalent to 3 seeds per test unit. (worst-case exposure as intended application rate was 180 kg coated seeds/ha (2.3 seeds per test unit) Toxic reference: 500 mL/ha BAS 152 11 I
Exposure route:	Round glass beakers (inner dimensions: 9.1 cm diameter, height 5.5 cm) were used as test units. The test units (surface area 65 cm^2) were filled with 60 g moistened LUFA 2.1 soil (1 cm fill height). Then, 3 wheat seeds were laid in two rows with similar distance between each other on the soil surface. Afterwards, the remaining soil was filled in the glass beaker (total fill height of 4 cm), which concluded in a sowing depth of 3 cm. The larvae were introduced into the test units within about two hours after application.
Feeding:	Fly pupae (*Calliphora* sp.) obtained from commercial supplier. Beetles were fed in

	the first 2 weeks 3 x per week, then, from the 3rd to the 6th week 2 x per week and afterwards until end of the bioassay 1 x per week.
Test conditions:	Temperature: 19-23 °C; relative humidity: 61 - 88 %, 24 hours dark
Test parameters:	Development time: Daily check of beetles hatch, by the beginning of the 6th week of exposure. Weight of beetles already seen with the dark colour; determination of sex. Mortality: Determination if hatched beetles were alive or dead, weighing of beetles already seen with the dark colour
Statistics:	Fisher's Exact Binomial test (α = 0.05) for mortality STUDENT-t (α = 0.05) test each for weight and development time. For statistical analysis ToxRatPro (Version 2.10) was used.

Findings:

Table 9.5-8: Mortality of *Poecilus cupreus* larvae following exposure of BAS 590 01 F under extended laboratory conditions

Nominal application rate	Mortality after 70 days (out of 40 individuals/treatment)	Corrected mortality[a]
Control - untreated	10% (4/40)	-
BASF 595 01 F (200 mL/100 kg wheat seeds)	5% (2/40)	-5.6 %
Toxic reference, BAS 152 11 I (500 mL/ha)	92.5 % (37/40)	91.7

[a]According to Schneider-Orelli, negative value means decreased mortality compared to the control.
*Statistically significant compared to the control (Fisher Exact Binomial Test; α = 0.05)

Table 9.5-9: Effects on development time and hatching weight of *Poecilus cupreus* larvae following exposure of BAS 590 01 F under extended laboratory conditions

	Sowing rate of seeds [kg/ha]	Rate [g ai/ha]	Mean hatching weight [mg]	Effect on mean hatching weight [%]	Mean development time [days]	Delay in mean development time [days]
Control	233	-	69.8	-	38.4	-
BAS 595 01 F	233	11.65	72.9	4.4	38.9	0.5
Reference Item	-	200	68.3	-2.2	40.0	1.6

Conclusion: No effects on survival and the sublethal parameters hatching weight and development time of the larvae were observed when exposed to wheat seeds coated with 200 mL BAS 595 01 F per 100 kg seeds and sown at a rate of 233 kg seeds/ha.

Comment RMS:	The study was evaluated following the recommendations of the currently valid test guideline IOBC (2000), Heimbach et. al., A method for testing effects of plant protection products on the carabid beetle *Poecilus cupreus* (Coleoptera, Carabidae) under laboratory and semi-field conditions.

	It has to be noted that the study design was adapted to an extended laboratory test with larvae of *Poecilus cupreus* tested instead of the adult beetles and duration of 70 days. Therefore for the evaluation of the study *Heimbach, U. et al 2002; First ring test results of a laboratory method to evaluate effects of plant protection products on larvae of Poecilus cupreus* (Coleoptera: Carabidae), has also been considered. **Check of validity criteria (derived from Heimbach, U. *et.al*., 2002)** - Control Mortality should not be more than 10%. In the current study the mortality was 10% after 70 days. Fulfilled. - The application of the reference item (approx. 45 g dimethoate/ha) should result in a mortality rate of 36 to 100% after 28 days. In the current study the mortality for the reference item was 91.7% after 70 days at an application rate of 200 g dimethoate/ha. Fulfilled. **In addition, the RMS would like to point out the following uncertainty:** - According to Heimbach, 2002 the temperature should be 20 ± 2 °C. Result of the ring testing shows that already small differences in temperature may influence the development time of the larvae. In the current test the temperature ranged between19 and 23 °C. No detailed information is reported about the temperature measurement method and no temperature curves are given. **Acceptability of the analytical methods used in the test:** No information regarding the analytical methods was reported. **Endpoints:** The RMS agrees on the endpoints given in the study report No statistically significant effects at an application rate of 11.65 g ai/ha after 70 days were observed. 70 day ER_{50} > 11.65 g ai/ha **Conclusion of the RMS:** The test application rate was slightly lower than the application rate for the intended use. However, the endpoint is a greater than value and only marginal effects < 10% were observed. Based on the evaluation of the study the chronic toxicity test with *Poecilus cupreus* is considered valid.

Reference:	**Effects of BAS 595 01 F applied as treated wheat seeds on the reproduction of rove beetles *Aleochara bilineata* – extended laboratory study**
Author(s), year:	Schmitzer, S., 2007a
Report/Doc. number:	BASF DocID 2007/1023106
Guideline(s):	Grimm *et al.* 2000: A test for evaluating the chronic effects of plant protection products on the rove beetle *Aleochara bilineata* Gyll. (Coleoptera. Staphylinidae) under laboratory and extended laboratory conditions.
GLP:	Yes
Deviations:	Please refer to the commenting box below
Validity:	Acceptable

Material and Methods:

Test substance:	BAS 595 01 F, batch no.: 84002, Content of triticonazole nominal: 5.0 g/100 kg seeds, analysed: 5.6 g/100 kg seeds
Crop, variety:	Wheat seeds GUADELUPE, thousand seed weight: 41.5 g
Control:	Wheat seeds GUADELUPE, untreated
Toxic reference:	Perfekthion EC (BAS 152 11 I), content of dimethoate nominal: 400 g/L, analysed: 414.4 g/L
Test species:	*Aleochara bilineata*, adult (1-4 days old); De groene Vlieg, Duivenwaardsedijk 1; Nl- 3244 LG – Nieuwe Tonge
Host organism:	*Delia antiqua* Meig. pupae (Diptera, Anthomyiidae)
Type of test:	Extended laboratory test, 80 days (28 days exposure)
Number of organisms:	4 replicates for treatment, reference and control, 10 females and 10 males each
Test substrate:	LUFA 2.1 soil, moistened to about 35% of its maximum water holding capacity. The water holding capacity of the soil batch was 27%.
Food:	Frozen midge larvae – commercial food for aquarium fish; *Chironomus sp.*
Treatments:	Control: 9 untreated seeds per unit Test item: 192 kg seeds/ha, corresponding to 9 seeds per test unit, corresponding to 9.6 g ai/ha. Reference item: 2.75 mL Perfekthion EC /250 mL, corresponding to 11.0 mL/L; 400 L spray liquid/ha.
Exposure route:	Each test unit was filled with a bottom layer of 250 g moistened LUFA 2.1 soil. The treated seeds were placed on the soil surface in the middle of the test unit in two rows of 4 and 5 seeds with a distance of 3 cm between the rows. Subsequently a second layer, 750 g soil was filled into each test unit on top of the seeds, leading to a seeding depth of approx. 3 cm. After 28 days of exposure all surviving adult beetles were removed from the substrate. 35 days after application the onion fly pupae were washed out of the soil and the pupae of each replicate were transferred into a separate emergence

container. Emergence of the F1-generation was monitored until the control treatment fell below a rate of two beetles per replicate per day.

Test conditions: Controlled environment room.
Temperature: 18-22°C; relative humidity: acclimatisation: 69 - 88 %, exposure: 67-87%; post-exposure: 67-90%; light intensity: acclimatisation: 980 lux, exposure: 300-870 lux, post-exposure: 550-620 lux; 16 hours light, 8 hours dark; the test room was ventilated to avoid accumulation of test item vapour.

Test parameter: Reproduction efficiency by counting the total number of beetles emerged from the offered fly pupae until the emerging of the F1-generation was finished.

Statistics: No statistical analysis of the reproduction data for the test item treatment was performed, since mean number of emerged beetles in the test item treatment was higher compared to the control treatment and therefore, no negative effect on *A. bilineata* is considered.

Findings:

Table 9.5-10: Summary of the effects of BAS 595 01 F on the beetle *Aleochara bilineata* following exposure under extended laboratory conditions

Treatment	Reproduction
	No. of emerged beetles
Control	588 ± 83
BAS 595 01 F	626 ± 63
Reference item	2 ± 2*

* Statistical significant reduction compared to the control; Welch t-test, one-sided smaller (pairwise comparison), α = 0.05)

Conclusion: No relevant effects on reproduction capacity were observed after exposure to wheat seeds treated with 200 mL BAS 595 01 F per 100 kg seeds and sown with a sowing rate equivalent to 192 kg seeds/ha, corresponding to 9.6 g/ha triticonazole.

Comment RMS: The study was evaluated following the recommendations of the currently valid test guideline IOBC (2000), Grimm, C. *et al.:* A test for evaluating the chronic effects of plant protection products on the tove beetle Aleochara bilineata Gyll. (Coleoptera: Staphylinidae) under laboratory and extended laboratory conditions

Check of validity criteria:

- The average number of beetles emerging from the fly pupae should be above 400 in the control, i.e. a minimum of 26.7 % of the 6000 introduced fly pupae should be parasitized. In the current study 588 beetles emerged in the control. It is not reported how many pupae have been parasitized.
- A minimum reduction of 50% reproductive capacity relative to the control should be achieved in the reference item treatment. In the current study the reduction of reproduction in the reference item compared to the control was 99.7%.

	In addition, the RMS would like to point out the following uncertainty: - According to Grimm et al. the mean number of offspring produced per beetle shall be calculated for each treatment. In the current test, the mean number of offspring per treatment group was calculated. **Acceptability of the analytical methods used in the test:** No information regarding the analytical methods was reported. **Endpoints:** The RMS agrees on the endpoints given in the study report No statistically significant effects on reproduction at an application rate of 9.6 g ai/ha after 80 days were observed. 80 day ER_{50} > 9.6 g ai/ha **Conclusion of the RMS:** The test application rate was lower than the application rate for the intended use. However no effect was observed as the number of emerged beetles in the treatment group was greater than in the control. Despite the reported uncertainties above, the reproductive toxicity test with *Aleochara bilineata* is considered valid and suitable for risk assessment.

B.9.6. RISK ASSESSMENT FOR ARTHROPODS

B.9.6.1. Risk assessment for honeybees

Considering the EU representative use as seed treatment on cereals, honeybees may be exposed to formulated triticonazole from dust particles, when bees are either foraging the treated crop, weeds in the field, plants in field margin or the adjacent crop They may also be exposed through contact with fresh or dry residues or by oral uptake of contaminated pollen, nectar and honey dew.

The risk assessment for honeybees was conducted according to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) and according to the draft EFSA Guidance Document (EFSA Journal 2013;11(7):3295). The input parameters for the risk assessment according the EFSA Guidance Document are presented in Table 9.6-1.

Table 9.6-1: Input parameter for risk assessment

Application rate [kg/ha]	Application rate [mg ai/seed]*	Water solubility [mg ai/L]	PEC_{sw} (FOCUS Step 1) [mg ai/L]	$PEC_{runoff\ watermax}$ [mg ai/L]
0.0125	0.00105-0.0032	9.3	0.00251	0.001272

*overall minimum and maximum thousand grain weight values of all intended cereals: 21-64 g

Acute risk assessment:

Table 9.6-2: Summary of effects of triticonazole on honeybees - acute exposure

Test substance	Exposure route	Endpoint	Toxicity	Reference
Triticonazole	Acute oral Acute contact	48 h LD_{50}	> **155.5** µg ai/bee **> 100** µg ai/bee	Schmitzer, S., 1998
	Acute oral Acute contact	48 h LD_{50}	**>** 96.26 µg ai/bee > 100 µg ai/bee	Hernádi, D., 2006a
BAS 595 01 F	Acute oral Acute contact	48 h LD_{50}	**76.74** µg ai/bee (3287.54 µg formulated product/bee) **> 20** µg ai/bee (856.8 µg product/bee	Hernádi, D., 2007a

Bold values were used for risk assessment

In the following, the risk assessment is presented according to SANCO/10329/2002. This can be seen as a worst case estimate as the HQ approach actually applies for spray applications.

Table 9.6-3: Risk to honeybees from acute oral and contact exposure to triticonazole according to SANCO/10329/2002

Test substance	Exposure route	Application rate [g ai/ha]	Endpoint [µg ai/bee]	Q_H
Triticonazole	Oral	1 x 12.5	48 h LD_{50} > 155.5	< 0.08
	Contact		48 h LD_{50} > 100	< 0.125
BAS 595 01 F	Oral	1 x 12.5	48 h LD_{50} = 76.74	0.163
	Contact		48 h LD_{50} > 20	< 0.625

According to SANCO/10329/2002 the acute risk for bees was expressed as a Hazard Quotient (Q_H)

The resulting Hazard Quotients are clearly below the trigger of 50 indicating a low risk to honeybees after the use of triticonazole according to representative uses.

In the following, the risk assessment is presented according to the EFSA Journal 2013;11(7):3295 using the EFSA Bee Tool version 3.

Table 9.6-4: Risk to honeybees from acute oral exposure to triticonazole – screening step

Crop*	Test substance	Endpoint [µg ai/bee]	CF	$ETR_{acute\ adult\ oral}$	Trigger
Cereals 1 x 12.5 g ai/ha	Triticonazole	48 h LD_{50} > 155.5	2.28	< 0.001	0.2
	BAS 595 01 F	48 h LD_{50} = 76.74		0.001	
Cereals 0.0032 mg ai/seed	Triticonazole	48 h LD_{50} > 155.5	0.7	< 0.001	
	BAS 595 01 F	48 h LD_{50} = 76.74		0.001	
Cereals 0.00105 mg ai/seed	Triticonazole	48 h LD_{50} > 155.5	0.7	< 0.001	
	BAS 595 01 F	48 h LD_{50} = 76.74		0.001	

CF…Calculation factor according to EFSA Journal 2013;11(7):3295
*overall minimum and maximum thousand grain weight values of all intended cereals: 21-64 g
Bold…trigger exceeded

The $ETR_{acute\ adult\ oral}$ is below the trigger of 0.2 in the screening assessment for oral exposure, indicating an acceptable risk.

Table 9.6-5: Risk to honeybees from acute contact exposure to triticonazole – screening step

Crop	Test substance	Endpoint [µg ai/bee]	CF	$HQ_{contact}$	Trigger
Cereals 1 x 12.5g ai/ha	Triticonazole	LD_{50} > 100	0.099	< 0.01	14
	BAS 595 01 F	LD_{50} > 20		< 0.06	

CF…Calculation factor according to EFSA Journal 2013;11(7):3295

The $HQ_{contact}$ is below the trigger of 14, hence the acute contact toxicity to adult honey-bees is considered acceptable. No first tier risk assessment is required.

Chronic risk assessment:

Table 9.6-6: Summary of effects of formulated triticonazole on honeybees - chronic exposure

Test substance	Exposure route	Endpoint	Toxicity	Reference
BAS 595 01 F.	Chronic oral	10 d LC_{50}	674.2 mg ai/kg (12.9 µg ai/bee/d)	Schmitzer, S., 2014a
		10 d NOEC	312.5 mg ai/kg (8.0 µg ai/bee/d)	

In the following, the risk assessment is presented according to the EFSA Journal 2013;11(7):3295 using the EFSA Bee Tool version 3.

Table 9.6-7: Chronic oral toxicity to bees – screening step

Crop	Test substance	Endpoint	CF	ETR	Trigger
Cereals 1 x 12.5 g ai/ha	BAS 595 01 F	10d LDD_{50} = 12.9 µg ai/bee/d	2.28	0.002	0.03
Cereals 0.0032 mg ai/seed			0.7	0.0001	
Cereals 0.00105 mg ai/seed				0.0001	

CF…Calculation factor according to EFSA Journal 2013;11(7):3295
*overall minimum and maximum thousand grain weight values of all intended cereals: 21-64 g

The $ETR_{chronic\ adult\ oral}$ is below the trigger value of 0.03 indicating an acceptable chronic risk to adult honey-bees.

Risk assessment for honeybee larvae:

Table 9.6-8: Summary of effects of formulated triticonazole on honeybees and honeybee larvae

Test substance	Exposure route	Endpoint	Toxicity	Reference
BAS 595 01 F	Acute larval, single exposure	72 hours LC_{50}	2.526 mg ai/kg (= 85.6 µg ai/larva)	Kleebaum, K., 2014b
		72 hours NOEC	0.731 mg ai/kg (= 24.8 µg ai/larva)	

In the following, the risk assessment is presented according to the EFSA Journal 2013;11(7):3295 using the EFSA Bee Tool version 3.

Table 9.6-9: larval toxicity to bees – screening step

Crop	Test substance	Endpoint	CF	ETR	Trigger
Cereals 1 x 12.5 g ai/ha	BAS 595 01 F	72 hours NOED = 24.8 µg ai/larva/d	1.32	0.00	0.2
Cereals 0.0032 mg ai/seed			0.4	0.00	
Cereals 0.00105 mg ai/seed				0.00	

CF…Calculation factor according to EFSA Journal 2013;11(7):3295
*overall minimum and maximum thousand grain weight values of all intended cereals: 21-64 g

The $ETR_{chronic\ larval}$ is below the trigger value of 0.2 indicating an acceptable chronic risk to honey-bee larvae.

Exposure to contaminated water: The risk due to exposure via contaminated water was estimated according to EFSA Journal 2013;11(7):3295 using the EFSA Bee Tool version 3.

1st tier for guttation				
	water cons. (µL)	ETR	Trigger	Risk indicator
acute	11,4	0,00	0,2	OK
chronic	11,4	0,004	0,03	OK
larvae	111	0,03	0,2	OK

Surface water				
	water consumption (µL)	ETR	Trigger	Risk indicator
acute	11,4	0,00	0,2	OK
chronic	11,4	0,000	0,03	OK
larvae	111	0,00	0,2	OK

Puddle water				
	water consumption (µL)	ETR	Trigger	Risk indicator
acute	11,4	0,00	0,2	OK
chronic	11,4	0,000	0,03	OK
larvae	111	0,00	0,2	OK

Overall conclusion:

The exposure to triticonazole used as a seed treatment in cereals poses a low risk to bees. Also a low risk due to contaminated drinking water via surface water, puddle water and guttation water respectively could be identified. No specific information is available regarding the toxicity of the metabolites to bees. However, it can be assumed that the metabolites are not more toxic than the active substance. Furthermore contamination of bee relevant matrices is not likely.

B.9.6.2. Risk assessment for non-target arthropods

A summary of the effects of triticonazole on non-target arthropods is provided in Table 9.6-10.

Table 9.6-10: Summary of effects of triticonazole on non-target-arthropods (extended laboratory studies)

Test species	Exposure	Test item	Rate [g ai/ha]	Type of effect	Effect [%]*	Reference
Poecilus cupreus (larvae)	Exposure to treated wheat seeds in soil	BAS 595 01 F	7.25	Corrected mortality / mean hatching weight/ delay in development time	-5.6 / 6.0 / 0.4	Drexler, A., 2004a
				70 d LR_{50} > 7.25 g ai/ha 70 d ER_{50} > 7.25 g ai/ha		
Poecilus cupreus (larvae)	Exposure to treated wheat seeds in soil	BAS 595 01 F	11.65	Corrected mortality / mean hatching weight/ delay in development time	-5.6 / 4.4 / 1.3	Sattler, F., 2009a
				70 d LR_{50} > 11.65 g ai/ha 70 d ER_{50} > 11.65 g ai/ha		
Aleochara bilineata	Exposure to treated wheat seeds in soil	BAS 595 01 F	9.6	Reproduction (emerged beetles)	- 6.5	Schmitzer, S., 2007a
				80 days ER_{50} > 9.6 g ai/ha		

*negative value means decreased mortality/hatching weight/emerged beetles compared to the control

Overall conclusion:

Non-target arthropods may be exposed to formulated triticonazole by contact with treated seeds in soil. The concentrations tested do not cover the intended application rate of 12.5 g ai/ha. However, the LR_{50} and ER_{50} values estimated by the studies are > values. Observed effects are all less than 10% or even positive.

Further testing was conducted with the macro-soil organisms *Folsomia candida* and *Hyposapis aculeifer*. The risk assessment shows an acceptable risk for these soil dwelling organisms (for details please refer to B.9.7.2 and B.9.8). Considering all available information regarding soil-organisms, the risk can be assumed acceptable.

B.9.7. EFFECTS ON NON-TARGET SOIL MESO- AND MACROFAUNA

The study summaries for studies with the active substance triticonazole and the soil metabolites RPA 407922, RPA406341 and RPA 404766 are provided in the RAR, Volume 3, B.9 –CA. The study summaries for the studies with the formulation BAS 595 01 F are given below.

B.9.7.1. Earthworms

For the first EU approval of the active substance triticonazole acute earthworm studies were submitted addressing the risk to earthworms. According to the current data requirements for active substances and plant protection products (Regulation No 284/2013 and Regulation No 284/2013) acute toxicity studies are no longer required. Nevertheless, the study summaries from the DAR are included in the RAR as additional information.

Lührs U., 2001b – Acute toxicity (14 days) of EXP80472B to the earthworm Eisenia fetida in artificial soil

Document number C017899

Guideline: OECD Guidelines for Testing of Chemicals (1984), No. 207; ISO-Guideline 11268-1

GLP: Yes

Material and methods:

The purpose of this study was to determine the acute toxicity of EXP80472B to the earth worm Eisenia fetida 7 and 14 days after exposure and to estimate the LC50 of EXP80472B. The FS formulation contains 25.0 g triticonazole/l (nominal).The concentrations of the test substance (formulation) mixed into the artificial soil were 198, 296, 444, 667 and 1000 mg/kg. The control was treated with deionised water and quartz sand. Toxic standard: 2-Chloroacetamide. The following soil was used:

10 % Sphagnum-peat

20 % Kaolin clay

0.5 % CaCO3

69.5 % fine quartz sand

The pH of the soil ranged from 5.6 to 5.7 (beginning of the study) and from 5.8-6.0 (study end). Water content at the start of the study was 32.5-33.6% (52.6-54.4% WHC), and 30.7- 33.4% (49.7 –54.1% WHC) at study termination. The test was carried out at 19-21°C and under continuous light regime.

LC50 and its 95% confidence limits at days 7 and 14 were not determined by a statistical analysis as no mortality was observed.

Data on earthworm body weight were tested for normality and homogeneity of variance using Kolmogoroff-Smirnov test ($\alpha = 0.05$) and Cochran test ($\alpha = 0.05$).

Because the body weight data did fulfil the criterion of homogeneity (Cochran test), the Dunnett test was used (multiple comparison, two-sided, $\alpha = 0.05$).

Findings:

After 14 days exposure no mortality was recorded in the control group and in the treatment groups up to 1000 mg/kg. There were no observed behaviour effects and no significant effect on earthworm weights up to 1000

mg/kg. The toxicity of the positive control was within the expected range for the laboratory.

Table B.9.6.1-5: Earthworm body weight changes (mean of 4 replicates)

EXP80472B (mg/kg)	*Test start*	*After 14 d*		
	mg/worm	*mg/worm*	*% difference*	*significance*
Control	*518.5*	*466.8*	*-9.9*	*-*
198	*529.5*	*462.9*	*-12.4*	*not signif.*
296	*475.1*	*442.5*	*-6.7*	*not signif.*
444	*531.9*	*479.5*	*-9.6*	*not signif.*
667	*541.0*	*486.3*	*-10.0*	*not signif.*
1000	*502.2*	*458.2*	*-8.7*	*not signif.*

Conclusions:

According to the results of this study the 14 day LC50 and the Lowest Observed Effect Concentration (LOEC) of EXP80472B for earthworms was determined to be >1000 mg/kg artificial soil (dw). The No Observed Adverse Effect Concentration (NOAEC) was determined to be 1000 mg/kg.

For the current EU approval of triticonazole the applicant submitted a new earthworm reproduction study with the representative formulation BAS 595 01 F. The study report is summarised below.

Reference:	**Effects of BAS 595 01 F on growth and reproduction of earthworms (*Eisenia fetida*) in artificial soil**
Author(s), year:	Wolf, A., 2009a
Report/Doc. number:	BASF DocID 2009/1117741
Guideline(s):	OECD 222 (2004)
GLP:	Yes
Deviations:	Please refer to the commenting box below
Validity:	Acceptable

Material and methods:

Test substance:	BAS 595 01 F, batch no.: FRE-000660, content of triticonazole nominal: 25.0 g/L, analysed: 25.7 g/L
Test species:	Earthworm *Eisenia fetida*; in-house culture
Number of organisms:	8 replicates per control and 4 replicates per treatment group, each with 10 individuals.
Weight, age:	Mean: 300 - 500 mg/worm, adults with clitellum, < 1 year old
Type of test, duration:	Laboratory sub-lethal test, 8 weeks (4 weeks adult mortality, 4 weeks juvenile development)
Applied concentrations:	Control, 0.71, 1.42, 2.84, 5.68 and 11.36 mg prod./kg soil dw corresponding to

	0.0166, 0.0332, 0.0664, 0.1328 and 0.2656 mg ai/kg soil dw, incorporated into the soil
Solvent:	None
Toxic standard:	Benlate (BAS 321 00 F), content Benomyl nominal: 50.0 %, analysed: 51.4% tested at 5 mg prod./kg soil dw
Test conditions:	
Test substrate:	Artificial soil, 5 % sphagnum peat, 20 % kaolin clay, approx. 75 % industrial quartz sand, approx. 0.3% calcium carbonate
Substrate/test vessel:	600 g dry weight/test container
Temperature:	19 – 21 °C
Light regime:	16 hours light, 8 hours dark; light intensity: 400-800 lux
Water content:	About 60% of the maximum holding capacity Not stated in more detail in the study report.
pH:	Test start: 5.26 – 5.30 Test end: 6.40 – 6.80
Feeding:	Powdered cow manure; feeding interval was weekly during the first 4 weeks, weekly amount of manure (5 g) depended on the feeding activity.
Test parameters:	Temperature was recorded continuously during the whole test period. The pH of the artificial soil was determined at the start and the end of the test. Mortality of adults (assessed after 28 days), mean body weight of adults (measured at day 0 and after 28 days), morphological and behavioural changes of adults (observed at day 28), number of juvenile earthworms (counted after 8 weeks) and condition and behaviour of juveniles (observed after 8 weeks)
Statistics:	For treatment groups Shapiro-Wilk´s Test and Levene's test were used, respectively, to test the data for normality and homogeneity of variance. Statistical analysis on worm biomass and number of offspring was evaluated by analysis of variance and Bonferroni t-test. The statistical analysis was performed with the software ToxRatPro 2.10 (Toxrat Solutions GmbH).
Findings:	No behavioural changes or abnormalities (including feeding activities) of the earthworms were observed.

Table 9.7-1: Effects of BAS 595 F 01 on mortality and reproduction of *Eisenia fetida* in a sub-chronic test

Treatment group [mg product/kg soil d.w.]	Mortality of adult earthworms after 4 weeks [%]	Statistical evaluation	Body weight differences per adult earthworm after 4 weeks relative to initial fresh weight [%] (SD)	Statistical evaluation	Reproduction (mean number of young earthworms per container	Statistical evaluation
Control	0.0	-	59.31 (11.46)	-	70.75 (19.7)	-
0.71	0.0	n.s.	63.05 (1.82)	n.s.	100.25 (13.3)	n.s.
1.42	0.0	n.s.	62.25 (10.09)	n.s.	109.00 (20.2)	n.s.

Treatment group [mg product/kg soil d.w.]	Mortality of adult earthworms after 4 weeks [%]	Statistical evaluation	Body weight differences per adult earthworm after 4 weeks relative to initial fresh weight [%] (SD)	Statistical evaluation	Reproduction (mean number of young earthworms per container	Statistical evaluation
2.84	0.0	n.s.	63.30 (6.75)	n.s.	107.50 (19.4)	n.s.
5.68	0.0	n.s.	62.76 (10.32)	n.s.	97.00 (25.8)	n.s.
11.36	0.0	n.s.	55.70 (17.27)	n.s.	81.25 (10.3)	n.s.
Toxic reference	0.0	n.s.	12.24 (13.02)	*	0.00 (0.0)	*

SD standard deviation
*statistically significantly different compared to control
n.s. not significantly different compared to control

Conclusion: 28 day NOEC (adult mortality, body weight) = 11.36 mg prod./kg soil dw
56 day NOEC (reproduction) = 11.36 mg prod./kg soil dw
56 day EC_{50} (reproduction) = not determinable

Comment RMS: The study was evaluated following the recommendations of the currently valid test guideline OECD 222 (2016)

Check of validity criteria:

- Each replicate (containing 10 adults) of the control should have produced ≥ 30 juveniles by the end of the test. In the current test number of juveniles per replicate was 70.75 ± 19.7. Fulfilled.
- The coefficient of variation of reproduction in the control should be ≤ 30 %. In the current study the coefficient of variation was 27.9%. Fulfilled.
- Adult mortality over the initial 4 weeks of the test in the control should be ≤ 10 %. In the current study the mortality was 0.0 %. Fulfilled.

Acceptability of the analytical methods used in the test: No information regarding the analytical methods was reported.

Endpoints:

The RMS agrees on the endpoints given in the study report.

28 day NOEC = 11.36 mg test item/kg soil dw (adult mortality, body weight) (equivalent to 0.2656 mg ai/kg soil dw)

56 day NOEC = 11.36 mg test item/kg soil dw (reproduction) (equivalent to 0.2656 mg ai/kg soil dw)

EC_{50} > 11.36 mg test item/kg soil dw (equivalent to 0.2656 mg ai/kg soil dw)

According to ToxRat® 3.1.0. EC_{10} values could not be calculated.

Conclusion of the RMS: All treatment groups showed a higher number of juveniles than in the control group (it ranged from 14.8% in 11.36 mg test item/kg soil dw to 54.1 % more juveniles, in 1.42 mg test item/kg soil dw than in the control). However, the

	Guideline recommends a one-sided t-test, not considering an increase in reproduction as an adverse effect. Based on the evaluation of the study the chronic earthworm toxicity test is considered valid.

B.9.7.2. Effects on non-target soil meso- and macrofauna (other than earthworms)

According to the data requirements on active substances (Regulation 283/2013) and formulations (Regulation 284/2013) the risk to soil dwelling organisms has to be addressed (1) if a risk to non-target arthropods was identified or (2) if the product is applied to the bare soil (pre-emergence).

Under consideration of the intended uses as a seed treatment the risk to soil meso- and macrofauna from exposure to the active substance and its major soil metabolites has to be addressed. Therefore, the risk to soil dwelling organisms has to be considered.

Hence, laboratory studies with the soil organisms *Folsomia candida* and *Hypoaspis aculeifer* were submitted by the applicant.

Reference:	**Effects of BAS 595 01 F on the reproduction of the Collembola *Folsomia candida* in artificial soil**
Author(s), year:	Lührs, U., 2004a
Report/Doc. number:	BASF DocID 2004/1014986
Guideline(s):	ISO 11267 (1999)
GLP:	Yes
Deviations:	Please refer to the commenting box below
Validity:	Acceptable

Material and methods:

Test substance:	BAS 595 01 F, batch no.: 84002, triticonazole content nominal: 25.0 g/L, analysed: 26.0 g/L
Test species:	Collembola *Folsomia candida* (Willem), bred at IBACON
Number of organisms:	5 replicates per treatment group and control, 1 additional replicate per treatment to check the pH and water content of the test substrate after 28 days, each with 10 individuals.
Life stage, age:	Juveniles, 10-12 days old
Type of test, duration:	Chronic laboratory test, 28 days
Applied concentrations:	62.5, 125, 250, 500, and 1000 mg prod./kg soil dw corresponding to 1.5, 3.0, 6.1, 12.2 and 24.4 mg ai/kg soil dw (calculated based on analysed content of triticonazole in BAS 595 01 F, considering its density) incorporated into the soil.
Solvent:	None
Toxic standard:	Aventis PMP (phenmedipham 157 g/L); the toxic reference test is performed at least once a year.

Test conditions:

Test substrate:	Artificial soil, 10 % sphagnum peat, 20 % kaolin clay, 69.5 % fine quartz sand, 0.5% calcium carbonate
Substrate/test vessel:	30 g wet weight/test container
Temperature:	19-22 °C

Light regime:	16 hours light (610- 710 lx) / 8 hours dark
Water content:	Test start: 33% (equivalent to 53% of WHC) Test end: 31 – 33% (equivalent of 50 – 53% of WHC)
pH:	Test start: 6.4 – 6.5 Test end: 5.8 – 6.2
Feeding:	Approximately 2 mg of granulated dry yeast were spread over the soil surface at test start. After 14 days, 2 mg of granulated dry yeast were added.
Test parameters:	pH and water content were determined at test start and test end. Water content maintenance was checked on day 13 after application. Mortality of adults, behavioural effects and number of juvenile Collembola were assessed after 28 days
Statistics:	Mortality data were statistically analysed using Fisher Exact test. Reproduction data were tested for normal distribution and homoscedascity using Kolmogoroff-Smirnov test and Cochran test ($\alpha = 0.05$, one-sided smaller). The software used to perform the statistical analysis was SYSTAT Version 9.0 ©1999 SPSS Inc. and Tox Rat Professional 2.07, ©2001-2003 Toxrat Solutions.

Findings:

Biological effects: No abnormal behaviour was observed with the surviving Collembola.

Table 9.7-2: Effects on mortality and reproduction of *Folsomia candida* in a sub-chronic test

Treatment group [mg product/kg soil d.w.]	Mean number of surviving parental collembolans after 28 d	Mortality of adult Collembola after 28 d [%](± SD)	Statistical evaluation	Mean number of juveniles after 28 d (± SD)	Reproduction [% of control]	Statistical evaluation
Control	8.0	20 (0)	n.s.	490 (46)	-	n.s.
62.5	8.2	18 (8)	n.s.	568 (36)	116	n.s.
125	9.0	10 (7)	n.s.	579 (75)	118	n.s.
250	8.4	16 (13)	n.s.	483 (23)	99	n.s.
500	9.0	10 (10)	n.s.	513 (21)	105	n.s.
1000	9.0	20 (10)	n.s.	570 (55)	116	n.s.

SD…Standard Deviation
n.s….not statistically significant

Phenmedipham showed an EC_{50} of 10.3 mg /kg soil dw (95% C.I. 9.9 – 10.8 mg /kg soil dw). The NOEC based on reproduction was calculated to be < 3.95mg /kg soil dw. This shows that the test organisms are sufficiently sensitive.

Conclusion: 28 day NOEC (mortality and reproduction) = 1000 mg prod./kg soil dw (= 24.4 mg ai/kg soil dw

28 day LC_{50} > 1000 mg prod./kg soil dw (= 26 mg ai/kg soil dw)

Comment RMS:	The study was evaluated following the recommendations of the currently valid test guideline OECD 232 (2016). **Check of validity criteria:** - Mean adult mortality in the controls should not exceed 20% at the end of the test. In the current study mortality was 20 % in the control. Fulfilled. - The mean number of juveniles per vessel in the controls should be at least 100 at the end of the test. In the current study the mean number of juveniles per vessel was 490 in the control. Fulfilled. - The coefficient of variation calculated for the number of juveniles in the controls should be less than 30% at the end of the definitive test. In the current study the coefficient of variation 9.4%. Fulfilled. **In addition, the following points deviated from the test guideline or were not reported in detail:** - According to OECD 232 for determination of the NOEC/LOEC, at least five concentrations in a geometric series should be tested. Four replicates for each test concentration treatment plus eight controls are recommended. The concentrations should be spaced by a factor not exceeding 1.8. A combined approach allows for determination of both the NOEC/LOEC and EC_x. For this combined approach, eight treatment concentrations in a geometric series should be used. Four replicates for each treatment plus eight controls are recommended. The concentrations should be spaced by a factor not exceeding 1.8. In the current study 5 concentrations with each 5 replicates were tested with a spacing factor of 2. The testing series seems not to be suitable to determine EC_x values. **Acceptability of the analytical methods used in the test:** No information regarding the analytical methods was reported. **Endpoints:** The RMS agrees on the endpoints given in the study report. 28 day NOEC = 1000 mg test item/kg soil dw (24.4 mg ai/kg soil dw) 28 day LC_{50} > 1000 mg test item/kg soil dw (24.4 mg ai/kg soil dw) According to ToxRat® 3.1.0. EC_{10} values could not be calculated **Conclusion of the RMS:** The treatment groups 62.5, 125, 500 and 1000 mg test item/kg soil dw showed a higher number of juveniles than in the control group (16 to 18%). However, the guideline recommends a one-tailed hypothesis testing, not considering an increase in reproduction as an adverse effect. Based on the evaluation of the study the chronic collembolan toxicity test is considered valid.

Reference:	**Effects of BAS 595 01 F on the reproduction of the predatory mite *Hypoaspis aculeifer***
Author(s), year:	Schulz, L., 2013b
Report/Doc. number:	BASF DocID 2013/1103637
Guideline(s):	OECD 226 (2008)
GLP:	Yes
Deviations:	Please refer to the commenting box below
Validity:	Acceptable

Material and methods:

Test substance:	BAS 595 01 F, batch no.: 84210, content triticonazole nominal: 25.0 g/L analysed: 26.1g/L; density: 1.069 g/cm^3
Test species:	Predatory mites, *Hypoaspis aculeifer* (CANESTRINI), in-house culture (originally purchases from "Katz Biotech AG")
Number of organisms:	8 replicates for control, 4 replicates for the treatment groups, each with 10 individuals. 2 additional replicates per treatment control for measurement purposes.
Life stage, age:	Adult females from a synchronised culture with an age difference of 3 days
Type of test, duration:	Laboratory sub-lethal test, 14 days
Applied concentrations:	62.5, 125, 250, 500 and 1000 mg product/kg soil dw, corresponding to 1.5, 2.9, 5.8, 11.7, 23.4 mg ai/kg soil dw.
Solvent:	None
Toxic standard:	Dimethoate EC 400 tested at concentrations 4.10, 5.12, 6.40, 8:00 and 10.00 mg ai/kg soil dw in a separate study.

Test conditions:

Test substrate:	Artificial soil, 5 % sphagnum peat, 20 % kaolin clay, 74.7 % industrial quartz sand, 0.3% calcium carbonate
Substrate/test vessel:	20 g dry weight/test container
Temperature:	19.5-21.5 °C
Light regime:	16 hours light, 8 hours dark; light intensity: 520 lux
Water content:	Test start: 20.92 – 21.23% (equivalent to 52.71 – 53.48% of WHC) Test end: 19.54 – 20.30% (equivalent of 49.23 – 51.14% of WHC)
pH:	Test start: 5.7 – 5.9 Test end: 5.7 – 5.8
Feeding:	The mites were fed with cheese mites *Tyrophagus putrescentiae* twice to three times a week
Test parameters:	pH and water content were determined at test start and test end. Mortality of adults, differences in morphology, behavioural effects and number of juveniles were assessed after 14 days

Statistics: The statistical analysis was performed with the software ToxRat Professional, Version 2.10.05, ® ToxRat Solutions GmbH.

Findings:

Table 9.7-3: Effects on mortality and reproduction of *Hypoaspis aculeifer* in a sub-chronic test

Treatment group [mg product/kg soil d.w.]	Mean number of surviving adult mites after 14 d (± SD)	Mortality of adult mites after 14 d [%]	Statistical evaluation	Mean number of juveniles after 14 d (± SD)	Reproduction [% of control]	Statistical evaluation
Control	8.8 (0.7)	12.5	n.s.	298.5 (33.7)	100	n.s.
62.5	9.3 (0.5)	7.5	n.s.	294.5 (39.6)	99	n.s.
125	9.3 (0.5)	17.5	n.s.	287.0 (20.6)	96	n.s.
250	8.0 (1.2)	20.0	n.s.	294.5 (57.6)	99	n.s.
500	8.3 (1.3)	17.5	n.s.	290.3 (11.3)	97	n.s.
1000	8.8 (1.3)	12.5	n.s.	262.3 (37.1)	88	n.s.

SD…Standard Deviation
n.s.…not statistically significant

Dimethoate EC 400 showed an EC_{50} of 6.64 mg ai/kg soil dw.

Conclusion: 14 day NOEC (mortality, reproduction) = 1000 mg prod./kg soil dw (= 23.4 mg ai/kg soil dw.)
14 day LC_{50}/EC_{50} > 1000 mg prod./kg soil dw (23.4 mg ai/kg soil dw)

Comment RMS: The study was evaluated following the recommendations of the currently valid test guideline OECD 226 (2016).

Check of validity criteria:

- Mean adult mortality of the females in the controls should not exceed 20% at the end of the test. In the current study mortality was 12.5 % in the control. Fulfilled.
- The mean number of juveniles per replicate in the controls should be at least 50 at the end of the test. In the current study the mean number of juveniles per vessel was 298.5 in the control. Fulfilled.
- The coefficient of variation calculated for the number of juvenile mites in the controls should not be higher than 30% at the end of the definitive test. In the current study the coefficient of variation was 11.3 in the control. Fulfilled.

In addition, the following points deviated from the test guideline or were not reported in detail:

- According to OECD 226 for determination of the EC_x (e.g. EC_{10}, EC_{50}), twelve concentrations should be tested. At least two replicates for each test concentration and six control replicates are recommended. The spacing factor may vary, i.e. less than or equal to 1.8 in the expected effect range and above 1.8 at the higher and lower concentrations. For

	determination of the NOEC, at least five concentrations in a geometric series should be tested. Four replicates for each test concentration plus eight controls are recommended. The concentrations should be spaced by a factor not exceeding 2.0. A combined approach allows for determination of both the NOEC and EC_x. Eight treatment concentrations in a geometric series should be used. Four replicates for each treatment plus eight controls are recommended. The concentrations should be spaced by a factor not exceeding 1.8. In the current study 5 concentrations with each 4 replicates were tested with a spacing factor of 2. The testing series seems not to be suitable to determine EC_x values. **Acceptability of the analytical methods used in the test:** No information regarding the analytical methods was reported. **Endpoints:** The RMS agrees on the endpoints given in the study report. 14 day NOEC = 1000 mg test item/kg soil dw (23.4 mg ai/kg soil dw) 14 day LC_{50} > 1000 mg test item/kg soil dw (23.4 mg ai/kg soil dw) **Conclusion of the RMS:** Based on the evaluation of the study the chronic predatory mite toxicity test is considered valid.

In addition to the studies on earthworms and other soil macro-organisms (*Folsomia candida* and *Hypoaspis aculeifer*) a litter bag study with the formulation EXP80472B was submitted addressing possible adverse effects on the soil litter degradation.

The study was already evaluated for the first EU approval of the active substance triticonazole. However, as this is not a data requirement according to the data requirements for active substances (Commission Regulation (EU) 283/2013) and/or plant protection products (Commission Regulation (EU) 284/2013) and the test item was not the representative formulation the study has not been re-evaluated. The study summary given in the DAR for the first EU approval is given below as additional information.

Förster B., 2002– Effects of EXP80472B on the decomposition of organic material in the field

Document number C020499

Guideline: "Minutes of a meeting on the requirement of data according to Annex III, point 10.6.2" organised by the BBA dated March 2001

GLP: Yes

Material and methods:

The objective of the study was to evaluate the effects of EXP 80472 B on the decomposition of organic matter in the field. The test was performed on an agricultural site in Germany with winter wheat as the crop. Litterbags filled with about 4 g of wheat straw internodes were placed on the soil surface of the field plots and both, soil surface and litter-bags were exposed to spray applications of 2 concentrations of the test item (16.50 g ai/ha and 158.25 g ai/ha) or one concentration rate of the reference substance Benomyl (5.0 kg ai/ha). After application the litter bags were buried at about 5 cm below the soil surface. The size of the litter bags was 10 cm x 20 cm,

mesh size of the bags was 5 mm.

The ash free dry weight of the remaining organic material inside the litter-bags was measured at 3 time points within 6 months following the application. The decomposition rates in treated plots were compared to the decomposition in the control plots. After 6 months more tha 50 % of the initial weight of the straw in the litter-bags was decomposed in the control plots.

The history of the site was known with regardes to the crop and soil management and the use of fertilisers and PPPs. A preliminary assessment of the abundance of earthworms of the study site was performed.

The experimental field was divided into 16 plots of 5 m x 5 m each (4 plots per treatment).

The individual plots were arranged in four rows of four plots each plot separated by a pathway of 2 m. 8 bags per sampling date were collected from each of the 16 plots.

The weight of remaining wheat straw in the litter-bags at each sampling date was calculated as percent of the initial ash-free dry weight. The non parametric Mann and Whitney U-Test was used to test wheather statistically significant differences between control and treated plots occurred at any sampling date.

Table B.9.7-1: Soil Characteristics

% sand	% silt	% clay	% total C	% OM	pH	% WHC
6.9	74.3	18.8	1.45	2.5	5.3	68.4

Findings:

The mean number of earthworms was found to be 31 ind/m2. This number was classified as "medium", and the earthworm populations (species) found were characterised as typical for central European arable land.

The mean values for each plot are given in Table B.9.7-2 for each treatment and for each of the four sampling dates.

Table B.9.7-2: Ash free dry weight of wheat straw exposed in litter-bags: Mean of 8 bags per plot and sampling date - % of the initial weight and overall mean per treatment.

Treatment replicates (plots)	0 days (27.3.2001)	28 days	85 days	196 d
Control (water)	100	99.9	83.4	48.0
	100	100.9	76.7	30.3
	100	97.0	79.2	40.9
	100	98.0	77.3	39.7
Mean	100	98.9	79.2	39.7
16.50 g ai/ha	100	99.1	74.6	31.1
	100	105.4	81.0	52.1
	100	97.3	83.4	41.3
	100	96.7	77.8	47.5
mean	100	99.6	79.2	43.0
158.25 g ai/ha	100	102.3	80.0	54.7
	100	99.5	81.4	46.5
	100	100.6	83.6	56.2

Treatment replicates (plots)	*0 days (27.3.2001)*	*28 days*	*85 days*	*196 d*
	100	*100.1*	*83.2*	*46.7*
mean	*100*	*100.6*	*82.0*	*51.0*
5 kg Benomyl/ha	*100*	*102.5*	*75.9*	*46.3*
	100	*100.7*	*68.9*	*27.8*
	100	*98.6*	*68.6*	*23.8*
	100	*100.2*	*77.1*	*37.1*
mean	*100*	*100.5*	*72.6*	*33.7*

The high application rate of the test item (158.25 g ai/ha) caused a reduced average decomposition rate as compared to the control. Using the non-parametric Mann and Whithney U-test the difference between the treatment and the control was not significant (based on a two-sided comparison with p = 0.05).

For this report it was assumed that the overall contribution of earthworms to the weight loss of wheat straw buried in the soil of the field site was small and therefore Benomyl had no measurable negative effect on the weight loss of wheat straw.

Conclusions:

From the PEC calculations it has been shown that triticonazole could reach a plateau concentration of 0.0014 mg/kg in soil after several years of application at a rate of 12.5 g ai/ha. Peak concentrations (after the yearly applications) would be 0.0055 mg/kg. The concentrations are calculated on the basis of 20 cm soil depth. The application rates used in the litterbag study were 16.50 g ai/ha and 158.25 g ai/ha. The calculated concentrations in soil for the 20 cm soil layer would be 0.0055 mg/kg and 0.0528 mg/kg respectively. No statistically significant effects were observed. According to the results of this test triticonazole will not pose an unaccaptable risk to soil organic matter breakdown when used at the supported application rate and according to GAP.

B.9.8. RISK ASSESSMENT FOR NON-TARGET SOIL MESO- AND MACROFAUNA

A summary of the toxicity of the formulation BAS 595 01 F, the active substance triticonazole and its soil metabolites to earthworms and other soil macro-organisms is provided in Table 9.8-1.

Table 9.8-1: Summary of effects on soil meso- and macrofauna

Species	Substance	Endpoint	Reference
Eisenia fetida	Triticonazole	56 d NOEC = 125 mg ai/kg soil dw*	Lührs, U., 1999a
	BAS 595 01 F	56 d NOEC = 5.7 mg product/kg soil dw (0.1328 mg ai/kg soil dw)*	Wolf, A., 2009a
	Metabolite RPA 404766 (Reg.No. 5079285)	56 d NOEC = 250 mg ai/kg soil dw	Friedrich, S., 2013a
	Metabolite RPA 407922 (Reg.No. 5079288)	56 d NOEC = 125 mg ai/kg soil dw	Friedrich, S., 2013b
	Metabolite RPA 406341 (Reg.No. 5059144)	56 d NOEC = 5 mg ai/kg soil dw*	Wolf, A., 2006a
Folsomia candida	Triticonazole	28 d NOEC = 62.5 mg/kg soil dw*	Friedrich, S., 2013c
	BAS 595 01 F	28 d NOEC = 500 mg product/kg soil dw (12.2 mg ai/kg soil dw)*	Lührs, U., 2004a
	Metabolite RPA 404766 (Reg.No. 5079285)	28 d NOEC = 500 mg/kg soil dw	Friedrich, S., 2013d
	Metabolite RPA 406341 (Reg.No. 5059144)	28 d NOEC = 25 mg /kg soil dw*	Royer, S., 2006a
	Metabolite RPA 407922 (Reg.No. 5079288)	28 d NOEC = 250 mg /kg soil dw	Friedrich, S., 2013e
Hypoaspis aculeifer	Triticonazole	14 d NOEC = 250 mg ai/kg soil dw*	Schulz, L., 2014a
	BAS 595 01 F	14 d NOEC = 500 mg product/kg soil dw (11.7 mg ai/kg soil dw)*	Schulz, L., 2013b
	Metabolite RPA 406341 (Reg.No. 5059144)	14 d NOEC = 5 mg /kg soil dw*	Ganßmann, M., 2014a

* corrected by a factor of 2 due to the log P_{OW} of triticonazole > 2 (log P_{OW} triticonazole: 3.3; log P_{OW} for RPA 406341: 2.2)

The risk assessment for soil organisms was conducted according to the Terrestrial Guidance Document (SANCO/10329/2002).

TER values for soil organisms were calculated as the ratio between sublethal no observed effect concentrations (NOEC), and the maximum PECsoil. The PEC_{soil} used for the 1st tier risk assessment is based on a single application of 12.5 g ai/ha on cereals. For triticonazole and for the metabolite RPA 406341 worst-case $PEC_{soil\ accumulation}$ of 0.0189 and 0.0037 mg/kg soil, respectively, were used. For the Metabolite RPA 407922 no PEC_{soil} values are available as after re-evaluation in the e-fate section no exposure assessment is triggered. Two unknown fractions were discovered during the re-evaluation process. For these unknown metabolites Met 6 (MWT 333) and Met 7 (MWT 315) no toxicity studies are available. (for details please refer to fate section B.8).

The endpoints for the active substance / the representative formulation were corrected by a factor of 2

irrespective of the peat content in the study. During an EFSA expert meeting (PRAS 91, April 2012) the use of a correction factor for substances with a log P_{OW} > 2 was discussed and it was agreed that the correction factor should always be used for those substances. Unless it can be demonstrated that toxicity to earthworms is independent of f_{oc}.

The log P_{OW} value of the active substance triticonazole is 3.3. The log P_{OW} for the metabolite RPA 404766 is 1.6 for RPA 406341 it is 2.2.

Table 9.8-2: TER long-term for earthworms and other soil macro-organisms

Species	Test substance	NOEC [mg/kg soil dw]	max PECsoil [mg/kg soil dw]	TER_{LT}	Trigger
Eisenia fetida	Triticonazole	125 mg ai/kg soil dw*	0.0189	6614	5
	BASF 595 01 F	5.7 mg product/kg soil dw (0.1328 mg ai/kg soil dw)*	0.0189	7.03	
	Metabolite RPA 404766 (Reg.No. 5079285)	250 mg ai/kg soil dw	0.0027	> 10000	5
	Metabolite RPA 406341 (Reg.No. 5059144)	5 mg ai/kg soil dw*	0.0037	1351	
	Metabolite MET 6[a]	131 mg ai/kg soil dw*	0.0022	> 10000	
	Metabolite MET 7[b]	124 mg ai/kg soil dw*	0.0010	> 10000	
Folsomia candida	Triticonazole	62.5 mg/kg soil dw*	0.0189	3307	5
	BASF 595 01 F	500 mg product/kg soil dw (12.2 mg ai/kg soil dw)*	0.0189	646	
	Metabolite RPA 404766 (Reg.No. 5079285)	500 mg/kg soil dw	0.0027	> 10000	
	Metabolite RPA 406341 (Reg.No. 5059144)	25 mg /kg soil dw*	0.0037	6757	
	Metabolite MET 6[a]	65.5 mg ai/kg soil dw*	0.0022	> 10000	
	Metabolite MET 7 [b]	61.9 mg ai/kg soil dw*	0.0010	> 10000	
Hypoaspis aculeifer	Triticonazole	250 mg ai/kg soil dw*	0.0189	> 10000	5
	BASF 595 01 F	14 d NOEC = 500 mg product/kg soil dw (11.7 mg ai/kg soil dw)*	0.0189	619	
	Metabolite RPA	26 mg/kg soil dw**	0.0027	9630	

Species	Test substance	NOEC [mg/kg soil dw]	max PECsoil [mg/kg soil dw]	TER_{LT}	Trigger
	404766 (Reg.No. 5079285)[a]				
	Metabolite RPA 406341 (Reg.No. 5059144)	5 mg /kg soil dw*	0.0037	1351	
	Metabolite MET 6[a]	262 mg ai/kg soil dw*	0.0022	> 10000	
	Metabolite MET 7 [b]	248 mg ai/kg soil dw*	0.0010	> 10000	

* corrected by a factor of 2 due to the log P_{OW} of triticonazole > 2 (log P_{OW} triticonazole: 3.3; log P_{OW} for RPA 406341: 2.2)
**worst case assumption, that the metabolite is ten times more toxic than the parent.
[a]calculated by considering the molecular weight of the metabolite of 333 g/mol and assuming 10-times more toxicity than the parent
[b]calculated by considering the molecular weight of the metabolite of 315 g/mol and assuming 10-times more toxicity than the parent

With the metabolites RPA 407922 and RPA 404766 studies with earthworms and collembolans were conducted, but not with the soil mite *Hypoaspis aculeifer* With *Hypoaspis aculeifer* only the metabolite RPA 406341 was tested, showing the highest DT_{50} in laboratory testing. Studies on *Eisenia fetida* and *Folsomia candida* with the metabolite RPA 406341 were also conducted. The results of the studies showed that the soil mite Hypoaspis aculeifer is not considered to be the most sensitive species. Hence, the RMS considers the testing approach (10-times more toxic than parent) acceptable to address the risk assessment for earthworms and collembolans from exposure to the metabolite RPA 404766.

Based on the risk assessment an acceptable long-term risk to earthworms and other soil macro-organisms from exposure to the formulated active substance and its metabolites was identified. The TER_{LT} values were above the trigger of 5.

Overall conclusion:

Overall, the risk to soil macro- and mesofauna is considered low and no further information is required addressing the risk to soil organisms.

B.9.9. EFFECTS ON SOIL NITROGEN TRANSFORMATION

In addition to the studies with the active substance a new nitrogen transformation study with the representative formulation BAS 595 01 F was submitted. A summary of the study is provided below.

Reference:	**Effects of BAS 595 01 F on the activity of soil microflora (nitrogen transformation test)**
Author(s), year:	Schulz, L., 2013a
Report/Doc. number:	BASF DocID 2013/1003204
Guideline(s):	OECD 216 (2000)
GLP:	Yes
Deviations:	Please refer to the comments below
Validity:	Acceptable

Material and methods:

Test substance:	BAS 595 01 F, batch no.: 84210, content of triticonazole nominal: 25.0 g/L, analysed: 26.1 g/L
Test species:	Soil microflora
Type of test, duration:	Nitrogen transformation test, 28 days
Applied concentrations:	Control, 0.71 and 7.13 mg product/kg soil dw (equivalent to 0.017 and 0.167 mg ai/kg soil dw), 3 replicates
Solvent/vehicle:	None
Toxic standard:	Dinoterb, tested in a separate study at concentrations of 6.8, 16.00 and 27.00 mg/kg soil dw

Test conditions:

Test substrate:	Agriculturally utilised soil (loamy sand), removed to a depth of 20 cm, from a field located in Canitz, Germany. No application of fertilizers and plant protection products since 2003. organic Carbon 1.49 %, pH: 6.5, Humus content: 2.56%, Carbon content of microbial biomass: 34.69 mg C/100 g soil dw (corresponding to 2.33% of organic C) Total nitrogen content: 0.14% Water holding capacity (WHC): 35.17%, water content [g/100 g soil d.w.]: 10.21 Texture according to ISO 11277: 9.6 % clay, 37.1 % silt, 53.3 % sand 0.5% (i.e. 1 g/ 200 g soil dw) lucerne meal
Substrate/test vessel:	200 g soil dw
Incubation:	19.4 – 21.5°C, darkness
Water content	15.12-15.92 g/100 g soil dw (equivalent 42.99-45.26 % of WHC)
pH:	Test start: 6.4 Test end: 6.4
Test parameters:	The nitrogen transformation was determined on day 0 (after approx. 3 hours), and

at intervals of 7, 14 and 28 days after application.

10 g soil dw per replicate was extracted by adding 50 mL 1 M KCl solution to the equivalent of 10 g soil dw and mixing on a rotator at 150 rpm for 60 minutes. For the quantitative determination of the mineralized part of nitrogen the Autoanalyzer was used.

Statistics: The mean nitrogen-content, standard deviation and coefficient of variation were calculated for each treatment group and sampling date.

Findings:

Table 9.9-1: Effects of BAS 595 01 F on nitrogen transformation

Sampling date (DAA)	Treatment	Measured values [mg NO_3-N/ 100 g sdw]	Mean value [mg NO_3-N/ 100 g sdw] (SD)	CV [%]	mg NO_3-N/ kg sdw/day	Deviation from control [%]
0	Control	1.13	1.09 (0.04)	3.5	-	-
		1.07				
		1.06				
	0.71 mg/kg sdw	1.06	1.05 (0.02)	1.6	-	-
		1.06				
		1.03				
	7.13 mg/kg sdw	1.05	1.06 (0.02)	1.6	-	-
		1.08				
		1.05				
7	Control	3.75	3.77 (0.02)	0.6	5.4	-
		3.78				
		3.79				
	0.71 mg/kg sdw	3.79	3.66 (0.14)	3.7	5.2	-2.7
		3.52				
		3.68				
	7.13 mg/kg sdw	3.75	3.72 (0.03)	0.7	5.3	-1.0
		3.71				
		3.70				
14	Control	4.59	4.59 (0.04)	0.8	3.3	-
		4.62				
		4.55				
	0.71 mg/kg sdw	4.67	4.50 (0.17)	3.8	3.2	-1.4
		4.33				
		4.50				
	7.13 mg/kg sdw	4.86	4.52 (0.31)	6.8	3.2	-1.1
		4.26				
		4.44				
28	Control	5.80	5.93 (0.12)	2.1	2.1	-
		6.04				
		5.96				
	0.71 mg/kg sdw	5.60	5.86 (0.23)	3.9	2.1	-0.8
		5.97				
		6.01				
	7.13 mg/kg sdw	6.58	6.42 (0.14)	2.1	2.3	+10.7
		6.32				
		3.37				

sdw…soil dry weight
DAA…Days after application

CV %...Coefficient of Variation in %

In a separate study the reference item Dinoterb caused an effect on nitrogen transformation of +17.6%, +33.7% and + 42.6% at concentrations of 6.80, 16.00 and 27.00 mg dinoterb/kg soil dw, respectively, 28 days after application.

Conclusion:	BAS 595 01 F caused no long-term adverse effects (difference to control < 25 %, OECD 216) on the soil nitrogen transformation (expressed as NO_3-N production) at the end of 28-day incubation period.

Comment RMS:	The study was evaluated following the recommendations of the currently valid test guideline OECD 216 (2000). **Check of validity criteria:** - Evaluations of test results with agrochemicals are based on relatively small differences (i.e. average value ± 25 %) between nitrate concentrations in control and treated soil samples, so large variations in the controls can lead to false results. Therefore, the variation between replicate control samples should be less than ± 15%. In the current study the variation coefficient of replicate control samples ranged between 0.6 and 3.5% for the single sampling dates. The overall coefficient of variation for the control, estimated by ToxRat® 3.1.0., was 2.1%. Fulfilled. **Acceptability of the analytical methods used in the test:** Evaluation of the analytical methods (water/sediment/soil) according to the Guidance Document SANCO/3029/99 rev. 4. The chemicals for the calibration solutions were NANo2, (NH4)2SO4 and KNO3 from Merck. The autoanalyzer was calibrated before each measurement series by establishing a calibration curve. Each 30 samples a standard was measured for recalibrations and adjusting the calibration curve. The calibration curve was calculated with linear regression. LOQ: 0.6 mg/ kg soil dw LOD: not reported The analytical method fulfils the requirements of guideline SANCO/3029/99 rev. 4. **Endpoints:** Only the mean transformation rate over the replicates of one sampling was provided in the study report, transformation rates per replicate were not reported and could therefore not be recalculated by the RMS with ToxRat® 3.1.0. However, the data presented in the study report appears to be plausible and is considered acceptable. 28 day EC_{25} > 7.13 mg product/kg soil dw (0.167 mg ai/kg soil dw)

	Conclusion of the RMS: Based on the evaluation of the study the nitrogen transformation test on soil microorganisms is considered valid.

Reference:	**Impact of selected seed dressings on soil microbiological activity in spring barley cultivation**
Author(s), year:	Niewiadomska A., Sawińska Z., Wolna-Maruwka A., 2011
Source:	Fresenius Environmental Bulletin, 20(5A):1252-1261, pp. 1252-1261
Report/Doc. number:	Public literature
Guideline(s):	None
GLP:	No

Executive Summary:

The objective of this study was to examine changes in counts of total bacteria and numbers of oligotrophs, copiothrophs, actinomycetes and fungi, as well as changes in enzymatic activity of dehydrogenases and acid phosphatase following the application of different seed dressings, including triticonazole containing products. The applied seed dressings were found to exert a statistically highly significant or significant influence on total counts of bacteria, oligotrophs, copiotrophs, actinomycetes and fungi at different dates of analysis. However, the direction (stimulating or inhibiting) of the effect on the number of selected microorganisms was ambiguous. For fungi the effect was only significant on one of the five dates. Changes in enzymatic activity in the soil induced by triticonazole were not statistically significant.

Conclusions:

The influence on changes in number of individual groups of microorganisms in the soil of triticonazole are, depending on the applied concentration, ambiguous. Changes in enzymatic activity in the soil induced by triticonazole were not statistically significant.

The study showed effects of triticonazole on enzymatic activity, and no clear conclusions on the directions on the effect on count of soil bacteria. The authors performed no multifactorial analysis, although figures indicate a stronger influence of seasonal changes than the effects of different treatments. Considering the presented information, influence of the use of triticonazole in not expected to affect its degradation rate in soil.

Comment RMS:	Results of the performed investigations revealed a trend of growth in total bacterial counts at different dates of analysis following the application of various seed dressings. However application of 200 ml Premis 025 FS/100 kg grain, caused a drop in total bacterial counts by 66% with regard to control at the first investigation date. Application of 150 ml Premis 025 FS/100 kg grain also caused a reduction of total bacterial counts but no percentage is reported. At the fifth investigation date (after harvest), while other fungicides tested showed an increase of total bacterial counts, numbers of bacteria were still reduced for the application with Premis 025 FS. No information is reported about the extent of the reduction. At dough stage, the performed statistical analysis revealed highly significant

	differences in numbers of copiotrophs under the influence of Premis 025 FS at a higher dose. Numbers of the examined microorgnisms increased 1.5 times.On the third date of analysis, all the examined seed dressings exerted a highly significant influence on numbers of actinomycetes in soil, whereas Premis 025 FS caused declines of 53 and 46% at application rates of 100 ml product/100 kg grain and 200 ml product/100 kg grain, respectively. Research results indicate declining activity of dehydrogenases following treatments with different pesticide preparations with exception of the Premis 025 FS – treatment on investigation date 5 (after harvest) where 25% increase of dehydrogenases activity was observed. However the results for dehydrogenases activity were not statistically significant. Also no significant effects could be shown on the activity of acid phosphatase but the results indicate that all fungicides applied in the experiment caused a decline in soil acid phosphatase activity on the first, third and fifth date of analysis. **Conclusion of the RMS:** These results are considered relevant. However, the study was not conducted according to OECD TG 2016 with the study mainly focussing on structural parameters than on functionality. Therefore results cannot be used in the risk assessment but are considered as supplemental information.

B.9.10. RISK ASSESSMENT FOR SOIL NITROGEN TRANSFORMATION

The toxicity of triticonazole on soil micro-organisms is summarised below. The study with the active substance was not considered reliable. However, a study with the formulated triticonazole is available and considered sufficient to address the risk.

Table 9.10-1: Summary of effects on non-target micro-organisms (nitrogen transformation)

Test substance	Test concentration	Time	Effects (deviation from control)	Reference
BASF 595 01 F	0.71 mg prod./kg soil dw (0.017 mg ai/kg soil dw)	28 d	-0.8 %	Schulz, L., 2013a
	7.13 mg prod./kg soil dw (0.167 mg ai/kg soil dw)		+10.7 %	
Metabolite RPA 406341 (Reg.No. 5059144)	1 mg/kg soil dw	28 d	-9.59 %	Royer, S., 2006b
	10 mg/kg soil dw		-12.33 %	
Metabolite RPA 404766 (Reg.No. 5079285)	0.1 mg/kg soil dw	42 d	-4.73 %	Stojanowitsch, née Gehrig, M., 2015a
	1 mg/kg soil dw		-24.8 %	
Metabolite RPA 407922 (Reg.No. 5079288)	0.1 mg/kg soil dw	28 d	+7.5%	Schulz, L., 2014b
	1 mg/kg soil dw		+3.5%	

+…increase of nitrogen transformation; -…decrease of nitrogen transformation

According to the Terrestrial Guidance Document (SANCO/10329/2002) the risk is considered acceptable if the effect on nitrogen mineralisation at a recommended application rate is below 25% after 100 days.

For the Metabolite RPA 407922 no PEC_{soil} values are available as after re-evaluation in the e-fate section no exposure assessment is triggered. Two unknown fractions were discovered during the re-evaluation process. For these unknown metabolites Met 6 (MWT 333) and Met 7 (MWT 315) no toxicity studies are available (for details please refer to fate section B.8).

Table 9.10-2: Risk assessment

Test substance	Effects < 25% at test concentration	$PEC_{soil, accumulation}$	Risk acceptable Yes/No
BASF 595 01 F	0.167 mg ai/kg soil dw	0.0189 mg ai/kg soil dw	Yes
Metabolite RPA 406341 (Reg.No. 5059144)	10.0 mg/kg soil dw	0.0037 mg/kg soil dw	Yes
Metabolite RPA 404766 (Reg.No. 5079285)	1.0 mg/kg soil dw	0.0027 mg/kg soil dw	Yes

Test substance	Effects < 25% at test concentration	$PEC_{soil, accumulation}$	Risk acceptable Yes/No
Metabolite MET 6[a]	0.017 mg /kg soil dw	0.0022	Yes
Metabolite MET 7[b]	0.166 mg /kg soil dw	0.0010	Yes

[a]calculated by considering the molecular weight of the metabolite of 333 g/mol and assuming 10-times more toxicity than the parent
[b]calculated by considering the molecular weight of the metabolite of 315 g/mol and assuming 10-times more toxicity than the parent

The formulated active substance triticonazole did not significantly affect the activity of the soil nitrogen transformation under test conditions at application rates up to 0.167 mg ai/kg soil dw. The PECsoil accumulation for the intendeds seed treatment cereals was calculated to be 0.019 mg ai/kg soil. Thus the exposure concentration used in the tests was approximately 8 times higher than the maximal expected PECsoil when applied according to the GAP.

Based on the results a toxicity endpoint for the metabolite RPA 406341 of 10.0 mg/kg soil dw and for the metabolites RPA 404766 and RPA 407922 of 1 mg/kg soil dw was determined.
Under consideration of a $PEC_{soil\ accumulation}$ of 0.0038 mg/kg soil dw for RPA 406341, a $PEC_{soil\ maximum}$ of 0.0027 mg/kg soil dw for RPA 404766 and a $PEC_{soil\ maximum}$ of 0.0022 mg/kg soil dw for Met 6 and 0.0010 mg/kg soil dw for Met 7 the risk to soil micro-organisms from exposure to the metabolite can be considered acceptable.

Overall conclusion:

According to the results of the data provided for the active substance triticonazole it can be assumed that the risk for soil micro-organisms is low when applied according to the GAP. A public literature study is available showing a decline of reduction in numbers of microorganisms by applying Premis 025 FS at a dose of 200 ml/100 kg grain and 150 ml/100 kg grain at harvest. These results are considered relevant. However, the study was not conducted according to OECD TG 2016 with the study mainly focussing on structural parameters than on functionality. Therefore results cannot be used in the risk assessment but are considered as supplemental information.

B.9.11. EFFECTS ON TERRESTRIAL NON-TARGET HIGHER PLANTS

B.9.11.1. Summary of screening data

In the first EU peer review evaluation of triticonazole no data and no risk assessment for non-target terrestrial plants was provided justified due to the intended use as a seed treatment. For the current application the applicant provided a study with the representative formulation on seedling emergence and plant growth. However, according to the data requirements for active substances (Commission Regulation (EU) 283/2013) and/or plant protection products (Commission Regulation (EU) 284/2013) no testing on non-target terrestrial plants is necessary for seed treatments.

B.9.11.2. Testing on non-target plants

As testing of non-target terrestrial plants is not part of the data requirements and in the submitted test, the application mode does not coincide with the application mode of the intended use as a seed treatment the study is considered not relevant and was not evaluated by the RMS. The reference is given below.

Reference:	**Effect of BAS 59501 F on seedling emergence and seedling growth of ten species of terrestrial plants under greenhouse conditions.**
Author(s), year:	Strömel, C., Brockmann, A., Teresiak, H., 2013a
Report/Doc. number:	BASF DockID: 2013/1003205
Guideline(s):	OECD 208 (2006), OCSPP 850.4100 (2012)
GLP:	Yes

B.9.11.3. Extended laboratory studies on non-target plants

For seed treatments testing on non-target terrestrial plants is not required.

B.9.11.4. Semi-field and field tests on non-target plants

For seed treatments testing on non-target terrestrial plants is not required.

B.9.12. RISK ASSESSMENT FOR TERRESTRIAL NON-TARGET HIGHER PLANTS

Overall conclusion:

As the intended use is a seed treatment, the exposure to non-target plants is considered to be negligible and a risk assessment is not required.

B.9.13. EFFECTS ON OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA)

No data available.

B.9.14. RISK ASSESSMENT FOR OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA)

No data available

B.9.15. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCP 10.1.1.2 and 10.1.2.2	Scrimshaw O.	2006	Rate of degradation of prochloraz and triticonazole under field conditions on spring wheat seed exposed on the soil surface following treatment with Kinto (BAS 591 01 F) seed treatment in UK BASF, DocID 2006/1015760 GLP Yes unpublished	N	N	-	BASF	As confirmatory Data (2009) for the first approval (2003)
KCP 10.1.1.2 and 10.1.2.2	Moreno S.	2008	Rate of degradation of triticonazole under field conditions on spring wheat seeds treated with Premis 25 FS (BAS 595 01 F) exposed on the soil surface after sowing in Spain (2007) BASF, DocID 2007/1016397 GLP Yes unpublished	N	N	-	BASF	As confirmatory Data (2009) for the first approval (2003)
KCP 10.1.1.2 and 10.1.2.2	Plier S.	2016	Determination of residues of BAS 595 F (Triticonazole) in spring wheat seeds treated with BAS 728 00 F exposed on the soil surface in Germany and the Netherlands, 2016 and amendment No. 1 BASF DocID: 2017/1000581 and BAS DocID: 2016/1321103 GLP Yes unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.1.1.2 and 10.1.2.2	Plier S., Elze M.	2017a	Determination of residues of BAS 595 F (Triticonazole) in spring wheat seeds treated with BAS 728 00 F exposed on the soil surface in Germany and the Netherlands, 2016 BASF DocID: 2017/1000582 BioChem agrar, Labor für biologische und chemische Analytik GmbH, Gerichshain, Germany GLP Yes unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.1.1.2	Not reported	2018	Additional information regarding the initial residue values of triticonazole on treated seeds – Position Paper BASF DocID 2018/1011232 GLP No unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.1.1.2 and 10.1.2.2	Szegedi K.	2017a	Calculation of DT_{50} dissipation times for BAS 595 F - triticonazole in treated spring wheat seeds from field trials conducted in Europe	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
			BASF DocID 2017/1070086 BASF SE Crop Protection Ecoltoy and Environmental Analytics, Limburgerhof, Germany GLP Yes unpublished					
KCP 10.1.1.2 and 10.1.2.2	Szegedi K.	2017b	Calculation of DT_{50} dissipation times for BAS 595 F - triticonazole in treated winter wheat seeds from field trials conducted in Europe BASF DocID 2017/1134017 BASF SE Crop Protection Ecoltoy and Environmental Analytics, Limburgerhof, Germany GLP Yes unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.1.1.2	Moosmayer P.	2008a	Exposure of birds in cereals in Germany in spring - Attractiveness of cereal fields, portion of time and diet composition BASF DocID 2008/1097311 RIFCon GmbH, Heidelberg, Germany Fed.Rep. GLP Yes Unpublished	N	N	-	BCS Letter of Access	Submitted for the purpose of renewal (2015)
KCP 10.1.1.2	Sadowski J. *et al.*	2014a	Generic field study on portion of time (PT), diet (PD) and feeding rates of yellowhammers, chaffinches and skylarks on freshly drilled spring cereal fields BASF DocID 2014/1263159 tier3 solutions GmbH, Leverkusen, Germany Fed.Rep. GLP Yes Unpublished	N	N	-	Syngenta Letter of Access	Submitted for the purpose of renewal (2015)
KCP 10.1.1.2	Erni, M. *et al.*	2017a	Generic GLP field study on skylark PT in freshly-drilled spring cereals in Central Europe (Germany) BASF DocID 2017/1121782 Rifcon GmbH, Hirschberg, Germany GLP Yes unpublished	N	N	-	Syngenta Letter of Access	Submitted for the purpose of renewal (2015)
KCP 10.1.1.2	Dittrich R., Benito M.,	2017a	PT of the skylark (Alauda arvensis) in pre-emergence winter cereal fields in autumn in Germany BASF 2016/1234467 tier3 solutions GmbH, Leverkusen, Germany GLP Yes unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.1.1.2	Barfknecht R.	2006a	Generic field monitoring of birds in freshly drilled spring cereal fields in autumn in Germany	N	N	-	BCS Letter of Access	Submitted for the purpose of renewal (2015)

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
			BASF DocID 2006/1047473 Bayer CropScience AG, Institute for Ecotoxicology, Monheim, Germany GLP Yes unpublished					
KCP 10.1.1.2	[redacted]	2014	Triticonazole Document N5 – Consideration of isomeric compositions on the risk assessment	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)	Y
KCP 10.1.1.2	Spangler, Ch., *et al.*	2015	Determination of BAS 595 F and M595F014 in wheat seed after seed treatment with BAS 595 01 F BASF docID2015/1189076 BASF SE Crop Protection Ecology and Environmental Analytics, Limburgerhof, Germany GLP No unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.1.1.2	[redacted]	1992 a	Trials to evaluate the consumption of fungicide-coated wheat seeds by Greay partridges (*Perdix perdix*) in captivity Document No: R013096 [redacted] GLP No unpublished	Y	N	-	BASF	As confirmatory Data (2009) for the first approval (2003)
KCP 10.1.1.2	[redacted]	2001a	A test for avoidance of treated barley seed with the northern bobwhite (*Colinus virginianus*) Document No: C017903 [redacted] GLP Yes unpublished	Y	N	-	BASF	As confirmatory Data (2009) for the first approval (2003)
KCP 10.1.1.2	Laucht, S.	2013	Abundance and density of unburied seeds in freshly drilled cereal fields in Germany BASF DocID 2012/1126440 Rifcon GmbH Hirschberg Germany GLP Yes unbpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.1.2.2	Fülling O., Miersch Ch.	2016	Generic Field Study on PT of Wood Mice in freshly drilled Spring Cereal Fields (Germany) BASF DocID 2016/1326919 tier3 solutions GmbH, Leverkusen, Germany GLP Yes	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.1.2.2	Barfknecht R.	2008	Generic field monitoring of mammals on freshly drilled summer cereals in Hunsrück, Germany	N	N	-	BCS Letter of Access	Submitted for the purpose of renewal (2015)

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
			BASF DocID 2008/1097310 Bayer CropScience AG. Institute for Ecotoxicology, Monheim, Germany GLP Yes unpublished					
KCP 10.1.2.2	Fülling O., Sainz-Elipe S.	2017	Generic Field Study on PT of Wood Mice in freshly drilled Winter Cereal Fields (Germany) BASF DocID 2017/1025731 tier3 solutions GmbH, Leverkusen, Germany GLP Yes unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.1.2.2	Barfknecht R.	2006b	Generic field monitoring of mammals on freshly drilled winter cereal fields in autumn in Germany BASF DocID 2006/1047474 Bayer CropScience AG. Institute for Ecotoxicology, Monheim, Germany GLP Yes unpublished	N	N	-	BCS Letter of Access	Submitted for the purpose of renewal (2015)
KCP 10.2.1	Janson G.-M.	2009a	Acute toxicity of BAS 595 01 F to *Daphnia magna* STRAUS in a 48 hour static test BASF DocID 2009/1072605 BASF SE, Limburgerhof, Germany Fed.Rep. GLP Yes Unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.2.1	Hoffmann F.	2009a	Effect of BAS 595 01 F on the growth of the green alga *Pseudokirchneriella subcapitata* BASF DocID 2009/1072606 BASF SE, Limburgerhof, Germany Fed.Rep. GLP Yes Unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.2.1	[redacted].	2001	CRLD001002: Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Generated by: Safepharm Laboratories Limited, Derby [redacted] GLP Yes un-published	N	N	-	BASF	In the DAR (2003)
KCP 10.2.1	Wetton P.M., Mullee D.M.	1999b	EXP10642A: Acute Toxicity to *Daphnia magna* Generated by: Safepharm Laboratories Limited, Derby GBR; Rhône Poulenc Secteur Agro, France; Document No: C020490 GEP Yes unpublished	N	N	-	BASF	In the DAR (2003)
KCP 10.2.1	Mead C., Mullee D.M.	1999a	EXP10642A: Algal Inhibition Test	N	N	-	BASF	In the DAR (2003)

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
			Generated by: Safepharm Laboratories Limited, Derby GBR; Rhône Poulenc Secteur Agro, France; Document No: C020489 GLP Yes unpublished					
KCP 10.3.1.1.	Hernadi D.	2007a	Effects of BAS 595 01 F (acute contact and oral) on honey bees (*Apis mellifera* L.) in the laboratory BASF DocID 2007/1052765 LAB International Research Centre Hungary Ltd., Veszprem, Hungary GLP Yes Unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.3.2.2	Mead-Briggs M.	1998b	A laboratory evaluation on the effects of EXP80523A on the parasite wasp *Aphidius rhopalosiphi* -Poulenc; Agrochemical Evaluation Unit, Southampton, UK; Rhone-Poulenc Secteur Agro, Lyon, France; Document No: R005707 GLP Yes unpublished	N	N	-	BASF	In the DAR (2003)
KCP 10.3.2.2	Moll M., Buetzler R.	2002a	Effects of EXP80472B on the parasitoid *Aphidius rhopalosiphi* in the laboratory - Dose response test Aventis CropScience GmbH, DEU; Ecotoxicology, Frankfurt IBACON GmbH, Rossdorf, DEU; Document No: C020491 GLP Yes unpublished	N	N	-	BASF	In the DAR (2003)
KCP 10.3.2.2	Vinall S.	1998a	A labaratory evaluation of the effect of EXP80523A on the phytoseiid mite *Typhlodromus pyri* Rhone-Poulenc Secteur Agro, Lyon, France; Agrochemical Evaluation Unit, Southampton, Uk; Document No: R005711 GLP Yes unpublished	N	N	-	BASF	In the DAR (2003)
KCP 10.3.2.2	Kühner Ch.	1996a	EXP80560B: Acute Toxicity to the Ground Beetle, *Poecilus cupreus* L. (Coleoptera, Carabidae) in the Laboratory Rhône-Poulenc; GAB & IFU, Niefern-Öschelbronn, Germany; Document No: R005429 GLP Yes unpublished	N	N	-	BASF	In the DAR (2003)
KCP 10.3.2.2	Kühner Ch.	1996b	EXP80527B: Acute Toxicity Test to the Ground Beetle, *Poecilus cupreus* L.	N	N	-	BASF	In the DAR (2003)

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
			(Coleoptera, carabidae) in the Laboratory GAB Biotechnologie GmbH; Rhone-Poulenc Secteur Agro, Lyon, France; Document No: R005451 GLP Yes unpublished					
KCP 10.3.2.2	Kühner Ch.	1996c	EXP80560B: Acute Toxicity to the Rove Beetle, *Aleochara bilineata* Gyll. (Coleoptera, Staphilinidae) in the Laboratory GAB & IFU, Niefern-Öschelbronn, Germany; Document No: R005432 and C018900 GLP Yes unpublished	N	N	-	BASF	In the DAR (2003)
KCP 10.3.2.2	Kühner Ch.	1996d	EXP80527B: Acute Toxicity to the Rove Beetle, *Aleochara bilineata* Gyll. (Coleoptera, Staphilinidae) in the Laboratory Generated by: GAB Biotechnologie GmbH; Rhone-Poulenc Secteur Agro, Lyon, France; Document No: R005447 GLP Yes unpublished	N	N	-	BASF	In the DAR (2003)
KCP 10.3.1.2	Schmitzer S.	2014a	Chronic oral toxicity test of BAS 595 01 F on the honeybee (*Apis mellifera* L.) in the laboratory and amendment BASF DocID 2014/1000023 Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. GPL Yes Unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.3.1.3	Kleebaum K.	2014b	Acute toxicity of BAS 595 01 F to honeybee larvae (*Apis mellifera* L.) under laboratory conditions (in vitro) BASF DocID 2014/1000024 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. GLP Yes Unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.3.2.2	Drexler A.	2004a	Effects of BAS 595 01 F applied as a seed treatment of wheat seeds on larvae of the ground dwelling arthropod Poecilus cupreus (Coleoptera, Carabidae) in an extended laboratory trial BASF DocID 2004/1025180 BASF AG Agrarzentrum Limburgerhof,	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
			Limburgerhof, Germany Fed.Rep. GLP Yes Unpublished					
KCP 10.3.2.2	Sattler F.	2009a	Effects of BAS 595 01 F applied as a seed treatment of wheat seeds on larvae of the ground dwelling arthropod *Poecilus cupreus* (Coleoptera, Carabidae) in an extended laboratory trial BASF DocID 2009/1098729 BASF SE, Limburgerhof, Germany Fed.Rep. GLP Yes Unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.3.2.2	Schmitzer S.	2007a	Effects of BAS 595 01 F applied as treated wheat seeds on the reproduction of rove beetles *Aleochara bilineata* - Extended laboratory study BASF DocID 2007/1023106 Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. GLP Yes Unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
Annex III, 10.6.1.3	Lührs, U.	2001b	Acute toxicity (14 days) of EXP80472B to the earthworm Eisenia fetida in artificial soil Generated by: Aventis CropScience GmbH, DEU; IBACON GmbH, Rossdorf, DEU; Document No: C017899 GLP / GEP Yes unpublishedGLP Yes unpublished	N	N	-	BASF	In the DAR (2003)
KCP 10.4.1.1	Wolf A.	2009a	Effects of BAS 595 01 F on growth and reproduction of earthworms (*Eisenia fetida*) in artificial soil BASF DocID 2009/1117741 BASF SE, Limburgerhof, Germany Fed.Rep. GLP Yes Unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.4.2.1	Lührs U.	2004a	Effects of BAS 595 01 F on reproduction of the collembola *Folsomia candida* in artificial soil BASF DocID 2004/1014986 Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. GLP Yes Unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.4.2.1	Schulz L.	2013b	Effects of BAS 595 01 F on the reproduction of the predatory mite *Hypoaspis*	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
			aculeifer BASF DocID 2013/1103637 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. GLP Yes Unpublished					
Annex III, 10.6.2.2	Förster B.	2002	Effects of EXP80472B on the decomposition of organic material in the field Generated by: Aventis CropScience GmbH, DEU; ECT Oekotoxikologie GmbH, Floersheim, DEU; Document No: C020499 GLP / GEP Yes unpublished	N	N	-	BASF	In the DAR (2003)
KCP 10.5	Schulz L.	2013a	Effects of BAS 595 01 F on the activity of soil microflora (Nitrogen transformation test) BASF DocID 2013/1003204 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. GLP Yes Unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)
KCP 10.6.2	Stroemel C. et al.	2013a	Effect of BAS 595 01 F on seedling emergence and seedling growth of ten species of terrestrial plants under greenhouse conditions BASF DocID 2013/1003205 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. GLP Yes Unpublished	N	Y	New data for AIR 3 renewal	BASF	Submitted for the purpose of renewal (2015)