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TRITICONAZOLE

Volume 3 – B.7 (AS)

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When	What
2003/ September	Initial DAR, first version
2004/ September	Addendum 1
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B.7. RESIDUE DATA

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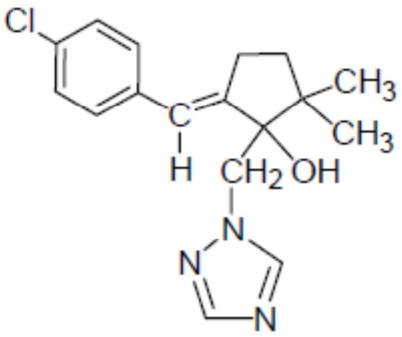
INTRODUCTION

Triticonazole is a fungicidal active substance and was evaluated in the framework of Directive 91/414/EEC with Austria being the designated Rapporteur Member State (RMS). The representative use supported for the peer review process was a seed treatment of wheat grains with an application rate of 50 g a.s./ton seed. The use was supported for both the Northern and Southern European region. Following the peer review a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was taken and published in Directive 2006/39/EC. The Annex I inclusion entered into force on 01 February 2007.
Directive 91/414/EEC has been repealed by Regulation (EC) No 1107/2009 of 21 October 2009 concerning the placing of plant protection products on the market.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 be 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 (enry No. 29).
This renewal assessment report (DRAR) 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. All studies, which were already submitted for the Annex I inclusion under Directive 91/414/EEC, are contained in the Monograph (DAR Triticonazole, 2005). These studies are summarized in tables written in grey typeface in this report. However to increase the readability and comprehensibility of the present renewal assessment report, main data and results of some previously evaluated studies are briefly summarized.

Triticonazole is the ISO common name for (±)-(E)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol (IUPAC).



Triticonazole belongs to the class of conazole fungicides. Triticonazole can be used only as fungicide and it is used for the control a broad range of fungi belonging to several groups of plant pathogens (Ascomycetes, Adelomycetes, Basidiomycetes) in wheat seeds. Triticonazole is taken up slowly by the seedlings via the seed, teguments and roots and act as a C-14 demethylation inhibitor in the sterol biosynthesis pathway. The soil around the roots acts as a reservoir to feed the plant with triticonazole for several months after sowing.

Triticonazole is a **racemic mixture** of the two enantiomers (1*R*,5*E*)-5-[(4-chlorophenyl)methylene]-2,2-dimethyl-1-(1,2,4-triazol-1-ylmethyl)cyclopentanol and (1*S*,5*E*)-5-[(4-chlorophenyl)methylene]-2,2-dimethyl-1-(1,2,4-triazol-1-ylmethyl)cyclopentanol. Triticonazole possesses a chiral centre in C-1 of the cyclopentane ring and an exocyclic double bond in C-2 of the cyclopentane ring. The minimum purity of the dry material (racemate) is 950 g/kg.
The ratio of the enantiomers in the technical material and in formulations **(racemic mixture; 1:1 ratio) is deemed to be stable**.
The Z-isomer, which could theoretically exist due to the E/Z-isomerism at the double bond, is not included in the definition of the active substance and is not observed in the technical material.
All studies were done with the racemic mixture of Triticonazole. There are no detectable residues of Triticonazole at harvest, therefore a separation of enantiomers was not necessary.
Due to the planned use as seed treatment, triticonazole is not expected to be exposed to light and therefore, the formation of the Z isomer (photometabolite RPA 406203) is not considered to be relevant for residue studies. The Z-isomer was also not detected in edible matrices in the plant metabolism study.

Further considerations regarding the influence of isomers on the outcome of the residue behaviour and therefore on the consumer risk assessments are not needed.

B.7.1. STORAGE STABILITY OF RESIDUES

For the active substance triticonazole, data on the stability of residues were reviewed during the Annex I inclusion process under the 91/414/EEC framework.

Report:	**R006867; Chenevier, A.; Kieken, J. L. (1995)**
Title:	Triticonazole or RPA 400727: Storage Stability in Maize (Grain) and in Winter Wheat (Grain and Straw)
Guidelines:	EPA Pesticide Assessment Guidelines, Subdivision 0,171-4(a), Nov 1989
GLP	Yes

Maize (grain) and winter wheat (grain and straw) fortified prior to extraction at a level of 0.1 mg triticonazole/kg (grain) and 0.5 mg triticonazole/kg (straw) were stored under deep freeze conditions of < -20°C. After sampling intervals of about 0, 3, 6, and 12 months samples were analysed for triticonazole: the residues were extracted with water/acetone and the determination was performed with GC and thermoionic specific detector. The mean recovery efficiency was reported to be 107.5 % (maize grains), 102.3 % (wheat grains) and 104.3 % (wheat straw), resp. and the limit of quantification 0.01 mg/kg (grains) and 0.05 mg/kg (straw).

Analytical method : AR92-92
Principle : Triticonazole is extracted by maceration with water/acetone mixture. The extract is purified using a C18 cartridge followed by an aminopropyl (NH2) cartridge
The final extract is quantified by GC using a thermoionic specific detector (TSD). Quantification is carried out by comparison with external standard.
5 points calibration was performed (linearity : r = 1). Procedural recoveries were conducted along analysis :

Table 7-1: Procedural recovery results from grain (maize, winter wheat) and straw samples fortified with triticonazole at a nominal level of 0.1 mg/kg and 0.5 mg/kg, resp.

Sample	Sampling interval [months]	Recovery %
Maize (grain) fortification level 0.1 mg/kg	0	109
	3	107
	6	107
	12	107
Winter wheat (grain) fortification level 0.1 mg/kg	0	112
	3	88
	6	98
	12	111
Winter wheat (straw) fortification level 0.5 mg/kg	0	85
	3	75
	6	122
	12	135

Results:
For all sampling intervals, the mean measured residue levels in stored grain (maize, winter wheat) and straw ranged from 71 – 120 % of the nominal level.

The results are summarised in Table 7-2 :

Table 7-2: Stability results from grain (maize, winter wheat) and straw samples fortified with triticonazole at a nominal level of 0.1 mg/kg and 0.5 mg/kg, resp.

Sample	Sampling interval [months]	triticonazole values [mg/kg]	Mean triticonazole values [mg/kg]	Mean [%] of nominal triticonazole residues uncorrected	Mean [%] of nominal triticonazole residues corrected to day 0
Maize (grain) fortification level 0.1 mg/kg	0	0.112 0.112 0.111	0.112	112	*100*
	3	0.100 0.102 0.098	0.100	100	89
	6	0.088 0.089 0.090	0.089	89	80
	12	0.102 0.092 0.106	0.100	100	89
Winter wheat (grain) fortification level 0.1 mg/kg	0	0.0.108 0.110 0.113	0.110	110	*100*
	3	0.091 0.094 0.093	0.093	93	85
	6	0.112 0.107 0.072	0.097	97	88
	12	0.106 0.102 0.117	0.108	108	98
Winter wheat (straw) fortification level 0.5 mg/kg	0	0.509 0.385 0.512	0.469	94	*100*
	3	0.339 0.351 0.378	0.356	71	76
	6	0.512 0.494 0.510	0.505	101	107
	12	0.589 0.604 0.678	0.624	120	128

Conclusion :
The study is considered acceptable and compliant to OECD guideline 506. Triticonazole residues remain stable after storage under deep freeze conditions up to 12 months. Thus the maximum storage period of of the residue trials is covered also for the new residue trial (maximum storage interval from harvest until extraction 311 days).
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B.7.2. METABOLISM, DISTRIBUTION AND EXPRESSION OF RESIDUES

An overview of metabolites identified during consumer safety studies is given below.

Table 7.2-1: Notations of parent and metabolites of triticonazole

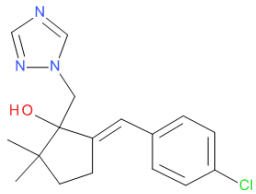
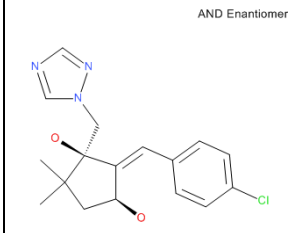
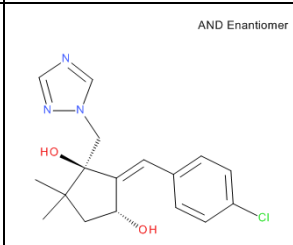
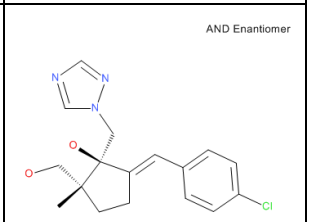
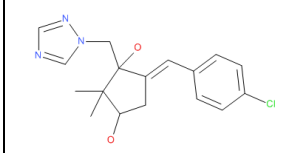
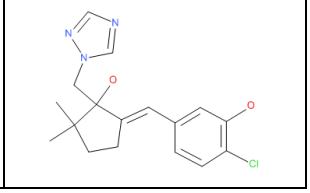
Code Number		Description		Relevant compartments	Structure
Manufacturing code	**Reg No.**	**Chemical name**	**CAS-No.**		
BAS 595 F Triticonazole former BAS 9318 F RPA 400727 M595F000	4378513	(*RS*)-(*E*)-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol	131983-72-7	Rat Livestock (goat) Plant Fish Rot Crop Soil Surface water	
cis-diol RPA 404766 M595F001 R2	5079285	(1RS,2E,3SR)-2-(4-chlorobenzylidene)-5,5-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)-1,3-cyclopentanediol	none	Rat Plant Rot Crop Soil Surface water	
trans-diol RPA 406341 AE 0540093 M595F002	5059144	(1RS,2E,3RS)-2-(4-chlorobenzylidene)-5,5-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)-1,3-cyclopentanediol	none	Plant Rot Crop Soil Surface water	
RPA 404886 M595F005 R4	5079247	(1RS,5E,2RS)-5-(4-chlorobenzylidene)-2-hydroxymethyl-2-methyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	none	Rat Livestock (goat) Rot Crop Plant	
RPA 406780 M595F007 R5	5079286	E-5-(4-chlorobenzylidene)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentane-1,3-diol	none	Rat Plant	
RPA 407922 M595F013 R1	5079288	(RS)-(E)-5-(4-chloro-3-hydroxybenzylidene)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	none	Rot Crop Soil Surface water Plant	

Table 7.2-1: Notations of parent and metabolites of triticonazole

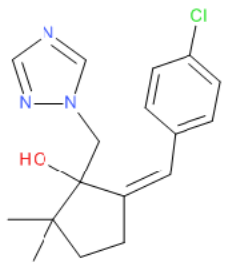
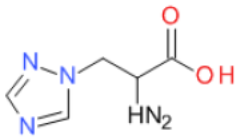
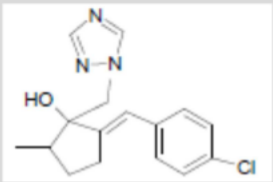
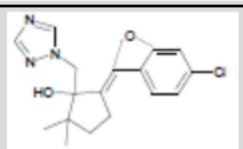
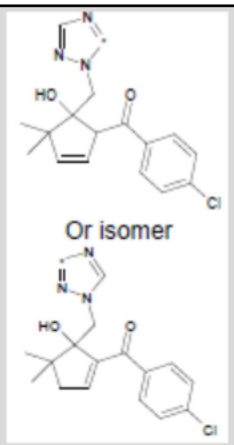
Code Number		Description		Relevant compartments	Structure
Manufacturing code	Reg No.	Chemical name	CAS-No.		
RPA 406203 Photometabolite Z isomer of parent M595F014	5079359	(1RS, Z)-5-(4-chlorobenzylidene)- 2, 2- dimethyl- 1- ((1H)-1,2,4-triazol-1-ylmethyl)-cyclopentan-1-ol	none	Plant (barley, forage, and straw. <10% TRR) Rot Crop (soil only) Soil surface (from soil photolysis, not relevant for seed treatment uses) Surface water (from aqueous photolysis)	
Triazole-alanine R9	270412	2-amino-3-(1H-1,2,4-triazol-1-yl)propionic acid	86362-20-1	Plant	
R3 (Impurity)	47010773			Plant	
M595F015 (proposed structure)		Tentatively identified as a mono oxidised form of Triticonazole with the oxidation taking place more probably in the position 2 of the 4 Chloro-phenyl group or in the methylene group between the Chloro-Phenyl and the cyclopentanol ring.		Plant (straw)	

Table 7.2-1: Notations of parent and metabolites of triticonazole

Code Number		Description		Relevant compartments	Structure
Manufacturing code	Reg No.	Chemical name	CAS-No.		
M595F004 (proposed structure)		Tentatively identified as a mono oxidised form of Triticonazole with the addition of a double bond. The oxidation takes place more probably in the Chloro benzyl part of the molecule while the double bond is probably located in the only available position of the cyclopentanol system		Plant (straw)	

B.7.2.1. Plants

In context of the previous submission for Annex I inclusion, three plant metabolism studies in cereal crops were evaluated:

Report:	**R000502; Parsons R.G., Ayliffe J.M., John A.E., Lowden P., McMillan-Staff S. (1998b)**
Title:	Fungicides: RPA 400727-[14C-Triazole]: Field Study in Spring Cereals
Guidelines:	USEPA (=EPA) 171-4(a)
GLP	Yes

Report:	**R012989; Doble M.L., Jones M.K., Lowden P., Parsons R.G., McMillan-Staff S. (1997a)**
Title:	Final report: Fungicides: RPA 400727 [14C-Phenyl]: Field Study on Winter Cereals
Guidelines:	USEPA (=EPA) 171-4(a)
GLP	Yes

Report:	**C021046; Oddy A., (2002)**
Title:	[^{14}C]-Triticonazole: Metabolism in Barley Following Seed Treatment
Guidelines:	European Commission Directive 96/68/EC (21st October 1996) Section 6.1 Metabolism, Distribution and Expression of Residues in Plants
GLP	Yes

Following seed treatment with triticonazole 14C-labeled in the phenyl ring, only low total radioactive residues were found in grains at harvest (<0.001 – 0.05 mg/kg). Triticonazole formed the majority of the residue, ranging from 19 – 33% of the recovered radioactivity. Triticonazole was also the largest radioactive component detected in plants (15 – 63%), in chaff (6.4 – 18%) and in straw (28 – 35%). Several hydroxylated metabolites of triticonazole exceeded 10% of the recovered radioactivity in one or more matrices: RPA 406780/RPA 404766, RPA 404886 and RPA 406341.

Following seed treatment with triticonazole 14C-labeled in the triazole ring, the pattern of observed metabolism was rather different. The majority of the recovered radioactivity in nearly all plant parts investigated consisted of numerous polar and natural compounds (15 – 88% in plants; 91% in ears; 91 – 93% in grains; 18 – 52% in straw; 51% in chaff). These compounds are derived through the incorporation of fragments of the triazole ring into

polar natural products. Intact 1,2,4-triazole was not identified. Parent triticonazole was also detected, as were three of the hydroxylated metabolites: RPA 406780, RPA 404766 and RPA 404886.
The studies were adequate to conclude that the metabolism of triticonazole occurs by hydroxylation, with separation and destruction of the triazole moiety, leading to incorporation of the triazole-derived material into polar natural products.
The desired goal of a Metabolism in Crops study is the identification and characterisation of at least 90% of the total radioactive residue (TRR) in each raw agricultural commodity (RAC) of the treated crop. In many cases it was not possible to identify significant portions of the TRRs as seed treatment does produce very low total amounts of residue. In the studies, presence and levels of the components were presented clearly, and adequate attempts were made to characterise them.
An overview of the metabolism studies is given in the Tables below:

Table 7.2.1-1 Summary of metabolism studies in primary crops presented in the first monograph prepared under Directive 91/414/EEC

Triticonazol	Field study											
Crop	Wheat							Barley				
Year	**1997 Doble et al.**											
Rate	279 g a.s./ha * (180g / 100 kg seed); 180 kg seed/ha							454 g a.s./ha ** (242 g / 100 kg seed). 187.5 kg seed/ha				
Label	PHENYL											
GS	Z 30	Z 47	Z 62	Z 65	Z 87-91	Z 87-91	Z 87-91	Z 61	Z 65	Z91	Z91	Z91
Anthesis is the period during which a flower is fully open and functional.	**Stem elongation**	**Flag leaf opening**	**Early anthesis**	**Mid anthesis**	**Harvest**	**Harvest**	**Harvest**	**Beginning of anthesis**	**Mid anthesis**	**Harvest**	**Harvest**	**Harvest**
Crop part	Plant	Ears	Plant	Ears	Grain	Chaff	Straw	Ear	Ears	Grain	Chaff	Straw
PHI (d)	136	176	188-211	188-211	240	240	240	176	188	224	224	224
TRR (mg/kg)	**0.91**	**<0.01**	**0.710**	**0.010**	**<0.01**	**0.150**	**2.23**	**<0.01**	**0.03**	**0.05**	**1.070**	**1.690**
	%	%	%	%	%	%	%	%	%	%	%	%
Triticonazole	**63**	-	**27**	-	-	**18**	**28**	-	-	**33**	6	**32**
RPA 406780	-	-	-	-	-	-	7	-	-	-	13	1
RPA 404766	-	-	-	-	-	-	-	-	-	-	-	5
RPA 404886	2	-	-	-	-	27	17	-	-	-	25	-
RPA 406341	3	-	-	-	-	9	12	-	-	**33**	8	8
Polar components	18	-	61	-	-	25	9	-	-	-	31	11
Others characterised by chromatographic behaviour	-	-	-	-	-	-	-	-	-	**19**	--	**15**
Total identified	**68**	**0**	**27**			**53**	**74**	**0**		**66**	**83**	**57**
Total characterised	**18**	**0**	**61**	**0**	**0**	**25**	**9**	**0**	**0**	**19**	**31**	**11**
Totals (OECD 501)	**86**	**0**	**88**	**0**	**0**	**79**	**83**	**0**	**0**	**85**	**114**	**68**
PES	14		20			13	25			11	14	24

* 22.3 N
** 36.3 N

Triticonazole	Field study									
Crop	Wheat							Barley		
Year	**1993 (updated 1998) Ayliffe et al.**									
Rate	Target:487 g a.s./ha; actual: **384 g a.s./ha *** (186.6 g a.s. / 100 kg seed) ; 206 kg seed/ha							Target: 744 g a.s./ha; actual: **483 g a.s./ha **** (297.5 g a.s. / 100 kg seed); 162.5 kg seed/ha		
Label	TRIAZOLE									
GS	Z 30	Z 50	Z 65	Z 65	Harvest	Harvest	Harvest	Harvest	Harvest	Harvest
	ear 1 cm	inflores-cence emergence	flowering	flowering						
Crop part	Whole plant	Whole plant	Whole plant	Ears	**Grain**	Chaff	Straw	**Grain**	Chaff	Straw
TRR (mg/kg)	**5.61**	**0.29**	**0.54**	**0.50**	**0.87**	**1.05**	**2.08**	**0.95**	**1.43**	**2.35**
	%	%	%	%	%	%	%	%	%	%
Triticonazole	94	-	3	-	-	27	18	-	6	28
RPA 404766	0.5	-	-	-	-	25	10	-	9	7
RPA 404886	0.5	-	-	-	-	24	13	-	10	15
Metabolite B	-	-	-	-	-	-	-	-	-	1
Metabolit C	-	-	-	-	-	-	-	-	-	1
Metabolit D	-	-	-	-	-	-	-	-	6	-
others characterised	-	57	42	91	91	-	18	91	51	21
Total identified	**95**	**0**	**3**	**0**	**0**	**76**	**41**	**0**	**25**	**50**
Total characterised	**0**	**57**	**42**	**91**	**91**	**0**	**18**	**91**	**57**	**23**
Totals (OECD 501)	**95**	**57**	**45**	**91**	**91**	**76**	**59**	**91**	**82**	**73**
PES	5	43	55	9	9	26	40	9	15	24

PES: post extraction solids

* 30.7 N
** 38.6 N

Triticonazole	Field study											
Crop	Barley											
Year	**2002 (Oddy)**											
Rate	Target: 12.5 g a.s./ha (5 g a.i./100 kg seed). Actual: 11.96 g a.i./ha *						Target 12.5 g a.s./ha(5 g a.i./100 kg seed). Actual: 10.65 g a.i./ha **					
Label	PHENYL						TRIAZOLE					
GS	Z24	Z65	Harvest				Z24	Z65	Harvest			
Crop part	Plant	Plant	Grain	Straw	Chaff	Stubble	Plant	Plant	Grain	Straw	Chaff	Stubble
TRR (mg/kg)	**0.01**	**0.00**	**0.001**	**0.005**	**0.003**	**0.01**	**0.01**	**0.01**	**0.01**	**0.01**	**0.01**	**0.01**
	%	%	%	%	%	%	%	%	%	%	%	%
Triticonazole	-	-	-	-	-	-	-	-	-	10	-	-
RPA 404766	-	-	-	-	-	-	-	-	-	3	-	-
RPA 404886	-	-	-	-	-	-	-	-	-	3	-	-
RPA 406341	-	-	-	-	-	-	-	-	-	2	-	-
unknown 1	-	-	-	-	-	-	-	-	93	52	-	-
unknown 2	-	-	-	-	-	-	-	-	-	3	-	-
unknown 3	-	-	-	-	-	-	-	-	-	4	-	-
unknown 4	-	-	-	-	-	-	-	-	-	-	-	-
unknown 5	-	-	-	-	-	-	-	-	-	7	-	-
unknown 6	-	-	-	-	-	-	-	-	-	-	-	-
unknown 7	-	-	-	-	-	-	-	-	-	-	-	-
others characterised	-	-	-	-	-	-	-	-	-	-	-	-
Total identified	0	0	0	0	0	0	0		0	17	0	
Total characterised	0	0	0	0	0	0	0	0	93	66	0	0
Totals (OECD 501)	0	0	0	0	0	0	0	0	93	83	0	0
PES	-	-	-	-	-	-	-	-	7	17	-	-

PES: post extraction solids

* 1 N
** 0.9 N

Triticonazole	**Field study**											
Crop	Barley											
Year	**2002 (Oddy)**											
Rate	Target: 150 g a.s./ha (60 g a.i./100 kg seed). Actual: 138.98 g a.i./ha*						Target: 150 g a.s./ha (60 g a.i./100 kg seed). Actual: 109.53 g a.i./ha**					
Label	PHENYL						TRIAZOLE					
GS	Z24	Z65	Harvest				Z24	Z65	Harvest			
Crop part	Plant	Plant	Grain	Straw	Chaff	Stubble	Plant	Plant	Grain	Straw	Chaff	Stubble
TRR (mg/kg)	**0.13**	**0.01**	**0.002**	**0.050**	**0.015**	**0.07**	**0.12**	**0.03**	**0.07**	**0.08**	**0.01**	**0.08**
	%	%	%	%	%	%	%	%	%	%	%	%
Triticonazole	28	15	19	35			20	2		2		2
RPA 406780	13	10	5	3			11	1				
RPA 404766	3	4	13	6			2	0				
RPA 404886	2	2	8	5						6		6
RPA 406341	3	4	9	9			2	0		2		2
RPA 406203 (Z isomer)		7		5			1					
RPA 407922										2		2
unknown 1	1	4	9				15	88	93	50		50
unknown 2	5	7	3	6			4			3		3
unknown 3	12	17		5			12	2		3		3
unknown 4	10	11	2				11	1				
unknown 5	4	2		2			4	0		7		7
unknown 6	2						2					
unknown 7	2						3					
others characterised												
Total identified	49	41	54			0	37	3	0	11	0	11
Total characterised	37	41	14	12	0	0	51	91	93	63	0	63
Totals (OECD 501)	86	82	68	12	0	0	88	95	93	74	0	74
PES	14	19	32	25			12	5	7	**0.08**	**0.01**	**0.08**

* 11 N

** 8.8 N

PES: post extraction solids

Two of the three older metabolism studies were overdosed (8.8N to 38.6N the representative GAP) and do not reflect the intended use pattern. In common with other triazole fungicides, triticonazole has the potential to generate the so-called "triazole-derived metabolites" (TDMs): triazole, triazole alanine, triazole acetic acid, though for triticonazole none of these metabolites were identified in significant amounts.In order to completely address any potential issues arising from the TDMs, a new metabolism study in wheat after seed-treatment with triticonazole was conducted:

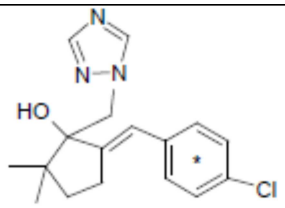
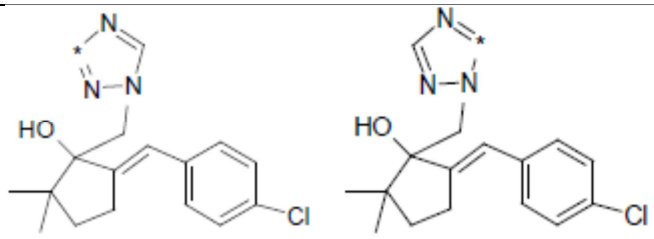
Report:	KCA 6.2.1/1; Williams D., 2015a
Title:	Metabolism of 14C-BAS 595 F with two labels in spring wheat after seed treatment (Final Report 2016)
Report No:	BASF Study Identification Number (Study ID): 407773 IES Study Number (Study ID): 20120192
Document No:	2014/1090812
Guidelines:	OECD 501, EPA 860.1000: EPA Residue Chemistry Test Guidelines, EPA 860.1300: Nature of the Residue in Plants Livestock, PMRA Residue Chemistry Guidelines Section 97.2 Nature of the Residue - Plants - Livestock (Canada), JMAFF No 12 Nosan No 8147
GLP/GEP:	Yes (certified by Swiss Federal Office of Public Health, Berne, Switzerland)

The objective of the present study in wheat was to investigate the uptake, translocation and metabolism of [phenyl-^{14}C] and [triazol-3(5)-^{14}C]-BAS 595 F and the nature of BAS 595 F degradation products after one seed application.

Material and methods:

Spring wheat seeds were treated with ^{14}C-labelled BAS 595 F at a nominal rate of 13.5 g a.s. / ha. Actual application rates were 11.5 g a.s./ha for [phenyl-^{14}C] BAS 595 F (P-Label) corresponding to 85.2 % of nominal and 11.7 g a.s./ha for [triazol-3(5)-^{14}C]-BAS 595 F (T-Label), corresponding to 86.8 % of nominal.

Table B 7.2.1-1: Structures of test items and position of radiolabel

Triticonazole ([phenyl-^{14}C] BAS 595 F (P-Label)) Purity: 99.4% (radiochemical)	
Triticonazole ([triazol-3(5)-14C]-BAS 595 F (T-Label)) Purity: 99.3% and 98.8% (radiochemical)	

The cultivation of the wheat (variety: monsoon) took place in four containers (external dimension each 0.40 m x 0.60 m = 0.24 m^2) in sandy loam soil under controlled climatic conditions without the influence of rain, in a greenhouse. Separate batches of wheat seeds were treated, each with a single application of either phenyl-U-^{14}C or triazole-3(5)-^{14}C radiolabelled triticonazole (BAS 595 F) at a nominal application rate of 13.50 g a.s./ha. The maintenance of the crop was performed in accordance with normal agricultural practice. Fertilizer was applied to achieve an adequate plant growth.

Approximately 40 g spring wheat (var. Monsoon) seeds were added to each diluted formulation and the glass round bottom flask containing the seeds and the formulation rotated until the seeds appeared homogenously coated. The seeds were sown on the day of application; ca. 4 g seeds were sown per crate (pot). Approximately 4 g seeds were also taken for washing and combustion to determine the application rate.

The actual application rate was calculated according to the LSC results of seed combustion and quantification of residues on glassware used for each treatment, resulting in an actual application rate of between 11.5 g a.s./ha for the P-Label (85.2 % of nominal) and 11.7 g a.s./ha for the T-Label (86.8 % of nominal).

Sampling and Sample Storage

Wheat was harvested at three intervals; the first harvest (forage) was 7 weeks after sowing treated seeds (50 DAA), the second harvest (hay) was 9 weeks after sowing treated seeds (65 DAA)and the final (maturity, straw and grain) harvest was 18 weeks after sowing treated seeds (134 DAA). At each harvest whole wheat plants were cut using scissors approximately 5 cm above the soil surface.

Forage was cut into smaller pieces with scissors then frozen and homogenized with liquid nitrogen in a food processor then stored frozen (approximately -18°C) until extraction. The hay and the mature wheat harvests were sampled using the same method but allowed to air-dry before freezing and further processing. The air dried mature wheat was separated by hand into ears and straw. The grain was separated from the ears by hand with the assistance of air and the resulting husks and chaff were combined with the straw sample. The straw and grain were homogenized with grinding mills.

The storage conditions stayed the same until analysis started and during the whole period of the study. Extracts were stored in a freezer (approximately -18°C).

Maximum time intervals of storage:

From sampling to extraction: 223 days

From extraction to first analysis: 143 days

From sampling to first analysis: 291 days

Comparison of initial and final radio-component profiles of contrasting plant extract matrices showed the same general metabolite pattern illustrating that no significant changes in the profiles had occurred in the extracts during the interim period of storage. Additionally, radio-component profiles obtained from re-extraction, work up and analysis of contrasting plant tissues demonstrated the storage stability of the crop tissues for the duration of the study..

Measurement of Radioactivity

- Combustion of Solid Samples

For the determination of the TRR combusted, generally five aliquots of homogenized plant material were weighed and combusted by means of the sample oxidizer. For the measurement of solid, homogenized residues after solvent extraction or solubilization procedures, five aliquots were used. The combustion products were absorbed in OxySolve solution (Zinsser Analytic GmbH) and the radioactivity absorbed was determined by Liquid Scintillation Counting (LSC).

Carbon-14 standards and blanks were combusted at the beginning and at regular intervals throughout each series to check the carry over between samples and to determine the efficiency of the combustion process. Combustion efficiencies were 100 ± 4%; no correction factors were applied to the data reported

In order to determine the background radioactivity, untreated samples of forage, hay and mature wheat (straw and grain) were combusted under the same conditions. The limit of quantification in mg/kg was not calculated from the background radioactivity level.

- LSC Measurement of Liquid Samples

For the measurement of radioactivity in liquid samples, volumes of extracts were determined and dispensed aliquots were assayed for radioactivity in duplicate by LSC. The individual aliquots were mixed with a known volume of a suitable scintillator and analyzed using a Packard liquid scintillation counter equipped with DPM and luminescence options.

The efficiency of the counters was checked daily by measuring a Packard-vial containing a known amount of radioactivity. All measurements were counted at a time interval of up to 5 minutes or an interval allowing a counting error below 5%. Efficiency correlation curves were routinely checked using commercially available quenched standards quenched over the range observed in test samples. The Limit of Detection (LOD) was taken as twice the background radioactivity. All values are expressed in decays per minute (dpm).

- High-Performance Liquid Chromatography (HPLC)

HPLC co-chromatography

The confirmation of the identification of the test item and radioactive components was performed by HPLC co-chromatography with non-radiolabelled test item and reference standards. An aliquot of concentrated extract was admixed with the non-radiolabelled test and reference items. UV-absorbance and radioactivity was recorded for HPLC analysis of these aliquots as well. The time delay between the UV-absorbance and radio-detectors was compensated by a parameter set in the software. Chromatographic correspondence was assessed by comparison of the UV-trace with the unlabelled test item/reference standard and the associated ^{14}C-trace. In the case of ^{14}C

labelled reference items, separate solutions were run and the retention time observed in the radio-detector matched with peaks observed in the concentrated plant extracts.
Recovery: The HPLC recovery was checked for methods of quantification and confirmation for the T-Label straw extract and was 93.96%.

- TLC

TLC analysis was used for confirmatory chromatographic profiling of wheat extracts. The identification of the compounds detected in the extracts was performed by TLC co-chromatography with non-radiolabelled test item and reference items and also the ^{14}C labelled reference items. For TLC co-chromatography non-labelled test item and reference item were co-applied with the extract as well as separate spots on the same plate. After developing the plates, the non-labelled compounds were detected using a UV lamp (at 254 nm) and the positions of (UV) visible bands were marked with a pencil. Chromatographic correspondence was assessed by comparison of the ^{14}C-labelled spots of the extract with the spots of the unlabelled test item loaded as a separate spot. In the case of ^{14}C labelled reference items, no co-application was conducted and matching was solely performed via comparison of separate spots run on the same plate.

For **analysis of the extractable radioactive residues (ERR)** in homogenized forage, material was extracted once with acetonitrile, followed by three times with acetonitrile:water (4:1). The pure acetonitrile extraction was performed only for the forage samples because of the amount of naturally occurring water present in the (immature, green) samples this was treated the same as an acetonitrile:water extract. All extracts with a sufficient level of radioactivity were pooled, concentrated, centrifuged as appropriate and subjected to HPLC and TLC analysis, in order to identify, characterise and quantify labelled components.
For analysis of the ERR in homogenized hay, straw and grain, material was extracted up to seven times with acetonitrile:water (4:1). Extracts with a sufficient level of radioactivity were pooled, concentrated, centrifuged as appropriate and subjected to HPLC and TLC analysis, in order to identify, characterise and quantify labelled components.

In the case of **all matrices, identification of metabolites** was mainly based on reversed-phase HPLC with co-chromatography of unlabelled and labelled reference standards. Peak assignment was based on comparison of the retention times of the reference standards with the 14C-signals of the peaks determined in the extract. Quantification was performed using HPLC method LC02 (T-Label straw and grain) or LC03 (all other matrices). Confirmatory analyses were carried out using the contrasting normal phase (TLC method 1) with co-chromatography of unlabelled and labelled reference standards. Greater resolution of some of the smaller metabolites (e.g., triazole-alanine, R9) was found with TLC method 1 so this was used in the identification of the triazole-metabolites.

Findings:

The levels of **total radioactive residues (TRR)** of triticonazole (and related compounds) found in wheat forage, hay, straw and grain are reported in Table B 7.2.1 2:

Table B 7.2.1-2: Total radioactive residues in wheat samples

Wheat matrix	Sampling Interval (DAA[1])	TRR determined [mg/kg]	TRR calculated [2] [mg/kg]
Phenyl Label (P-Label)			
Forage	49	0.048	0.047
Hay	63	0.207	0.225
Straw	126	0.249	0.217
Grain	126	0.002	not applicable
Triazole Label (T-Label)			
Forage	49	0.047	0.048
Hay	63	0.183	0.191
Straw	126	0.182	0.204
Grain	126	0.036	0.038

[1)] DAA = Days After Application
[2)] TRR was calculated as the sum of ERR (extraction with acetonitrile and water) + RRR

The Total Radioactive Residue (TRR) was calculated by summarizing the Extractable Radioactive Residues (ERR) and the Residual Radioactive Residue (RRR) after solvent extraction. The calculated TRR of forage was 0.047 mg/kg (P-Label) and 0.048 mg/kg (T-Label). The calculated TRR of hay was 0.225 mg/kg (P-Label) and 0.191 mg/kg (T-Label). The calculated TRR of straw was 0.217 mg/kg (P-Label) and 0.204 (T-Label). The calculated TRR of T-label grain was 0.038 mg/kg. Results from direct combustion of P-label grain were <0.002 mg/kg therefore no extractions were performed. For all matrices (except P-Label grain) the calculated TRR was set to 100 % TRR.

Extraction of residues
The extractability of the wheat matrices with acetonitrile and/or acetonitrile:water mixtures is summarized in Table 7.2.1-3.

Table B 7.2.1-3: Extractability of radioactive residues in wheat samples

Matrix	Acetonitrile extract		Acetonitrile/water extracts		ERR[2)]		RRR		TRR calculated [1]
	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	
Phenyl Label (P-Label)									
Forage	0.031	66.0	0.010	21.2	0.041	87.2	0.006	12.8	0.047
Hay	n.a.	n.a.	0.178	79.1	0.178	79.1	0.047	20.7	0.225
Straw	n.a.	n.a.	0.168	77.7	0.168	77.7	0.048	22.3	0.217
Grain	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Triazole Label (T-Label)									
Forage	0.030	63.4	0.011	23.8	0.041	87.2	0.006	12.8	0.048
Hay	n.a.	n.a.	0.145	75.9	0.145	75.9	0.046	24.1	0.191
Straw	n.a.	n.a.	0.157	76.8	0.157	76.8	0.048	23.3	0.204
Grain	n.a.	n.a.	0.026	66.4	0.026	66.4	0.013	33.5	0.038

[1)] TRR was calculated as the sum of ERR + RRR
[2)] Extractable Radioactive Residue (ERR) calculated as sum of acetonitrile and/or acetonitrile:water extracts
n.a. not applicable (not conducted)

For forage matrices the total extractability was 87.2 % TRR for both P-Label and T-Label. The major part of the radioactivity was extracted with acetonitrile (P-Label: 66.0 % TRR and T-Label: 63.4 % TRR) and the remaining radioactivity was subsequently released by extraction with acetonitrile:water mixtures (P-Label: 21.2 % TRR and T-Label: 23.8 % TRR).
For hay, straw and grain matrices all the extractable radioactivity was obtained with acetonitrile:water mixtures. Extractability of hay (79.1 % TRR for P-label and 75.9 % TRR for T-Label) was comparable to that of straw (77.7 % TRR for P-label and 76.8 % TRR for T-Label). The extractability of T-Label grain was lower (66.4 %). The radioactivity levels determined for the P-Label grain by direct combustion were low enough (<0.002 mg/kg) that no extraction was required.

Additionally, the TRR was measured by direct combustion analysis followed by LSC. The measured TRR of both matrices showed no major differences to the calculated TRR values.

Identification, characterization and quantitation of extractable residues
For all matrices, identification was based on co-chromatography and comparison of the retention times with those of the labelled and unlabelled reference items (HPLC retentions times and TLC Rf values). Reversed phase HPLC was used as the primary quantification method, with confirmation of major metabolites by normal phase TLC. In the majority of cases HPLC method LC03 was used as the primary quantification method. Exceptionally, HPLC method LC02 was used to quantify components in T-Label straw and T-label grain extracts due the better resolving power for polar metabolites.

Forage extracts mainly were comprised of parent compound (BAS 595 F) which accounted for 65.3 % TRR (0.031 mg/kg) and 62.7 % TRR (0.030 mg/kg) in the P-label and T-label forage extracts respectively. Low levels of the triazole derivative Triazole alanine (R9; Reg. No.: 270412) were detected in the T-label forage extract (8.9 % TTR, 0.004 mg/kg). Two additional minor unknown metabolites were also detected in each extract, none of which singularly accounted for levels >0.01 mg/kg.

Analysis of P-Label hay extract via HPLC with co-chromatography using reference standards allowed the assignation of **parent** (BAS 595 F; 24.9 % TRR, 0.056 mg/kg), and the uncleaved hydroxy metabolites **R1** (M595F013; Reg. No.: 5079288; 7.1 % TRR, 0.016 mg/kg), **R2** (M595F001; Reg. No.: 5079285; 9.6 % TRR, 0.022 mg/kg), **R3** (**Impurity**; [redacted], 6.9 % TRR, 0.015 mg/kg) These assignations were confirmed by means of TLC. **Five unknown** metabolites, four of which occurred at levels above 0.010 mg/kg (between 0.010-0.020 mg/kg) but < 10 % of the TRR (4.4 % to 8.8 % TRR) were also detected.
In the T-label hay extract the degradation pattern was slightly more complex, with **parent** (BAS 595 F) accounting for only 17.2 % TRR (0.033 mg/kg). The most major metabolite detected showed co-chromatography with the 14C labelled reference standard of the triazole derivative **R9 (Triazole alanine)** and accounted for 0.021 mg/kg (11.1 % TRR). HPLC with co-chromatography using reference standards allowed the assignation of the uncleaved hydroxy metabolites **R1** (M595F013; Reg. No.: 5079288; 3.4 % TRR, 0.007 mg/kg) and **R2** (M595F001; Reg. No.: 5079285; 5.2 % TRR, 0.010 mg/kg) and these assignations were confirmed by means of TLC. **Five unknown** metabolites were detected, three of these occurred at levels above 0.010 mg/kg (between 0.010 to 0.023 mg/kg). The levels detected were under 10 % of the TRR for all but one unknown, occurring at 29.5 min and accounting for 0.023 mg/kg (12.1 % TRR). Attempts were made to identify this unknown but were unsuccessful, however based on close HPLC retention time, this component is thought to be the same (**M595F004)** as that found in the T-Label straw extract, described below. Two minor unknown metabolites were also detected, none of which singularly accounted for levels >0.01 mg/kg (0.007 to 0.008 mg/kg, 3.8 to 4.3 % TRR).

Analysis of extracts of straw treated with the P-Label confirmed the assignation of **parent** (BAS 595 F) and the uncleaved hydroxyl metabolites **R1** (M595F013; Reg. No.: 5079288; 3.8 % TRR, 0.008 mg/kg), **R2** (M595F001; Reg. No.: 5079285; 3.2 % TRR, 0.007 mg/kg) and **R5** (M595F007; Reg. No.: 5079286; 3.3 %, 0.007 mg/kg). The presence of **three unknown** metabolites occurring at levels **≥ 0.010 mg/kg** (0.010 mg/kg to 0.018 mg/kg) but <10 % of the TRR (4.8 % to 8.5 %) was also observed. Additionally, **seven minor unknown** metabolites were additionally detected in the extract, none of which singularly accounted for levels >0.01 mg/kg (2.9 % to 4.4 % TRR, 0.006 mg/kg to 0.009 mg/kg).
T-Label straw extracts comprised **parent** (BAS 595 F; 15.6 % TRR, 0.032 mg/kg, verified by LC/MS), the **impurity R3** ([redacted]; 3.1 % TRR, 0.006 mg/kg), the hydroxylated metabolite **R4** (M595F005; Reg. No.: 5079247, 5.8 % TRR, 0.012 mg/kg) and the triazole derivative **R9 (Triazol-alanine**; 6.7 % TRR, 0.014 mg/kg). Attempts were made to additionally confirm R9 by LC/MS and although the data suggested it was Triazol-alanine, it could not be definitively assigned due to radio-detection void volume limitations.
Six unknown metabolites occurring at levels slightly **above 0.010 mg/kg** (between 0.011 to 0.019 mg/kg) were also observed. The levels detected were **<10 % TRR**. Two of the unknown components, the first occurring at 28.5 min (9.4% TRR, 0.019 mg/kg) and the second at 29.7 min (8.8%, 0.018 mg/kg) were investigated by LC/MS. The first was tentatively identified as a mono oxidised form of Triticonazole with the oxidation taking place more probably in the position 2 of the 4 Chloro-phenyl group or in the methylene group between the Chloro-Phenyl and the cyclopentanol ring (this metabolite was coded **M595F015**). The second unknown was identified as a mono oxidised form of Triticonazole with the addition of a double bond by LC/MS and is likely to be the same component as seen in the T-Label hay sample (this metabolite was coded **M595F004**).

Grain treated with the T-Label contained **R9 (Triazol-alanine** 37.5% TRR, 0.015 mg/kg), an **unknown** metabolite eluting at 7.1 min accounting for 0.009 mg/kg (**22.9 % TRR**) and a minor unknown metabolite which accounted for levels <0.01 mg/kg (0.001 mg/kg, 2.1 % TRR).

Table B 7.2.1-4: Summary of components in wheat matrices treated with ^{14}C BAS 595 F (Triticonazole)

Crop	Wheat (greenhouse)															
Year	2015 (Williams, D.)															
Rate	Target: 13.5 g/ha. Achieved: 11.5 g a.s./ha (6.4 g/100 kg seed)								Target: 13.5 g/ha. Achieved: 11.7 g a.s./ha (6.5 g/100 kg seed)							
Label	PHENYL								TRIAZOLE							
Crop part	Forage		Hay		Straw		Grain		Forage		Hay		Straw		Grain	
PHI (d)	50		65		134		134		50		65		134		134	
TRR (mg/kg) calculated	**0.05**		**0.23**		**0.22**		**n.a.**		**0.05**		**0.19**		**0.2**		**0.04**	
	%	*mg/kg*	*%*	*mg/kg*	*%*	mg/kg	*%*	*mg/kg*	*%*	*mg/kg*	*%*	*mg/kg*	*%*	*mg/kg*	*%*	*mg/kg*
Triticonazole	**65**	**0.031**	**25**	**0.056**	**20**	**0.044**			**63**	**0.03**	**17**	**0.033**	**16**	**0.032**	-	-
RPA 406780 (**R5,** 5079286)	-	-	-	-	3	0.007			-	-	-	-	-	-	-	-
RPA 404766 (**R2,** 5079285)	-	-	**10**	**0.022**	3	0.007			-	-	5	0.01	-	-	-	-
RPA 404886 (**R4,** 5079247)	-	-	-	-					-	-	-	-	6	0.012	-	-
RPA 407922 (**R1,** 5079288)	-	-	7	0.016	4	0.008			-	-	3	0.007	-	-	-	-
R3, 47010773	-	-	7	0.015					-	-	-	-	3	0.006	-	-
R9, 270412**, triazole-alanin**	-	-	-	-					9	0.004	11	0.021	7	0.014	38	0.015
M595F015 (proposed structure)	-	-	-	-	-	-			-	-	-	-	9	0.019	-	-
M595F004 (proposed structure)	-	-	-	-	-	-			-	-	**12**	**0.023**	9	0.018	-	-
unknown metabolites (characterised by retention times)	11	0.005	4	0.01	3	0.007	Not extracted.		8	0.004	4	0.008	7	0.014	2	0.001
	9	0.004	5	0.012	5	0.011			5	0.002	9	0.017	5	0.011	23	0.009
	-	-	9	0.02	4	0.009			-	-	5	0.01	5	0.011	-	-
	-	-	3	0.006	3	0.006			-	-	4	0.007	7	0.013	-	-
	-	-	6	0.013	4	0.008			-	-	-	-	-	-	-	-
	-	-	-	-	5	0.01			-	-	-	-	-	-	-	-
	-	-	-	-	4	0.008			-	-	-	-	-	-	-	-
	-	-	-	-	3	0.006			-	-	-	-	-	-	-	-
	-	-	-	-	3	0.006			-	-	-	-	-	-	-	-
others characterised (driselase solubilized fraction of PES)	-	-	3	0.007	-	-			-	-	4	0.008	3	0.006	-	-
Total identified	65		49		31		Not applicable.		72		37		50		38	
Total characterised	20		30		34				13		38		24		25	
Totals (OECD 501)	85		79		65				85		75		76		63	
PES	**13**	0.006	**21**	0.047	**22**	0.048			13	0	24	0.046	23	0.048	34	0.013

PES: Post extraction solid (Residual Radioactive Residue)

Solubilization of the Residual Radioactive Residue

The Residual Radioactive Residue of T-Label grain (0.013 mg/kg or 33.5 % TRR) was solubilized with a hot water extraction procedure. Thereby, 23.1 % TRR of T-Label grain was additionally released and ascribed to soluble starch.

For hay and straw, a subsample of each residue following solvent extraction was subject to enzymatic hydrolysis with driselase (used to digest plant cell walls and release cell wall carbohydrates) this treatment solubilized between 2.7 to 4.0 % of the TRR (0.006 to 0.008 mg/kg) of the residues, leaving the final RRR of the samples at 17.7 to 24.1% TRR (0.038 to 0.042 mg/kg). The results indicate that the RRR after solvent extraction must be associated with non-carbohydrate components, such as proteins. No chromatographic analysis of any solubilized fraction was undertaken due to the low residue levels released and the high levels of endogenous co-extractives present.

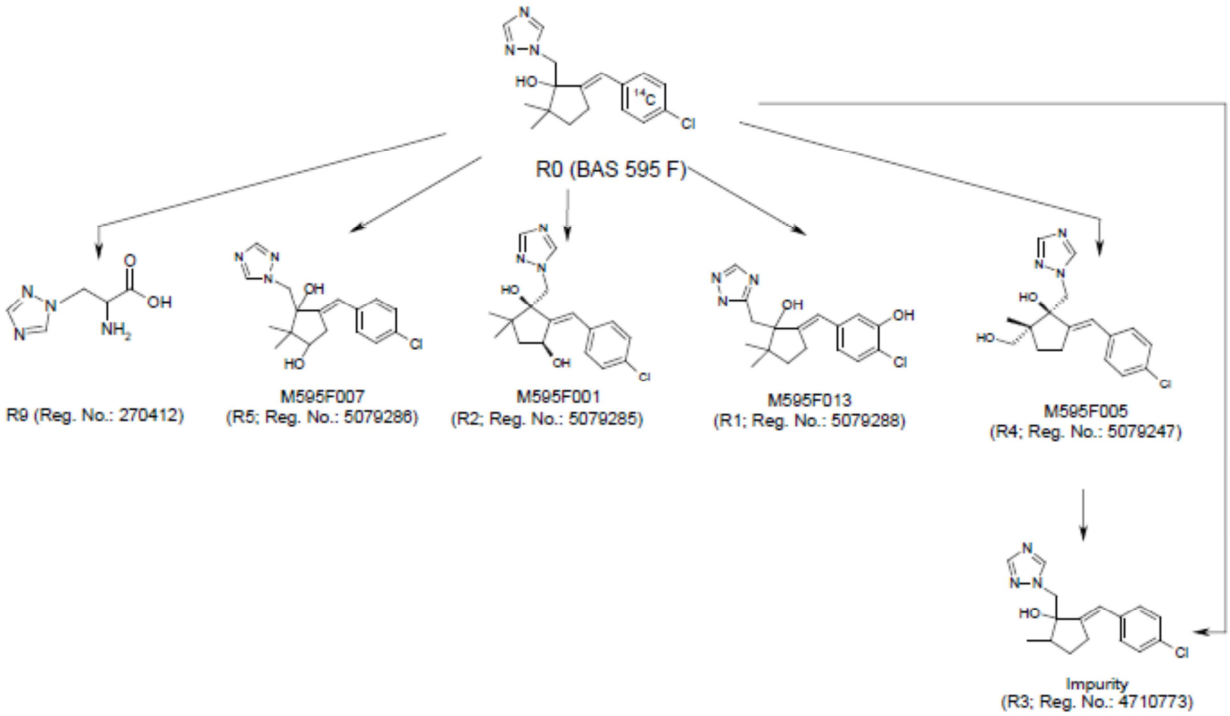
Conclusion:

After a single application of either [phenyl-^{14}C] or [triazole-3(5)-^{14}C]-(BAS 595 F) on wheat seeds (actual application rate ranging from 11.5 to 11.7 g a.s. / ha), highest amounts of BAS 595 F residues were detected in hay and straw samples (0.191 to 0.225 mg/kg), whereas residues in forage and grain were significantly lower (0.038 to 0.047 mg/kg). The parent compound (BAS 595 F) was the major component identified in forage (62.7 to 65.3 % TRR), whereas in straw, significantly smaller portions of BAS 595 F were detected (14.0 to 20.0 % TRR) and no quantifiable BAS 595 F residues were detected in grain samples. Hence, BAS 595 F was extensively metabolised in mature wheat, particularly wheat grain.

As seed treatment does produce very low total amounts of residue, identification and characterisation of at least 90% of the total radioactive residue (TRR) in each raw agricultural commodity (RAC) of the treated crop was not possible However, presence and levels of the components were presented clearly, and adequate attempts were made to characterise them.

The study is considered acceptable and the metabolic pathway proposed in the other metabolism studies can be confirmed: metabolism of triticonazole occurs by hydroxylation, with separation and destruction of the triazole moiety, leading to incorporation of the triazole-derived material into polar natural products.

Figure 7.2.1-1: Proposed Biotransformation Pathway for [^{14}C]-BAS 595 F in cereals



B.7.2.2. Poultry

No studies on the metabolism, distribution and expression of residues in livestock were submitted for Annex 1 inclusion of triticonazole. Since at that time no residues above the limit of determination were expected to be found in possible feed items, studies are regarded as not necessary.

B.7.2.3. Lactating ruminants

Residues of triticonazole and its metabolites in crop commodities fed to animals are low, but some residues are detectable (see B.7.2.1) in early-stage green plant material (BBCH 11-23), which could be grazed. In whole plants without roots (which might be used as forage or fodder), no residues above the LOQ (0.01 mg/kg) were determined. Nevertheless, these young plants might potentially contain residues of triticonazole and also of the TDMs. To address the possible occurrence of residues in feed, and because the general potential for TDMs arising from triazole fungicides to occur in animal commodities is a current regulatory concern, a metabolism study was conducted in the lactating goat.

Please note:

For triticonazole, a metabolism study in ruminant was not triggered. Therefore, the study is considered additional information. However, the study has been evaluated and was used for the Assessment following Guidance on the establishment of the residue definition for dietary risk assessment (EFSA Journal 2016;14(12):4549) in agreement with EFSA and the applicant.

Report:	KCA 6.2.3/1; [redacted] 2015a
Title:	The metabolism of 14C-BAS 595 F in the lactating goat
Report No:	Study ID 221658
Document No:	2014/1090814
Guidelines:	EPA 860.1300: Nature of the Residue in Plants Livestock, EEC 91/414 (7030(VI/95 Rev. 3), OECD Test Guideline 503 - Metabolism in livestock
GLP/GEP:	Yes (certified by Department of Health of the Government of the United Kingdom, United Kingdom)

Material and methods

The metabolism and distribution of Triticonazole was investigated in a single lactating goat following a repeated oral administration of [Triazole-3(5)-^{14}C]-BAS 595 F (Reg. No. 4378513) at a target dose level of 12 mg/kg feed for 7 consecutive days. The mean achieved daily dose administered was 22.2 mg/kg food consumed (dry weight equivalent) by the goat (Variation from the nominal dose rate of 12 mg/kg was due to decreased food consumption during the dosing period.). The dose formulation was prepared by mixing ^{14}C and non-labeled BAS 595 F in the ratio 2:5, leading to an actual specific activity of 1.87 MBq/mg.

The test substance was administered orally in a gelatine capsule via dosing gun. Details of the study design are summarized in Table B 7.2.3-1.

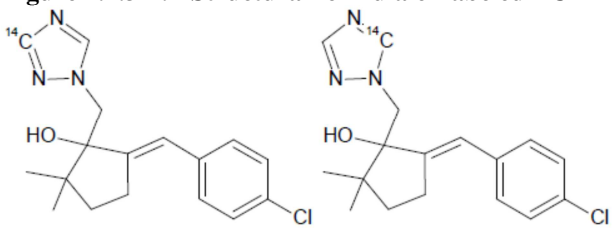
The goat remained in good general health throughout the acclimatization and dosing periods of the study.

Table B 7.2.3-1: Dosing of Lactating Goat with triazole labelled ^{14}C BAS 595 F (Triticonazole)

Dose	Duration of dosing in days	Number of animals	Bodyweight [kg]; mean of the experimental phase	Nominal dose level [mg/kg bw/day]	Actual dose level received [mg/kg bw/day]	Actual average dose per day [mg/kg feed DM]	Mean feed consumption [kg dry weight]	Total administered dose (dosing: once daily, 7 days
Orally in a gelatine capsule via dosing gun Timing: Once daily	7	1	76.5	0.32 (24.624 mg per capsule)	0.35 (26.6 mg per capsule)	22.2	1.253 (0.05 - 2.644 kg feed/day (dry weight)	Nominal: 174.2 Actually received: 186.2 mg

The structural formula of the labeled 14C-BAS 595 F is given in Figure 7.2.3-1 respectively.

Figure 7.2.3-1: Structural formula of labeled ^{14}C-BAS 595 F



Sampling and Storage

Urine and faeces were collected in time intervals of 24 hours for seven days. In addition, following removal of the goat for sacrifice, any urine and faeces remaining in the metabolism cage was collected. The goat was milked twice daily (AM and PM) throughout the acclimatization and study period. On day 5, milk was separated into cream and skim milk. The following tissues were dissected from the lactating goats 3 h after the last administration: Liver, kidneys, omental fat, renal fat, subcutaneous fat, flank muscle, loin muscle, gastrointestinal tract and contents and bile carcass. All samples were stored at ca -20 °C.

Description of analytical procedures

Prior to analysis milk samples from days 4, 5, and 6 were combined as one pooled sample. As there were no significant differences between the different types of muscle the flank and loin muscle were pooled in a ratio 1:2 to produce a single composite sample.

Measurement of Radioactivity

-LSC

TRR combusted:

For the determination of the TRR combusted, homogenized sample material was weighed and combusted by means of a sample oxidizer. The $^{14}CO_2$ evolved during combustion was trapped by an absorption liquid, and the collected radioactivity was measured by liquid scintillation counting (LSC).

Extraction:

Muscle, liver and kidney were extracted using combinations of the following solvents: methanol, methanol:water (4:1 v/v), methanol:water (3:7 v/v). Milk was extracted three times with methanol. The combined results of extractions are referred to as extractable radioactive residues (ERR). The radioactivity in extracts was determined by LSC analysis.

Extracts containing significant amounts of radioactivity were proportionately combined and concentrated. Where necessary, any fat in the sample extracts was partitioned out using a non-polar solvent (e.g. hexane). The radioactivity content of the concentrated extract was determined by LSC analysis.

Residual Radioactive Residue (RRR) was analyzed for radioactivity content by combustion analysis followed by LSC.

Quantification and Identification of Residues:

-HPLC analysis was carried out **for relevant samples with a sufficient level of radioactivity**. The quantification of metabolites and the confirmation of metabolite assignments in sample extracts were determined by HPLC Method 3 and Method 4. The columns used were Imtakt Scherzo SSC18 (150 x 4.6 mm, 3 µm) and Phenomenex Inertsil Phenyl (250 x 4.6 mm, 5 µm). Both eluent systems consisted of 2 mobile phases (method 3: A: 0.1%, TFA acid in MQ-water, B: 0.1%, TFA acid in Acetonitrile; method 4: A: 2% acetic acid in MQ-water; B: 2% acetic acid in acetonitrile). The eluents were used applying gradient elution. The identity of radiolabeled components was based on co-chromatography with authentic reference items.

-**TLC method was used to aid the identification of the polar metabolites in tissue and milk extracts**.

To confirm the identification of polar metabolites in extracts of muscle and milk, HPLC method 5 (Luna Hilic-Column (250 x 4.6 mm, 5 µm) and two eluents (A: 100 mM Ammonium Formate pH 3.3. + 0.1% formic acid, B: 2% formic acid in acetonitrile) were used.

Tissue, excreta and bile extracts were analyzed by **HPLC-MS/MS to identify components which did not correspond to a reference standard** and to confirm the assignments made using co-chromatography.

Isomerization:

In order to investigate the isomer ratio of BAS 595 F and M595F006 (Reg. No. 5079450) these components were isolated with HPLC Method 3 from the liver extract. The resulting BAS 595 F and Reg. No. 5079450 fractions were analyzed by HPLC Method 6 and 7, respectively. An aliquot of the dose solution was also analyzed by HPLC Method 6 to determine the initial isomer ratio of the test item. (HPLC method 6: Column:

Chiral PAK IC (150 x 4.6 mm, 5 µm), Eluent: Acetonitrile + 0.1% diethyl amine; HPLC method 7: Column: Chiral PAK IC (150 x 4.6 mm, 5 µm), Eluent: MQ-water + 0.2% formic acid:Acetonitrole (60:40 v/v)).

Storage stability

Initial analyses of the tissue, milk and excreta extracts were carried out within 6 months of sacrifice. The original concentrated and reconstituted extracts from milk, liver and kidney (stored at -20°C) were analyzed seventeen months after their initial analysis. The profiles are comparable to the initial profiles obtained showing stability in the sample extracts following long term storage at -20°C.

Subsamples of the liver and kidney tissues and a subsample of milk (stored at -20°C) were re-extracted thirteen (milk) or eighteen (liver and kidney) months after the original extraction and analysis was carried out. The profiles of the kidney and milk extracts are comparable to the initial profiles obtained showing stability in the milk and kidney tissue following long term storage at -20°C.

The profile of the extract obtained from liver tissue following long term storage (stored at -20°C) was not quantitatively comparable to the initial liver extract profile obtained.

M595F010, the glucuronide present in the liver sample was shown to degrade in the tissue during long term storage and this was accompanied by an increase in M595F006 (Reg No. 5079450). The conjugate however is stable in the liver extract following long term storage at -20°C as demonstrated by the reanalysis of the initial extract seventeen months later. The extract from the re-extracted milk sample and liver and kidney tissues were not used for quantification. The extracts obtained following re-extraction of the liver and kidney were used for investigation of the storage stability only, while the extract obtained from milk following re-extraction was also used to aid metabolite identification.

Findings

Total radioactive residues (TRRs)

Approximately 81.5% of the total dose was recovered, the majority of which was present almost equally between feces (36.5%) and urine (29.7%). There was also a large proportion present in the GI tract contents (7.9%) and relatively low proportions recovered in the cage wash (3.4%). Radioactivity associated with edible portions (milk and tissues) accounted for ≤ 1% of the administered dose. The recovery for the labeled ^{14}C- BAS 595 F is shown in Table B 7.2.3-2.

Table B 7.2.3-2: Recovery of Radioactivity after Dosing of Lactating Goat with triazole [^{14}C]-BAS 595 F

Sample	% Administered Dose Recovered from 001F
Urine	29.7
Faeces	36.5
Cage Wash	3.4
Milk	0.1
Kidneys	< 0.1
Liver	0.7
Plasma	< 0.1
GI contents and Rinsings	7.9
GI tract	3.1
Bile	0.1
Total	**81.5**

The radioactive residues in milk, muscle and fat were very low and accounted for a maximum of 0.026 mg/kg. Residues in milk had reached steady state within 5 days. The plateau concentration accounted for approximately 0.019 mg/kg. The ratio of residues associated with the skimmed milk and cream was determined in a representative 24 h composite sample from the plateau and shown to be 1.2:1.

The residues in the other edible matrices accounted for 1.028 mg/kg (liver) and 0.394 mg/kg (kidney). The total radioactive residues of the labeled substance are summarized in Table B7.2.3-3 for tissue and bile samples and in Table B 7.2.3-4 for milk samples.

Table B 7.2.3-3: Total Radioactive Residues in Tissues and Bile after dosing of Lactating Goat with [14C]-BAS 595 F

Matrix	Total radioactive residue [mg/kg]
Bile	23.592
Liver	1.028
Kidneys	0.394
Muscle: Loin	0.022
Muscle: Flank	0.026
Fat: Subcutaneous	0.008
Fat: Omental	0.005
Fat: Renal	0.007

Table B 7.2.3-4:Total Radioactive Residues (TRR) in 24h Milk Samples after dosing of Lactating Goat with [^{14}C]-BAS 595 F

Timepoint (day)	Total radioactive residue[1]	
	[%]	[mg/kg]
1	0.007	0.008
2	0.013	0.012
3	0.018	0.015
4	0.018	0.019
5	0.017	0.019
6	0.020	0.023
7	n.a.	n.a.

[1] 24 h Milk Sample data calculated from PM and AM milk collections.

Extraction of residues

Milk
The extractability of milk was high. The milk sample was extracted with methanol, resulting in 100.0% TRR (0.023 mg/kg) in the extract. Less than LOQ was present in the Residual Radioactive Residue (RRR), which was determined by combustion analysis. Aliquots of the extracts containing significant radioactivity (95.6% TRR; 0.022 mg/kg) were proportionately combined and concentrated. During concentration, the extract was partitioned against hexane to remove fat resulting in 12.4% TRR (0.003 mg/kg) partitioning into the hexane fraction. Following concentration of the aqueous fraction the precipitated protein fraction was further extracted and the extracts added back to the concentrated extract, resulting in a final concentrated extract containing 64.4% TRR (0.015 mg/kg). A protein precipitate formed during concentration accounted for 0.1% TRR (<0.001 mg/kg).

Liver
The homogenized liver sample was extracted with methanol and methanol/water mixtures, resulting in extraction of 98.7% TRR (1.062 mg/kg). The RRR was analyzed by combustion analysis and contained 1.4% TRR (0.015 mg/kg). Aliquots of the extracts containing significant radioactivity (98.0% TRR) were proportionately combined and partitioned against hexane resulting in an aqueous soluble fraction containing 98.6% TRR. The extract was concentrated, resulting in a sample which contained 91.8% TRR (0.988 mg/kg) and was analyzed by HPLC and TLC.

Kidney
The homogenized kidney sample was extracted with methanol and methanol/water mixtures, resulting in extraction of 99.5% TRR (0.426 mg/kg). The Residual Radioactive Residue was analyzed by combustion analysis and contained 0.5% TRR (0.002 mg/kg). Aliquots of the extracts containing significant radioactivity (98.7% TRR) were proportionately combined and partitioned against hexane resulting in an aqueous soluble fraction containing 92.3% TRR. The extract was concentrated, resulting in a sample which contained 87.3% TRR (0.375 mg/kg) and was analyzed by HPLC and TLC.

Muscle
The pooled and homogenized muscle sample was extracted with methanol and methanol/water mixtures, resulting in extraction of 100.0% TRR (0.025 mg/kg). Less than LOQ was present in the Residual Radioactive Residue which was determined by combustion analysis. Aliquots of the extracts containing significant radioactivity (99.9% TRR) were proportionately combined and partitioned against hexane resulting in an aqueous soluble fraction containing 99.1% TRR. The extract was concentrated, resulting in a sample which contained 84.8% TRR (0.021 mg/kg) and was analyzed by HPLC.

A summary of the extraction behaviour is given in Table B 7.2.3 5:

Table B 7.2.3-5: Extractability of Goat Matrices after dosing of Lactating Goats with [^{14}C]-BAS 595 F

Matrix	TRR	ERR	RRR	Recovery
	mg/kg (% TRR)	mg/kg (% TRR)	mg/kg (% TRR)	%
Liver	1.076 (100%)	1.062 (98.7%)	0.015 (1.4%)	100.1%
Milk	0.023 (100%)	0.023 (100.0%)	< LOQ (< LOQ)	100.0%
Kidney	0.429 (100%)	0.426 (99.5%)	0.002 (0.5%)	100.0%
Muscle	0.025 (100%)	0.025 (99.9%)	< LOQ (< LOQ)	99.9%

TRR: Total Radioactive Residue
ERR: Extractable Radioactive Residue
RRR: Residual (= non-released) Radioactive Residue

Identification, characterization and quantitation of extractable residues
Milk:
Analysis of milk extract led to a pattern of 4 peaks one of which was identified as M595F009 (Reg. No.87084; 0.020 mg/kg; 86.2% TRR). The other peaks were not identified and individually accounted for less than 0.001 mg/kg (4.6% TRR).

Liver:
Analysis of liver extract led to a pattern of 22 peaks. The residues were identified as unchanged BAS 595 F (0.157 mg/kg; 14.6% TRR) and M595F006 (Reg. No. 5079450) (0.251 mg/kg; 23.4% TRR). The other peaks did not correspond to reference standards. One peak was identified as M595F010 from mass spectral analysis and accounted for 0.219 mg/kg (20.4% TRR). The other peaks were not identified and individually accounted for less than 0.041 mg/kg (3.8% TRR). Following analysis by TLC, M595F009 (Reg. No. 87084) was identified as a minor metabolite accounting for 0.030 mg/kg (2.8% TRR).

Kidney:
Analysis of kidney extract led to a pattern of 13 peaks. The major peak was identified as M595F006 (Reg No.5079450) (0.244 mg/kg; 56.8% TRR) and unchanged BAS 595 F was identified as a minor component (0.004 mg/kg; 0.8% TRR). The other peaks did not correspond to reference standards and remained unidentified individually accounting for less than 0.025 mg/kg (5.9% TRR). Following analysis by TLC, M595F009 (Reg. No. 87084) was identified as a minor metabolite accounting for 0.020 mg/kg (5.2% TRR).

Composite Muscle:
Analysis of muscle extract led to a pattern of 9 peaks one of which was identified as M595F009 (Reg. No.87084) (0.014 mg/kg; 57.5% TRR). Two other components were identified as M595F006 (Reg. No.5079450) (0.004 mg/kg; 14.6% TRR) and unchanged BAS 595 F (0.001 mg/kg; 2.6% TRR). The other peaks did not correspond to reference standards and remained unidentified individually accounting for less than 0.001 mg/kg (3.2% TRR).

Chiral Analysis
The ratio of the isomers of BAS 595 F was ca 1:1 in the dose solution and ca 3:2 in the liver extract. The ratio of the isomers of M595F006 (Reg. No. 5079450) were ca 1:1 in the isolate from the liver extract.

A summary of identified and characterized ^{14}C-residues is shown in Table B 7.2.3 6:

Table B 7.2.3-6: Summary of Identified and Characterized 14C-Residues extracted from tissues and excreta after dosing of Lactating Goat with [^{14}C]-BAS 595 F

Triticonazole	**Lactating goat**															
Year	**2015**															
Rate	**0.32 mg/kg bw/day (22.2 mg/kg DM)**															
Label	**Triazole**															
Duration (d)	**7**															
Commodity	**Liver**		**Kidney**		**Muscle**		**Fat**		**Milk ***		**Urine ***		**Faeces ***		**Bile**	
TRR (mg/kg)	**1.08**		**0.43**		**0.03**		**<0.01**		**0.02**		**5.61**		**5.24**		**23.59**	
	%	mg/kg	%	mg/kg	%	mg/kg	%	mg/kg	%	mg/kg	%	mg/kg	%	mg/kg	%	mg/kg
Triticonazole parent	**15**	**0.157**	1	0.004	3	0.001	Not extracted		-	-	-	-	2	0.099	-	-
M595F009 (1,2,4-Triazole, 87084)	-	-	-	-	57	0.014			**86**	**0.020**	-	-	-	-	-	-
M595F010	**20**	**0.219**	-	-	-	-			-	-	-	-	-	-	70	16
M595F0006 (RPA406972, 5079450)	**23**	**0.251**	**57**	**0.244**	**15**	**0.004**			-	-	**82**	**4.611**	**87**	**4.808**	**12**	**3**
M595F0005 (RPA 404886, R4, 5079247)	-	-	-	-	-	-			-	-	-	-	5	0.284	-	-
others characterised (polar)	33	0.360	30	0.127	10	0.002			8	0.001	4	0.235	-	-	-	-
Total identified	58		58		75		Not applicable.		86							
Total characterised	33		30		10				8							
Totals (OECD 503)	91		88		85		Not applicable		94							
PES (post extraction solids)	1		1		<LOQ				<LOQ							

* pooled sample
n.a.: not applicable

Conclusion

Following administration through **7 days of a mean daily dose of 22.2 mg [Triazole-3(5)-^{14}C]-BAS 595 F per kg food consumed** (dry weight equivalent) to a lactating goat, the **radioactive residues in milk, muscle and fat were very low and accounted for a maximum of 0.026 mg/kg.** Residues in milk had reached steady state within **5 days. The plateau concentration** accounted for approximately **0.019 mg equiv/kg**.

The residues in the other edible matrices accounted for 1.028 mg/kg (liver) and 0.394 mg/kg (kidney).

Approximately 81.5% of the total dose was recovered, the majority of which was present almost equally between feces (36.5%) and urine (29.7%). There was also a large proportion present in the GI tract contents (7.9%) and relatively low proportions recovered in the cage wash (3.4%). Radioactivity associated with edible portions (milk and tissues) accounted for ≤ 1% of the administered dose.

The **extractability** of milk was high (100.0% TRR), equivalent to 0.023 mg/kg. The extractability of the edible tissues was also high, ranging from 98.7% (liver) to 99.9% (muscle) of the TRR.

BAS 595 F (Reg. No. 4378513) was extensively metabolized in the lactating goat. **The unchanged parent was not detected in samples of milk or muscle and was found in portions below 0.8% TRR in kidney**.

There was a greater proportion of BAS 595 F found in the liver which accounted for 14.6% TRR.

The **main component in extracts of liver and kidney** was **M595F006** (Reg. No. 5079450), formed by oxidation of the cyclopentane alkyl side chain to yield a carboxyl group. This component was also identified in composite muscle at lower proportions (14.6% TRR, 0.004 mg/kg). **M595F010** was also found in the liver in significant proportions.

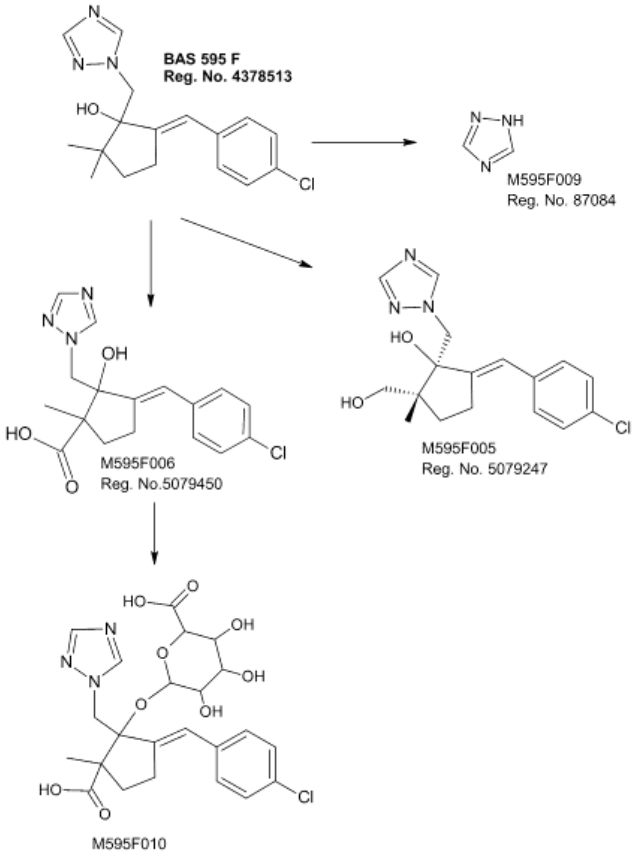
The **main component in extracts of milk and composite muscle** was **M595F009** (**triazole-alanine**. Reg. No. 87084), formed by the cleavage of the triazole moiety from the parent compound. M595F009 (Reg. No. 87084) was also identified as a minor component in the liver and kidney.

Presence and levels of the components were presented clearly, and adequate attempts were made to characterise them. The study is considered acceptable and the metabolic pathway proposed to occur:

- mainly via oxidation followed by glucuronide conjugation and
- Cleavage of the triazole moiety.

A proposed metabolic pathway for BAS 595 F in lactating goats is given in Figure 7.2.3-2.

Figure 7.2.3-2: Proposed Biotransformation Pathway for [^{14}C]-BAS 595 F in the Lactating Goat



B.7.2.4. Pigs

No metabolism study was performed in pigs, since the metabolite patterns in rodents (rats) and ruminants (goats) did not differ significantly.

B.7.2.5. Fish

According to Commission Regulation 283/2013, metabolism studies in fish may be required where the plant protection product is used in crops whose parts or products, also after processing, are fed to fish and where residues in feed may occur from the intended applications. Green forage does not form part of fish diets and since there are no detectable residues in grain or straw, a fish metabolism study is not required.

B.7.3. MAGNITUDE OF RESIDUE TRIALS IN PLANTS

Triticonazole is registered in multiple crops belonging to different EU crop groups. Within this dossier residue data are only provided for the representative uses supporting the renewal of approval. The FS formulation BAS 595 01 F (25 g/L triticonazole) has been selected as representative formulation.

Consequently, in this dossier section the relevant data are summarized for the representative use:

B.7.3.1. Wheat

Crop residue data from 23 field studies on wheat, barley and rye (40 trial sites conducted in Germany, Denmark, Italy, Spain and Greece) were submitted for Annex I inclusion of triticonazole. All 40 trials (20 in northern Europe and 20 in southern Europe) match the intended use as a seed treatment for cereals. At harvest, no residues at or above the LOQ (0.01 mg/kg) were detected in any of the grain samples. In context of the existing residue studies only residues of triticonazole were determined. In view of the current concern over possible occurrence of the common TDMs, a new set of residue trials was conducted. Eight trials with triticonazole applied as a seed treatment to wheat at a rate of 6.25 g as/100 kg seed based on a seeding rate of 180 kg/ha were performed in Europe (four in northern Europe and four in Southern Europe) in the growing season 2012/2013. This number of trials is adequate to support use on all cereal crops, since the use is a seed treatment. A second year of residue trials was conducted in 2013/2014 to evaluate possible residues in feed items (plants at different growth stages, fodder, forage).

Table B 7.3.1-1: Summary of the critical GAP for the proposed use in cereals for BAS 595 01 F

Crop	Outdoor/ Protected	Growth stage (BBCH)	Maximum number of applications	Minimum application interval (days)	Application Method	Maximum		Minimum PHI (days)
						Rate* (g as/ha)	Water (L/ha)	
Wheat	O	BBCH 00 Spring and autumn	1	-	Seed treatment	12.5 * based on 5 g as/100 kg seed, 250 kg seed/ha	Used undiluted or diluted with water at a max ratio of 1:5 (prod:water)	n.a.

n.a. not applicable

Table B 7.3.1-2: Number of residue trials conducted per geographical region and vegetation period

Crop	Vegetation period	Number of trials					Reference
		EU North	Country	EU South	Country	Total	
Wheat	1994	4	DE	-	-	4	C016577
Wheat	1995	2	DE	-	-	2	C016014 C017676
Wheat	1995-1996	2	DK	-	-	2	R003472
Barley	1994	4	DE	-	-	4	C016581
Barley	1995	2	DE	-	-	2	C016580
Barley	1995	2	DK	-	-	2	C015362
Barley	1996	2	DK	-	-	2	C015364
Rye	1995-1996	2	DK	-	-	2	R003473
Wheat	1995-1996	-	-	1	IT	1	R003257
Wheat	1993-1994	-	-	1	IT	1	C017252
Wheat	1994	-	-	1	IT	1	C017316
Wheat	1994-1995	-	-	1	IT	1	C014706
Wheat	1994-1995	-	-	2	IT	2	R002862
Wheat	1995-1996	-	-	1	GR	1	R013164
Wheat	1993-1994	-	-	2	ES	2	C017251
Wheat	1994-1995	-	-	1	IT	1	C014710
Wheat	1994-1995	-	-	2	IT	2	R002860
Wheat	1995-1996	-	-	1	IT	1	R003235
Barley	1993-1994	-	-	1	IT	1	C017317
Barley	1993-1994	-	-	1	ES	1	C017659
Barley	1994-1995	-	-	2	IT	2	C014712
Barley	1995-1996	-	-	1	GR	1	R013162
Barley	1995-1996	-	-	2	IT	2	C014734
Total number of trials per region (old trials, evaluated in context of Annex I inclusion)		**20**		**20**	**Total number of trials (old trials, evaluated in context of Annex I inclusion)**	**40**	
Wheat	2012-2013	4	DE (2x), FR, UK	4	FR, GR, IT, ES	8	6.3.1/1
	2013-2014	4	DE, NL, FR, UK	4	FR, GR, IT, ES	8	6.3.1/2
Total number of trials per region (new trials)		**8**		**8**	**Total number of trials (new trials)**	**16**	

Report:	KCA 6.3.1/1; Martin T., 2015a
Title:	Study on the residue behavior of Triticonazole after seed treatment (with BAS 595 01 F) on wheat under field conditions in Germany, United Kingdom, France (North and South), Greece, Italy and Spain, 2012-2013
Report No:	Study ID 407785
Document No:	2014/1043281
Guidelines:	EC 1107/2009 of the European Parliament and of the Council of 21 Oct 2009, EEC 7029/VI/95 rev. 5 (July 22 1997), EEC 7525/VI/95 rev. 9 (March 2011)
GLP/GEP:	Yes (certified by ENAC, Entidad Nacional de Acreditación, Madrid Spain)

During the 2012-2013 growing season, a total of 8 field trials were conducted in different representative growing areas in Germany, United Kingdom, France (North and South), Greece, Italy and Spain to determine the residue level of triticonazole (BAS 595 F) in wheat (whole plant no roots, grain and straw) after seed treatment.

Material and methods

Each field trial consisted of one untreated (plot 1) and one treated plot (plot 2). Seeds for plot 2 were treated using formulation BAS 595 01 F (25 g/L of BAS 595 F, FS) at a rate equivalent to 6.25 g as per 100 kg seed. Seeds for plot 1 remained untreated. The seeding rate for both plots was 180 kg/ha (plot 1 seeded before plot 2), the application rate at plot 2 was 11.25 g as/ha.

All applications were made using mechanical drilling machines with the exception of trial L120656 where a manual seeding machine was used. No product containing the test item was used on the test plots during the years 2013.

Table B 7.3.1-3: Target application rates and timings

Wheat seeds	Active substance	Plot number	Application number	Product application rate	Active substance application rate	Seeding rate	Target/timing
Wheat untreated	Not applied	1	1	Not applied	Not applied	180 kg/ha	Sowing according the GAP
Wheat treated	Triticonazole	2	1	0.45 L/ha	11.25 g/ha	180 kg/ha	Sowing according the GAP

Sampling:
Control (untreated) specimens were taken at every time point, and were collected prior to collection of the treated specimens to avoid contamination.
In the decline trials L120653, L120654, L120659 and L120660 specimens of whole plant (no roots) were collected at 11-12 BBCH, 13-14 BBCH and 49 BBCH, and specimens of grain and straw were collected at 89 BBCH. While the plant samples collected at BBCH 11/12 and 13/14 are considered not considered relevant as feed item for livestock, the BBCH 49 samples are considered relevant to be fed to animals (forage and fodder).
In trials L120655, L120656, L120657 and L120658 specimens of whole plant (no roots) were collected at 49 BBCH and specimens of grain and straw were collected at 89 BBCH.

Table B 7.3.1-4: Target Sampling Parameters in Wheat

Sampling occasion	Quantity	Specimen material
11- 12 BBCH [1)]	20 g, 12 plants	Whole plant (no roots)
13 - 14 BBCH [1)]	20 g, 12 plants	Whole plant (no roots)
49 BBCH	1.0 kg, 12 plants	Whole plant (no roots)
89 BBCH	1.0 kg	Grain
89 BBCH	0.5 kg	Straw

1) Sampling only done in trials L120653, L120654, L120659 and L120660

Storage:
Generally the specimens were frozen within 6 hours after being taken, and remained frozen at or below -18°C, including during transportation, until analysis.
The maximum storage interval from harvest until extraction was 311 days for triticonazole and 597 days for the triazole metabolites. Storage stability for triticonazole was shown for at least 12 months, and for the triazole metabolites for 53 months (Murphy I (2008). Stability of 1,2,4-Triazole, Triazolylalanine, and Triazolylaceticacid in Various Crop Matrices and Processed Commodities during Frozen Storage.)

Analytical method:
All wheat specimens were analyzed for triticonazole according to BASF analytical method No L0106/01 (= method no. 562/0): The method is considered acceptable according to guidance document SANCO 3029/99 rev.4. (see Volume 3 – B.5 (AS)
BAS 595 F is extracted with a mixture of methanol and water. An aliquot of the extract is centrifuged and partitioned against dichlormethane. The final determination of BAS 595 F is performed by HPLC-MS/MS. The limit of quantitation (LOQ) of the method for BAS 595 F is 0.01 mg/kg.
The mean recovery results for triticonazole were between 76 and 99% (overall recovery: 87.9%, overall RSD: 15.7%) for wheat whole plant w/o roots, grain and straw at fortification levels between 0.01 and 1.0 mg/kg.

The results of procedural recovery experiments are summarized in the following table:

Table B 7.3.1-5: Summary of recoveries for triticonazole on wheat

Matrix	Fortification level (mg/kg)	Summary recoveries		
		n	Average (%)	RSD (%)
BASF analytical method No L0106/01 (=562/0)		**Triticonazole (FS)**		
Wheat / Whole Plant (no roots)	0.01, 0.10, 1.0	3	99.3	13.8
Wheat / Grain	0.01, 0.10	2	82.4	not applicable
Wheat / Straw	0.01, 0.10	2	76.3	not applicable

The wheat specimens were analyzed for the triazole metabolites 1,2,4-triazole, triazolylalanine, triazole acetic acid and triazole lactic acid according to BASF method No. L0170/02.
The metabolites 1,2,4-triazole, triazolylalanine, triazole acetic acid and triazole lactic acid were extracted with methanol/water (80/20, v/v). An aliquot of the extract was filtered, concentrated to an aqueous reminder and cleaned-up by a simple dispersive C18-SPE step. The final determination was performed by LC-DMS/MS/MS. Residues were quantified using isotopically labelled internal standards. The limit of quantitation (LOQ) of the method for BAS 595 F is 0.01 mg/kg.

The mean recovery results for the triazole metabolite were between 77 and 112% (overall recoveries: 90.3-105%%, overall RSDs: 16.7-20.8%) for wheat whole plant w/o roots, grain and straw at fortification levels between 0.01 and 0.5 mg/kg.

The results of procedural recovery experiments are summarized in the following table:

Table B 7.3.1-6: Summary of recoveries for triazole metabolites on wheat

Matrix	Fortification level (mg/kg)	Summary recoveries		
		n	Average (%)	RSD (%)
BASF analytical method No L0170/02		**1,2,4-Triazole**		
Wheat / Whole Plant (no roots)	0.01, 0.10	4	106	27.9
Wheat / Grain	0.01, 0.10	2	104	not applicable
Wheat / Straw	0.01, 0.10, 0.50	3	104	11.8
BASF analytical method No L0170/02		**Triazolalanine**		
Wheat / Whole Plant (no roots)	0.01, 0.10	4	103	17.1
Wheat / Grain	0.01, 0.10	2	77.1	not applicable
Wheat / Straw	0.01, 0.10, 0.50	3	82.5	13.3
BASF analytical method No L0170/02		**Triazole Acetic acid**		
Wheat / Whole Plant (no roots)	0.01, 0.10	4	100	18.1
Wheat / Grain	0.01, 0.10	2	97.7	not applicable
Wheat / Straw	0.01, 0.10, 0.50	3	83.2	10.1
BASF analytical method No L0170/02		**Triazole Lactic Acid**		
Wheat / Whole Plant (no roots)	0.01, 0.10	4	112	16.8
Wheat / Grain	0.01, 0.10	2	99.1	not applicable
Wheat / Straw	0.01, 0.10, 0.50	3	78.0	8.3

Findings

The triticonazole residues in the whole plant (no roots) specimens taken at BBCH 11-12 ranged between 0.13 and 0.64 mg/kg. At BBCH 13-14, triticonazole residues ranged between < 0.01 and 0.18 mg/kg and at BBCH 49 (forage and fodder) residues were below the limit of quantitation (0.01 mg/kg). The triticonazole residues in the straw and grain samples taken at BBCH 89 were below the limit of quantitation (0.01 mg/kg). No residues of triticonazole at or above the limit of quantitation (0.01 mg/kg) were detected in the untreated specimens of this study.

Table B 7.3.1-7: Residues of triticonazole in wheat after one application of BAS 595 01 F (FS) in Northern Europe

Study details		Crop	Country	Formulation application rate (g a.s./ha)[0)]	GS [2)] BBCH	DALA[1)]	Residues found (mg/kg)	
							Matrix	Triticonazole
Study code:	407785	Wheat	Germany	BAS 595 01 F FS 1 x 11.25	n.a.	21	Wh. plant*	0.64
DocID:	2014/1043281					31	Wh. plant*	0.11
Trial No:	L120653					72	Wh. plant*	< 0.01
GLP:	Yes					129	Grain	< 0.01
Year:	2013					129	Straw	< 0.01
Study code:	407785	Wheat	United Kingdom	BAS 595 01 F FS 1 x 11.25	n.a.	51	Wh. plant*	0.13
DocID:	2014/1043281					71	Wh. plant*	< 0.01
Trial No:	L120654					100	Wh. plant*	< 0.01
GLP:	Yes					170	Grain	< 0.01
Year:	2013					170	Straw	< 0.01
Study code:	407785	Wheat	France (North)	BAS 595 01 F FS 1 x 11.25	n.a.	94	Wh. plant*	< 0.01
DocID:	2014/1043281					163	Grain	< 0.01
Trial No:	L120655					163	Straw	< 0.01
GLP:	Yes							
Year:	2013							
Study code:	407785	Wheat	Germany	BAS 595 01 F FS 1 x 11.25	n.a.	68	Wh. plant*	< 0.01
DocID:	2014/1043281					136	Grain	< 0.01
Trial No:	L120656					136	Straw	< 0.01
GLP:	Yes							
Year:	2013							

[1] Days after last application [2] At last application * Whole plants without roots, n.a. not applicable
_ underlined values are used for MRL calculation

Table B 7.3.1-8: Residues of triticonazole in wheat after one application of BAS 595 01 F (FS) in Southern Europe

Study details		Crop	Country	Formulation application rate (g a.s./ha)	GS 2) BBCH	DALA1)	Residues found (mg/kg)	
							Matrix	Triticonazole
Study code:	407785	Wheat	France (South)	BAS 595 01 F FS 1 x 11.25	n.a.	98	Wh. plant*	< 0.01
DocID:	2014/1043281					161	Grain	< 0.01
Trial No:	L120657					161	Straw	< 0.01
GLP:	Yes							
Year:	2013							
Study code:	407785	Wheat	Greece	BAS 595 01 F FS 1 x 11.25	n.a.	59	Wh. plant*	< 0.01
DocID:	2014/1043281					105	Grain	< 0.01
Trial No:	L120658					105	Straw	< 0.01
GLP:	Yes							
Year:	2013							
Study code:	407785	Wheat	Italy	BAS 595 01 F FS 1 x 11.25	n.a.	23	Wh. plant*	0.20
DocID:	2014/1043281					36	Wh. plant*	0.087
Trial No:	L120659					71	Wh. plant*	< 0.01
GLP:	Yes					123	Grain	< 0.01
Year:	2013					123	Straw	< 0.01
Study code:	407785	Wheat	Spain	BAS 595 01 F FS 1 x 11.25	n.a.	20	Wh. plant*	0.52
DocID:	2014/1043281					34	Wh. plant*	0.18
Trial No:	L120660					84	Wh. plant*	< 0.01
GLP:	Yes					153	Grain	< 0.01
Year:	2013					153	Straw	< 0.01

[1] Days after last application [2] At last application * Whole plants without roots, n.a. not applicable
_ underlined values are used for MRL calculation

The range of residues for the triazole metabolites in the matrices of concern are shown in the tables below:

Table B 7.3.1-9: Residues of triazole metabolites in wheat after one application of BAS 595 01 F (FS) and in untreated samples in Northern Europe

Study details		Crop	Country	TREATED Residues found (mg/kg)								UNTREATED Residues found (mg/kg)					
				Formulation application rate (g a.s./ha)[0)]	GS [2)] BBCH	DALA[1)]	Matrix	T	TA	TAA	TLA	DALA[1)]	Matrix	T	TA	TAA	TLA
Study code:	407785	Wheat	Germany	BAS 595 01 F	n.a.	21	Wh. plant*	<0.01	0.13	0.023	0.044	21	Wh. plant*	<0.01	0.13	0.023	0.033
DocID:	2014/1043281			FS		31	Wh. plant*	<0.01	0.035	<0.01	0.030	31	Wh. plant*	<0.01	0.063	<0.01	0.037
Trial No:	L120653			1 x 11.25		72	Wh. plant*	<0.01	0.023	<0.01	0.030	72	Wh. plant*	<0.01	0.023	<0.01	0.031
GLP:	Yes					129	Grain	<0.01	0.063	0.043	<0.01	129	Grain	<0.01	0.15	0.086	<0.01
Year:	2013					129	Straw	<0.01	<0.01	0.018	0.023	129	Straw	<0.01	<0.01	0.038	0.042
Study code:	407785	Wheat	United Kingdom	BAS 595 01 F	n.a.	51	Wh. plant*	<0.01	0.034	0.012	0.071	51	Wh. plant*	<0.01	0.030	<0.01	0.062
DocID:	2014/1043281			FS		71	Wh. plant*	<0.01	0.015	<0.01	0.035	71	Wh. plant*	<0.01	0.018	<0.01	0.040
Trial No:	L120654			1 x 11.25		100	Wh. plant*	<0.01	0.013	<0.01	0.021	100	Wh. plant*	<0.01	0.013	<0.01	0.017
GLP:	Yes					170	Grain	<0.01	0.026	0.013	<0.01	170	Grain	<0.01	0.035	0.016	<0.01
Year:	2013					170	Straw	<0.01	<0.01	<0.01	<0.01	170	Straw	<0.01	<0.01	<0.01	<0.01
Study code:	407785	Wheat	France (North)	BAS 595 01 F	n.a.	94	Wh. plant*	<0.01	<0.01	<0.01	0.016	94	Wh. plant*	<0.01	<0.01	<0.01	0.011
DocID:	2014/1043281			FS		163	Grain	<0.01	0.050	0.027	<0.01	163	Grain	<0.01	0.042	0.015	<0.01
Trial No:	L120655			1 x 11.25		163	Straw	<0.01	<0.01	0.011	<0.01	163	Straw	<0.01	<0.01	<0.01	<0.01
GLP:	Yes																
Year:	2013																
Study code:	407785	Wheat	Germany	BAS 595 01 F	n.a.	68	Wh. plant*	<0.01	<0.01	<0.01	0.023	68	Wh. plant*	<0.01	0.010	<0.01	0.015
DocID:	2014/1043281			FS		136	Grain	<0.01	0.052	0.021	<0.01	136	Grain	<0.01	0.066	0.023	<0.01
Trial No:	L120656			1 x 11.25		136	Straw	<0.01	<0.01	0.014	<0.01	136	Straw	<0.01	0.010	0.016	<0.01
GLP:	Yes																
Year:	2013																

[1] Days after last application [2] At last application * Whole plants without roots, n.a. not applicable

Table B 7.3.1-10: Residues of triazole metabolites in wheat after one application of BAS 595 01 F (FS) and in untreated samples in Southern Europe

Study details		Crop	Country	TREATED Residues found (mg/kg)								UNTREATED Residues found (mg/kg)					
				Formulation application rate (g a.s./ha)[0)]	GS [2)] BBCH	DALA[1)]	Matrix	T	TA	TAA	TLA	DALA[1)]	Matrix	T	TA	TAA	TLA
Study code:	407785	Wheat	France	BAS 595 01 F	n.a.	98	Wh. plant*	< 0.01	0.052	0.016	0.044	98	Wh. plant*	< 0.01	< 0.01	< 0.01	0.015
DocID:	2014/1043281		(South)	FS		161	Grain	< 0.01	0.24	0.13	<0.01	161	Grain	< 0.01	0.038	0.017	< 0.01
Trial No:	L120657			1 x 11.25		161	Straw	< 0.01	<0.01	0.078	0.066	161	Straw	< 0.01	< 0.01	0.014	0.012
GLP:	Yes																
Year:	2013																
Study code:	407785	Wheat	Greece	BAS 595 01 F	n.a.	59	Wh. plant*	< 0.01	<0.01	<0.01	0.033	59	Wh. plant*	< 0.01	< 0.01	< 0.01	0.025
DocID:	2014/1043281			FS		105	Grain	< 0.01	<0.01	<0.01	<0.01	105	Grain	< 0.01	< 0.01	< 0.01	< 0.01
Trial No:	L120658			1 x 11.25		105	Straw	< 0.01	<0.01	<0.01	<0.01	105	Straw	< 0.01	< 0.01	< 0.01	< 0.01
GLP:	Yes																
Year:	2013																
Study code:	407785	Wheat	Italy	BAS 595 01 F	n.a.	23	Wh. plant*	<0.01	0.046	<0.01	0.031	23	Wh. plant*	<0.01	0.040	< 0.01	0.021
DocID:	2014/1043281			FS		36	Wh. plant*	<0.01	0.027	<0.01	0.043	36	Wh. plant*	<0.01	0.025	< 0.01	0.052
Trial No:	L120659			1 x 11.25		71	Wh. plant*	<0.01	0.054	0.036	0.084	71	Wh. plant*	<0.01	0.044	0.028	0.062
GLP:	Yes					123	Grain	<0.01	0.18	0.12	<0.01	123	Grain	<0.01	0.11	0.088	< 0.01
Year:	2013					123	Straw	<0.01	0.023	0.062	0.028	123	Straw	<0.01	0.020	0.052	0.020
Study code:	407785	Wheat	Spain	BAS 595 01 F	n.a.	20	Wh. plant*	<0.01	0.044	<0.01	0.052	20	Wh. plant*	<0.01	0.020	<0.01	0.036
DocID:	2014/1043281			FS		34	Wh. plant*	<0.01	0.049	<0.01	0.075	34	Wh. plant*	<0.01	0.016	<0.01	0.040
Trial No:	L120660			1 x 11.25		84	Wh. plant*	<0.01	0.021	<0.01	0.018	84	Wh. plant*	<0.01	<0.01	<0.01	0.010
GLP:	Yes					153	Grain	<0.01	0.36	0.089	<0.01	153	Grain	<0.01	0.076	0.018	<0.01
Year:	2013					153	Straw	<0.01	<0.01	0.024	0.035	153	Straw	<0.01	<0.01	<0.01	<0.01

[1] Days after last application [2] At last application * Whole plants without roots, n.a. not applicable

Conclusion:
The study is considered acceptable.
A total of 8 field trials were conducted in different representative growing areas Northern and Southern Europe during the 2012-2013 growing season to determine the residue level of triticonazole (BAS 595 F) in wheat (whole plant no roots, grain and straw) after seed treatment.
Each field trial consisted of one untreated (plot 1) and one treated plot (plot 2). Seeds for plot 2 were treated using formulation BAS 595 01 F (25 g/L of BAS 595 F, FS) at a rate equivalent to 6.25 g as per 100 kg seed. Seeds for plot 1 remained untreated. The seeding rate for both plots was 180 kg/ha (plot 1 seeded before plot 2), the application rate at plot 2 was 11.25 g as/ha.
Triticonazole
The triticonazole residues in the whole plant (no roots) specimens taken at BBCH 11-12 ranged between 0.13 mg/kg and 0.64 mg/kg. And subsequently a steady decline was observed: at BBCH 13-14 ranged between < 0.01 mg/kg and 0.18 mg/kg and at BBCH 49 were below the limit of quantitation (0.01 mg/kg).
The triticonazole residues in the straw and grain samples taken at BBCH 89 were below the limit of quantitation (0.01 mg/kg).
No residues of triticonazole at or above the limit of quantitation (0.01 mg/kg) were detected in the untreated specimens of this study.

Comparing results obtained from the untreated with results from the treated plots demonstrates that no significant differences in residue concentrations for 1,2,4-Triazole, Triazolylalanine, Triazole acetic acid and Triazole lactic acid can be determined in any of the specimens after seed treatment with BAS 595 01 F. In some Northern European trials, residues of Triazolylalanine, Triazole acetic acid and Triazole lactic acid were higher in the untreated plots than in the treated plots.

Report:	KCA 6.3.1/2; Martin T., 2015b
Title:	Study on the residue behaviour of Triticonazole after seed treatment (with BAS 595 01 F) on wheat under field conditions in Germany, France (North and South), Netherlands, United Kingdom, Greece, Italy and Spain, 2013-2014
Report No:	Study ID 721605
Document No:	2014/1090813
Guidelines:	EC 1107/2009 of the European Parliament and of the Council of 21 Oct 2009, EEC 7029/VI/95 rev. 5 (July 22 1997), EEC 7525/VI/95 rev. 9 (March 2011)
GLP/GEP:	Yes (certified by ENAC, Entidad Nacional de Acreditación, Madrid Spain)

During the 2013-2014 growing season, a total of 8 field trials were conducted in different representative growing areas in Germany, United Kingdom, France (North and South), Netherlands, Greece, Italy and Spain to determine the residue level of triticonazole (BAS 595 F) in wheat (whole plant no roots, grain and straw) after seed treatment.

Material and methods

Each field trial consisted of one untreated (plot 1) and one treated plot (plot 2). Seeds for plot 2 were treated using formulation BAS 595 01 F (25 g/L of BAS 595 F, FS) at a rate equivalent to 6.25 g as per 100 kg seed. Seeds for plot 1 remained untreated. The seeding rate for both plots was 180 kg/ha (plot 1 seeded before plot 2), the application rate at plot 2 was 11.25 g as/ha.

No product containing the test item was used on the test plots during the years 2014.

Table B 7.3.1-11: Target application rates and timings

Wheat seeds	Active substance	Plot number	Application number	Nominal loading rate	Active substance application rate	Seeding rate	Target/timing
Wheat untreated	Not applied	1	1	Not applied	Not applied	180 kg/ha	Sowing according the GAP
Wheat treated	Triticonazole	2	1	6.25 g a.i. / 100 kg/seeds	11.25 g/ha	180 kg/ha	Sowing according the GAP

Sampling:
Control (untreated) specimens were taken at every time point, and were collected prior to collection of the treated specimens to avoid contamination.
Specimens of whole plant (no roots) were collected at 12-13 BBCH, 21-23 BBCH and 59 BBCH and specimens of grain and straw were collected at 89 BBCH.

Table B 7.3.1-12: Target Sampling Parameters in Wheat

Sampling occasion	Quantity	Specimen material
12 - 13 BBCH	50 g, 12 plants	Whole plant (no roots)
12 - 13 BBCH	100 g, 12 plants	Whole plant (no roots)
59 BBCH	500 g, 12 plants	Whole plant (no roots)
89 BBCH	1.0 kg	Grain
89 BBCH	0.5 kg	Straw

Storage:
Generally the specimens were frozen within 6 hours after being taken, and remained frozen at or below -18°C, including during transportation, until analysis.
The maximum storage interval from harvest until extraction was 275 days.

Analytical method:
All wheat specimens were analysed for triticonazole according to BASF analytical method No 562/0 (adapted for triticonazole). BAS 595 F is extracted with a mixture of methanol and water. An aliquot of the extract is centrifuged and partitioned against dichlormethane. The final determination of BAS 595 F is performed by HPLC-MS/MS. The limit of quantitation (LOQ) of the method for BAS 595 F is 0.01 mg/kg.
The mean recovery results for triticonazole were between 103 and 108% (RSD: 2.8 - 7.9%) for wheat whole plant, grain and straw at fortification levels between 0.01 and 1.0 mg/kg.
The results of procedural recovery experiments are summarized in the following table:

Table B 7.3.1-13: Summary of recoveries for triticonazole on wheat

Matrix	Fortification level (mg/kg)	Summary recoveries		
		n	Average (%)	RSD (%)
BASF analytical method No 562/0		**Triticonazole (FS)**		
Wheat / Whole Plant (no roots)	0.01, 0.10, 1.0	7	103	6.0
Wheat / Grain	0.01, 0.10	6	108	2.8
Wheat / Straw	0.01, 0.10	6	104	7.9
	Overall:	**19**	**105**	**5.9**

Findings

The triticonazole residues in the whole plant (no roots) specimens taken at BBCH 12-13 ranged between 0.052 and 0.46 mg/kg. At BBCH 21-23, triticonazole residues ranged between < 0.01 and 0.064 mg/kg and at BBCH 59 residues were below the limit of quantitation (0.01 mg/kg). The triticonazole residues in the straw and grain samples taken at BBCH 89 were below the limit of quantitation (0.01 mg/kg). No residues of triticonazole at or above the limit of quantitation (0.01 mg/kg) were detected in the untreated specimens of this study.

Table B 7.3.1-14: Residues of triticonazole in wheat after one application of BAS 595 01 F (FS) in Northern Europe

Study details		Crop	Country	Formulation application rate (g a.s./ha)[0)]	GS [2)] BBCH	DALA[1)]	Residues found (mg/kg)	
							Matrix	Triticonazole
Study code:	721605	Wheat	Germany	BAS 595 01 F FS 1 x 11.25	n.a.	32	Wh. plant*	0.134
DocID:	2014/1090813					46	Wh. plant*	0.023
Trial No:	L130814					86	Wh. plant*	< 0.01
GLP:	Yes					142	Grain	< 0.01
Year:	2014					142	Straw	< 0.01
Study code:	721605	Wheat	France (N)	BAS 595 01 F FS 1 x 11.25	n.a.	28	Wh. plant*	0.202
DocID:	2014/1090813					50	Wh. plant*	0.028
Trial No:	130815					85	Wh. plant*	< 0.01
GLP:	Yes						+	+
Year:	2014							
Study code:	721605	Wheat	Netherlands	BAS 595 01 F FS 1 x 11.25	n.a.	15	Wh. plant*	0.462
DocID:	2014/1090813					29	Wh. plant*	0.020
Trial No:	L130816					72	Wh. plant*	< 0.01
GLP:	Yes					126	Grain	< 0.01
Year:	2014					126	Straw	< 0.01
Study code:	721605	Wheat	UK	BAS 595 01 F FS 1 x 11.25	n.a.	30	Wh. plant*	0.259
DocID:	2014/1090813					49	Wh. plant*	0.028
Trial No:	L130817					83	Wh. plant*	< 0.01
GLP:	Yes					139	Grain	< 0.01
Year:	2014					139	Straw	< 0.01

[1] Days after last application [2] At last application * Whole plants without roots, n.a. not applicable
_ underlined values are used for MRL calculation
+ No grain and straw values as by mistake, plots were harvested by the farmer too early.

Table B 7.3.1-15: Residues of triticonazole in wheat after one application of BAS 595 01 F (FS) in Southern Europe

Study details		Crop	Country	Formulation application rate (g a.s./ha)	GS 2) BBCH	DALA1)	Residues found (mg/kg)	
							Matrix	Triticonazole
Study code:	721605	Wheat	France (S)	BAS 595 01 F FS 1 x 11.25	n.a.	47	Wh. plant*	0.052
DocID:	2014/1090813					67	Wh. plant*	< 0.01
Trial No:	L130818					97	Wh. plant*	< 0.01
GLP:	Yes					147	Grain	< 0.01
Year:	2014					147	Straw	< 0.01
Study code:	721605	Wheat	Greece	BAS 595 01 F FS 1 x 11.25	n.a.	33	Wh. plant*	0.097
DocID:	2014/1090813					49	Wh. plant*	< 0.01
Trial No:	L130819					87	Wh. plant*	< 0.01
GLP:	Yes					124	Grain	< 0.01
Year:	2014					124	Straw	< 0.01
Study code:	721605	Wheat	Italy	BAS 595 01 F FS 1 x 11.25	n.a.	35	Wh. plant*	0.064
DocID:	2014/1090813					48	Wh. plant*	< 0.01
Trial No:	L130820					104	Wh. plant*	< 0.01
GLP:	Yes					136	Grain	< 0.01
Year:	2014					136	Straw	< 0.01
Study code:	721605	Wheat	Spain	BAS 595 01 F FS 1 x 11.25	n.a.	22	Wh. plant*	0.446
DocID:	2014/1090813					39	Wh. plant*	0.064
Trial No:	L130821					79	Wh. plant*	< 0.01
GLP:	Yes					134	Grain	< 0.01
Year:	2014					134	Straw	< 0.01

[1] Days after last application [2] At last application * Whole plants without roots, n.a. not applicable
_ underlined values are used for MRL calculation

Conclusion
The study is considered acceptable.
A total of 8 field trials were conducted in different representative growing areas Northern and Southern Europe during the 2013-2014 growing season to determine the residue level of triticonazole (BAS 595 F) in wheat (whole plant no roots, grain and straw) after seed treatment.
Each field trial consisted of one untreated (plot 1) and one treated plot (plot 2). Seeds for plot 2 were treated using formulation BAS 595 01 F (25 g/L of BAS 595 F, FS) at a rate equivalent to 6.25 g as per 100 kg seed. Seeds for plot 1 remained untreated. The seeding rate for both plots was 180 kg/ha (plot 1 seeded before plot 2), the application rate at plot 2 was 11.25 g as/ha
The triticonazole residues in the whole plant (no roots) specimens taken at BBCH 12-13 ranged between 0.052 and 0.46 mg/kg. At BBCH 21-23, triticonazole residues ranged between < 0.01 and 0.064 mg/kg and at BBCH 59 residues were below the limit of quantitation (0.01 mg/kg). The triticonazole residues in the straw and grain samples taken at BBCH 89 were below the limit of quantitation (0.01 mg/kg).
No residues of triticonazole at or above the limit of quantitation (0.01 mg/kg) were detected in the untreated specimens of this study.

B.7.4. FEEDING STUDIES
No feeding studies have been submitted for Annex I inclusion of triticonazole.
In grain, all residues were below the LOQ (0.01 mg/kg) and also in harvestable forage (whole plant without root) no residues above the LOQ were determined. In the 16 new trials throughout Europe, at BBCH 49 and 59 in specimens of "whole plant without root" the triticonazole residues were always <0.01 mg/kg (see B 7.3).
Based on the calculations, the trigger of 0.004 mg/kg bw/day was not exceeded for livestock (dairy ruminants, meat ruminants, poultry and pigs).
Therefore, no feeding studies are required.

B.7.4.1. Poultry
See point B.7.4.

B.7.4.2. Ruminants
See point B.7.4.

B.7.4.3. Pigs
See point B.7.4.

B.7.4.4. Fish
According to the Commission Regulations (EU) No 283/2013 (active substances) and 284/2013 (plant protection products) as of 1 March 2013, metabolism studies on fish and fish feeding studies might be required in future (latest by 31 Dec 2015), if residues occur in crops that are intended as feed items for fish. Green rest of plants do not form part of fish diets and since there are also no detectable residues in cereal grain or straw, a fish feeding study is not required.

B.7.5. EFFECTS OF PROCESSING

No studies on the effects of industrial processing and/or household preparation have been submitted for Annex I inclusion of triticonazole because of the residue situation: as no residues above the LOD are expected because of the application regime (seed treatment), and based on the results of the residue trials provided, these studies are not regarded as necessary.

However, current guidance requires that a study on the nature of the residue in processed commodities (high-temperature hydrolysis study) is required in any case where residues at or above 0.01 mg/kg may be found. In view of this low threshold, and to provide information on the fate of any possible residues in cereal commodities to be processed, a high-temperature hydrolysis study was conducted (BASF No. 2013/1135885). The study was not reviewed during the Annex I inclusion process and is included in this dossier.

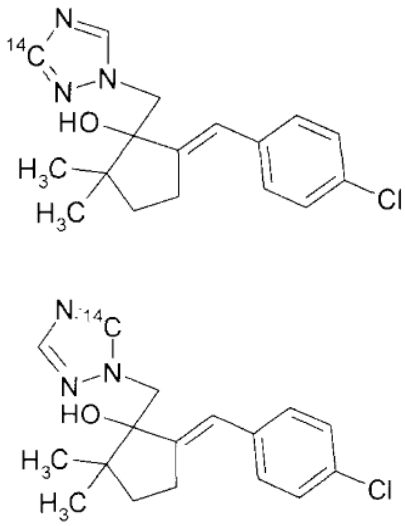
B.7.5.1. Nature of the residue

Report:	KCA 6.5.1/1; Adam D., 2013a
Title:	14C-Triticonazole (BAS 595 F): Stimulated processing - Hydrolysis at 90°C, 100°C and 120°C
Report No:	Study ID 430480
Document No:	2013/1135885
Guidelines:	OECD Test Guideline 507 - Nature of the residues in processed commodities - High temperature hydrolysis, EPA 860.1520, EEC 91/414 Annex II (Part A Section 6), EEC 91/414 Annex III (Part A Section 8), EEC 7035/VI/95 rev. 5
GLP/GEP:	Yes (certified by Swiss Federal Office of Public Health, Berne, Switzerland)

Material and methods

The hydrolytic stability of ^{14}C-triticonazole (BAS 595 F) was investigated in sterile aqueous acetate buffer solutions at three pH values and temperatures in order to simulate processing practice.

Figure 7.5.1-1: Structural formula of triazole-3(5)-^{14}C labeled BAS 595 F



The study was performed at pH 4, 5 and 6 at temperatures of 90°C, 100°C and 120°C for 20 or 60 minutes, respectively. The range of hydrolytic conditions used, represent the processes of pasteurisation, baking/brewing/boiling and sterilisation. Buffer solutions containing the radiolabelled test item at an initial concentration of 0.251 mg/L were incubated in closed high pressure stainless steel vessels placed in an autoclave at the desired temperature. At time 0 and after 20 or 60 minutes of incubation, duplicate samples per pH value were taken, measured for total radioactivity and analyzed for the parent compound and eventual degradates. The conditions for the hydrolysis study are shown in Table B 7.5.1-1:

Table B 7.5.1-1: Simulated conditions for the hydrolysis study

Temperature (°C)	Time (min)	pH	Process Represented	Remarks
90	20	4	Pasteurisation	In closed high pressure stainless steel vessels using autoclave
100	60	5	Baking, Brewing, Boiling	In high pressure stainless steel vessels using autoclave
120	20	6	Sterilisation	In closed high pressure stainless steel vessels using autoclave

Analytical procedure
Samples were measured for total radioactivity by Liquid Scintillation Counting (LSC).
HPLC was the primary analytical method used to determine the amount of the parent and degradation products in the samples. The column used was a Phenomenex Luna C18, the eluent system consisted of 2 mobile phases (A: water with 0.1% trifluoroacetic acid, B: acetonitrile with 0.1% trifluoroacetic acid), which were used applying gradient elution.
TLC was the secondary analytical method used to confirm the identity of the parent and degradation products in the samples. The following solvent system was used: Chloroform/Methanol/Water/Formic acid (77/20/2/1; v/v/v/v).

The following Limit of Detection (LOD) and Limit of Quantifiation (LOQ) values were obtained by LSC and HPLC (values in percent of applied radioactivity):

Table B 7.5.1-2: LOD and LOQ (% of applied radioactivity)

^{14}C Triticonazole	LOD	LOQ
LSC	0.5	0.7
HPLC	0.5	0.9

Findings
Total radioactive residues:
Individual recoveries of radioactivity during the respective incubation periods represented 99.0% at pH 4 at 90°C (20 min). Corresponding values for pH 5 at 100°C (60 min) and pH 6 at 120°C (20 min) ranged from 104.4% to 104.9% and from 101.8% to 104.3%, respectively. The results are summarised in the tables below:

Table B 7.5.1-3: Balance of radioactivity

Sample	Replicate	Incubation time (min)					
		pH 4, 90°C		pH 5, 100°C		pH 6, 120°C	
		0	20	0	60	0	20
Radioactivity in buffer solution	A	98.5	99.0	98.2	104.4	99.7	104.3
	B	101.5	99.0	101.8	104.9	100.3	101.8
	Mean	100.0	99.0	100.0	104.7	100.0	103.1

Values are given in percent of applied radioactivity (AR)

Identification, characterization and quantitation of extractable residues:
At pH 4 and 90°C:
^{14}C-BAS 595 F was shown to be stable to hydrolysis at pH 4 and 90°C, representing a mean amount of 95.3% of the radioactivity in the solution after 20 minutes of incubation in the buffer solution. One other peak above the Limit of Detection (LOD) of 0.5% AR was detected: Metabolite M2, which represented 3.2% of AR. The distribution pattern of radioactivity at pH 4 and 90°C is shown in Table 6.5.1-3.

Table B 7.5.1-4: Distribution pattern of radioactivity at pH 4 at 90°C, incubation time 20 min.

Substance	Replicate	Incubation time (min)	
		0	**20**
Triticonazole	A	95.4	94.5
	B	97.8	96.2
	mean	96.6	**95.3**
M1	A	0.8	0.9
	B	0.9	*
	mean	0.8	0.4
M2	A	2.3	3.6
	B	2.9	2.8
	mean	2.6	**3.2**
M3	A	*	*
	B	*	*
	mean	*	*

*not detected or below detection limit
Values are given in percent of applied radioactivity (AR)
Since M2 was detected under all three incubation conditions, as well as in the non-incubated samples and application solution, its appearance was correlated with an impurity of the application solution.

At pH 5 and 100°C:
^{14}C BAS 595 F represented 10l .7% of the solution radioactivity after 60 minutes of incubation at pH 5 and 100°C and was shown to be stable under the mentioned conditions. One other peak above the Limit of Detection (LOD) of 0.5% AR was detected: Metabolite M2, which represented 2.9% of AR. The distribution pattern of radioactivity at pH 5 and 100°C is shown in the following table:

Table B 7.5.1-5: Distribution pattern of radioactivity at pH 5 at 100°C, incubation time 60 min.

Substance	Replicate	Incubation time (min)	
		0	**60**
Triticonazole	A	95.2	101.3
	B	98.6	102.1
	mean	96.9	**101.7**
M1	A	*	*
	B	*	*
	mean	*	*
M2	A	3.0	3.0
	B	3.2	2.8
	mean	3.1	**2.9**
M3	A	*	*
	B	*	*
	mean	*	*

*not detected or below detection limit
Values are given in percent of applied radioactivity (AR)

At pH 6 and 120°C:
At pH 6 at 120°C, the test item was shown to be stable as well. ^{14}C BAS 595 F represented a mean amount of 99.3% of the solution radioactivity after 20 minutes of incubation in the buffer solution. One other peak above the Limit of Detection (LOD) of 0.5% AR was detected: Metabolite M2, which represented 2.8% of AR. The distribution pattern of radioactivity at pH 6 and 120°C is shown in Table 6.5.1-5.

Table B 7.5.1-6: Distribution pattern of radioactivity at pH 6 at 120°C, incubation time 20 min.

Substance	Replicate	Incubation time (min)	
		0	**20**
Triticonazole	A	96.9	101.1
	B	97.2	97.6
	mean	97.0	**99.3**
M1	A	*	*
	B	*	0.9
	mean	*	0.4
M2	A	2.8	3.3
	B	3.1	2.3
	mean	3.0	**2.8**
M3	A	*	*
	B	*	0.9
	mean	*	0.5

*not detected or below detection limit
Values are given in percent of applied radioactivity (AR)

Storage stability
No degradation of the test item was observed in time 0 samples, thereby proving the stability during treatment procedure.

Conclusion:
The study is considered acceptable.
^{14}C-triticonazole (BAS 595 F) was hydrolytically stable in sterile buffer solution pH 4 at a temperature simulating pasteurisation (90°C) after 20 minutes, at pH 5 at 100°C after 60 minutes (simulating baking/brewing/boiling) and at pH 6 at 120°C after 20 minutes simulating sterilisation.

B.7.5.2. Distribution of the residue in peel and pulp
Not relevant for the intended uses in cereals.

B.7.5.3. Magnitude of residues in processed commodities
The residue studies show residues in grain to be < 0.01 mg/kg, and therefore industrial processing studies are not required.

B.7.6. RESIDUES IN SUCCEEDING OR ROTATIONAL CROPS

B.7.6.1. Metabolism in rotational crops
A metabolism study in rotational crops was evaluated previously for Annex I inclusion of triticonazole.

Report:	**R012993; Lowden, P.; Maycey, P. A (1996)**
Title:	[^{14}C]-Triticonazole: A Confined Rotational Crop Study Using Radish, Lettuce and Wheat.
Guidelines:	USEPA (=EPA) Subdiv. N Sect. 165-1
GLP	Yes

[Phenyl-^{14}C] radiolabelled triticonazole was applied as a spray rate of 285.9 g a.i./ha (22.8 N the intended application rate) and was incorporated into soil since triticonazole is to be applied as a seed dressing. 30, 149 and 366 days after the application, both the treated and the control plots were planted with seeds of radish (root crop), lettuce (leafy crop) and wheat (grain crop). All lettuce plots, the control wheat plots and one treated wheat plot at 366 days did not germinate and were therefore reseeded 41 days after the original planting.
Radish and lettuce plants were sampled as immature (radish: 41 – 75 days after planting; lettuce: 61 – 86 days after planting) and mature plants (radish: 61 – 90 days after planting; lettuce: 87 – 98 days after planting). After washing, radishes and lettuce were separated into leaves and roots. Immature wheat samples (Z30/31, i.e. ear at 1 cm/first node detectable) were taken 68 – 111 days after planting. Mature wheat samples (113 – 175 days after planting) were divided into straw, chaff and grain.

The extraction procedure was described as follows: Lettuce and radish were extracted with methanol/water; some of the 30 day radish samples were subjected to addition procedures in order to remove more radioactivity from fibres: The filter cake was washed in water for 30 minutes and macerated in methanol. The fibres resulting from this procedure together with those from methanol/water extractions of the interim leaves, bulbs and harvest leaves were soxhlet-extracted with acetonitrile. These procedures did not result in any significant amounts of radioactivity and therefore were not used for the analysis of any other samples. Wheat grain samples were macerated in methanol followed by methanol/water (30 and 149 day samples) and acetone followed by acetone/water (366 day samples). Straw and chaff were extracted using the same procedure like the 366 day grain samples.
Total radioactive residue was determined by combustion and LSC; the radioactivity of the liquid samples (extracts) was measured using LSC directly. The identification of the metabolites was carried out by HPLC; TLC was performed as a preliminary investigation for several 30 day radish extracts.

Findings:
After application of radiolabelled triticonazole to bare soil, the following total radioactive residues and metabolites could be found in the various crop samples:

Radish:
The total radioactivity found in roots ranged from 0.023 – 0.043 mg/kg (30 day plot) to 0.039 – 0.043 mg/kg (366 day plot) and in leaves from 0.077 – 0.15 mg/kg (30 day plot) to 0.022 – 0.033 (366 day plot). The major part of the radioactivity detected in roots and leaves from the first rotation was shown to be triticonazole (30.7 – 47.4 % in the roots; 46.8 – 54.8 % in the leaves); leaves at immature stage contained 5 minor components, that did not exceed 0.01 mg/kg. Leaves at harvest were shown to contain two unidentified components (U10 and U11) with 13 % of recovered radioactivity (0.01 mg/kg) and 26.9 % (0.021 mg/kg), resp. For the 149 day plot, triticonazole was the only component identified in the roots of harvest (39.3 %); the extracts of the interim leaves, roots and harvest leaves contained three to five unidentified compounds with levels below 0.01 mg/kg. Analysis of the interim leaves of the last rotation showed the presence of triticonazole (42.2 %) together with

four minor components, each less than 0.01 mg/kg. The harvest extracts of leaves and roots contained nine and two components, resp, again each accounted for less than 0.01 mg/kg.

Lettuce:
The total radioactive residues in lettuce leaves were found to be in the range from 0.048 – 0.066 mg/kg (30 day plot) to 0.025 – 0.033 mg/kg (366 day plot). The majority of the radioactivity detected in the extracts of the 30 day plot was shown to be triticonazole (66.7 – 70.6 % in the root, 83.3 – 84.5 % in the leaves). The roots of the second rotation contained triticonazole as major part as well (30.1 – 49.9 %); 2 – 8 unidentified compounds were detected in both, interim and harvest leaves, each below 0.01 mg/kg. Leaves of the 366 day plot indicated the presence of 7 to 8 components at levels below 0.01 mg/kg. The interim roots extract contained triticonazole only (47.5 %); the harvest root contained one component to be 23.9 % of recovered radioactivity (0.014 mg/kg) but remained unidentified; nevertheless it was characterised to have a polar nature. One further compound was detected to be less than 0.01 mg/kg.

Wheat:
Total radioactive residues in immature wheat plants declined from 0.049 mg/kg (first rotation) to 0.029 mg/kg (last rotation) and in straw from 0.16 mg/kg to 0.11 mg/kg; grains contained low radioactivity ranging from 0.0029 mg/kg to 0.004 mg/kg. The majority of the recovered radioactivity in immature wheat plants were found to be triticonazole (31.5 – 77 %); the plant sample of the last rotation contained fourteen different compounds less than 0.01 mg/kg, each. Besides triticonazole (19.9 – 25.7 %), hydroxylated products could be idetnified in straw samples (RPA 406341: 16.2 – 30.9 %; RPA 404886: 10.3 – 14.4 %; RPA 404766: 10.3 – 13 %). Because of the low radioactivity present, the radioactive residues in grain samples were not further investigated.

Conclusion
Edible parts of plants from the first rotation (30 day plant-back) contained total radioactive residues of 0.23 mg/kg (radish roots), 0.048 mg/kg (lettuce leaves) and 0.003 mg/kg (wheat grain). Total radioactive residues declined with the planting interval and the major component of the recovered radioactivity was unchanged triticonazole.
The uptake and metabolism of triticonazole residues in succeeding crops are adequately understood and no further data are required.
However, in the framework of the inclusion into Annex I according to Directive 91/414/EEC, five additional field trials on the magnitude of the residue in rotational crops were evaluated.

Compliance with OECD 502 for renewal:
Some minor deviations to the current guideline: OECD 502, 2007 have been identified:

- The pesticide should be applied label at the maximum label rate and the maximum number of applications. The studies are more than 20N overdosed.
- According OECD 502, the desired goal of a Metabolism in Rotational Crops study is the identification and characterisation of at least 90% of the total radioactive residue (TRR) in each raw agricultural commodity (RAC) of the treated crop. In many cases it was not possible to identify significant portions of the TRRs as seed treatment does produce very low total amounts of residue. In the studies, presence and levels of the components were presented clearly, and adequate attempts were made to characterise them.

However, based on the findings, the endpoints are relevant to support the application for renewal.

An overview of the confined rotational crop study is given in the tables below:

Table 7.6.1-1: Summary of the confined rotational crop study presented in the first monograph prepared under Directive 91/414/EEC

Year	**Rotational crops**					
	1994					
Rate	**spray 285.9 g a.s./ha** (22.8 N)					
Label	*PHENYL*					
PBI (d)	**30**		**149**		**366**	
sampling interval	**interim**	**harvest**	**interim**	**harvest**	**interim**	**harvest**
TRR	**[mg/kg]**	**[mg/kg]**	**[mg/kg]**	**[mg/kg]**	**[mg/kg]**	**[mg/kg]**
radish bulbs	0.043	0.022	<0.008	<0.008	<0.008	<0.008
radish leaves	0.15	0.077	0.05	0.032	0.033	0.022
radish roots	0.43	0.23	0.042	0.049	0.039	0.043
lettuce leaves	0.066	0.048	0.041	0.015	0.025	0.033
lettuce roots	0.2	0.045	0.046	0.087	0.038	0.056
Wheat whole plant	0.049		0.058		0.029	
Wheat - Grain		<0.005		<0.005		<0.005
Wheat - Straw		0.16		0.17		0.11
Wheat - Chaff		0.03		0.02		0.06

Table 7.6.1-2: Identification of metabolites in radish

Matrix	Bulbs i 30 day tillering		**Bulbs** h 30 day tillering		Leaves i 30 day tillering		Leaves h 30 day tillering		Roots i 30 day tillering		Roots h 30 day tillering		Leaves i 149 day tillering		Leaves h 149 day tillering		Roots i 149 day tillering		Roots h 149 day tillering		Leaves i 366 day tillering		Leaves h 366 day tillering		Roots i 366 day tillering		Roots h 366 day tillering	
TRR (mg/kg)	**0.043**		**0.022**		**0.15**		**0.077**		**0.43**		**0.23**		**0.05**		**0.032**		**0.042**		**0.049**		**0.033**		**0.022**		**0.039**		**0.043**	
non-extractable	13	0.006	23	0.005	11	0.017	12	0.010	45	0.190	76	0.170	14	0.007	12	0.004	61	0.026	43	0.021	18	0.006	23	0.005	53	0.021	54	0.023
extractable	75	0.032	70	0.015	74	0.117	100	0.079	47	0.200	35	0.079	67	0.033	70	0.023	36	0.015	39	0.019	86	0.028	74	0.016	41	0.016	28	0.012

Matrix	Bulbs i 30 day tillering		**Bulbs** h 30 day tillering		Leaves i 30 day tillering		Leaves h 30 day tillering		Roots i 30 day tillering		Roots h 30 day tillering		Leaves i 149 day tillering	Leaves h 149 day tillering	Roots i 149 day tillering	Roots h 149 day tillering	Leaves i 366 day tillering	Leaves h 366 day tillering	Roots i 366 day tillering	Roots h 366 day tillering
TRR (mg/kg)	**0.043**		**0.022**		**0.15**		**0.077**		**0.43**		**0.23**		**0.05**	**0.032**	**0.042**	**0.049**	**0.033**	**0.022**	**0.039**	**0.043**
	%	[mg/kg]	%	[mg/kg]	%	[mg/kg]	%	[mg/kg]	%	[mg/kg]	%	[mg/kg]								
Triticonazole	41	0.018	49	0.012	47	0.070	55	0.042	47	0.200	31	0.070								
RPA 406341	---	---	---	---	---	---	---	---	---	---	---	---								
RPA 404886	---	---	---	---	---	---	---	---	---	---	---	---								
RPA 404766	---	---	---	---	---	---	---	---	---	---	---	---								
others characterised	---	---	---	---	---	---	40	0.031	---	---	---	---								
total	41 %		49 %		47 %		95 %		47 %		31 %		**Not further analysed.**							

Table 7.6.1-3: Identification of metabolites in lettuce

	Leaves i 30 day tillering		Leaves h 30 day tillering		Roots i 30 day tillering		Roots h 30 day tillering		Leaves i 149 day tillering		Leaves h 149 day tillering		Roots i 149 day tillering		Roots h 149 day tillering		Leaves i 366 day tillering		Leaves h 366 day tillering		Roots i 366 day tillering		Roots h 366 day tillering	
TRR (mg/kg)	**0.066**		**0.048**		**0.2**		**0.045**		**0.041**		**0.015**		**0.046**		**0.087**		**0.025**		**0.033**		**0.038**		**0.056**	
non-extractable	14	0.009	28	0.014	66*	0.130	35	0.016	42	0.017	16	0.002	38	0.017	49	0.043	15	0.040	13	0,005	47	0,017	31	0,017
extractable	83	0.055	85	0.041	67	0.130	71	0.032	68	0.028	56	0.008	61	0.028	37	0.033	75	0.019	73	0,024	48	0,018	39	0,023
	%	[mg/kg]	%	[mg/kg]	%	[mg/kg]	%	[mg/kg]					%	[mg/kg]	%	[mg/kg]					%	[mg/kg]	%	[mg/kg]
Triticonazole	83	0.055	85	0.041	67	0.130	71	0.032					50	0.023	30	0.026					48	0.018		
RPA 406341	---	---	---	---	---	---	---	---					---	---	---	---					---	---	---	---
RPA 404886	---	---	---	---	---	---	---	---	**Not further analysed.**				---	---	---	---	**Not further analysed.**				---	---	---	---
RPA 404766	---	---	---	---	---	---	---	---					---	---	---	---					---	---	---	---
others characterised	---	---	---	---	---	---	---	---					---	---	---	---					---	---	24	0.014
total	83 %		85 %		67 %		71 %						50 %		30 %						48 %		24 %0	

*fibres were contaminated with sand from extraction procedure, giving unexplained, high results

Table 7.6.1-4: Identification of metabolites in wheat

	Plant i 30 day tillering		plant i 149 d tillering		plant i 366 d tillering		Chaff h 30 d tillering		Chaff h 149 d tillering		Chaff h 366 d tillering		Straw h 30 d tillering		Straw h 149 d tillering		Straw h 366 d tillering	
TRR (mg/kg)	**0.049**		**0.058**		**0.029**		**0.03**		**0.02**		**0.058**		**0.16**		**0.17**		**0.11**	
non-extractable	29	0.014	28	0.016	30	0.009			27	0.005	21	0.012	30	0.048			24	0.026
extractable	77	0.038	72	0.042	61	0.018	104	0.023	78	0.015	74	0.043	66	0.104	82		86	0.093
	%	**[mg/kg]**	**%**	**[mg/kg]**	**%**	**[mg/kg]**	**%**	**[mg/kg]**	**%**	**[mg/kg]**	**%**	**[mg/kg]**	**%**	**[mg/kg]**	**%**	**[mg/kg]**	**%**	**[mg/kg]**
Triticonazole	77	0.038	32	0.020	**Not further analysed.**								21	0.028	20	0.034	26	0.030
RPA 406341 (5059144)	---	---	---	---									20	0.026	16	0.029	31	0.036
RPA 404886 (R4, 5079247)	---	---	---	---									14	0.019	10	0.018	---	---
RPA 404766 (R2, 5079285)	---	---	---	---									13	0.018	10	0.018	---	---
others characterised	---	---	36	0.023									---	---	6	0.011	11	0.013
total	77 %		68 %										68 %		63 %		68 %	

The uptake and metabolism of triticonazole residues in succeeding crops are adequately understood and no further data are required.

B.7.6.2. Magnitude of residues in rotational crops

In the framework of the inclusion into Annex I according to Directive 91/414/EEC, five additional field trials on the magnitude of the residue in rotational crops were evaluated:

Report:	**R013104; Richard, M.; Muller, M. (1994)**
Title:	Triticonazole or RPA400727; Formulation EXP80380A (FS): Residues in Soil, Protein Peas (seeds), Beets (Leaves and Beetroot), Sunflowers (Seeds). Rotational Crop Following a Trial with Soft Winter Wheat Turned over in April.
Guidelines:	Not reported
GLP	Yes
Report:	**R013123; Muller, M. (1994a)**
Title:	Triticonazole; Formulation EXP80378A (FS): Trial Conducted in France from 1991 to 1993, Residues in Oilseed Rape (Seeds) and in Soil (Before Sowing Oilsees Rape), Crop Rotation Study (Treated Wheat Followed by untreated Oilseed Rape)
Guidelines:	Not reported
GLP	Yes
Report:	**R013124; Muller, M. (1994b)**
Title:	Triticonazole; Formulation EXP80378A (FS): Trial Conducted in France from 1991 to 1993, Residues in Soft Winter Wheat (Grain and Straw) and in Soil (Before Sowing Wheat), Crop Rotation Study (Treated Wheat Followed by untreated Wheat)
Guidelines:	Not reported.
GLP	Yes
Report:	**R013122; Muller, M. (1994c)**
Title:	Triticonazole; Formulation EXP80378A (FS): Trial Conducted in France from 1991 to 1993, Residues in Sugar Beet (Beetroot, Tops) and in Soil Before Sowing Sugar Beets, Crop Rotation Study (Treated Wheat Followed by untreated Sugar Beets)
Guidelines:	Not reported.
GLP	Yes
Report:	**R013120; Muller, M. (1994d)**
Title:	Triticonazole; Formulation EXP80378A (FS): Trial Conducted in France from 1991 to 1993, Residues in Sunflowers (Seeds) and in Soil (Before Sowing Sunflowers), Crop Rotation Study (Treated Wheat Followed by untreated Sunflowers)
Guidelines:	Not reported.
GLP	Yes

R013104; Richard, M.; Muller, M. (1994):

Seeds of soft winter wheat were treated with the formulation EXP 80380A (suspension concentrate containing 300 g triticonazole/l) with an application rate of 120 g triticonazole/100 kg seed. Wheat was sown in December, turned over in April and than replaced by protein peas, sugar beet and sunflowers. The following intervals have been considered: 236 days between planting of wheat and harvesting of protein peas (i.e. 117 days after planting of peas), 288 days between planting of wheat and harvesting of sugar beets (i.e. 169 days after planting of beets) and 279 days between planting of wheat and harvesting of sunflowers (i.e. 160 days after planting of sunflowers).

Analytical method:
Method AR 92-92 “Determination of RPA 400727 residues in cereals”.

Triticonazole residues were determined after extraction with acetone or acetone/water using GC/TSD.
The LOQs were reported to be:
for peas and beets 0.01 mg/kg (recovery: 102 % - peas and 86 – 110 % - beets)
for sunflower seeds 0.02 mg/kg (recovery: 113 %), and
for soil 0.005 mg/kg

Storage:
The maximum storage interval from sampling to analysis was 6 months. This period is covered by storage stability studies for commodities with high starch content for sugar beets. No storage stability studies for high protein or high oil content commodities are available.

Results:
At harvest, no triticonazole residues above the LOQ in the succeeding crops could be detected (0.01 mg/kg for peas and beets; 0.02 mg/kg for sunflower seeds).
The results are summarised in the following table:

Table B.7.6.2-1 Residues of triticonazole in succeeding crops (protein peas, sugar beets and sunflowers) after application of 120 g triticonazole/100 kg seed to winter wheat (trials compiled in Northern France)

Crops	Sample	PHI [days after application/ days after planting]	Residues[1)]
Protein peas	Peas	236/117	<0.01
Sugar beets	Beets	288/169	<0.01
Sunflower	Seeds	279/160	<0.02
Soil (loamy silt)	0-10 cm 10-20 cm 20-30 cm	121	0.072 <0.005 <0.005

1) Residues expressed as mg triticonazole/kg

R013123; Muller, M. (1994a)

Seeds of winter wheat were treated with the formulation EXP 80378A (suspension concentrate containing 200 g triticonazole/l and 84 g Anthraquinone/l) with an application rate of 180 g triticonazole/100 kg seed. Wheat was sown in November and than replaced by oil seed rape 295 days after planting of wheat. The following intervals have been considered: 588 days between planting of wheat and harvesting of oil seed rape (i.e. 292 days after planting of rape).

Analytical method:
Method AR 96-93 “Determination of flurtamone and triticonazole in soil”.
Triticonazole residues present in soil or plant were determined using GC/TSD following extraction with acetone/water and cleaning by C18 and NH5 cartridges. Analysis was carried out using external standards.
The limit of quantitation was reported to be for seeds of rape 0.01 mg/kg (recovery: 122 %) and
for soil 0.005 mg/kg (recovery: 91-100 %).

Storage:
The maximum storage interval (-20 °C) from sampling to analysis was 7 months for soil and 9 months for OSR. No storage stability studies for high oil content commodities are available.

Results:
At harvest, no triticonazole residues above the limit of determination in the succeeding crops (seeds of oil seed rape) could be detected (0.01 mg/kg).
The results are summarised in the following table:

Table B.7.6.2-2 Residues of triticonazole in succeeding crops (oil seed rape) after application of 180 g triticonazole/100 kg seed to winter wheat (trials compiled in Southern France)

Crops	Sample	PHI [days after application/ days after planting]	Residues[1)]
Oil seed rape	Seeds	588/292	<0.01
Soil (type not specified)	0-10 cm 10-20 cm 20-30 cm	293	0.023 0.035 ≤0.010

1) Residues expressed as mg triticonazole/kg

R013124; Muller, M. (1994b)

Seeds of winter wheat were treated with the formulation EXP 80378A (suspension concentrate containing 200 g triticonazole/l and 84 g Anthraquinone/l) with an application rate of 180 g triticonazole/100 kg seed. Wheat was sown in October and than replaced by soft winter wheat 375 days after planting of wheat. The following intervals have been considered: 628 days between planting of winter wheat and harvesting of the second rotation - wheat (i.e. 252 days after planting of winter wheat, second rotation).

Analytical method:
Method AR 96-93 "Determination of flurtamone and triticonazole in soil".
Triticonazole residues present in soil or plant were determined using GC/TSD following extraction with acetone/water and cleaning by C18 and NH5 cartridges. Analysis was carried out using external standards.
The limits of determination were reported to be for grain 0.01 mg/kg (recovery: 81 - 84 %), for straw 0.05 mg/kg (recovery: 93 %) and for soil 0.005 mg/kg (recovery: 89-115 %).

Storage:
The maximum storage interval (-20 °C) from sampling to analysis was 5 months for soil and 8 months for wheat. This period is covered by storage stability studies for wheat.

Results:
At harvest, no triticonazole residues above the limit of quantitation in the succeeding crops could be detected in grains (LOQ: 0.01 mg/kg) and straw (LOQ: 0.05 mg/kg).
The results are summarised in the following table:

Table B.7.6.2-3 Residues of triticonazole in succeeding crops (winter wheat) after application of 180 g triticonazole/100 kg seed to winter wheat (trials compiled in Northern France)

Crops	Sample	PHI [days after application/ days after planting]	Residues[1)]
Winter wheat	Grain straw	628/252 628/252	<0.01 <0.05
Soil (type not specified)	0-10 cm 10-20 cm 20-30 cm	386	0.018 0.017 <0.005

1) Residues expressed as mg triticonazole/kg

R013122; Muller, M. (1994c)

Seeds of winter wheat were treated with the formulation EXP 80378A (suspension concentrate containing 200 g triticonazole/l and 84 g Anthraquinone/l) with an application rate of 180 g triticonazole/100 kg seed. Wheat was sown in October and than replaced by sugar beet 515 days after planting of wheat. The following intervals have been considered: 675 days between planting of winter wheat and harvesting of sugar beet (i.e. 160 days after planting of sugar beet).

Analytical method:
Method AR 96-93 "Determination of flurtamone and triticonazole in soil".
Triticonazole residues present in soil or plant were determined using GC/TSD following extraction with acetone/water and cleaning by C18 and NH5 cartridges. Analysis was carried out using external standards.
The LOQs were reported to be:
for beet roots 0.01 mg/kg (recovery: 94 %)
for tops 0.05 mg/kg (recovery: 80-81%)
for soil 0.005 mg/kg (recovery: 84-121%)

Storage:
Beetroot and tops were stored under ambient temperature.

Results:
At harvest, no triticonazole residues above the limit of determination in the succeeding crops could be detected in beet root (LOQ: 0.01 mg/kg) and tops (LOQ: 0.05 mg/kg).
The results are summarised in the following table:

Table B.7.6.2-4 Residues of triticonazole in succeeding crops (sugar beet) after application of 180 g triticonazole/100 kg seed to winter wheat (trials compiled in Northern France)

Crops	Sample	PHI [days after application/ days after planting]	Residues[1)]
Sugar beet	Beet root tops (leaves)	675/160 675/160	<0.01 <0.05
Soil (type not specified)	0-10 cm 10-20 cm 20-30 cm	540	0.012 0.016 <0.005-0.006

1) Residues expressed as mg triticonazole/kg

R013120; Muller, M. (1994d)

Seeds of winter wheat were treated with the formulation EXP 80378A (suspension concentrate containing 200 g triticonazole/l and 84 g Anthraquinone/l) with an application rate of 180 g triticonazole/100 kg seed. Wheat was sown in November and than replaced by sunflower 501 days after planting of wheat. The following intervals have been considered: 617 days between planting of winter wheat and harvesting of sunflower seed (i.e. 116 days after planting of sunflower).

Analytical method:
Method AR 96-93 "Determination of flurtamone and triticonazole in soil".
Triticonazole residues present in soil or plant were determined using GC/TSD following extraction with acetone/water and cleaning by C18 and NH5 cartridges. Analysis was carried out using external standards.
The LOQs were reported to be:
for sunflower seed 0.01 mg/kg (recovery: 78-83%)
for soil 0.005 mg/kg (recovery: 74-87%)

Storage:
No storage conditions were reported.

Results:
At harvest, no triticonazole residues above the limit of determination in the succeeding crops could be detected in sunflower seed (LOQ: 0.01 mg/kg).
The results are summarised in the following table:

Table B.7.6.2-5 Residues of triticonazole in succeeding crops (sun flower) after application of 180 g triticonazole/100 kg seed to winter wheat (trials compiled in Northern France)

Crops	Sample	PHI [days after application/ days after planting]	Residues[1)]
Sunflower	Seed	617/116	<0.01
Soil (type not specified)	0-10 cm 10-20 cm 20-30 cm	540	<0.005-0.006 <0.005-0.006 <0.005

1) Residues expressed as mg triticonazole/kg

Overall Conclusion on the MOR trials in succeeding crops:

Conclusion on acceptability in the DAR:
The five studies wereconducted in compliance with Good Laboratory Practices (GLP); no guideline was mentioned in the study report, but the study was regarded as scientifically valid and is therefore acceptable.

Compliance with OECD 504 for renewal:
There are deviations to the new guideline which are pointed out below:

- The pesticide should be applied label at the maximum label rate and the maximum number of applications. The studies are more than 20N overdosed. The overdosing facrors are also listed in Table B.7.6.2-6
- Untreated control plots should also be included for each test site. It is desirable to use sites on which the test substance has not previously been applied. Control values were only investigated for soil scores.
- One of the test sites should be a sandy loam soil. In four of the five studies the soil type was not specified; in the first study the soil was a loamy silt.
- Storage stability data for soil are missing (however, sampling of the soil for pesticide residue analysis is not required).
- Storage stability data for high protein and high oil content commodities are missing for the succeeding crops under evaluation.

However, based on the findings, it can be expected that seed treatment of cereals with triticonazole will not lead to detectable residues in succeeding crops. The endpoints are relevant to support the application for renewal.

A summary of the results is given in the table below:

Table B.7.6.2-6 Residues of triticonazole in succeeding crops

Study	Application regime	Crops	Sample	PHI [days after application/ days after planting]	Residues[1)]
R013104; Richard, M.; Muller, M. (1994)	120 g triticonazole/100 kg seed to winter wheat (Northern France) *(24N)*	Protein peas	Peas	236/117	<0.01
		Sugar beets	Beets	288/169	<0.01
		Sunflower	Seeds	279/160	<0.02
R013123; Muller, M. (1994a)	180 g triticonazole/100 kg seed to winter wheat (Southern France) *(36N)*	Oil seed rape	Seeds	588/292	<0.01
R013124; Muller,	180 g	Winter wheat	Grains	628/252	<0.01

Study	Application regime	Crops	Sample	PHI [days after application/ days after planting]	Residues[1)]
M. (1994b)	triticonazole/100 kg seed to winter wheat (Northern France) *(36N)*		Straw	628/252	<0.05
R013122; Muller, M. (1994c)	180 g triticonazole/100 kg seed to winter wheat (Northern France) *(36N)*	Sugar beet	Beet root	675/160	<0.01
			Tops/leaves	675/160	<0.05
R013120; Muller, M. (1994d)	180 g triticonazole/100 kg seed to winter wheat (Northern France) *(36N)*	Sunflower	Seed	617/116	<0.01

1) Residues expressed in mg triticonazole/kg

B.7.7. OTHER STUDIES

B.7.7.1. Effect on the residue level in pollen and bee products

The objective of such studies shall be to determine the residue in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom.
The representative use of this dossier is seed treatment in wheat. Considering the low TRR levels in the metabolism studies at BBCH 65 (flowering), no residues in pollen are expected and residue studies in honey are therefore not required.

Triticonazole	Field study						
Crop	Barley						
Year	**2002 (Oddy)**						
Rate	Target: 12.5 g a.s./ha. Actual: 11.96 g a.i./ha			Target 12.5 g a.s./ha. Actual: 10.65 g a.i./ha		
Label	PHENYL			TRIAZOLE		
GS	Z24	**Z65**	**1 N**	Z24	**Z65**	**1 N**
Crop part	Plant	Plant		Plant	Plant	
TRR (mg/kg)	**0.01**	**0.00**		**0.01**	**0.01**	
Rate	Target: 150 g a.s./ha. Actual: 138.98 g a.i./ha			Target: 150 g a.s./ha. Actual: 109.53 g a.i./ha		
Label	PHENYL			TRIAZOLE		
GS	Z24	**Z65**	**11 N**	Z24	**Z65**	**9 N**
Crop part	Plant	Plant		Plant	Plant	
TRR (mg/kg)	**0.13**	**0.01**		**0.12**	**0.03**	

Triticonazole	Field study				
Crop	Wheat				
Year	**1993 (updated 1998) Ayliffe et al.**				
Rate	Target:487 g a.s./ha; actual: **384 g a.s./ha** (186.6 g a.s. / 100 kg seed) ; 206 kg seed/ha				
Label	TRIAZOLE				
GS	Z 30	Z 50	**Z 65**	**Z 65**	**31 N**
	ear 1 cm	inflores-cence emergen ce	**flowe ring**	**flowe ring**	
Crop part	Whole plant	Whole plant	**Whol e plant**	**Ears**	
TRR (mg/kg)	**5.61**	**0.29**	**0.54**	**0.50**	

Triticonazol	Field study							
Crop	Wheat					Barley		
Year	**1997 Doble et al.**							
Rate	279 g a.s./ha (180g / 100 kg seed); 180 kg seed/ha					454 g a.s./ha (242 g / 100 kg seed). 187.5 kg seed/ha		
Label	PHENYL							
GS	Z 30	Z 47	Z 62	**Z 65**	**22 N**	Z 61	**Z 65**	**36 N**
	Stem elongation	**Flag leaf opening**	**Early anthesis***	**Mid anthesis***		**Beginning of anthesis**	**Mid anthesis**	
Crop part	Plant	Ears	Plant	Ears		Ear	Ears	
PHI (d)	136	176	188-211	188-211		176	188	
TRR (mg/kg)	**0.91**	**<0.01**	**0.710**	**0.010**		**<0.01**	**0.03**	

*Anthesis is the period during which a flower is fully open and functional.

B.7.7.2. Review of scientific peer-reviewed open literature for residues of triticonazole

A scientific peer-reviewed open literature search as required by Article 8(5) of Regulation (EC) No 1107/2009 and according to the guidance of EFSA (EFSA Journal 2011;9(2):2092) has been conducted on the active substance Triticonazole and the common product trade names was performed.

Literature Search Report on Triticonazole BASF DocID 2015/1216973
The report was performed by the BASF Group Information Center describes the general search and evaluation process as well as details on search profiles, search histories and summary tables.
The first step of the search result processing based on summary records was done by the Information Center and involved the separation into "hits" and "ballast" (obviously irrelevant records). The “ballast” was not further processed. The “hits” were further evaluated by the scientific experts and categorized into “not relevant”, “not reliable”, and “used for dossier”.

Literature Search was done following the relevance and reliability criteria as set out in the EXTERNAL SCIENTIFIC REPORT “Case studies for the application of the Guidance of EFSA on Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009, using substances for which dossiers are submitted under Regulation (EU) No 1141/2010”:
In this project, the relevance criteria were generally derived from the respective data requirements. However, in specific cases, additional criteria going beyond the data requirements (e.g. cross-contamination for products used in storehouses, mode of action for certain effects, information on sensitivity of some strains) were considered to possibly be relevant and could be included, on a case by case basis, in the literature search in order to allow a possible refinement of the risk assessment. For the reliability criteria the assumption was that non-guideline data (e.g. from academic laboratories) following good scientific principles in design, conduct and reporting as well as employing appropriate statistics, were judged as being of equal quality to the studies conducted according to up-to-date Test Guidelines by a GLP-accredited facility.

Additionally defined **relevance criteria:**
- Studies dealing with any crop treated with the active substance triticonazole were considered relevant and not just studies dealing with the representative crops only. A broader spectrum of relevant literature might therefore show useful information considering the MRL setting and MRL review program at EU level; ’real‘ residue data that do not reflect the representative uses might be put in a separate box called ’for MRL setting’.
- Bibliographic databases may also contain useful information about minor uses. Such studies can be considered as relevant for inclusion into the dossier, although the chances to find such studies in the literature databases are rather limited: residue trials performed on minor uses are usually conducted by grower´s associations and those studies are usually not published in peer-reviewed journals.
- Genetically modified (GMO) crops are covered by the present search concept and the corresponding studies should be selected for further considerations.
- Monitoring studies are not considered data requirements for the review of the active substance. However, in some cases monitoring data can be the basis for MRL setting, for example when
a) an active substance is very persistent in soil and residues are taken up by rotational crops or
b) when an active substance is not used anymore and there would be a need for setting an MRL because of contamination or because the substance is very persistent in soil (e.g. HCB, DDT, etc).
Monitoring data could be included on a case-by-case basis, after careful consideration. However, for triticonazole, the criteria for inclusion of monitoring data into the search strategy were not given.
- For active substances that are used in stores and containers, cross-contamination may be an issue. Therefore, it might be useful to address this issue on a case-by-case basis. However, cross-contamination is not an issue for triticonazole.
- Regarding the term ’unknown metabolites’, a search term such as ’unknown’ would most likely result in an exorbitantly high number of hits without any benefit. Nevertheless, the search term ‘metabolite’ is included in the present search strategy. Studies on unknown metabolites are covered by the relevance selection process.
-Studies dealing with analytical methods investigating residues in food of plant and animal origin are found in large numbers in scientific bibliographic databases. The results of analytical method studies are not directly connected to risk assessment. In fact, the methods have to be provided by the applicant in order to show that possible residues in food of plant and animal origin may be analysed using little effort so that they can be applied on a routine basis. Therefore it was concluded to not consider such studies relevant for the dossiers.

Criteria for reliability of research studies to be used for consumer exposure assessment

Data requirement (data point number)	Criteria for reliability	
	Test method	Guidance document
Stability of residues prior to analysis (Point 6.1)	1. OECD (2007), Test No 506: Stability of Pesticide Residues in Stored Commodities, OECD Guidelines for the Testing of Chemicals, Section 5, 15 October 2007.	1. OECD (2009). Guidance Document on Overview of Residue Chemistry Studies (as revised in 2009). Environment, Health and Safety Publications. Series on Testing and Assessment No. 64 and Series on Pesticides No. 32. 2. EC (European Commission), 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5.
Metabolism, distribution and expression of residues in plants (Point 6.2)	1. OECD (2007), Test No. 501: Metabolism in Crops, OECD Guidelines for the Testing of Chemicals, Section 5, 25 January 2007	1. OECD (2009). Guidance Document on Overview of Residue Chemistry Studies (as revised in 2009). Environment, Health and Safety Publications. Series on Testing and Assessment No. 64 and Series on Pesticides No. 32. 2. EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3.
Metabolism, distribution and expression of residues in livestock (Point 6.2)	1. OECD (2007), Test No. 503: Metabolism in Livestock, OECD Guidelines for the Testing of Chemicals, Section 5, 25 January 2007.	1. OECD (2009). Guidance Document on Overview of Residue Chemistry Studies (as revised in 2009). Environment, Health and Safety Publications. Series on Testing and Assessment No. 64 and Series on Pesticides No. 32. 2. EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3. 3. Draft Guidance Document on Nature of Pesticide Residues in Fish, Revision 3
Residues resulting from supervised trials (Point 6.3)	1. OECD (2009), Test No. 509: Crop Field Trial, OECD Guidelines for the Testing of Chemicals, Section 5, 15 October 2007.	1. EC (European Commission), 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. 7029/VI/95-rev.5. 2. OECD (2011) Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)
Feeding studies (Point 6.4)	1. OECD (2007), Test No. 505: Residues in Livestock, OECD Guidelines for the Testing of Chemicals, Section 5, 25 January 2007.	1. OECD (2009). Guidance Document on Overview of Residue Chemistry Studies (as revised in 2009). Environment, Health and Safety Publications. Series on Testing and Assessment No. 64 and Series on Pesticides No. 32. 2. EC (European Commission), 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95 rev.4.
Effects of industrial processing and/or household preparation (Point 6.5)	1. OECD (2007), Test No. 507: Nature of the Pesticide Residues in Processed Commodities - High Temperature Hydrolysis, OECD Guidelines for the Testing of Chemicals, Section 5, 15 October 2007. 2. OECD (2008), Test No. 508:	1. EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5. 2. OECD (2008). Guidance document on magnitude of pesticide residues in processed commodities. Environment, Health and Safety Publications. Series on Testing and Assessment No. 96.

Data requirement (data point number)	Criteria for reliability	
	Test method	Guidance document
	Magnitude of the Pesticide Residues in Processed Commodities, OECD Guidelines for the Testing of Chemicals, Section 5, 16 October 2009. 3. OECD (2009), Test No. 509: Crop Field Trial, OECD Guidelines for the Testing of Chemicals, Section 5, 15 October 2007.	
Residues in rotational crops (Point 6.6)	1. OECD (2007), Test No. 502: Metabolism in Rotational Crops, OECD Guidelines for the Testing of Chemicals, Section 5, 25 January 2007.	1. OECD (2009). Guidance Document on Overview of Residue Chemistry Studies (as revised in 2009). Environment, Health and Safety Publications. Series on Testing and Assessment No. 64 and Series on Pesticides No. 32. 2. EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2.
Estimation of the potential and actual exposure through diet and other sources (Point 6.9)	1. OECD (2007), Test No. 504: Residues in Rotational Crops (Limited Field Studies), OECD Guidelines for the Testing of Chemicals, Section 5, 25 January 2007. 2. OECD (2009), Test No. 509: Crop Field Trial, OECD Guidelines for the Testing of Chemicals, Section 5, 15 October 2007.	EFSA calculation model Pesticide Residue Intake Model "PRIMo" - revision 2
Residue level in pollen and bee products (Point 6.10.1)	No agreed test method available	No agreed guidance document available
Further issues under discussion	No agreed test method available	No agreed guidance document available

Results

According to the strategy for scientific literatur research, no literature was identified as relevant for further evaluation.

Conclusion

An extensive search of the published literature did not reveal any studies that would affect the regulatory assessment of triticonazole.

B.7.8. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Compagny 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
KCA, 6	Chenevier, A.; Kieken, J. L.	1995	Triticonazole or RPA 400727: Storage Stability in Maize (Grain) and in Winter Wheat (Grain and Straw) Rhone-Poulenc Report Nr. 94-49 GLP not published	N	N	---	BASF	In DAR (2005)
KCA 6.2.1/1	Williams D.	2015 a	Interim report: Metabolism of 14C-BAS 595 F with two labels in spring wheat after seed treatment 2014/1090812 IES - Innovative Environmental Services Ltd., Witterswil, Switzerland yes Unpublished	N	Y	New data for AIR3 renewal	BASF	Submitted for the purpose of renewal.

Data Point	Author(s)	Year	Title Compagny 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
KCA, 6.1	Ayliffe, J. M.; John, A. E.; Lowden, P.; McMillan-Staff, S.; Parsons, R. G.	1993	Fungicides: RPA 400727-[^{14}C-Triazole]: Field Study in Spring Cereals Rhone-Poulenc Agriculture Ltd. Report No. P 91/110 GLP not published	N	N	---	BASF	In DAR (2005)
KCA, 6.1	Doble, M. L.; Jones, M. K.; Lowden, P.; Parsons, R. G.; McMillan-Staff, S.	1997	Final Report: Fungicides: RPA 400727 [^{14}C-Phenyl]: Field Study on Winter Cereals Rhone-Poulenc Agriculture Ltd. Report No. P91/358 GLP not published	N	N	---	BASF	In DAR (2005)
KCA, 6.1	Lowden; P.	1998	Triticonazole: An Overview of Metabolism in Cereals Rhone-Poulenc RPA Document 201927 no GLP not published	N	N	---	BASF	In DAR (2005)
KCA, 6.1	Oddy, A.	2002	[^{14}C]-Triticonazole: Metabolism in Barley Following Seed Treatment Aventis CropScience SA Report No. CX/01/010 GLP not published	N	N	---	BASF	In DAR (2005)
KCA 6.2.3/1	[redacted]	2015 a	The metabolism of 14C-BAS 595 F in the lactating goat 2014/1090814 [redacted],	Y	Y	New data for AIR3 renewal	BASF	Submitted for the purpose of renewal.

Data Point	Author(s)	Year	Title Compagny 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
			[redacted] yes Unpublished					
KCA 6.3.1/1	Martin T.	2015 a	Study on the residue behavior of Triticonazole after seed treatment (with BAS 595 01 F) on wheat under field conditions in Germany, United Kingdom, France (North and South), Greece, Italy and Spain, 2012-2013 2014/1043281 Agrologia SLU, Utrera, Spain yes Unpublished	N	Y	New data for AIR3 renewal	BASF	Submitted for the purpose of renewal.

Data Point	Author(s)	Year	Title Compagny 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
KCA 6.3.1/2	Martin T.	2015 b	Study on the residue behaviour of Triticonazole after seed treatment (with BAS 595 01 F) on wheat under field conditions in Germany, France (North and South), Netherlands, United Kingdom, Greece, Italy and Spain, 2013-2014 2014/1090813 Agrologia SLU, Utrera, Spain yes Unpublished	N	Y	New data for AIR3 renewal	BASF	Submitted for the purpose of renewal.
KCA, 6.3	Holmgaard, M.	1996a	Determination of the Residues of Iprodione and Triticonazole in Spring Barley after Application of Premis Delta as Seed Dressing – Season 1995, Denmark Rhone-Poulenc Agro Norden A/S Report No. 95-690, C 015362 GLP not published	N	N	---	BASF	In DAR (2005)
KCA, 6.3	Holmgaard, M.	1996b	Iprodione and Triticonazole – Formulation EXP80524C (FS) – Trials Denmark 1996 – Residue in Spring Barley Rhone-Poulenc Agro Report No. 96-701, C 015364 GLP not published	N	N	---	BASF	In DAR (2005)

Data Point	Author(s)	Year	Title Compagny 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
KCA, 6.3	Holmgaard, M.	1997a	Guazatine and Triticonazole – Formulation EXP 80525D (FS) – Trials Denmark 1995-1996 – Residue in winter Wheat Rhone-Poulenc Agro Report No. 95-691, R 003472 GLP not published	N	N	---	BASF	In DAR (2005)
KCA, 6.3	Holmgaard, M.	1997b	Guazatine and Triticonazole – Formulation EXP 80525D (FS) – Trials Denmark 1995-1996 – Residue in Winter Rye Rhone-Poulenc Agro Report No. 95-692, R 003473 GLP not published	N	N	---	BASF	In DAR (2005)
KCA, 6.3	Fuchsbichler, G.	1996	Determination of the Residues of Triticonazole in Wheat, Shoot, Grain and Straw and Guazatine in Grain and Straw Rhone-Poulenc Agrochemie Report No HVA 4/96, C 016014 GLP not published	N	N	---	BASF	In DAR (2005)
KCA, 6.3	Maestracci, M.	1997a	Triticonazole and Guazatine: Formulation EXP80525D (FS). Trial Italy 1995 – 1996. Residues in Durum Winter Wheat (Straw	N	N	---	BASF	In DAR (2005)

Data Point	Author(s)	Year	Title Compagny 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
			and Grain) Rhone-Poulenc Agro Report No. 96-604, R 003257 GLP not published					
KCA, 6.3	Maestracci, M.	1997b	Triticonazole: Formulation EXP80523A (DS). Trial Greece 1995 – 1996. Residues in Durum Winter Wheat (Grain) Rhone-Poulenc Agro Report No. 96-601, R 013164 GLP not published	N	N	---	BASF	In DAR (2005)
KCA, 6.3	Maestracci, M.	1997c	Triticonazole and Guazatine: Formulation EXP80525D (FS). Trial Italy 1995 – 1996. Residues in Soft Winter Wheat (Straw and Grain) Rhone-Poulenc Agro Report No. 96-603, R 003235 GLP not published	N	N	---	BASF	In DAR (2005)
KCA, 6.3	Maestracci, M.	1997d	Triticonazole: Formulation EXP80523A (DS). Trial Greece 1995 – 1996. Residues in Winter Barley (Grain) Rhone-Poulenc Agro Report No. 96-602, R 013162	N	N	---	BASF	In DAR (2005)

Data Point	Author(s)	Year	Title Compagny 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
			GLP not published					
KCA, 6.3	Maestracci, M.	1997e	Triticonazole - Iprodione: Formulation EXP80524C (FS). Trials Italy 1995 – 1996. Residues in Winter Barley (Grain, Straw) Rhone-Poulenc Agro Report No. 96-605, C 014734 GLP not published	N	N	---	BASF	In DAR (2005)
KCA, 6.3	Muller, M.A.	1995	Triticonazole: Formulation EXP80472A (FS) Trials Conducted in Spain from 1993 to 1994. Residues in Winter Barley (Grain and Straw) Rhone-Poulenc Agro Report No. 94-671, C 017659 GLP not published	N	N	---	BASF	In DAR (2005)
KCA, 6.3	Muller, M.A.	1996a	Triticonazole – Iprodione: Formulation EXP80524C (FS) Trial Italy from 1994 – 1995. Residues in Durum Winter Wheat (Grain – Straw) Rhone-Poulenc Agro Report No. 95-606, C 014706 GLP	N	N	---	BASF	In DAR (2005)

Data Point	Author(s)	Year	Title Compagny 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
			not published					
KCA, 6.3	Muller, M.A.	1996b	Triticonazole – Guazatine: Formulation EXP80525C (FS) Trial Italy 1994 – 1995. Residues in Durum Winter Wheat (Grain – Straw) Rhone-Poulenc Agro Report No. 95-610, R 002862 GLP not published	N	N	---	BASF	In DAR (2005)
KCA, 6.3	Muller, M.A.	1996c	Triticonazole – Iprodione: Formulation EXP80524C (FS) Trial Italy 1994 – 1995. Residues in Soft Winter Wheat (Grain – Straw) Rhone-Poulenc Agro Report No. 95-607, C 014710 GLP not published	N	N	---	BASF	In DAR (2005)
KCA, 6.3	Muller, M.A.	1996d	Triticonazole – Guazatine: Formulation EXP80525C (FS) Trial Italy 1994 – 1995. Residues in Soft Winter Wheat (Grain – Straw) Rhone-Poulenc Agro Report No. 95-609, R 002860 GLP not published	N	N	---	BASF	In DAR (2005)

Data Point	Author(s)	Year	Title Compagny 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
KCA, 6.3	Muller, M.A.	1996e	Triticonazole – Iprodione: Formulation EXP80524C (FS) Trials Italy 1994 – 1995. Residues in Winter Barley (Grain – Straw) Rhone-Poulenc Agro Report No. 95-608, C 014712 GLP not published	N	N	---	BASF	In DAR (2005)
KCA, 6.3	Richard, M; Muller, M.A.	1995a	Triticonazole Formulation EXP80523A (DS) Trial Conducted in Italy from 1993 – 1994. Residues in Durum Winter Wheat Rhone-Poulenc Agro Report No. 94-640, C 017252 GLP not published	N	N	---	BASF	In DAR (2005)
KCA, 6.3	Richard, M; Muller, M.A.	1995b	Triticonazole – Iprodione: Formulation EXP80524A (FS) Trial Conducted in Italy in 1994. Residues in Durum Spring Wheat Rhone-Poulenc Agro Report No. 94-643, C 017316 GLP not published	N	N	---	BASF	In DAR (2005)
KCA, 6.3	Richard, M; Muller,	1995c	Triticonazole: Formulation EXP80472A	N	N	---	BASF	In DAR (2005)

Data Point	Author(s)	Year	Title Compagny 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
	M.A.		(FS) Trials Conducted in Spain from 1993 - 1994. Residues in Soft Winter Wheat Rhone-Poulenc Agro Report No. 94-670, C 017251 GLP not published					
KCA, 6.3	Richard, M; Muller, M.A.	1995d	Triticonazole – Iprodione: Formulation EXP80524A (FS) Trial Conducted in Italy from 1993 to 1994. Residues in Winter Barley Rhone-Poulenc Agro Report No. 94-648, C 017317 GLP not published	N	N	---	BASF	In DAR (2005)

Data Point	Author(s)	Year	Title Compagny 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
IIA, 6.3	Strätz, J.	1995a	Determination of the Residue Behaviour of the Fungicidal Active Ingredient Triticonazole in the Seed Treatment Product RPA 80525 F in Spring Wheat Rhone Poulenc Agro GmbH Report No. R1/94; C 016577 GLP not published	N	N	---	BASF	In DAR (2005)
IIA, 6.4	Lowden, P.; Maycey, P. A.	1996	[^{14}C]-Triticonazole: A Confined Rotational Crop Study Using Radish, Lettuce and Wheat. Rhone-Poulenc Agriculture Limited Report Nr. P 93/192 GLP not published	N	N	---	BASF	In DAR (2005)
IIA, 6.4	Muller, M.	1994a	Triticonazole; Formulation EXP80378A (FS): Trial Conducted in France from 1991 to 1993, Residues in Oilseed Rape (Seeds) and in Soil (Before Sowing Oilsees Rape), Crop Rotation Study (Treated Wheat Followed by untreated Oilseed Rape)	N	N	---	BASF	In DAR (2005)

Data Point	Author(s)	Year	Title Compagny 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
			Rhone-Poulenc Agro Report No. R013123 (C 017106) GLP not published					
IIA, 6.4	Muller, M.	1994b	Triticonazole; Formulation EXP80378A (FS): Trial Conducted in France from 1991 to 1993, Residues in Soft Winter Wheat (Grain and Straw) and in Soil (Before Sowing Wheat), Crop Rotation Study (Treated Wheat Followed by untreated Wheat) Rhone-Poulenc Agro Report No. R013124 (C 017174) GLP not published	N	N	---	BASF	In DAR (2005)
IIA, 6.4	Muller, M.	1994c	Triticonazole; Formulation EXP80378A (FS): Trial Conducted in France from 1991 to 1993, Residues in Sugar Beet (Beetroot, Tops) and in Soil Before Sowing Sugar Beets, Crop Rotation Study (Treated Wheat Followed by untreated Sugar Beets) Rhone-Poulenc	N	N	---	BASF	In DAR (2005)

Data Point	Author(s)	Year	Title Compagny 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
			Agro Report No. R013124 (C 017174/C 017132) GLP not published					
IIA, 6.4	Muller, M.	1994d	Triticonazole; Formulation EXP80378A (FS): Trial Conducted in France from 1991 to 1993, Residues in Sunflowers (Seeds) and in Soil (Before Sowing Sunflowers), Crop Rotation Study (Treated Wheat Followed by untreated Sunflowers) Rhone-Poulenc Agro Report No. R013120 (C 017116) GLP not published	N	N	---	BASF	In DAR (2005)
IIA, 6.4	Richard, M.; Muller, M.	1994	Triticonazole or RPA400727; Formulation EXP80380A (FS): Residues in Soil, Protein Peas (seeds), Beets (Leaves and Beetroot), Sunflowers (Seeds). Rotational Crop Following a Trial with Soft Winter Wheat Turned over in April. Rhone-Poulenc Agro Report No.	N	N	---	BASF	In DAR (2005)

Data Point	Author(s)	Year	Title Compagny 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
			R013104 (C 017878) GLP not published					
KCA 6.5.1/1	Adam D.	2013 a	^{14}C-Triticonazole (BAS 595 F): Simulated processing - Hydrolysis at 90°C, 100°C and 120°C 2013/1135885 IES - Innovative Environmental Services Ltd., Witterswil, Switzerland yes Unpublished	N	Y	New data for AIR3 renewal	BASF	Submitted for the purpose of renewal.

ANNEX I - RESIDUE TRIALS (PRIMARY CROPS)

Wheat (Northern Europe)

RESIDUE DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name)	Triticonazole	Commercial Product (name)	-
Crop/crop group:	Wheat (Cereals)	Producer of commercial product	67056 Ludwigshafen, Germany
Responsible body for reporting (name, address)	BASF SE, 67056 Ludwigshafen	Indoor/Glasshouse/Outdoor	Outdoor
Country	Germany	Other active substance in the formulation	None
Content of active substance (g/kg or g/L)	25 g/L	(common name and content)	
Formulation (e.g. WP)	BAS 595 01 F (FS)	Residues calculated as:	Triticonazole

1	2	3	4	5			6	7	8	9	10	11
Report-No. Location (Trial No.)	Commodity/ Variety	Date of : 1. Sowing/Planting 2. Flowering 3. Harvest	Method of Treatment	Application Rate per Treatment			No of Treatm. and Last Date	Growth Stage (BBCH)[1]	Portion Analysed	Residues (mg/kg)	PHI (days)	Remarks
				kg a.s./hL	Water (L/ha)	g as/ha				Triticonazole		
407785 2014/1043281 67294 Mauchenheim Rheinhessen, Germany L120653	GR 0654 KWS CHAMSIN	1. 02.04.2013 2. 18.06. - 30.06.2013 3. 09.08.2013	Seeding of treated seeds	n.a.	n.a.	11.25	1 02.04.13	n.a.	Whole plant[2)] Whole plant[2)] Whole plant[2)] Grain Straw	0.64 0.11 < 0.01 < 0.01 < 0.01	21 30 72 129 129	BASF Method No. 562/0
407785 2014/1043281 CO11 2NF Lawford Essex, UK L120654	GR 0654 KWS CHAMSIN	1. 06.03.2013 2. 24.06. - 15.07.2013 3. 23.08.2014	Seeding of treated seeds	n.a.	n.a.	11.25	1 06.03.13	n.a.	Whole plant[2)] Whole plant[2)] Whole plant[2)] Grain Straw	0.13 < 0.01 < 0.01 < 0.01 < 0.01	51 71 100 170 170	BASF Method No. 562/0
407785 2014/1043281 49700 Meigné sous Doué, Maine-et-Loire France (N) L120655	GR 0654 KWS CHAMSIN	1. 04.03.2013 2. 30.06. - 10.07.2013 3. 15.08.2013	Seeding of treated seeds	n.a.	n.a.	11.25	1 04.03.13	n.a.	Whole plant[2)] Grain Straw	< 0.01 < 0.01 < 0.01	94 163 163	BASF Method No. 562/0

RESIDUE DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name)	Triticonazole	Commercial Product (name)	-
Crop/crop group:	Wheat (Cereals)	Producer of commercial product	67056 Ludwigshafen, Germany
Responsible body for reporting (name, address)	BASF SE, 67056 Ludwigshafen	Indoor/Glasshouse/Outdoor	Outdoor
Country	Germany	Other active substance in the formulation	None
Content of active substance (g/kg or g/L)	25 g/L	(common name and content)	
Formulation (e.g. WP)	BAS 595 01 F (FS)	Residues calculated as:	Triticonazole

1	2	3	4	5			6	7	8	9	10	11
Report-No. Location (Trial No.)	Commodity/ Variety	Date of : 1. Sowing/Planting 2. Flowering 3. Harvest	Method of Treatment	Application Rate per Treatment			No of Treatm. and Last Date	Growth Stage (BBCH)[1]	Portion Analysed	Residues (mg/kg)	PHI (days)	Remarks
				kg a.s./hL	Water (L/ha)	g as/ha				Triticonazole		
407785 2014/1043281 47574 Goch Kleve, Germany L120656	GR 0654 KWS CHAMSIN	1. 12.04.2013 2. 07.07. - 19.07.2013 3. 26.08.2013	Seeding of treated seeds	n.a.	n.a.	11.25	1 12.04.13	n.a.	Whole plant[2)] Grain Straw	< 0.01 < 0.01 < 0.01	68 136 136	BASF Method No. 562/0
721605 2014/1090813 67294 Mauchenheim Rheinhessen, Germany L130814	GR 0654 KWS CHAMSIN	1. 08.03.2014 2. 08.06. - 16.06.2014 3. 25.07.2014	Seeding of treated seeds	n.a.	n.a.	11.25	1 08.03.14	n.a.	Whole plant[2)] Whole plant[2)] Whole plant[2)] Grain Straw	0.134 0.023 < 0.01 < 0.01 < 0.01	32 46 86 142 142	BASF Method No. 562/0
721605 2014/1090813 49700 Meigné sous Doué, Maine-et-Loire France (N) L130815	GR 0654 KWS CHAMSIN	1. 18.03.2014 2. 15.06. - 25.06.2014 3. 27.07.2014	Seeding of treated seeds	n.a.	n.a.	11.25	1 18.03.14	n.a.	Whole plant[2)] Whole plant[2)] Whole plant[2)] +	0.202 0.028 < 0.01 +	28 50 85	BASF Method No. 562/0
721605 2014/1090813 6599 AV Ven Zelderheide, Gennep Netherlands L130816	GR 0654 KWS CHAMSIN	1. 01.04.2014 2. 16.06. - 01.07.2014 3. 05.08.2014	Seeding of treated seeds	n.a.	n.a.	11.25	1 01.04.14	n.a.	Whole plant[2)] Whole plant[2)] Whole plant[2)] Grain Straw	0.462 0.020 < 0.01 < 0.01 < 0.01	15 29 72 126 126	BASF Method No. 562/0

RESIDUE DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name)	Triticonazole	Commercial Product (name)	-
Crop/crop group:	Wheat (Cereals)	Producer of commercial product	67056 Ludwigshafen, Germany
Responsible body for reporting (name, address)	BASF SE, 67056 Ludwigshafen	Indoor/Glasshouse/Outdoor	Outdoor
Country	Germany	Other active substance in the formulation	None
Content of active substance (g/kg or g/L)	25 g/L	(common name and content)	
Formulation (e.g. WP)	BAS 595 01 F (FS)	Residues calculated as:	Triticonazole

1	2	3	4	5			6	7	8	9	10	11
Report-No. Location (Trial No.)	Commodity/ Variety	Date of : 1. Sowing/Planting 2. Flowering 3. Harvest	Method of Treatment	Application Rate per Treatment			No of Treatm. and Last Date	Growth Stage (BBCH)[1]	Portion Analysed	Residues (mg/kg)	PHI (days)	Remarks
				kg a.s./hL	Water (L/ha)	g as/ha				Triticonazole		
721605	GR 0654	1. 18.03.2014	Seeding	n.a.	n.a.	11.25	1	n.a.	Whole plant[2)]	0.259	30	BASF Method
2014/1090813	KWS	2. 20.06. - 30.06.2014	of				18.03.14		Whole plant[2)]	0.028	49	No. 562/0
CO11 2NF Lawford	CHAMSIN	3. 01.08. - 22.08.2014	treated						Whole plant[2)]	< 0.01	83	
Essex, UK			seeds						Grain	< 0.01	139	
L130817									Straw	< 0.01	139	

1) at treatment
2) no roots
n.a. not applicable
+ No grain and straw values as by mistake, plots were harvested by the farmer too early.

Wheat (Southern Europe)

RESIDUE DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name)	Triticonazole	Commercial Product (name)	-
Crop/crop group:	Wheat (Cereals)	Producer of commercial product	67056 Ludwigshafen, Germany
Responsible body for reporting (name, address)	BASF SE, 67056 Ludwigshafen	Indoor/Glasshouse/Outdoor	Outdoor
Country	Germany	Other active substance in the formulation	None
Content of active substance (g/kg or g/L)	25 g/L	(common name and content)	
Formulation (e.g. WP)	BAS 595 01 F (FS)	Residues calculated as:	Triticonazole

1	2	3	4	5			6	7	8	9	10	11
Report-No. Location (Trial No.)	Commodity/ Variety	Date of : 1. Sowing/Planting 2. Flowering 3. Harvest	Method of Treatment	Application Rate per Treatment			No of Treatm. and Last Date	Growth Stage (BBCH)[1]	Portion Analysed	Residues (mg/kg)	PHI (days)	Remarks
				kg a.s./hL	Water (L/ha)	g as/ha				Triticonazole		
407785 2014/1043281 32600 Endoufielle Gers, France L120657	GR 0654 ESTEROS	1. 01.02.2013 2. 20.05. - 25.05.2013 3. 12.07.2013	Seeding of treated seeds	n.a.	n.a.	11.25	1 01.02.13	n.a.	Whole plant[2)] Grain Straw	< 0.01 < 0.01 < 0.01	98 161 161	BASF Method No. 562/0
407785 2014/1043281 59032 Platanos Imathia, Greece L120658	GR 0654 ESTEROS	1. 20.03.2013 2. 20.05. - 30.05.2013 3. 10.07. - 25.07.2013	Seeding of treated seeds	n.a.	n.a.	11.25	1 20.03.13	n.a.	Whole plant[2)] Grain Straw	< 0.01 < 0.01 < 0.01	59 105 105	BASF Method No. 562/0
407785 2014/1043281 40051 Altedo of Malalbergo Bologna, Italy L120659	GR 0654 ESTEROS	1. 04.03.2013 2. 28.05. - 08.06.2013 3. 05.07.2013	Seeding of treated seeds	n.a.	n.a.	11.25	1 04.03.13	n.a.	Whole plant[2)] Whole plant[2)] Whole plant[2)] Grain Straw	0.20 0.087 < 0.01 < 0.01 < 0.01	23 36 71 123 123	BASF Method No. 562/0
407785 2014/1043281 ES-41710 Utrera Sevilla, Spain L120660	GR 0654 ESTEROS	1. 09.01.2013 2. 10.04. - 16.04.2013 3. 11.06.2013	Seeding of treated seeds	n.a.	n.a.	11.25	1 09.01.13	n.a.	Whole plant[2)] Whole plant[2)] Whole plant[2)] Grain Straw	0.52 0.18 < 0.01 < 0.01 < 0.01	20 34 84 153 153	BASF Method No. 562/0
721605 2014/1090813 32600 Endoufielle Gers, France L130818	GR 0654 ESTEROS	1. 20.02.2014 2. 30.05. - 06.06.2014 3. 17.07.2014	Seeding of treated seeds	n.a.	n.a.	11.25	1 20.02.14	n.a.	Whole plant[2)] Whole plant[2)] Whole plant[2)] Grain Straw	0.052 < 0.01 < 0.01 < 0.01 < 0.01	47 67 97 147 147	BASF Method No. 562/0

RESIDUE DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name)	Triticonazole	Commercial Product (name)	-
Crop/crop group:	Wheat (Cereals)	Producer of commercial product	67056 Ludwigshafen, Germany
Responsible body for reporting (name, address)	BASF SE, 67056 Ludwigshafen	Indoor/Glasshouse/Outdoor	Outdoor
Country	Germany	Other active substance in the formulation	None
Content of active substance (g/kg or g/L)	25 g/L	(common name and content)	
Formulation (e.g. WP)	BAS 595 01 F (FS)	Residues calculated as:	Triticonazole

1	2	3	4	5			6	7	8	9	10	11
Report-No. Location (Trial No.)	Commodity/ Variety	Date of : 1. Sowing/Planting 2. Flowering 3. Harvest	Method of Treatment	Application Rate per Treatment			No of Treatm. and Last Date	Growth Stage (BBCH)[1]	Portion Analysed	Residues (mg/kg)	PHI (days)	Remarks
				kg a.s./hL	Water (L/ha)	g as/ha				Triticonazole		
721605 2014/1090813 59032 Platanos Imathia, Greece L130819	GR 0654 ESTEROS	1. 21.02.2014 2. 10.05. - 25.05.2014 3. 01.07. - 15.07.2014	Seeding of treated seeds	n.a.	n.a.	11.25	1 21.02.14	n.a.	Whole plant[2)] Whole plant[2)] Whole plant[2)] Grain Straw	0.097 < 0.01 < 0.01 < 0.01 < 0.01	33 49 87 124 124	BASF Method No. 562/0
721605 2014/1090813 12050 Castagnito d'Alba Cuneo, Italy L130820	GR 0654 ESTEROS	1. 25.02.2014 2. 10.06. - 17.06.2014 3. 11.07.2014	Seeding of treated seeds	n.a.	n.a.	11.25	1 25.02.14	n.a.	Whole plant[2)] Whole plant[2)] Whole plant[2)] Grain Straw	0.64 < 0.01 < 0.01 < 0.01 < 0.01	35 48 104 136 136	BASF Method No. 562/0

RESIDUE DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name)	Triticonazole	Commercial Product (name)	-
Crop/crop group:	Wheat (Cereals)	Producer of commercial product	67056 Ludwigshafen, Germany
Responsible body for reporting (name, address)	BASF SE, 67056 Ludwigshafen	Indoor/Glasshouse/Outdoor	Outdoor
Country	Germany	Other active substance in the formulation	None
Content of active substance (g/kg or g/L)	25 g/L	(common name and content)	
Formulation (e.g. WP)	BAS 595 01 F (FS)	Residues calculated as:	Triticonazole

1	2	3	4	5			6	7	8	9	10	11
Report-No. Location (Trial No.)	Commodity/ Variety	Date of : 1. Sowing/Planting 2. Flowering 3. Harvest	Method of Treatment	Application Rate per Treatment			No of Treatm. and Last Date	Growth Stage (BBCH)[1]	Portion Analysed	Residues (mg/kg)	PHI (days)	Remarks
				kg a.s./hL	Water (L/ha)	g as/ha				Triticonazole		
721605	GR 0654	1. 27.01.2014	Seeding	n.a.	n.a.	11.25	1	n.a.	Whole plant[2)]	0.446	22	BASF Method
2014/1090813	ESTEROS	2. 20.04. - 05.05.2014	of				27.01.14		Whole plant[2)]	0.064	39	No. 562/0
ES-41710 Utrera		3. 10.06.2014	treated						Whole plant[2)]	< 0.01	79	
Sevilla, Spain			seeds						Grain	< 0.01	134	
L130821									Straw	< 0.01	134	

1) at treatment
2) no roots
n.a. not applicable