## **BOSCALID (221)**

First draft prepared by Mr C Sieke, Federal Institute for Risk Assessment, Berlin, Germany

## **EXPLANATION**

Boscalid is a systemic fungicide first evaluated by JMPR in 2006 for residues and toxicology as a new active substance. For boscalid an ADI of 0–0.04 mg/kg bw was established while no ARfD was considered necessary. Due to incomplete data submission for residues in follow crops the Meeting decided that a final chronic risk assessment under consideration of these residues in rotational crops was not possible during the Meeting in 2006. In 2008 additional uses involving bananas and kiwi fruits were reviewed for residues. In correspondence to point 124 of the 41<sup>st</sup> CCPR Report from 2009 the Meeting reconsidered all data available on rotational crops for a finalization of the dietary risk assessment for boscalid.

In this report several key studies already described in the 2006 monograph are presented again in addition to recent studies for a complete overview of the available information. The task is focussed on the completion of the dietary risk assessment under special consideration of rotational crops. Therefore an update of chapters "Environmental fate in soil", "Rotational crops" and "Residues in animal commodities" is presented in this document. For further information please refer to the evaluation and reports for boscalid published by JMPR 2006 and 2008.

The following studies were already available at the 2006 Meeting and presented again for describing a complete picture of all data available on environmental fate in soil and rotational crops as well as for residues in animal commodities:

Author	Year	Title, Report-No.
Stephan A	1999	Metabolism of BAS 510 F ( <sup>14</sup> C-diphenyl and <sup>14</sup> C-pyridin) in soil under aerobic conditions. BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. BASF unpublished report 42381, issued 21.12.1999. 1999/11807
Ebert D and Harder U	2000	The degradation behaviour of $^{14}\text{C-BAS}$ 510 F in different soils (DT <sub>50</sub> /DT <sub>90</sub> ). BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. BASF unpublished report 41860, issued 20.06.2000. 2000/1013279
Staudenmaier H	2000	Anaerobic metabolism of BAS 510 F in soil (14C-pyridine-label). BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. BASF unpublished report 41858, issued 18.12.2000. 2000/1014990
Staudenmaier H and Schaefer C	2000	Anaerobic metabolism of BAS 510 F in soil (diphenyl- <sup>14</sup> C-label) BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. 2000/1014986
Kellner O and Keller W	2000	Field soil dissipation of BAS 510 F (300 355) in formulation BAS 510 KB F (1997-1998). BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. BASF unpublished report DE/FA/047/97, issued 25.01.2000. 2000/1000123
Bayer H and Grote C	2001	Field soil dissipation of BAS 510 F (300 355) in formulation BAS 510 KA F (1998–1999). BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. BASF unpublished report EU/FA/051/98, issued 16.02.2001. 2000/1013295
Hamm RT and Veit P	2001	Confined rotational crop study with <sup>14</sup> C-BAS 510 F. BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. BASF unpublished report 42560, issued 27.02.2001. 2000/1014862
Tilting	2001	Boscalid: Residues in milk and edible tissues following oral administration of BAS 510 F to lactating dairy cattle. BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. BASF unpublished report 42401, issued

Author Year Title, Report-No.

Boscalid 298 09.03.2001. 2000/1017228

Unless specifically stated within the study description other studies are reviewed by the 2009 Meeting for the first time.

## METABOLISM AND ENVIROMENTAL FATE

# Environmental fate in soil

#### Soil metabolism

A study on the aerobic soil metabolism of [<sup>14</sup>C]boscalid in a sandy loam soil submitted in 2006 showed that boscalid degraded slowly and identifiable metabolites were a minor part of the residue which in turn degraded almost at the same rate (Stephan, 1999, BOSC09\_001). The pyridine-labelled test compound was mineralized to <sup>14</sup>CO<sub>2</sub> more quickly than the diphenyl-labelled test compound. No volatiles other than <sup>14</sup>CO<sub>2</sub> were found. The non-extracted <sup>14</sup>C in the soil treated with diphenyl-labelled boscalid had begun to decline within 266 days and that in the soil treated with pyridine-labelled boscalid increased continuously during the whole period of incubation.

Aerobic soil metabolism Ref: Stephan, 1999, 1999/11807

Test material: [14C]boscalid, diphenyl-labelled Dose rate: 0.933 mg/kg dry soil

Sandy loam

pH: 7.4

Organic carbon: 1.3% Duration: 364 days

Temp: 20 °C Moisture: 40% maximum water holding

capacity

Half-life (boscalid): 108 days

% boscalid remaining, day 364: 16.7% % mineralisation, day 364: 15.5%

Metabolites	Max (% of dose)	Day
M510F49	0.2%	57
M510F50	0.1%	266
Others	1.0%	266
$^{14}CO_2$	15.5%	364
Non-extracted <sup>14</sup> C	62.7%	266

Test material: [14C]boscalid, pyridine-labelled Dose rate: 1.022 mg/kg dry soil

Half-life (boscalid): 108 days

% boscalid remaining, day 364: 17.3% % mineralisation, day 364: 25.4%

Metabolites	Max (% of dose)		
M510F49	0.2%	93	
M510F50	0.1%	93	

Others	1.0%	119
$^{14}\mathrm{CO}_2$	25.4%	364
Non-extracted <sup>14</sup> C	50.1%	364

Another study already reported in 2006 on the aerobic soil metabolism of [diphenyl-U-<sup>14</sup>C] boscalid in four different soils at different temperatures and soil moistures for 120 days showed again that boscalid degraded slowly and identifiable metabolites were a minor part of the residue which also mostly degraded relatively slowly (Ebert and Harder, 2000, BOSC09\_002). The volatiles including <sup>14</sup>CO<sub>2</sub> were not trapped in this study. The non-extracted <sup>14</sup>C in the soil treated with diphenyl-labelled boscalid had begun to decline within 266 days.

Aerobic soil metabolism Ref: Ebert and Harder, 2000, 2000/1013279

Test material: [14C]boscalid, diphenyl-labelled Dose rate: 1.0 mg/kg dry soil

Loamy sand pH: 5.6

Organic carbon: 2.5% Duration: 120 days

Temp: 20 °C Moisture: 40% maximum water holding

capacity

Half-life (boscalid): 384 days

% boscalid remaining, day 120: 78.8% % mineralisation: not measured

Metabolites	Max (% of dose)	
Others	0.7%	60
Non-extracted <sup>14</sup> C	16.8%	120

pH: 5.6

Organic carbon: 1.9% Duration: 120 days

Temp: 5 °C Moisture: 40% maximum water holding

capacity

Half-life (boscalid): stable

% boscalid remaining, day 119: 103.8% % mineralisation: not measured

Metabolites	Max (% of dose)	Day
Others	0.8%	0
Non-extracted <sup>14</sup> C	1.9%	119

pH: 5.7

Organic carbon: 2.18% Duration: 120 days

Temp: 30 °C Moisture: 40% maximum water holding

capacity

Half-life (boscalid): 365 days

% boscalid remaining, day 120: 84.4% % mineralisation: not measured

Metabolites Max (% of dose) Day

Others 1.6% 120 Non-extracted  ${}^{14}C$  13.0% 120

pH: 5.9

Organic carbon: 2.0% Duration: 120 days

Temp: 20 °C Moisture: 20% maximum water holding

capacity

Half-life (boscalid): stable

% boscalid remaining, day 120: 98.8% % mineralisation: not measured

MetabolitesMax (% of dose)DayOthers0.9%3Non-extracted  $^{14}$ C7.6%120

pH: 5.9

Organic carbon: 2.0% Duration: 120 days, sterile

Temp: 20 °C Moisture: 40% maximum water holding

capacity

Half-life (boscalid): stable

% boscalid remaining, day 120: 100.5% % mineralisation: not measured

MetabolitesMax (% of dose)DayOthers1.7%3Non-extracted  $^{14}$ C2.8%120

Sandy loam

pH: 7.0

Organic carbon: 0.6% Duration: 120 days

Temp: 20 °C Moisture: 40% maximum water holding

capacity

Half-life (boscalid): 376 days

% boscalid remaining, day 120: 80.9% % mineralisation: not measured

MetabolitesMax (% of dose)DayOthers0.5%120Non-extracted  $^{14}$ C21.5%120

Loamy sand

pH: 6.6

Organic carbon: 1% Duration: 120 days

Temp: 20 °C Moisture: 40% maximum water holding

capacity

Half-life (boscalid): 322 days

% boscalid remaining, day 120: 77.7% % mineralisation: not measured

Metabolites	Max (% of dose)		
Others	0.3%	91	
Non-extracted <sup>14</sup> C	16.6%	120	

Loam

pH: 7.7

Organic carbon: 5.2% Duration: 119 days

Temp: 20 °C Moisture: 40% maximum water holding

capacity

Half-life (boscalid): 133 days

% boscalid remaining, day 119: 53.6% % mineralisation: not measured

Metabolites	Max (% of dose)		
Others	1.3%	7	
Non-extracted <sup>14</sup> C	50.1%	119	

Two studies available already in 2006 on the anaerobic soil metabolism of [\frac{14}{C}]boscalid in two soil types showed that boscalid degraded very slowly and identifiable metabolites were a minor part of the residue, except for M510F47 where a maximum of 6.7% formed in the study using pyridine-labelled boscalid (Staudenmaier, BOSC09\_003, Staudenmaier, H and Schaefer, C, 2000, BOSC09\_004). The non-extracted \frac{14}{C} in the soil treated with diphenyl labelled and pyridine labelled boscalid increased continuously during the whole period of the incubation.

#### Anaerobic soil metabolism

Ref: Staudenmaier and Schäfer, 2000, 2000/1014986; Staudenmaier 2000/1014990

Test material: [14C]boscalid, diphenyl-labelled Dose rate: 1.0 mg/kg dry soil

Sandy loam

pH: 7.2

Organic carbon: 1.6% Duration: 120 days

Temp: 20 °C Moisture: 40% maximum water holding

capacity

Half-life (boscalid): 261 days

% boscalid remaining, day 120: 73.6% % mineralisation, day 120: 0.1%

Metabolites	Max (% of dose)	Day
Others	0.6%	90
Non-extractable <sup>14</sup> C	15.8%	120

Test material: [14C]boscalid, pyridine-labelled Dose rate: 1.0 mg/kg dry soil

Sandy loam

pH: 7.5

Organic carbon: 1.7% Duration: 120 days

Temp: 20 °C Moisture: 40% maximum water holding

capacity

Half-life (boscalid): 345 days

% boscalid remaining, day 120: 77.0% % mineralisation, day 120: 0.4%

Metabolites	Max (% of dose)	Day
M510F47	6.7%	120
Others	0.8%	0
<sup>14</sup> CO2	0.4%	120
Non-extractable <sup>14</sup> C	15.8%	120

## Soil dissipation

The degradation behaviour (field dissipation) of boscalid in two different soils described in the Evaluation 2006 was investigated by Kellner and Keller (2000, BOSC09\_005) under field conditions at two locations in Germany with three different application rates each on bare soil in 1997. Soil samples were taken at nine sampling times up to 545 days and down to a maximum soil depth of 50 cm from the plots. The  $DT_{50}$  values were shorter with higher application rates, and the  $DT_{90}$  was not reached within one year, after application to bare soil. The highest amounts of boscalid were found in the top layer (0–10 cm) of soil (Table 1). Minor amounts were found in the 10 to 25 cm layer.

Table 1 Field dissipation of boscalid in two different soils in Germany in 1997 (Kellner and Keller, 2000, 2000/1000123)

Trial	Applic. Rate, kg ai/ha	Initial conc. mg/kg	Boscalid as	Boscalid as % of original concentration in 0–10 cm soil				
			30 days	93 days	176days	365 days	449 days	544 days
Germany	Plot area: 8.4 i	m <sup>2</sup> , Silty loam:	pH 7.5, 11.5	% sand, 69.7	% silt, 18.8%	clay, 0.83% o	rganic carbon	
(Baden Württemberg) 1997	0.3	0.23	87%	51%	26%	33%	14%	9.7%
	0.6	0.63	63%	21%	15%	21%	12%	8.9%
treat in April	1.2	1.35	45%	25%	23%	17%	12%	6.7%
Germany	Plot area 8.6 m <sup>2</sup> . Silty sand: pH 5.4, 76.5% sand, 19.1% silt, 4.4% clay, 0.69% organic carbon.							
(Rheinland Pfalz) 1997	0.3	0.2	74%	56%	48%	42%	33%	27%
	0.6	0.41	78%	62%	43%	53%	35%	26%
treat in April	1.2	0.91	94%	49%	41%	47%	33%	27%

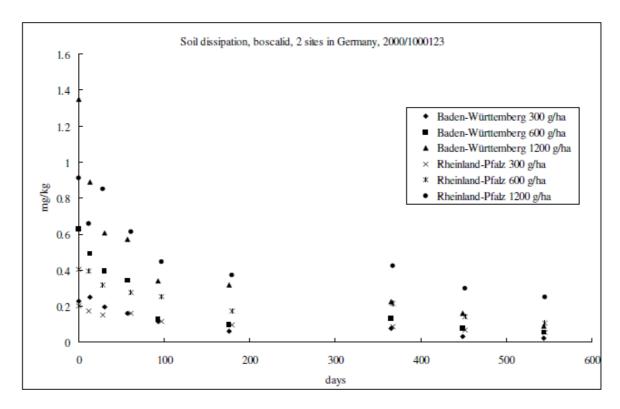


Figure 1 Disappearance of boscalid in soil at two sites in Germany at three different rates each on bare soil (Kellner and Keller, 2000, BOSC09\_005)

In a study reported in the Evaluation of 2006 the degradation behaviour of boscalid was also investigated, under field conditions on bare soil, at four locations in Europe in 1998 (Bayer and Grote 2001, BOSC09\_006). Soil samples were taken on either seven or eight occasions, for up to one year and down to a maximum soil depth of 50 cm. The  $DT_{50}$  values determined were shorter in Southern Europe than in Northern Europe, while the  $DT_{90}$  was not reached one year after application to bare soil (see Table 2). The highest amounts of boscalid were found in the top layer (0–10 cm) of the soils. Minor amounts were found in the 10 to 25 cm layer. No residues, above the limit of quantification, were found in the 25–50 cm layer.

Table 2 Field dissipation of boscalid at four locations in Europe in 1998 (Bayer and Grote, 2001, 2000/1013295)

Trial	Applic rate, kg/ha	Initial conc, mg/kg	Boscalid as % of original concentration in 0–10 cm soil				
			30 days	60 days	98 days	182 days	349 days
Spain	Plot area 6.25	m2. Sandy loan	n: pH 7.4, 589	% sand, 23% silt	, 19% clay, 0.6%	organic carbon	•
(Andalucia /Huelva) 1998 treat in May	0.74	0.29	55%	49%	54%	52%	49%
Spain			30 day	63 days	99 days	182 days	356 days
(Andalucia /Sevilla) 1998	Plot area 6.25	m2. Sandy loan	n: pH 7.7, 439	% sand, 35% silt	, 22% clay, 0.9%	6 organic carbon	
treat in May	0.76	0.30	97%	102%	56%	39%	55%

Trial	Applic rate, kg/ha	Initial conc, mg/kg	Boscalid as % of original concentration in 0-10 cm soil				
Sweden			31 days	60 days	101 days	182 days	352 days
(Skane) 1998	Plot area 9 m2. Loamy sand: pH 5.9, 76% sand, 13% silt, 11% clay, 1.0% organic carbon.						
treat in May	0.80	0.32	107%	138%	179%	114%	115%
Germany			30 days	59 days	97 days	181 days	357 days
(Schleswig- Holstein) 1998							
treat in may	0.78	0.52	71%	70%	59%	31%	42%

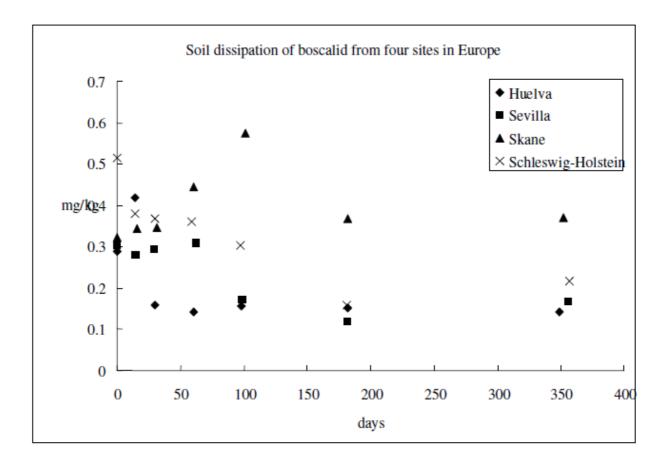


Figure 2 Disappearance of boscalid from soil at four sites in Europe after application to bare soil (Bayer and Grote, 2001, BOSC09\_006)

The degradation of boscalid in fresh soil and soil treated with boscalid over several years was investigated by Beck, I (2008, BOSC09\_017). For this study two field-fresh charges of one soil type ("Studernheim") were used, although one soil was collected from a field which had received repeated applications of boscalid over several years ("aged soil") while the other soil was from an untreated field ("virgin soil"). The "virgin soil" was fortified with boscalid levels corresponding to the levels found in the "aged soil" and incubated at 20 °C in the dark for a period of about 180 days. In the following table the percentages of boscalid found after specific incubation periods are summarized.

In "virgin soil" the degradation of boscalid was faster compared to soil treated with boscalid over several years. Under assumption of a  $1^{st}$  order kinetic DT<sub>50</sub> values were 746 days for "aged soil" and 336 days for "virgin soil".

Table 3 Degradation of boscalid in untreated soil in comparison to soil treated over several years

"Aged soil" (initial concentration 0.3 mg/kg)		"Virgin soil" (initial concentra	"Virgin soil" (initial concentration 0.21 mg/kg)		
Days	% boscalid remaining	Days	% boscalid remaining		
0	103	0	106		
0	102	0	109		
7	100	7	81		
14	108	15	91		
29	90	29	88		
62	105	58	76		
91	88	84	77		
91	86	84	81		
120	90	119	75		
152	87	149	64		
182	90	179	73		
182	87	179	71		
Estimated DT50 (1st order kinetics): 746 days		Estimated DT50 (1st order kinetics): 336 days			

The accumulation behaviour of boscalid in vineyards under field conditions was investigated by Keller *et al.* (2004, BOSC09\_008). From 1998 to 2003 one field trial including three subplots was conducted in Germany (Rheinland-Pfalz, loamy sand/sandy loam, pH: 7.5) receiving three applications of 0.7 kg ai/ha each per year. All applications were conducted at the appropriate growth stages according to GAP. Soil samples were taken down to a depth of 25 cm routinely three times a year (before first application and after last application in August and October). The samples were separated in layers of 0 to 10 and 10 to 25 cm. In the following table the results for all soil samples up to 25 cm depth are summarized.

Table 4 Residues found in soil of a vineyard treated with  $3 \times 0.7$  kg ai/ha for five consecutive years

Sampling date	Boscalid residues	in 25 cm soil equivalent	to kg/ha	
	Subplot 1	Subplot 2	Subplot 3	Mean
Aug. 1998	0.48	0.44	0.55	0.49
Oct. 1998	0.39	0.45	0.5	0.46
Jun. 1999	0.61	0.82	0.66	0.7
Aug. 1999	1.9	2.0	1.8	1.9
Oct. 1999	1.3	1.9	0.9	1.4
Jun. 2000	1.5	1.9	0.98	1.5
Aug. 2000	2.2	1.9	1.9	2.0
Oct. 2000	2.2	2.4	1.5	2.1
Jun. 2001	2.0	2.6	1.7	2.1
Aug. 2001	2.8	3.5	2.4	2.9
Oct. 2001	3.2	3.8	1.9	3.0
Jun. 2002	2.8	3.1	2.3	2.7
Aug. 2002	6.3	7.0	4.4	5.9
Oct. 2002	2.8	2.8	2.8	2.8
Jun. 2003	2.3	3.2	1.9	2.5

Another study under field conditions in Germany was conducted by Grote and Platz (2005, Interim Report, BOSC09\_009) and Penning (2009, Final Report, BOSC09\_022). Boscalid was applied in 1998 onto lettuce ( $2 \times 0.3$  kg ai/ha) and green beans ( $3 \times 0.5$  kg ai/ha) and in 1999 onto

carrots ( $3 \times 0.3$  kg ai/ha) and cauliflower ( $2 \times 0.4$  kg ai/ha). The total amount of boscalid applied were 2.1 kg ai/ha in 1998 and 1.7 kg ai/ha in 1999. In 2000 spring wheat was grown on the plot without any application of boscalid reflecting the common practice of crop rotation in Germany. This application and cultural pattern was repeated until 2009. In the final years of the study 2008 and 2009 carrots and cauliflower followed by spring wheat were planted as final crops. The total amounts of boscalid applied were 2.1 kg ai/ha in 1998, 2001, 2004 and 2007 and 1.7 kg ai/ha in 1999, 2002, 2005 and 2008. In 2000, 2003, 2006 and 2009 spring wheat cultivated did not receive treatments with boscalid.

Soil samples from the three subplots and a control plot not treated with boscalid were taken twice a year, once before application and once after the harvest. The samples were separated in layers of 10 cm depth from 0 to 50 cm. In the following table the results for the whole soil samples up to 50 cm depth are summarised.

Table 5 Residues found in soil of a vegetable field treated with  $5 \times 0.3$  kg ai/ha to  $5 \times 0.5$  kg ai/ha over a period of eleven years

Sampling date			Boscalid residues in 25 cm soil equivalent to kg/ha			
	DAFT	Control	Subplot 1	Subplot 2	Subplot 3	Mean of subplots
Oct. 1998	151	_	0.63	1.0	2.5	1.4
Mar. 1999	298	_	0.62	1.0	0.49	0.71
Nov. 1999	538	_	1.6	1.9	1.1	1.5
Mar. 2000 (n.T.)	669	_	1.1	0.93	0.82	0.95
Aug. 2000 (n.T.)	830	_	1.2	1.1	0.94	1.1
Apr. 2001	1056	_	0.48	0.63	0.56	0.55
Nov. 2001	1272	_	1.5	1.9	1.6	1.7
Feb. 2002	1386	_	1.2	1.4	1.3	1.3
Nov. 2002	1650	_	2.7	2.4	2.5	2.6
Mar. 2003 (n.T.)	1768	_	0.82	1.0	0.77	0.87
Aug. 2003 (n.T.)	1925	_	1.7	2.3	1.7	1.9
Mar. 2004	2135	_	1.0	1.1	1.1	1.1
Oct. 2004	2352	_	2.2	2.0	1.8	2.0
Apr. 2005	2517	_	1.6	Not analysed	1.1	1.3
Nov. 2005	2744	0.29	3.0	3.3	3.4	3.2
Mar. 2006 (n.T.)	2875	0.1	2.2	2.1	1.8	2.1
Aug. 2006 (n.T.)	3023	0.19	2.4	2.2	1.7	2.1
Nov. 2006 (n.T.)	3100	0.25	1.7	2.1	1.9	1.9
Apr. 2007	3245	0.08	1.2	1.1	1.7	1.3
Jul. 2007	3360	0.33	1.7	2.2	1.4	1.8
Nov. 2007	3485	1.2	3.6	4.8	3.5	4.0
Apr. 2008	3634	0.38	1.5	2.1	2.1	1.9
Aug. 2008	3749	1.3	3.7	1.8	1.4	2.3
Nov. 2008	3850	2.3	3.3	4.6	3.2	3.7
Apr. 2009 (n.T.)	3976	0.62	2.1	1.9	2.2	2.1

n.T. = no treatment due to crop rotation

DAFT = days after first treatment

<sup>-=</sup> no detection of boscalid

# Accumulation of boscalid residues in soil after 11 years

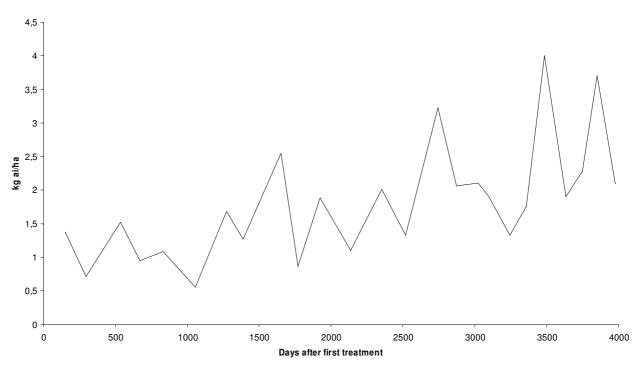


Figure 3 Accumulation of boscalid in soil after 11 years of treatment expressed as boscalid equivalent per ha (Penning, 2009, Final Report, BOSC09\_022)

In addition the uptake of boscalid into wheat, radish and spinach depending on "aged soil" or "virgin soil" was investigated by Schweda (2009, BOSC09\_019). Aged soil treated over several years with boscalid was analysed for the estimation of residues present. This level was used as a target application rate to untreated "virgin soil" for a comparable residue situation in the soil (0.96 mg/kg soil). In greenhouses both soils were used to cultivate wheat, spinach and radishes according to common agricultural practice. Samples of wheat plants, wheat grain, wheat straw, radish roots and leaves and spinach leaves were collected at the commercial points of harvest. In the following table the residue levels found in samples grown in "aged soil" or "virgin soil" are presented, as well as the ratio between both soils.

Table 6 Uptake of boscalid in rotational crops from aged and fresh soil

Commodity	Growth stage at sampling	Boscalid residu	ues in mg/kg	Proportion ("aged soil" to "virgin soil")
		"virgin soil"	"aged soil"	
Wheat, whole plant	39–49	0.54	0.3	56%
Wheat, grain	89	0.02	0.007	35%
Wheat, straw	89	3.9	2.0	51%
Radish, root	49	0.03	0.02	67%
Radish, leaf	49	0.15	0.09	60%
Spinach, leaf	14	0.08	0.04	50%
Spinach, leaf	49	0.06	0.02	33%
Mean:				50.3%

### Rotational crops

A confined rotational crop study in Germany (Hamm and Veit, 2001, BOSC09\_007) was conducted with [14C]boscalid (diphenyl- and pyridine-label) with a single application of 2.1 kg ai/ha to bare soil (loamy sand, 0.9% organic matter, pH 6.7) and was described in the 2006 Evaluation. Crops of lettuce, radish and wheat were sown into the treated soil at intervals of 30, 120, 270 and 365 days after the application. The crops were grown to maturity, harvested and analysed for 14C-content (Table 7). Samples were further examined by extraction and HPLC analysis. In all samples, unchanged [14C]boscalid was detected in various concentrations with the tendency for lower levels over the course of the study and with longer plant-back intervals. One metabolite, M510F61, a glucoside of the hydroxylated parent compound, was found in various matrices, but not in lettuce, radish roots or wheat grains. The concentration was generally low, except in wheat straw.

Table 7 Total radioactive residues in soil samples after treatment with [14C]boscalid (pyridine- and diphenyl- label) (Hamm and Veit, 2001, 2000/1014862)

	Boscalid	Boscalid
Soil samples	Pyridine label	Diphenyl label
	TRR [mg/kg]	TRR [mg/kg]
After application		
Plant back intervals (after soil aging and		
30 DAT	0.72	1.1
120 DAT	0.65	0.81
270 DAT	0.65	n.d.
365 DAT	0.36	0.43
After harvest of mature crops		
Plant back interval: 30 DAT		
Radish	n.d.	0.73
Lettuce	0.55	0.75
Wheat	0.38	0.39
Plant back interval: 120 DAT		
Radish	0.55	0.59
Lettuce	0.48	0.41
Wheat	0.39	0.51
Plant back interval: 270 DAT		
Radish	0.38	0.52
Lettuce	0.32	0.44
Wheat	0.54	0.55
Plant back interval: 365 DAT		
Radish	n.d.	0.46
Lettuce	n.d.	0.43
Wheat	0.13	0.34

n.d.: not determined

TRR: total radioactive residue DAT: days after treatment

Table 8 Investigation of the nature of the residues in rotational crops after treatment with [14C]boscalid (Hamm and Veit, 2001, 2000/1014862)

Crop part	TRR [mg/kg]	Extracted radioactive residue mg/kg (% TRR)	Unextracted radioactive residue mg/kg (% TRR)	Boscalid mg/kg (% TRR)	M510F61 mg/kg (% TRR)
Pyridine Label					
Plant back interval: 30 DAT					
Lettuce leaf	0.035	0.029 (83.1)	0.007 (18.8)	0.02 (58.5)	_

Crop part	TRR [mg/kg]	Extracted radioactive residue mg/kg (% TRR)	Unextracted radioactive residue mg/kg (% TRR)	Boscalid mg/kg (% TRR)	M510F61 mg/kg (% TRR)
Radish leaf	0.34	0.32 (92.2)	0.027 (7.8)	0.30 (87.6)	0.016 (4.6)
Radish root	0.048	0.04 (81.9)	0.009 (19.3)	0.03 (62.7)	-
Wheat forage	0.69	0.65 (94.7)	0.047 (6.8)	0.62 (89.8)	0.024 (3.4)
Wheat straw	3.6	3.3 (92.8)	0.35 (9.7)	3.2 (87.5)	0.10 (2.8)
Wheat grain	0.15	0.036 (24.7)	0.13 (88.3)	0.009 (6.1)	-
Plant back interval		10.000 (2)	(0010)	0.005 (0.1)	
Lettuce leaf	0.16	0.15 (90.8)	0.015 (9.2)	0.15 (90.8)	_
Radish leaf	0.21	0.18 (88.8)	0.024 (11.2)	0.17 (81.8)	0.015 (7.0)
Radish root	0.038	0.031 (81.6)	0.007 (18.4)	0.023 (60.1)	0.008 (21.5)
Wheat forage	0.43	0.38 (88.6)	0.054 (12.5)	0.38 (87.5)	_
Wheat straw	4.0	2.9 (71.9)	1.3 (32.3)	2.6 (64.8)	0.12 (2.9)
Wheat grain	0.29	0.074 (26.2)	0.26 (91.1)	0.015 (5.3)	-
Plant back interval		0.07 1 (20.2)	0.20 ()1.1)	0.015 (5.5)	
Lettuce leaf	0.031	0.023 (74.5)	0.008 (25.5)	0.020 (65.1)	
Radish leaf	0.031	0.023 (74.3)	0.008 (23.3)	0.104 (82.5)	0.004 (3.6)
Radish root	0.017	0.013 (77.1)	0.004 (22.9)	0.104 (82.3)	
Wheat forage	0.23	0.013 (77.1)	0.004 (22.9)	0.214 (92.8)	0.005 (2.3)
Wheat straw	1.6	1.0 (61.8)	0.70 (43.6)	0.808 (50.0)	0.003 (2.3)
Wheat grain	0.27	0.049 (17.9)	0.26 (96.0)	0.005 (1.9)	-
Plant back interval		0.047 (17.7)	0.20 (50.0)	0.003 (1.5)	
Lettuce leaf	0.022	0.017 (76.1)	0.005 (23.9)	0.014 (61.6)	
Radish leaf	0.022	0.017 (70.1)	0.010 (8.9)	0.088 (78.2)	0.013 (11.2)
Radish root	0.066	0.06 (91.0)	0.006 (9.0)	0.060 (91.0)	0.013 (11.2)
Wheat forage	0.26	0.00 (91.0)	0.042 (16.5)	0.19 (74.7)	0.008 (2.9)
Wheat straw	1.9	1.6 (82.1)	0.44 (22.7)	1.5 (77.3)	0.008 (2.9)
Wheat grain	0.15	0.029 (19.7)	0.14 (93.2)	0.006 (4.2)	<u> </u>
	0.13	0.029 (19.7)	0.14 (93.2)	0.000 (4.2)	
Diphenyl label	. 20 D AT				
Plant back interval		0.047 (02.8)	0.002 (6.2)	0.047 (02.9)	
Lettuce leaf  Radish leaf	0.050	0.047 (93.8)	0.003 (6.2)	0.047 (93.8) 0.30 (90.2)	0.020 (5.9)
		0.32 (96.1)	0.013 (3.9)		0.020 (5.9)
Radish root	0.072	0.067 (93.1)	0.005 (6.9)	0.064 (89.6)	- 0.022 (2.0)
Wheat forage	1.6	1.5 (97.2)	0.071 (4.5)	1.5 (93.5)	0.032 (2.0)
Wheat straw	9.8	9.2 (93.8)	1.4 (14.4)	8.0 (81.3)	0.42 (4.3)
Wheat grain	0.17	0.059 (35.3)	0.14 (81.6)	0.028 (16.8)	_
Plant back interval		0.075 (90.2)	0.000 (10.9)	0.072 (95.2)	1
Lettuce leaf	0.084	0.075 (89.2)	0.009 (10.8)	0.072 (85.2)	-
Radish leaf	0.29	0.26 (87.2)	0.046 (15.6)	0.21 (71.2)	0.006 (10.0)
Radish root	0.052	0.043 (82.1)	0.011 (21.3)	0.035 (67.8)	0.006 (10.9)
Wheat forage	0.98	0.91 (92.8)	0.11 (11.5)	0.85 (86.4)	0.021 (2.1)
Wheat straw	3.9	3.7 (94.7)	0.41 (10.6)	3.3 (84.6)	0.19 (4.8)
Wheat grain	0.24	0.062 (25.3)	0.21 (87.8)	0.023 (9.6)	<u> </u> -
Plant back interval		0.062.04.0	0.004 (7.0)	0.000.015	
Lettuce leaf	0.067	0.063 (94.1)	0.004 (5.9)	0.063 (94.1)	-
Radish leaf	0.15	0.14 (94.3)	0.009 (5.7)	0.11 (73.1)	0.032 (21.2)
Radish root	0.098	0.091 (92.8)	0.007 (7.2)	0.091 (92.8)	_
Wheat forage	0.56	0.51 (91.2)	0.066 (11.7)	0.35 (62.8)	0.10 (18.1)
Wheat straw	3.3	2.9 (88.8)	0.74 (22.9)	2.3 (70.8)	0.030 (0.9)
Wheat grain	0.023	0.013 (58.3)	0.015 (64.6)	0.008 (35.4)	_

Crop part	TRR [mg/kg]	Extracted radioactive residue mg/kg (% TRR)	Unextracted radioactive residue mg/kg (% TRR)	Boscalid mg/kg (% TRR)	M510F61 mg/kg (% TRR)
Plant back interval:	365 DAT				
Lettuce leaf	0.028	0.022 (76.3)	0.010 (37.2)	0.016 (55.6)	_
Radish leaf	0.21	0.20 (95.2)	0.018 (4.8)	0.14 (69.4)	0.032 (15.5)
Radish root	0.030	0.027 (89.9)	0.003 (10.1)	0.024 (78.4)	0.001 (4.0)
Wheat forage	0.27	0.26 (96.1)	0.018 (6.9)	0.20 (75.0)	0.026 (9.8)
Wheat straw	1.4	1.3 (95.1)	0.15 (10.7)	1.1 (77.6)	0.025 (1.8)
Wheat grain	0.048	0.019 (40.3)	0.036 (74.9)	0.011 (23.6)	_

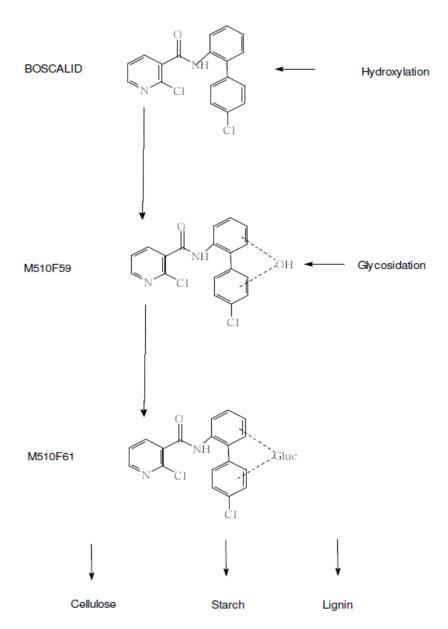


Figure 4 Proposed metabolic pathway for boscalid in succeeding crops (Hamm and Veit, 2001, 2000/1014862)

In addition to the confined study already described above and in the evaluation 2006, data on residues in follow crops under field conditions were submitted in October 2006 and May 2009.

In the first study Jordan (2002, BOSC09\_010) investigated the residues in <u>field corn</u>, <u>sweet corn</u>, <u>grain sorghum</u>, <u>rice</u>, <u>wheat</u> and <u>soya beans</u> grown in soil treated with boscalid. In the US 49 field trials were conducted, each trial (or site) consisting of two plots, an untreated control plot and a treated plot. Three sequential broadcast applications of boscalid were made to the bare soil of the treated plot at a rate of 0.8 kg ai/ha, 0.62 kg ai/ha and 0.62 kg ai/ha for each application, respectively, resulting in a maximum seasonal rate of 2.04 kg ai/ha. There was a 7 day interval between applications, beginning 28 days prior to the rotational crop planting date. The rotational crops were planted at a targeted plant-back interval of 14 days after the last application to the soil. All rotational crop RAC samples were collected at normal maturity.

All samples were analysed at least twice for residues of boscalid. In Table 9 the mean values for each samples collected are summarized.

Table 9 Results of cereal and soya bean commodities grown in soil treated with boscalid at a rate of 2.04 kg ai/ha

Commodity	Mean results per trial in mg/kg	Total mean in mg/kg	Total median in mg/kg	Total maximum in mg/kg
Wheat forage (winter and summer)	< 0.05, 0.06, 0.24, 0.28, <u>0.29</u> , 0.58, 0.77, 0.87, 1.1	0.47	0.29	1.1
Wheat hay (winter and summer)	0.06, 0.1, 0.17, 0.19, <u>0.27</u> , 0.57, 0.64, 0.85, 0.86	0.41	0.27	0.86
Wheat grain (winter and summer)	< 0.05(4), <u>0.05</u> , 0.06, 0.07, 0.12 <sup>a</sup> , 0.18a	0.06	0.05	0.07
Wheat straw (winter and summer)	0.13, 0.22, 0.41, 0.53, <u>0.65</u> , 0.81, 0.96, 1.3, 2.5	0.83	0.65	2.5
Sweet corn forage	< 0.05, < <u>0.05</u> , <u>0.06</u> , 0.08	0.06	0.055	0.08
Sweet corn kernel plus cob with husk removed	< 0.05(4)	< 0.05	< 0.05	< 0.05
Sweet corn stover	0.06, <u>0.06</u> , <u>0.09</u> , 0.49	0.17	0.075	0.49
Field corn kernel plus cob with husk removed	< 0.05(3), 0.86 <sup>a</sup>	< 0.05	< 0.05	< 0.05
Field corn forage	< 0.05(6), 0.07, 0.13, 0.50 <sup>a</sup>	0.055	< 0.05	0.13
Field corn grain	< 0.05(9)	< 0.05	< 0.05	< 0.05
Field corn stover	< 0.05(4), <u>0.06</u> , 0.07, 0.09, 0.10, 0.31	0.09	0.06	0.31
Rice grain	< 0.05(5), 0.12	0.06	< 0.05	0.12
Rice straw	< 0.05, 0.09, <u>0.1</u> , <u>0.16</u> , 0.3, 1.1	0.3	0.13	1.1
Sorghum forage	< 0.05(5), 0.23	0.08	< 0.05	0.23
Sorghum grain	< 0.05(6)	< 0.05	< 0.05	< 0.05
Sorghum stover	< 0.05(4), 0.05, 0.3	0.09	< 0.05	0.3
Soya bean forage	< 0.05(5), 0.05, 0.06, <u>0.07</u> , 0.07, 0.08, 0.08, 0.11, 0.12, 0.13, 0.18	0.08	0.07	0.18
Soya bean hay	0.06, 0.07, 0.07, 0.09(3), <u>0.11</u> , 0.12, 0.14, 0.18, 0.21, 0.21, 0.45	0.15	0.11	0.45
Soya bean seeds	< 0.05(14), 0.06	< 0.05	< 0.05	0.06

<sup>&</sup>lt;sup>a</sup> probably contaminated before analyses, no taken into account for further evaluation

A second study by Jordan (2002, BOSC09\_011) investigated residues in livestock feeding crops (grass, alfalfa and clover) grown as follow crops after treatment with boscalid in the US. Each of the 26 trials received three sequential bare ground applications of boscalid at rates of 0.8 kg ai/ha,

0.62 kg ai/ha and 0.62 kg ai/ha for each application, respectively, resulting in a maximum seasonal rate of 2.04 kg ai/ha. There was a 7 day target interval between applications, beginning 28 days prior to the rotational crop planting date. The interval from the last application to planting was targeted at 14 days.

For all matrices duplicate samples were collected in the field trials. In the following table the mean values of each trial is presented.

Table 10 Results of boscalid in livestock feed commodities grown in soil treated with boscalid at a rate of 2.04 kg ai/ha

Commodity	Mean results per trial in mg/kg	Total mean in mg/kg	Total median in mg/kg	Total maximum in mg/kg
Grass forage	0.08, 0.11, 0.12, 0.16, 0.19, <u>0.22</u> , <u>0.28</u> , 0.35, 0.42, 0.56, 1.1, 1.9	0.46	0.25	1.9
Grass hay	0.22, 0.23, 0.26, 0.38, 0.48, <u>0.57</u> , <u>0.65</u> , 1.1, 1.2, 1.6, 4.25, 6.8	1.5	0.61	6.8
Grass straw	0.15, 0.2	0.18	0.18	0.2
Alfalfa forage, 1 <sup>st</sup> cutting	< 0.05(3), <u>0.05</u> , 0.06, 0.17, 0.49	0.13	0.05	0.49
Alfalfa forage, 2 <sup>nd</sup> cutting	< <u>0.05(4)</u> , 0.05, 0.1, 0.49	0.12	< 0.05	0.49
Alfalfa forage, 3 <sup>rd</sup> cutting	< 0.05, < <u>0.05</u> , 0.07	0.06	< 0.05	0.07
Alfalfa hay, 1st cutting	< 0.05, 0.08, 0.09, <u>0.11</u> , 0.14, 0.46, 1.5	0.34	0.11	1.5
Alfalfa hay, 2 <sup>nd</sup> cutting	< 0.05, < 0.05, 0.07, <u>0.08</u> , 0.14, 0.38, 1.4	0.31	0.08	1.4
Alfalfa hay, 3 <sup>rd</sup> cutting	< 0.05, <u>0.1</u> , 0.2	0.12	0.1	0.2
Alfalfa seed	< 0.05	< 0.05	< 0.05	< 0.05
Clover forage	< 0.05, < 0.05, 0.06, <u>0.1</u> , 0.11, 0.15, 0.53	0.15	0.1	0.53
Clover hay	< 0.05, 0.1, 0.1, <u>0.22</u> , 0.24, 0.46, 0.48	0.24	0.22	0.48

Haughey and Abdel-Baky (2001, BOSC09\_012) conducted a study consisting of six field trials in the US on strawberries as the primary crop, followed by <u>radishes</u>, <u>cabbage</u> and <u>wheat</u> as rotational crops. The strawberry trials included two plots each treated five times with an application rate of 0.42 kg ai/ha, resulting in an annual rate of 2.04 kg boscalid per ha. Strawberries were harvested at normal maturity. The rotational crops were planted at 14, 30, and 45 day plant-back intervals (PBI).

Duplicate samples of wheat, cabbage, and radish were collected at normal crop maturity. The mean results of both samples are presented in Table 11.

Table 11 Boscalid residues in radish, cabbage and wheat planted following strawberries as primary crop

Commodity	Boscalid residues in mg/kg				
	PBI 14	PBI 30	PBI 45		
Radish roots	0.09, 0.3	< 0.05, 0.14	0.12, 0.17		
Radish tops	0.27, 0.77	0.12, 0.40	0.22, 0.49		
Cabbage with wrapper leaves	< 0.05, < 0.05	Not analysed	Not analysed		
Cabbage without wrapper leaves	< 0.05, < 0.05	Not analysed	Not analysed		
Wheat forage	0.21, 0.34	0.18, 0.39	0.25, 0.31		
Wheat hay	0.25, 1.53	0.22, 1.0	0.24, 0.97		
Wheat grain	< 0.05, 0.05	Not analysed	Not analysed		
Wheat straw	1.7, 2.84	0.72, 2.44	0.61, 2.39		

The uptake of boscalid into <u>beans</u> and <u>peas</u> was investigated by Versoi and Abdel-Baky (2001, BOSC09\_013) in the US. At three locations the soil was treated three times with application rates of 0.8, 0.62 and 0.62 kg ai/ha, respectively, resulting in an annual application rate of 2.04 kg ai/ha. Peas and beans were planted with a target plant back interval of 14 days. Duplicate samples were taken at the commercial points of harvest ranging form 44 to 105 days after planting. In the following table the results of the mean residues from both samples per plot and commodity are presented.

Table 12 Results of boscalid in peas and beans grown in soil treated with boscalid at a rate of 2.04 kg ai/ha

Commodity	Mean results per trial in mg/kg	Total mean	Total	Total
		in mg/kg	median	maximum
			in mg/kg	in mg/kg
Field pea, vines	< 0.05(9)	< 0.05	< 0.05	< 0.05
Field pea, hay	< 0.05, 0.07, 0.08, 0.09(3), 0.1, 0.11, 0.15	0.09	0.09	0.15
Bean (cow pea), forage	< 0.05(5), 0.05, 0.33, 0.49, 1.02	0.24	< 0.05	1.02
Bean (cow pea), hay	< 0.05(3), 0.17, 0.24, 0.28, 0.52, 0.67, 0.99	0.34	0.24	0.99

Fourteen field rotational crop trials were conducted in the principal growing regions for sugar beets in the US by Leonard (2002, BOSC09\_014) to investigate the uptake of boscalid into <u>root crops</u>. Three treatments of boscalid were applied to bare soil at rates of 0.8, 0.62 and 0.62 kg ai/ha, respectively, resulting in an annual application rate of 2.04 kg ai/ha. Sugar and garden beets as well as turnips were planted at a PBI of 14 days after the last application.

Replicate samples of roots and tops were collect at the commercial points of harvest. In Table 13 an overview of the mean results from both samples for each commodity is presented.

Table 13 Results of boscalid in root crops grown in soil treated with boscalid at a rate of 2.04 kg ai/ha

Commodity	Mean results per trial in mg/kg	Total mean in mg/kg	Total median in mg/kg	Total maximum in mg/kg
Sugar beet roots	< 0.05(7)	< 0.05	< 0.05	< 0.05
Sugar beet tops	< 0.05(6), 0.05	0.05	< 0.05	0.05
Garden beet roots	< 0.05, < 0.05	< 0.05	< 0.05	< 0.05
Garden beet tops	< 0.05, < 0.05	< 0.05	< 0.05	< 0.05
Turnip roots	< 0.05(5)	< 0.05	< 0.05	< 0.05
Turnip tops	< 0.05(4), 0.07	0.05	< 0.05	0.07

Beck (2003, BOSC09\_015) investigated the uptake of boscalid on <u>potatoes</u> in four field trials conducted in Northern Europe. Boscalid was spray applied once at a rate of 2.1 kg ai/ha 28 days before the planting of potato plants. The potatoes were grown according to common practice (including creation of potato dams) and samples were collected at the point of commercial harvest. In addition to potatoes soil samples were collected 0, 28 and 106–148 days after treatment. The results are summarized in Table 14.

Table 14 Results of boscalid in soil and in potatoes grown in soil treated with boscalid at a rate of 2.1 kg ai/ha

Commodity	Mean results per trial in mg/kg	Total mean	Total	Total
		in mg/kg	median	maximum
			in mg/kg	in mg/kg
Potatoes	< 0.05, < 0.05, 0.06, 0.06	0.06	0.055	0.06
Potatoes peeled	0.03	0.03	0.03	0.03
Potato peel	0.37	0.37	0.37	0.37
Soil, 0 days	0.36, 0.47, 0.67, 2.5	1	0.57	2.5

Commodity	Mean results per trial in mg/kg	Total mean in mg/kg		Total maximum
Soil, 28 days	0.38, 0.41, 0.85, 1.1	0.69	in mg/kg 0.63	in mg/kg 1.1
Soil, 106-148 days	0.058, 0.35, 0.76, 0.86	0.51	0.56	0.86

For cotton the uptake of boscalid was investigated by Jordan (2002, BOSC09\_016) in nine field trials in the US. Bare soil was treated using three applications with application rates of 0.8, 0.62 and 0.62 kg ai/ha, respectively, resulting in an annual application rate of 2.04 kg ai/ha. Fourteen days after the last application cotton was planted and cultivated according to the common practice. At the point of commercial harvest replicate samples of cotton seeds and gin by-products (trash) were collected and analysed for boscalid residues. An overview of the mean results for each trial is presented in the following table.

Table 15 Results of boscalid in cotton grown in soil treated with boscalid at a rate of 2.04 kg ai/ha

Commodity	Mean results per trial in mg/kg	Total mean in mg/kg	Total median in mg/kg	Total maximum in mg/kg
Cotton seed	< <u>0.05(</u> 9)	< 0.05	< 0.05	< 0.05
Cotton Gin By-products	< <u>0.05(5)</u> , 0.17	0.07	< 0.05	0.17

The uptake of Boscalid into <u>carrots</u> was observed in four field trials conducted in Europe by Schroth (2008, BOSC09\_018). In each of the trials boscalid was applied to bare soil at an application rate of 2.1 kg ai/ha under field conditions. After an interval of 30 days carrots were planted as the succeeding crop. Soil specimens were collected at the day of the application and about 30 days thereafter and as well when the crop reached BBCH 41 (sampling of whole plants) and BBCH 49 (sampling of roots and tops). The results are summarized in Table 16.

Table 16 Results of boscalid in soil and carrots grown in soil treated with boscalid at a rate of 2.1 kg ai/ha

Commodity	Mean results per trial in mg/kg	Total mean in mg/kg	Total median in mg/kg	Total maximum in mg/kg
Soil, 0 days	0.27, 0.32, 0.42, 0.46	0.37	0.37	0.46
Soil, 30 days	0.39, 0.47, 0.47, 0.90	0.56	0.47	0.90
Soil, BBCH 41	0.25, 0.40, 0.54, 0.57	0.44	0.47	0.57
Soil, BBCH 49	0.27, 0.31, 0.48, 0.78	0.46	0.395	0.78
Carrot plants with roots	0.02, <u>0.07</u> , <u>0.12</u> , 1.1 <sup>a</sup>	0.34	0.095	1.1
Carrot roots	0.01, <u>0.05</u> , <u>0.08</u> , 0.37 <sup>a</sup>	0.13	0.065	0.37
Carrot tops	< 0.01, <u>0.03</u> , <u>0.03</u> , 0.84 <sup>a</sup>	0.23	0.03	0.84

<sup>&</sup>lt;sup>a</sup> confirmed by double analysis

For Chinese <u>cabbage</u> and <u>radish</u> Kobayashi (2001, BOSC09\_021) investigated the uptake after applications of  $3 \times 0.705$  kg ai/ha to kidney beans and onions. The crops were sown 24 and 52 days after harvesting the onions or beans, respectively. Chinese cabbage was harvested after 70 days and radishes after 60 days. The results are presented in the following table.

Table 17 Results of boscalid in Chinese cabbage and radishes after application of boscalid to beans and onions at a rate of  $3 \times 0.705$  kg ai/ha

Commodity	Mean results per trial in mg/kg	Total mean in mg/kg	Total median in mg/kg	Total maximum in mg/kg
Chinese cabbage	< 0.005, < 0.005	< 0.005	< 0.005	< 0.005
Radish, roots	< 0.005, < 0.005	< 0.005	< 0.005	< 0.005
Radish, leaves	< 0.005, < 0.005	< 0.005	< 0.005	< 0.005

#### RESIDUES IN ANIMAL COMMODITIES

# Farm animal feeding studies

In the Evaluation of 2006 for boscalid a feeding study on dairy cattle (Tilting, 2001, BOSC09\_023) was presented which reported all residues as the sum of boscalid and its metabolite M510F01, expressed as boscalid equivalents. Since analytical data is also available for each of the analytes individually, Table 82–84 within the 2006 Evaluation is amended for the missing values (see Tables 18–21).

Table 18 Residues of boscalid and metabolite M510F01 in milk from lactating dairy cows dosed with boscalid at 1.5 (1 $\times$ ), 4.5 (3 $\times$ ) and 18 ppm (12 $\times$ ) in the dry-weight diet, for 28 consecutive days (Tilting, 2001, 2000/1017228). Reported values are means of 3 values for the 1.5 and 4.5 ppm groups and of four values in the 18 ppm group (Tilting, 2001, BOSC09\_023)

Day	1.5 ppm gr	1.5 ppm group (1×)			roup (3x)		18 ppm gro	18 ppm group (12×)		
	Boscalid	M510F01	Total <sup>a</sup>	Boscalid	M510F01	Total <sup>a</sup>	Boscalid	M510F01	Total <sup>a</sup>	
-3	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	
	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	
	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	
1			n.a.	< 0.01	< 0.01	< 0.02	0.011	< 0.01	0.02	
				< 0.01	< 0.01	< 0.02	0.013	< 0.01	0.02	
				< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	
							0.011	< 0.01	0.02	
							< 0.01	< 0.01	< 0.02	
3			n.a.	< 0.01	< 0.01	< 0.02	0.017	< 0.01	0.027	
				< 0.01	< 0.01	< 0.02	0.031	< 0.01	0041	
				0.012	< 0.01	0.02	0.029	< 0.01	0.039	
							0.013	< 0.01	0.023	
							0.037	< 0.01	0.047	
6	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	
	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.015	< 0.01	0.025	
	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.012	< 0.01	0.022	
							< 0.01	< 0.01	< 0.02	
							0.021	< 0.01	0.031	
9	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.02	< 0.01	0.030	
	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.035	< 0.01	0.045	
	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.026	< 0.01	0.036	
							< 0.01	< 0.01	< 0.02	

Day	1.5 ppm gr	1.5 ppm group (1x)			roup (3×)		18 ppm gro	18 ppm group (12x)		
	Boscalid	M510F01	Total <sup>a</sup>	Boscalid	M510F01	Total <sup>a</sup>	Boscalid	M510F01	Total <sup>a</sup>	
							0.035	< 0.01	0.045	
12	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.015	< 0.01	0.025	
	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.022	< 0.01	0.032	
	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.022	< 0.01	0.032	
							0.013	< 0.01	0.023	
							0.022	< 0.01	0.032	
15			n.a.	< 0.01	< 0.01	< 0.02	0.024	< 0.01	0.034	
				0.011	< 0.01	0.021	0.032	< 0.01	0.042	
				< 0.01	< 0.01	< 0.02	0.041	< 0.01	0.051	
							0.016	< 0.01	0.026	
							0.032	< 0.01	0.042	
18			n.a.	< 0.01	< 0.01	< 0.02	0.086	< 0.01	0.096	
				< 0.01	< 0.01	< 0.02	0.045	< 0.01	0.055	
				0.013	< 0.01	0.023	0.011	< 0.01	0.021	
							0.026	< 0.01	0.036	
							0.045	< 0.01	0.055	
21	< 0.01	< 0.01	< 0.02	0.01	< 0.01	0.02	0.028	< 0.01	0.038	
	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.033	< 0.01	0.043	
	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.021	< 0.01	0.031	
							0.030	< 0.01	0.040	
24			n.a.	< 0.01	< 0.01	< 0.02	0025	< 0.01	0.035	
				< 0.01	< 0.01	< 0.02	0.036	< 0.01	0.046	
				< 0.01	< 0.01	< 0.02	0.016	< 0.01	0.026	
							0.030	< 0.01	0.04	
28	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.029	< 0.01	0.039	
	< 0.01	< 0.01	< 0.02	0.01	< 0.01	0.02	0.033	< 0.01	0.043	
	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.018	< 0.01	0.028	
							0.036	< 0.01	0.046	
29			n.a.	< 0.01	< 0.01	< 0.02			n.a.	
				< 0.01	< 0.01	< 0.02				
				< 0.01	< 0.01	< 0.02				
32			n.a.			n.a.	< 0.01	< 0.01	< 0.02	
36			n.a.			n.a.	< 0.01	< 0.01	< 0.02	

<sup>&</sup>lt;sup>a</sup> Sum of boscalid and M510F01, expressed as boscalid equivalents

Table 19 Residues of boscalid and metabolite M510F01 in milk, skim milk and cream collected on day 21 from lactating dairy cows dosed with boscalid at 1.5 (1×), 4.5 (3×) and 18 ppm (12×) in the dry-weight diet, for 28 consecutive days (Tilting, 2001, BOSC09\_023).

Dose rate	Whole milk			Skim milk	kim milk			Cream		
	Boscalid	M510F01	Total a	Boscalid	M510F01	Total a	Boscalid	M510F01	Total a	
1.5 ppm	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.023	< 0.01	0.033	
	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.045	< 0.01	0.055	
	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.025	< 0.01	0.035	

n.a .Not analysed

Dose rate	Whole milk			Skim milk			Cream		
	Boscalid	M510F01	Total a	Boscalid	M510F01	Total a	Boscalid	M510F01	Total a
4.5 ppm	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.11	< 0.01	0.12
	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.12	< 0.01	0.13
	< 0.01	< 0.01	< 0.02	< 0.01	< 0.01	< 0.02	0.10	< 0.01	0.11
18 ppm	0.028	< 0.01	0.038	0.011	< 0.01	0.21	0.37	< 0.01	0.38
	0.033	< 0.01	0.043	< 0.01	< 0.01	< 0.02	0.37	< 0.01	0.38
	0.021	< 0.01	0.031	< 0.01	< 0.01	< 0.02	0.24	< 0.01	0.25
	0.030	< 0.01	0.040	< 0.01	< 0.01	< 0.02	0.34	< 0.01	0.35

<sup>&</sup>lt;sup>a</sup> Sum of boscalid and M510F01, expressed as boscalid equivalents

Table 20 Residues of boscalid and metabolite M510F01 in muscle, fat and liver from lactating dairy cows dosed with boscalid at 1.5 (1x), 4.5 (3x) and 18 ppm (12x) in the dry-weight diet, for 28 consecutive days (Tilting, 2001, BOSC09\_023)

Dose rate	Muscle			Fat	₹at			Liver		
	Boscalid	M510F01	Total <sup>a</sup>	Boscalid	M510F01	Total <sup>a</sup>	Boscalid	M510F01	Total <sup>a</sup>	
1.5 ppm	< 0.025	< 0.025	< 0.05	0.053	< 0.025	0.078	< 0.025	< 0.025	< 0.05	
	< 0.025	< 0.025	< 0.05	< 0.025	< 0.025	< 0.05	< 0.025	< 0.025	< 0.05	
	< 0.025	< 0.025	< 0.05	< 0.025	< 0.025	< 0.05	< 0.025	< 0.025	< 0.05	
4.5 ppm	< 0.025	< 0.025	< 0.05	0.099	< 0.025	0.124	< 0.025	0.03	0.055	
	< 0.025	< 0.025	< 0.05	0.084	< 0.025	0.109	< 0.025	0.026	0.051	
	< 0.025	< 0.025	< 0.05	0.057	< 0.025	0.082	< 0.025	0.039	0.064	
18 ppm	< 0.025	< 0.025	< 0.05	0.21	< 0.025	0.24	0.06	0.12	0.18	
	< 0.025	< 0.025	< 0.05	0.27	< 0.025	0.3	0.08	0.091	0.17	
	0.033	< 0.025	0.058	0.25	< 0.025	0.28	0.07	0.11	0.18	

<sup>&</sup>lt;sup>a</sup> Sum of boscalid and M510F01, expressed as boscalid equivalents

Note: One animal of the 18 ppm dose group gave residues below the LOQ of 0.025 mg/kg in all matrices after a withdrawal period of 7 days

Table 21 Residues of boscalid and metabolite M510F01 in kidney from lactating dairy cows dosed with boscalid at 1.5 (1 $\times$ ), 4.5 (3 $\times$ ) and 18 ppm (12 $\times$ ) in the dry-weight diet, for 28 consecutive days (Tilting, 2001, BOSC09\_023)

Dose rate	Kidney				
	Boscalid	M510F01	Total <sup>a</sup>		
1.5 ppm	< 0.025	< 0.025	< 0.05		
	< 0.025	< 0.025	< 0.05		
	< 0.025	< 0.025	< 0.05		
4.5 ppm	< 0.025	0.046	0.071		
	< 0.025	0.038	0.063		
	< 0.025	0.063	0.088		
18 ppm	0.044	0.29	0.33		
	< 0.025	0.18	0.21		
	< 0.025	0.14	0.17		

<sup>&</sup>lt;sup>a</sup> Sum of boscalid and M510F01, expressed as boscalid equivalents

Note: One animal of the 18 ppm dose group gave residues below the LOQ of 0.025 mg/kg in all matrices after a withdrawal period of 7 days

In a new study submitted to the 2009 Meeting the magnitude of boscalid residue in milk and tissues of lactating dairy cows was investigated by Malinsky and Pryadun (2009, BOSC09\_020). The animals were divided into two dose groups receiving doses of either 35.8ppm (Group 2, 3 animals) or 116.3 ppm (Group 3, 7 animals, but one animal had to be removed from the group due to a disease) via balling gun (equivalent to 1.22 and 3.56 mg ai/kg bw). In parallel, control Group 1 was dosed with empty capsules. The animals were dosed over a period of 29 consecutive days. Three cows from Group 3 were used to investigate the withdrawal of boscalid residues after the dosing period up to day 43.

During the whole study period samples of milk were collected and analysed with the tissues after sacrificing the animals. In addition the milk collected on day 22 and 28 was separated into skim milk and cream. The samples obtained were analysed for boscalid and its hydroxy metabolite M510F01 (including glucuronide conjugate M510F02) by LC/MS/MS (Method 471/0, please see evaluation by JMPR 2006).

In none of the samples obtained from the control group were any boscalid residues above the LOQ found. In milk a plateau was formed after approximately 1 week for both dose groups. In Group 2 residues in whole milk ranged from < 0.01 to 0.019 mg/kg. In the high dose group higher residues were found up to 0.08 mg/kg. In none of the samples were any residues of M510F01 above the LOQ of 0.01 mg/kg detected. The separation into skim milk and cream revealed that most of the residues are found in the cream, ranging up to 0.07 mg/kg for Group 2 and 0.23 mg/kg for Group 3. In skim milk residue levels of boscalid were at or below the LOQ of 0.01 mg/kg.

Muscle tissue gave no detectable residues of boscalid of M510F01 in any sample.

In liver and kidney the major part of the residues were found as M510F01 at levels of 0.04–1.5 mg/kg for liver and 0.07–0.22 mg/kg for kidney. Boscalid was measured at < 0.025–0.03 mg/kg in kidney and 0.04–0.09 mg/kg in liver.

In fatty tissues M510F01-residues were found at or below the LOQ of 0.025 mg/kg (< 0.025–0.03 mg/kg). Most of the residue consisted of unchanged boscalid ranging from 0.08–0.25 mg/kg.

An overview of the residues found in milk and tissues and the results of the withdrawal period for Group 3 are presented in Tables 22 to Table 24.

Table 22 Boscalid residues in milk, skim milk and cream from lactating cows dosed with 35.8ppm or 116.3pmm (group mean values in brackets)

Day	Group 2 (35.8ppm)		Group 3 (116.3ppm)	Group 3 (116.3ppm)		
	Boscalid [mg/kg]	M510F01 <sup>a</sup> [mg/kg]	Boscalid [mg/kg]	M510F01 <sup>a</sup> [mg/kg]		
-1	< 0.01, < 0.01, < 0.01 (< 0.01)	< 0.01, < 0.01, < 0.01 (< 0.01)	< 0.01, < 0.01, < 0.01 (< 0.01)	<0.01, <0.01, <0.01, <0.01, <0.01, <0.01 (<0.01)		
1	< 0.01, 0.01, 0.01 (0.01)	< 0.01, < 0.01, < 0.01 (< 0.01)	0.04, 0.04, 0.02, 0.05, 0.07, 0.05 (0.05)	<0.01, <0.01, <0.01, <0.01, <0.01, <0.01 (<0.01)		
4	0.02, 0.02, 0.02 (0.02)	< 0.01, < 0.01, < 0.01 (< 0.01)	0.05, 0.06, 0.03, 0.05, 0.07, 0.04 (0.05)	< 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01 (< 0.01)		
7	0.01, 0.02, 0.02 (0.02)	< 0.01, < 0.01, < 0.01 (< 0.01)	0.06, 0.08, 0.04, 0.09, 0.11, 0.09 (0.08)	<0.01, <0.01, <0.01, <0.01, <0.01, <0.01 (<0.01)		
10	< 0.01, 0.01, 0.01 (0.01)	< 0.01, < 0.01, < 0.01 (< 0.01)	0.06, 0.06, 0.04, 0.04, 0.06, 0.06 (0.05)	<0.01, <0.01, <0.01, <0.01, <0.01, <0.01 (<0.01)		
13	0.02, 0.01, 0.01 (0.01)	< 0.01, < 0.01, < 0.01 (< 0.01)	0.03, 0.06, 0.04, 0.03, 0.03, 0.04 (0.04)	<0.01, <0.01, <0.01, <0.01, <0.01, <0.01 (<0.01)		

Day	Group 2 (35.8ppm)		Group 3 (116.3ppm)		
	Boscalid [mg/kg]	M510F01 <sup>a</sup> [mg/kg]	Boscalid [mg/kg]	M510F01 <sup>a</sup> [mg/kg]	
16	0.01, < 0.01, < 0.01 (0.01)	< 0.01, < 0.01, < 0.01 (< 0.01)	0.04, 0.06, 0.05, 0.06, 0.05, 0.05 (0.05)	< 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01 (< 0.01)	
19	0.02, 0.01, 0.01 (0.01)	< 0.01, < 0.01, < 0.01 (< 0.01)	0.04, 0.08, 0.02, 0.06, 0.05, 0.05 (0.05)	< 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01 (< 0.01)	
22	0.02, 0.01, 0.02 (0.02)	< 0.01, < 0.01, < 0.01 (< 0.01)	0.03, 0.05, 0.04, 0.07, 0.06, 0.05 (0.05)	< 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01 (< 0.01)	
25	0.01, < 0.01, 0.01 (0.01)	< 0.01, < 0.01, < 0.01 (< 0.01)	0.03, 0.05, 0.04, 0.05, 0.05, 0.04 (0.04)	< 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01 (< 0.01)	
28	0.01, < 0.01, 0.01 (0.01)	< 0.01, < 0.01, < 0.01 (< 0.01)	0.03, 0.04, 0.03, 0.04, 0.03, 0.09 (0.04)	< 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01 (< 0.01)	
22 (skim milk)	< 0.01, < 0.01, < 0.01 (< 0.01)	< 0.01, < 0.01, < 0.01 (< 0.01)	< 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01 (< 0.01)	< 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01 (< 0.01)	
28 (skim milk)	< 0.01, < 0.01, < 0.01 (< 0.01)	< 0.01, < 0.01, < 0.01 (< 0.01)	< 0.01, < 0.01, < 0.01, < 0.01, < 0.01, 0.01 (0.01)	< 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01 (< 0.01)	
22 (cream)	0.07, 0.06, 0.06 (0.06)	< 0.01, < 0.01, < 0.01 (< 0.01)	0.18, 0.23, 0.18, 0.25, 0.29, 0.28 (0.23)	< 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01 (< 0.01)	
28 (cream)	0.06, 0.05, 0.05 (0.06)	< 0.01, < 0.01, < 0.01 (< 0.01)	0.13, 0.17, 0.13, 0.29, 0.41, 0.49 (0.23)	< 0.01, < 0.01, < 0.01, < 0.01, < 0.01, < 0.01 (< 0.01)	

<sup>&</sup>lt;sup>a</sup> including glucuronide conjugate M510F02

Table 23 Boscalid residues in tissues from lactating cows dosed with 35.8ppm or 116.3pmm (group mean values in brackets)

Tissue	Group 2 (35.8ppm)		Group 3 (116.3ppm)		
	Boscalid [mg/kg]	M510F01 <sup>a</sup> [mg/kg]	Boscalid [mg/kg]	M510F01 <sup>a</sup> [mg/kg]	
Liver	0.06, 0.04, 0.05 (0.05)	0.05, 0.05, 0.04 (0.05)	0.08, 0.09, 0.08 (0.09)	0.07, 0.15, 0.14 (0.12)	
Kidney	< 0.025, < 0.025, < 0.025 (< 0.025)	0.07, 0.09, 0.09 (0.08)	< 0.025, 0.03, < 0.025 (0.03)	0.09, 0.22, 0.17 (0.16)	
Muscle	< 0.025, < 0.025, < 0.025 (< 0.025)				
Fat, omental	0.21, 0.18, 0.06 (0.15)	< 0.025, < 0.025, < 0.025 (< 0.025)	0.21, 0.19, 0.16 (0.18)	< 0.025, < 0.025, < 0.025 (< 0.025)	
Fat, perirenal	0.22, 0.18, 0.09 (0.16)	0.03, < 0.025, < 0.025 (0.03)	0.17, 0.25, 0.23 (0.22)	0.03, < 0.025, < 0.025 (0.03)	
Fat, subcutaneous	0.18, 0.16, 0.08 (0.14)	< 0.025, < 0.025, < 0.025 (< 0.025)	0.06, 0.16, 0.16 (0.12)	< 0.025, < 0.025, < 0.025 (< 0.025)	

<sup>&</sup>lt;sup>a</sup> including glucuronide conjugate M510F02

Table 24 Boscalid residues in milk and tissues from lactating cows dosed with 116.3pmm—withdrawal period (group mean values in brackets)

Sample	Group 3 (116.3ppm)				
	Boscalid [mg/kg]	M510F01 <sup>a</sup> [mg/kg]			
Milk, day 31	< 0.01, < 0.01, 0.04 (0.02)	< 0.01, < 0.01, < 0.01 (< 0.01)			
Milk, day 35	< 0.01, < 0.01, < 0.01 (< 0.01)	< 0.01, < 0.01, < 0.01 (< 0.01)			
Milk, day 38	< 0.01, < 0.01 (< 0.01)	< 0.01, < 0.01 (< 0.01)			
Milk, day 42	< 0.01	< 0.01			
Skim milk, day 42	< 0.01	< 0.01			
Cream, day 42	< 0.01	< 0.01			
Kidney, day 35, 38 and 42	< 0.025, < 0.025, < 0.025 (< 0.025)	< 0.025, < 0.025, < 0.025 (< 0.025)			
Liver, day 35, 38 and 42	< 0.025, < 0.025, < 0.025 (< 0.025)	< 0.025, < 0.025, < 0.025 (< 0.025)			
Muscle, day 35, 38 and 42	< 0.025, < 0.025, < 0.025 (< 0.025)	< 0.025, < 0.025, < 0.025 (< 0.025)			
Omental fat, day 35	0.03	< 0.025			
Omental fat, day 38	< 0.025	< 0.025			
Omental fat, day 42	< 0.025	< 0.025			
Perirenal fat, day 35	0.04	< 0.025			
Perirenal fat, day 38	< 0.025	< 0.025			
Perirenal fat, day 42	< 0.025	< 0.025			
Subcutaneous fat, day 35. 38 and 42	< 0.025, < 0.025, < 0.025 (< 0.025)	< 0.025, < 0.025, < 0.025 (< 0.025)			

## **APPRAISAL**

Boscalid is a systemic fungicide first evaluated by JMPR in 2006 for residues and toxicology as a new active substance. An ADI of 0–0.04 mg/kg bw was established for boscalid, while no ARfD was considered necessary. Due to incomplete data submission for residues in follow crops the Meeting decided that a chronic risk assessment under consideration of these residues in rotational crops could not be finalized during the 2006 Meeting. In 2008 additional uses involving banana and kiwifruit were review for residues. In response to the request of the Forty-first CCPR (ALINORM 09/32/24, para 124) the Meeting reconsidered all data available for a finalisation of the dietary risk assessment for boscalid.

New data were submitted for metabolism and degradation of boscalid in soil, uptake in follow-up crops and livestock feeding to the 2009 JMPR. Further studies, GAP information and supervised residue trials referred to in this document are described in the evaluation of boscalid as a new active substance by the 2006 JMPR.

The following abbreviations are used for the metabolites discussed below:

boscalid 2-chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide

M510F01 2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl)nicotinamide

M510F02 4'-chloro-6-{[(2-chloro-3-pyridinyl)carbonyl]amino}biphenyl-3-yl

glycopyranosiduronic acid

# Environmental fate in soil

The Meeting received data on the degradation of boscalid in soil under aerobic and anaerobic conditions, investigation on the uptake of boscalid from newly treated and aged soil, confined metabolism of boscalid in rotational crops and field trials on succeeding crops for various commodities.

The <u>aerobic soil metabolism</u> of boscalid is very limited. Most of the radioactivity used in the studies was either recovered as unchanged parent substance, <sup>14</sup>CO<sub>2</sub>, or remained as unextracted radioactivity. Metabolites were found, but their levels were less than 1% of the applied doses. Estimated half-life times under assumption of first order kinetics ranged from 133 to 384 days.

The <u>anaerobic soil metabolism</u> gave comparable results. In one of the studies 2-chloronicotinic acid (M510F47) was found in amounts of 6.7% of the applied doses. Estimated half-life times under assumption of first order kinetics ranged from 261 to 345 days.

<u>Field dissipation</u> studies were submitted indicating that boscalid did not show a tendency to move into deeper layers of soil and was primarily detected in the top 10 cm soil layer during field dissipation trials (four different soils) of durations up to 12–18 months. Boscalid concentrations declined to half of their initial values in 28 days to 208 days. In all trials a  $DT_{90}$  could not be reached within one year after application to bare soil.

In a further study investigation of the <u>soil dissipation</u> of soil newly treated with boscalid, and soil treated over several years, revealed that a much slower dissipation of the active substance was observed in aged soil.  $DT_{50}$  values determined under laboratory conditions were estimated with 336 days for new soil and 746 days for aged soil.

In field studies on the <u>accumulation</u> of boscalid in soil over 11 years, a three year rotation was used to simulate the typical agricultural practices in Northern Europe. In the first two years lettuce/carrots and green beans/cauliflower were treated with annual application rates of 2.1 and 1.7 kg ai/ha, respectively. The third year of the cycle contained wheat, which was not treated with boscalid. The results indicate that boscalid residues increased during the time frame of the study, reaching a plateau equivalent to an application rate of boscalid to bare soil between 2 and 3 kg ai/ha.

In a <u>confined rotational crop study</u> in Germany, soil was treated directly with [<sup>14</sup>C]boscalid labelled in the diphenyl ring or the pyridine ring. Lettuce, radish and wheat were sown into the treated

soil at intervals of 30, 120, 270 and 365 days after treatment, grown to maturity, and harvested for analysis. The residues in the edible parts of succeeding crops destined for human consumption were low for lettuce and radish root, and slightly higher for wheat grain after all four plant-back intervals. The major part of the residues was identified as parent. The concentration of boscalid in lettuce leaf ranged from 55.6–94.1% TRR, in radish leaf from 69.4–90.2% TRR, in radish root from 52.6–92.8% TRR and in wheat straw from 50.0–87.5% TRR. In wheat grain the concentration of parent was lower (1.9–35.4% TRR, < 0.028 mg/kg).

In addition to the confined study further <u>field trials</u> investigating the uptake of boscalid under more realistic conditions were conducted on various crops in Europe, Japan and the US. All trials were conducted at a target annual application rate of 2.0 to 2.15 kg ai/ha per year. Pre-planting intervals and PHIs of the succeeding crops corresponded to the common agricultural practices. The results are summarized in the following table.

Group	Commodity	No. of trials	Mean in mg/kg	Median in mg/kg	Highest residue in mg/kg
Root and tuber vegetables	Radish roots	4	0.08	0.065	0.17
	Sugar beet roots	7	0.05	0.05	0.05
	Garden beet roots	2	0.05	0.05	0.05
	Turnip roots	5	0.05	0.05	0.05
	Potatoes	4	0.06	0.055	0.06
	Carrot roots	4	0.13	0.065	0.37
	TOTAL	26	0.07	0.05	0.37
Brassica vegetables	Cabbage	4	0.03	0.035	0.05
Fruiting vegetables	Sweet corn cobs	4	0.05	0.05	0.05
Pulses and oilseeds	Alfalfa seeds	1	0.05	0.05	0.05
	Soya bean seeds	15	0.05	0.05	0.06
	Cotton seed	9	0.05	0.05	0.05
	TOTAL	25	0.05	0.05	0.06
Cereal grains	Maize grain	9	0.05	0.05	0.05
	Rice grain	6	0.06	0.05	0.12
	Sorghum grain	6	0.05	0.05	0.05
	Wheat grain	9	0.05	0.05	0.07
	TOTAL	30	0.05	0.05	0.12
Legume animal feeds	Soya bean forage	15	0.08	0.065	0.18
	Soybean hay	13	0.15	0.105	0.45
	Alfalfa forage	17	0.11	0.05	0.49
	Alfalfa hay	17	0.29	0.1	1.46
	Clover forage	7	0.15	0.01	0.53
	Clover hay	7	0.24	0.22	0.48
	Pea vines	9	0.05	0.05	0.05
	Pea hay	9	0.09	0.09	0.15
	Cow pea forage	9	0.24	0.05	1.0
	Cow pea hay	9	0.34	0.24	0.99
	TOTAL	112	0.17	0.08	1.46

Group	Commodity	No. of trials	Mean in mg/kg	Median in mg/kg	Highest residue in mg/kg
Straw and fodder of cereal					
grains	Wheat Forage	11	0.45	0.29	1.1
	Wheat hay	11	0.50	0.265	1.5
	Wheat straw	11	1.1	0.81	2.8
	Maize forage	12	0.06	0.05	0.13
	Maize stover	13	0.12	0.06	0.49
	Rice straw	6	0.30	0.13	1.1
	Sorghum forage	6	0.08	0.05	0.23
	Sorghum stover	6	0.09	0.05	0.30
	Grass forage	12	0.46	0.25	1.9
	Grass hay	12	1.5	0.61	6.8
	Grass straw	2	0.18	0.175	0.2
	TOTAL	102	0.5	0.21	6.8
Root leaves and tops	Radish tops	4	0.26	0.14	0.77
	Sugar beet tops	7	0.05	0.05	0.05
	Garden beet tops	2	0.05	0.05	0.05
	Turnip tops	5	0.05	0.05	0.07
	Carrot tops	4	0.23	0.03	0.84
	TOTAL	22	0.12	0.05	0.84

An additional study was conducted to investigate the uptake behaviour of boscalid into plants grown in newly treated soil and aged soil. Wheat, radish and spinach were used as representative crops in this study. The results indicate that multiple applications of boscalid over several years resulted in a decreased uptake into the succeeding crops. On average only 52.8% of the residues were found in plants grown in aged soil in comparison to soil treated for the first time.

## Estimation of boscalid residues in soil

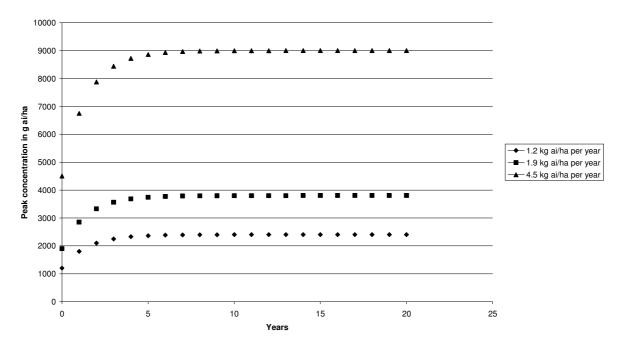
Boscalid is used in a broad variety of crops at various annual application rates. For the estimation of the highest boscalid levels in soil relevant for the evaluation of residues in follow crops, it must be assumed that boscalid is applied for several consecutive years due to the broad use pattern. Under consideration of the annual application rates for non-permanent crops and the  $DT_{50}$  values obtained from aerobic soil degradation and field dissipation studies, a  $1^{st}$  order kinetic model can be used to estimate the boscalid plateau reached in soil.

Annual application rates of boscalid on non-permanent crops are normally in the magnitude of 0.9 to 1.2 kg ai/ha per year (see GAP list in JMPR Evaluation 2006). The only uses involving higher application rates are reported from the US for bulb vegetables with 1.9 kg ai /ha per year ( $6 \times 0.32$  kg ai/ha) and various uses from Japan at the maximum rate of 4.5 kg ai/ha per year (up to  $3 \times 1.5$  kg ai/ha).

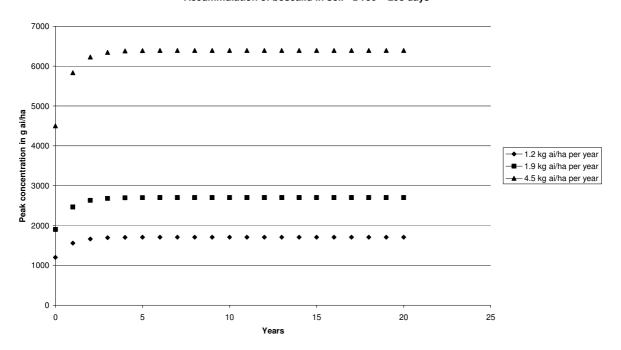
Concerning the rate of degradation  $DT_{50}$  values were determined for up to 208 days in field dissipation studies. Under laboratory conditions most  $DT_{50}$  values were in the magnitude of 1 year (365 days), while in aged soil receiving several consecutive applications the  $DT_{50}$  values were determined at up to 746 days.

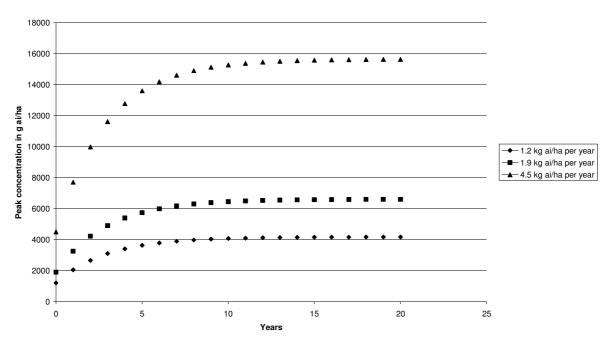
Under consideration of these input parameters, the plateau levels of boscalid equivalent to an application rate to bare soil after consecutive applications over several years can be estimated (1st order kinetics assumed):

# Accumulation of boscalid in soil - DT50 = 365 days



# Accumulation of boscalid in soil - DT50 = 208 days





#### Accumulation of boscalid in soil - DT50 = 746 days

The results for the estimation are dependent on the  $DT_{50}$  values for boscalid in soil. For a  $DT_{50}$  value of <u>208 days</u> estimated in field dissipation studies, the plateau is reached after five annual applications of boscalid. Plateau levels were equivalent to an application rate of 1.7 kg ai/ha to bare soil for a treatment using 1.2 kg ai/ha per year, 2.7 kg ai/ha for 1.9 kg ai/ha per year and 6.4 kg ai/ha for 4.5 kg ai/ha per year, respectively.

Under the assumption of a  $DT_{50}$  value of  $\underline{1}$  year (365 days) mainly found in aerobic soil metabolism and dissipation studies on soil treated for the first time plateau levels equivalent to an application rate to bare soil were estimated at 2.4 kg ai/ha for a treatment rate of 1.2 kg ai/ha per year, 3.8 kg ai/ha for 1.9 kg ai/ha per year and 9 kg/ha for 4.5 kg ai/ha per year.

The highest  $DT_{50}$  value for boscalid was found in aged soil under laboratory conditions with a half-live time of <u>746 days</u>. The resulting plateau levels equivalent to application rates to bare soil estimated in were 4.1 kg ai/ha following treatment at 1.2 kg ai/ha per year, 6.6 kg ai/ha for 1.9 kg ai/ha per year and 15.6 kg ai/ha after treatment at 4.5 kg ai/ha per year.

The Meeting noted that boscalid shows a reduced uptake into plants from soil (52.8% on average) when applied for several consecutive years. Since the plateau in soil is reached after 5 years at a minimum, the Meeting decided to apply an additional factor of 0.5 to the plateau concentration reflecting the reduced uptake of residues from aged soil. Field trials on succeeding crops were normally conducted using unaged soils resulting in higher residues potentially available for an uptake via the roots of the plants. The following table shows the derivation of the predicted plateau levels for boscalid residues in soil after the GAP application rates.

Application rate	Assumed DT <sub>50</sub> value in days	Predicted plateau level equivalent to an application to bare soil	Adjusted plateau level equivalent to an application to bare soil available for uptake from aged soil (factor 0.5)
1.2 kg ai/ha per year	208	1.7 kg ai/ha	0.85 kg ai/ha
	365	2.4 kg ai/ha	1.2 kg ai/ha
	746	4.1 kg ai/ha	2.05 kg ai/ha

Application rate	Assumed DT <sub>50</sub> value in days	Predicted plateau level equivalent to an application to bare soil	Adjusted plateau level equivalent to an application to bare soil available for uptake from aged soil (factor 0.5)
1.9 kg ai/ha per year	208	2.7 kg ai/ha	1.35 kg ai/ha
	365	3.8 kg ai/ha	1.9 kg ai/ha
	746	6.6 kg ai/ha	3.3 kg ai/ha
4.5 kg ai/ha per year	208	6.4 kg ai/ha	3.2 kg ai/ha
	365	9 kg ai/ha	4.5 kg ai/ha
	746	15.6 kg ai/ha	7.8 kg ai/ha

The Meeting noted that most of the GAPs globally reported involve an annual application rate of 1.2 kg ai/ha or less. Even under assumption of the most critical  $DT_{50}$  value of 746 days the level of boscalid available for an uptake into plants is at, or below, the dose range of the field trial data submitted for succeeding crops.

Under the assumption of the  $DT_{50}$  value of 208 days or the  $DT_{50}$  value of 365 days, the next higher GAP from the US on bulb vegetables using 1.9 kg ai/ha still results in a plateau within the treatment range of the field studies on succeeding crops.

The national GAPs involving up to 4.5 kg ai/ha per year may lead to a predicted plateau of at least 50% above the application rate of the field trial on succeeding crops submitted.

The Meeting decided that the field trial data submitted on succeeding crops represents the maximum residues in soil available for an uptake via the roots for all GAPs submitted, except for GAPs using more than 1.9 kg ai/ha per year. These results are also confirmed by field accumulation studies over eleven years, leading to plateau residue levels equivalent to an application rate to bare soil between 2 and 3 kg ai/ha. For the estimation of boscalid residues in commodities obtained from follow crops, the results from the field trial data on succeeding crops may be taken into account without further adjustment.

# Definition of the residue

The consideration leading to the residue definition for boscalid was presented in the JMPR Report 2006. Results were:

Definition of the residue (for compliance with the MRL for plant and animal commodities and for estimation of dietary intake for plant commodities): *boscalid*.

Definition of the residue (for estimation of dietary intake for animal commodities): *sum of boscalid, 2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl)nicotinamide* <sup>a</sup> *including its conjugate, expressed as boscalid.* 

The residue is fat soluble.

<sup>a</sup> Metabolite code: M510F01

## Estimation of residues in plant commodities grown as potential succeeding crops

For a recommendation on boscalid residues in plant commodities the addition of probable residues arising from direct treatment in combination with root uptake of boscalid applied in previous years must be taken into account. The Meeting decided to use the overall groups for plant food and feed established in the Codex Classification System to give recommendations on the overall residue levels of boscalid expected in these commodities.

The evaluation of residues in follow-up crops was conducted according to the principles outlined in the 2008 JMPR Report, as per General consideration item 2.9. The corresponding residue values from supervised field trials are obtained from the previous evaluation of boscalid as a new active substance by JMPR 2006.

The Meeting recognised that the use of statistical methods for the estimation of maximum residue levels is not possible in cases of potential carryover residues in following crops, since the bias arising from the additional root uptake cannot be adequately expressed within the models. All maximum residue levels recommended for boscalid are therefore based on the expertise of the Meeting only.

#### **Apples**

Apples are normally cultivated as permanent crops not expected to be subject to a potential uptake of boscalid from the soil. The Meeting confirms its previous recommendation of a maximum residue level and an STMR value for boscalid in apples of 2 and 0.365 mg/kg respectively.

## Stone fruit

Stone fruits are normally cultivated as permanent crops not expected to be subject to a potential uptake of boscalid from the soil. The Meeting confirms its previous recommendation of a maximum residue level and an STMR value for boscalid in stone fruit of 3 and 1.21 mg/kg respectively.

## Berries and other small fruits

In 2006 the Meeting recommended maximum residue levels and STMR values for berries and other small fruits (except strawberries) and grapes as well as for grapes individually. These crops are normally cultivated as permanent crops not expected to be subject to a potential uptake of boscalid from the soil.

The Meeting confirms its previous recommendations of maximum residue levels and STMR values for boscalid in <u>berries and other small fruits</u> (except strawberries) and grapes of 10 and 2.53 mg/kg respectively.

The Meeting also confirms its previous recommendation of a maximum residue level and an STMR value for boscalid in grapes of 5 and 1.09 mg/kg respectively.

For <u>strawberries</u> supervised field trials according to GAP were available, but no recommendation could be given due to the outstanding evaluation of the uptake through the soil. In 2006 the Meeting identified the following residues of boscalid in strawberries: 0.15, 0.19, 0.20, 0.23, 0.27 (2), 0.28, 0.31, 0.34, 0.35, 0.38, 0.41, <u>0.42</u>, <u>0.45</u>, 0.46 (2), 0.47, 0.49, 0.55, 0.57, 0.68 (2), 0.69, 0.89, 1.74 and 1.87 mg/kg.

No data from studies on follow crops on strawberries are available. In field studies on succeeding crops highest mean and median residue values of 0.12 mg/kg and 0.05 mg/kg respectively were found in non-dry commodities (leaves and tops of root vegetables, Brassica vegetables and fruiting vegetables). The Meeting concluded that residues in strawberries may be influenced significantly by an additional uptake of boscalid from the soil. It was decided to add the mean residue found in field studies on succeeding crops of 0.12 mg/kg to the median residue obtained from supervised field trials on strawberries of 0.435 mg/kg for an overall STMR for boscalid in strawberries of 0.555 mg/kg.

For the estimation of maximum residue levels the highest residue found in non-dry commodities in succeeding crops field trials was 0.84 mg/kg in carrot tops. The Meeting concluded that a maximum residue level of 3 mg/kg for boscalid in strawberries poses an acceptable value in view of a possible addition of the highest residue of 1.87 mg/kg found in supervised field trials and the highest residue of 0.84 mg/kg in non-dry commodities in the succeeding crops field trials.

The Meeting estimated a maximum residue level and an STMR value for boscalid in strawberries of 3 mg/kg and 0.555 mg/kg respectively.

#### Bananas

Bananas are normally cultivated as permanent crops not expected to be subject to a potential uptake of boscalid from the soil. The Meeting confirms its previous recommendation from 2008 of a maximum residue level and an STMR value, (based on banana pulp), for boscalid in banana, of 0.6 and 0.05 mg/kg respectively.

#### *Kiwifruit*

Kiwifruit were evaluated by JMPR 2008 for the application of boscalid as a post-harvest treatment. The Meeting confirms its previous recommendation from 2008 of a maximum residue level and an STMR value for boscalid in kiwifruit of 5 and 0.073 mg/kg respectively.

## **Bulb** vegetables

In 2006 the following residues were identified by the Meeting for green onions, bulb onions and leeks. A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues in ranked order on green onions were: 1.13, 2.01, 2.20, 2.39 and 2.73 mg/kg.

The residues in ranked order on bulb onions were: < 0.05, 0.05, 0.1, 0.11, 0.13, 0.22, 0.78, 0.92, 0.93 and 2.61 mg/kg.

The residues of boscalid in leeks in ranked order were: 0.58, 0.62, 0.8, 0.9, 0.93, 1.02, 1.16, 1.31 (2), 1.90 and 2.30 mg/kg.

The Meeting concluded that the dataset on green onions represents the highest residue population within the group of bulb vegetables. Although the number of field trial results is considered very small for a recommendation, the data on bulb onions and leeks support the approach of using green onions as the critical case for an estimation of maximum residue levels and STMR values for the whole group.

In field studies on succeeding crops data for root and tuber vegetables are available indicating mean, median and highest residues of 0.07 mg/kg, 0.05 mg/kg and 0.37 mg/kg, respectively in the roots, and 0.12 mg/kg, 0.05 mg/kg and 0.84 mg/kg respectively in the tops of the plants. In view of these residue levels the Meeting decided that in comparison to the STMR value of 2.2 mg/kg for bulb vegetables (based on the use on green onions) the impact on the overall residue levels due to an additional uptake from soil is insignificant for the estimation of the dietary intake.

For the estimation of maximum residue levels the highest residue found in tops of root and tuber vegetables was 0.84 mg/kg.

The Meeting concluded that a maximum residue level of 5 mg/kg for boscalid in bulb vegetables poses an acceptable value in view of a possible addition of the highest residue of 2.73 mg/kg found in supervised field trials and the highest residue of 0.84 mg/kg in tops of root and tuber vegetables in the succeeding crops field trials.

The Meeting estimated a maximum residue level and an STMR value for boscalid in bulb vegetables of 5 mg/kg and 2.2 mg/kg respectively.

# Brassica vegetables

In 2006 the following residues were identified by the Meeting for broccoli (USA and UK GAP), cabbage, cauliflower and Brussels sprouts. A recommendation on STMR values and maximum residue levels could not be made due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues on broccoli according to UK GAP in ranked order were:  $<\!0.05, <\!0.05$  and 0.20 mg/kg.

The residues on broccoli according to US GAP in ranked order were: 0.81, 0.98, 1.45, 1.59, 1.70 and 2.70 mg/kg.

The residues on cabbage according to US GAP in ranked order were: 0.64, 0.73, 1.06, 1.78, 2.22 and 2.33 mg/kg.

The residues on cauliflower according to UK GAP in ranked order were: < 0.05 (5), 0.06 and 0.55 mg/kg.

The residues on Brussels sprouts according to UK GAP in ranked order were: < 0.05 (2), 0.06, 0.10, 0.15, 0.16, 0.23, 0.34 and 0.40 mg/kg.

Based on the outcome of the Mann-Whitney-U-Test the 2006 Meeting concluded that the application of boscalid to broccoli and cabbage according to the US GAP for brassicas results in a comparable residue population and may be combined for a recommendation of an STMR value and a maximum residue level for the whole group of Brassica vegetables. In summary, residues of boscalid in broccoli and cabbage from the 12 US trials in rank order were: 0.64, 0.73, 0.81, 0.98, 1.06, 1.45, 1.59, 1.70, 1.78, 2.22, 2.33 and 2.70 mg/kg.

In field studies on succeeding crops mean, median and highest residues in Brassica vegetables were 0.03 mg/kg, 0.035 mg/kg and 0.05 mg/kg, respectively. The Meeting concluded that residues due to an additional uptake of boscalid via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level, an STMR value and a highest residues value for boscalid in Brassica vegetables of 5 mg/kg, 1.52 mg/kg and 2.7 mg/kg respectively.

Fruiting vegetables, other than Cucurbits (except fungi, mushrooms and sweet corn)

In 2006 the following residues were identified by the Meeting for cucumbers, cantaloupe, melons, summer squash, tomatoes and bell and non-bell peppers. A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues on cucumber in ranked order were: 0.05, 0.07 (3), 0.12, 0.13, 0.14 (2), 0.26 and 0.31 mg/kg.

The residues on cantaloupe in ranked order were: 0.14, 0.23, 0.29, 0.39, 0.56, 0.57, 0.71 and 1.27 mg/kg.

The residues on melons in ranked order were: < 0.05(8) mg/kg.

The residues in ranked order on summer squash were: 0.11, 0.12, 0.14, 0.16 (2), 0.19, 0.27, 0.31 and 0.95 mg/kg.

The residues on tomatoes in ranked order were: 0.17, 0.21, 0.22, 0.24, 0.25, 0.27, 0.28, 0.3, 0.59, 0.61, 0.79 and 0.92 mg/kg.

The residues on bell peppers in ranked order were: < 0.05, 0.08, 0.09, 0.14, 0.16 and 0.3 mg/kg.

The residues on non-bell peppers in ranked order were: 0.14, 0.30 and 0.83 mg/kg.

The Meeting concluded that the application of boscalid to cantaloupe results in the highest residue population in fruiting vegetables, except fungi, mushrooms and sweet corn and can be used for a recommendation of a STMR value and a maximum residue level for the whole group.

For fruiting vegetables, except fungi, mushrooms and sweet corn no data from studies on follow crops are available. The Meeting decided that the highest mean and median residue values of 0.12 mg/kg and 0.05 mg/kg respectively found in non-dry commodities in these studies (leaves and tops of root vegetables, Brassica vegetables and sweet corn) indicate a deviation of less than 25% in comparison to the STMR value derived from supervised field trials on cantaloupe of 0.565 mg/kg. The Meeting concluded that the STMR value of 0.565 mg/kg for boscalid in cantaloupe may be used

directly for the estimation of the dietary intake of the whole group. No separation of pulp and peel was conducted for cantaloupe.

For the estimation of maximum residue levels the highest residue found in non-dry commodities in succeeding crops field trials was 0.84 mg/kg in carrot tops.

The Meeting concluded that a maximum residue level of 3 mg/kg for boscalid in fruiting vegetables, except fungi, mushrooms and sweet corn (based on cantaloupe) poses an acceptable value in view of a possible addition of the highest residue of 1.27 mg/kg found in supervised field trials and the highest residue of 0.84 mg/kg in non-dry commodities in the succeeding crops field trials.

The Meeting estimated a maximum residue level and an STMR value for boscalid in fruiting vegetables, cucurbits and fruiting vegetables, non-cucurbits (except fungi, mushrooms and sweet corn) of 3 mg/kg and 0.565 mg/kg respectively.

The Meeting agreed to apply the default transfer factor of 10 for dried chilli peppers to the STMR and highest residue found for bell and non-bell peppers and estimated a maximum residue level and an STMR of 10 mg/kg and 1.4 mg/kg for boscalid in dried chilli peppers.

## Leafy vegetables

In 2006 the following residues were identified by the Meeting for mustard greens, head and leafy lettuce (US GAP) and lettuce (European GAP, indoor and outdoor). A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues on mustard greens in ranked order were: 0.45, 0.54, 0.92, <u>2.80</u>, <u>3.1</u>, 6.04, 12.9 and 14.4 mg/kg.

The residues on head and leafy lettuce (US GAP) in ranked order were: 0.11, 0.74, 0.98, 1.6, 1.63, 1.77, 1.91, 2.53, 2.68, 2.73, 3.18, 4.87, 5.14, 5.42, 9.36 and 9.55 mg/kg.

The residues on lettuce (European GAP, outdoor) in ranked order were: < 0.05, 0.09, 0.15, 0.21, 0.33, 0.36, 0.38, 0.39, 0.43, 0.45, 0.50, 0.64, 0.65, 0.73, 0.76, 0.86, 1.19 and 1.58 mg/kg.

The residues on lettuce (European GAP, indoor) in ranked order were: 0.37, 0.71, 1.52, 2.31, 2.50, 5.63, 5.96 and 6.11 mg/kg.

The Meeting concluded that the application of boscalid to mustard greens results in the highest residue population in leafy vegetables and can be used for a recommendation of a STMR value and a maximum residue level for the whole group.

In field studies on succeeding crops mean, median and highest residues in Brassica vegetables were 0.03 mg/kg, 0.035 mg/kg and 0.05 mg/kg, respectively. The Meeting concluded that the results obtained for Brassica vegetables are also applicable to estimated possible residues of boscalid in leafy vegetables. The residues due to an additional uptake of boscalid via the roots are considered insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level and an STMR value for boscalid in leafy vegetables of 30 mg/kg and 2.95 mg/kg respectively.

## Legume vegetables

In 2006 the following residues were identified by the Meeting for green beans with pods (French GAP, indoor and outdoor), shelled and podded peas (US GAP), immature soybeans (US GAP), snap beans (UP GAP) and lima beans (US GAP). A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues on green beans with pods (French GAP, outdoor) in ranked order were: 0.13, 0.22, 0.26, 0.29, 0.47, 0.50, 0.53, 0.62, 0.67, 0.83 and 0.95 mg/kg.

The residues on green beans with pods (French GAP, indoor) in ranked order were: 0.06, 0.28, 0.29, 0.61, 0.69, 1.65 and 1.67 mg/kg.

The residues on shelled peas (US GAP) in ranked order were: < 0.05 (2), 0.06, 0.07, 0.15, 0.19, 0.24 and 0.37 mg/kg.

The residues on podded peas (US GAP) in ranked order were: 0.64, 0.97 and 1.39 mg/kg.

The residues on immature soybeans (US GAP) in ranked order were: < 0.05 (11), 0.05, 0.06, 0.08, 0.09, 0.2 and 1.18 mg/kg.

The residues on snap beans (US GAP) in ranked order were: 0.13, 0.28, 0.36, 0.41, 0.42, 0.46, 0.52, 0.54, 0.72 and 0.97 mg/kg.

The residues on lima beans (US GAP) in ranked order were: < 0.05 (2), 0.07 (2), 0.08 (2) and 0.47 mg/kg.

The 2006 Meeting concluded that the application of boscalid to beans according to French GAP results in the highest residues may be extrapolated to the whole group. Based on the outcome of the Mann-Whitney-U-Test the use in field and glasshouse results in a comparable residue population, and may be combined. In summary, residues of boscalid in green beans with pods (French GAP, indoor and outdoor) in rank order were: 0.06, 0.08, 0.13, 0.22, 0.26, 0.28, 0.29, 0.29, 0.47, 0.50, 0.53, 0.61, 0.62, 0.67, 0.69, 0.83, 0.95, 1.65 and 1.67 mg/kg.

For legume vegetables no data from studies on follow crops are available. Data on pulses and oilseeds are available, but the high fat and low water content of the seeds are not representative for legume vegetables. The Meeting decided that the highest mean and median residue values of 0.12 mg/kg and 0.05 mg/kg respectively found in non-dry commodities (root and tuber vegetables, Brassica vegetables and fruiting vegetables) indicate a deviation of less than 25% in comparison to the STMR value derived from supervised field trials on green beans with pods of 0.5 mg/kg. The Meeting concluded that the STMR value of 0.5 mg/kg for boscalid in green beans with pods may be used directly for the estimation of the dietary intake of the whole group.

For the estimation of maximum residue levels the highest residue found in non-dry commodities in succeeding crops field trials was 0.84 mg/kg in carrot tops. The Meeting concluded that a maximum residue level of 3 mg/kg for boscalid in legume vegetables poses an acceptable value in view of a possible addition of the highest residue of 1.67 mg/kg found in supervised field trials and the highest residue of 0.84 mg/kg in non-dry commodities in the succeeding crops field trials.

The Meeting estimated a maximum residue level and an STMR value for boscalid in legume vegetables of 3 mg/kg and 0.5 mg/kg respectively.

## Pulses

In 2006 the following residues were identified by the Meeting for dry beans, peas and soya beans according to US GAP. A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues on dry beans in ranked order were: < 0.05 (4), 0.06, 0.09, 0.12, 0.14, 0.37 and 1.92 mg/kg.

The residues on dry peas in ranked order were: 0.05, 0.09, 0.11, 0.12, 0.16, 0.17, 0.23, 0.31 and 0.46 mg/kg.

The residues on dry soya beans in ranked order were: < 0.05 (17) mg/kg.

Based on the outcome of the Mann-Whitney-U-Test the 2006 Meeting concluded that the application of boscalid to beans and peas according to the US GAP for pulses results in a comparable residue population and may be combined for a recommendation of an STMR value and a maximum residue level for the whole group of pulses. In summary, residues of boscalid in beans and peas from the 19 US trials in rank order were: < 0.05(4), 0.05, 0.06, 0.09, 0.09, 0.11, 0.12, 0.12, 0.14, 0.16, 0.17, 0.23, 0.31, 0.37, 0.46 and 1.92 mg/kg.

In field studies on succeeding crops mean, median and highest residues in alfalfa and soybean seeds were 0.05 mg/kg, 0.05 mg/kg and 0.06 mg/kg, respectively, with most of the values below the LOQ of 0.05 mg/kg. The Meeting concluded that residues in pulses due to an additional uptake of boscalid via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level and an STMR value for boscalid in pulses of 3 mg/kg and 0.12 mg/kg respectively.

## Root and tuber vegetables

In 2006 the following residues were identified by the Meeting for carrots and potatoes. A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues on carrots in ranked order were: < 0.05, 0.06, 0.12, 0.17, 0.18, 0.19, 0.28 and 0.34 mg/kg.

The residues on potatoes in ranked order were: < 0.05 (16) mg/kg.

The Meeting concluded that the application of boscalid to carrots results in the highest residue population in root and tuber vegetables and can be used for a recommendation of a STMR value and a maximum residue level for the whole group.

In all field studies on succeeding crops mean, median and highest residues in root and tuber vegetables were 0.07 mg/kg, 0.05 mg/kg and 0.37 mg/kg, respectively. For carrot roots residues found were slightly higher with mean, median and highest residues of 0.13 mg/kg, 0.065 mg/kg and 0.37 mg/kg, respectively. The Meeting concluded that residues in carrots are the representative commodity for all root and tuber vegetables and may be influenced significantly by an additional uptake of boscalid from the soil. It was decided to add the mean residue found in field studies on succeeding crops of 0.13 mg/kg to the median residue obtained from supervised field trials on carrot roots of 0.175 mg/kg for an overall STMR for boscalid in carrot roots of 0.305 mg/kg.

For the estimation of maximum residue levels the highest residue found in root and tuber vegetables in succeeding crops field trials was 0.37 mg/kg in carrot roots. The Meeting concluded that a maximum residue level of 2 mg/kg for boscalid in root and tuber vegetables poses an acceptable value in view of a possible addition of the highest residue of 0.34 mg/kg found in supervised field trials and the highest residue of 0.37 mg/kg for carrot roots in the succeeding crops field trials. For the estimation of the livestock animals' dietary burden, both values are added for an overall highest residue in root and tuber vegetables of 0.71 mg/kg.

The Meeting estimated a maximum residue level, an STMR value and a highest residue value for boscalid in root and tuber vegetables of 2 mg/kg, 0.305 mg/kg and 0.71 mg/kg respectively.

#### Barley, oats, rye and wheat grain

In 2006 the following residues were identified by the Meeting for barley and wheat grain. A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues on barley in ranked order were: < 0.01(2), 0.02, 0.03, 0.12 and 0.19 mg/kg.

The residues on wheat in ranked order were: < 0.01, 0.01(3), 0.03, 0.06(2), and 0.27 mg/kg.

Based on the outcome of the Mann-Whitney-U-Test the 2006 Meeting concluded that the application of boscalid to barley and wheat grain results in a comparable residue population, and may be combined for a recommendation of an STMR value and a maximum residue level. In summary, residues of boscalid in barley and wheat grain in rank order were: < 0.01(3), 0.01(3), 0.02, 0.03, 0.03, 0.06, 0.12, 0.19 and 0.27 mg/kg.

In all field studies on succeeding crops mean, median and highest residues in wheat grain were 0.05 mg/kg, 0.05 mg/kg and 0.07 mg/kg, respectively. The Meeting concluded that residues in

barley and wheat grain may be influenced significantly by an additional uptake of boscalid from soil. It was decided to add the mean residue found in field studies on succeeding crops of 0.05 mg/kg to the median residue obtained from supervised field trials of 0.025 mg/kg for an overall STMR for boscalid in barley and wheat grain of 0.075 mg/kg.

For the estimation of maximum residue levels the highest residue found in wheat grain in succeeding crops field trials was 0.071 mg/kg. The Meeting concluded that a maximum residue level of 0.5 mg/kg for boscalid in barley and wheat grain poses an acceptable value in view of a possible addition of the highest residue of 0.27 mg/kg found in supervised field trials and the highest residue of 0.07 mg/kg for wheat grain in the succeeding crops field trials. In addition it was noted by the Meeting that residues on barley and wheat grain may be extrapolated to oats and rye.

The Meeting estimated a maximum residue level and an STMR value for boscalid in barley, oats, rye and wheat grain of 0.5 mg/kg and 0.075 mg/kg respectively.

#### Cereal grain except barley, oats, rye and wheat

Although boscalid is not used for treatment of further cereal grains (except barley, oats, rye and wheat), these crops may still be subject to crop rotation and therefore contain boscalid residues after uptake via the roots. The Meeting decided to use the mean, median and highest residue found in wheat grain in field studies on succeeding crops of 0.05 mg/kg, 0.05 mg/kg and 0.07 mg/kg respectively for an estimation of STMR and maximum residue values in cereal grains except barley, oats, rye and wheat.

The Meeting estimated a maximum residue level and an STMR value for boscalid in cereal grains, except barley, oats, rye and wheat grain of 0.1 mg/kg and 0.05 mg/kg respectively.

#### Tree nuts

Tree nuts are normally cultivated as permanent crops not expected to be subject to a potential uptake of boscalid from the soil. The Meeting confirms its previous recommendations of a maximum residue level and an STMR value for boscalid in tree nuts, except pistachio of 0.05 (\*) mg/kg and 0.05 mg/kg respectively. The Meeting also confirms its previous recommendations of a maximum residue level and an STMR value for boscalid in pistachio of 1 mg/kg and 0.27 mg/kg respectively.

#### Oilseeds

In 2006 the following residues were identified by the Meeting for sunflowers and peanuts. A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues in sunflower seeds in ranked order were: < 0.05, 0.08, 0.09, 0.13, 0.16, 0.16, 0.23 and 0.45 mg/kg.

The residues in peanut in ranked order were: < 0.05 (11) and 0.05 mg/kg.

The Meeting concluded that the application of boscalid to sunflowers results in the highest residues in oilseeds and can be used for a recommendation of a STMR value and a maximum residue level for the whole group.

In field studies on succeeding crops mean, median and highest residues in alfalfa, soybean and cotton seeds were 0.05 mg/kg, 0.05 mg/kg and 0.06 mg/kg, respectively with most of the values below the LOQ of 0.05 mg/kg. The Meeting concluded that residues in oilseeds due to an additional uptake of boscalid via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated a maximum residue level and an STMR value for boscalid in oilseeds of 1 mg/kg and 0.145 mg/kg respectively.

## Coffee

Coffee plants are normally cultivated as permanent crops not expected to be subject to a potential uptake of boscalid from the soil. The Meeting confirms its previous recommendations of a maximum residue level and an STMR value for boscalid in coffee of 0.05 (\*) mg/kg and 0.05 mg/kg respectively.

# Animal feedstuffs

#### Almond hulls

Almond trees are normally cultivated as permanent crops not expected to be subject to a potential uptake of boscalid from the soil. The Meeting confirms its previous recommendations of a maximum residue level and an STMR value for boscalid in almond hulls of 15 mg/kg and 4.1 mg/kg respectively (dry weight). A highest residue level of 13 mg/kg was estimated for calculating the dietary burden of farm animals.

Straw and fodder of barley, oats, rye and wheat

In 2006 the following residues were identified by the Meeting for barley and wheat straw. A recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues in barley straw in ranked order were: 0.51, 2.5, 5.8, 13, 14 and 27 mg/kg (fresh weight).

The residues in wheat straw in ranked order were: 3.0, 3.1, 5.3, 5.8, 7.9, 7.9, 11 and 15 mg/kg (fresh weight).

Based on the outcome of the Mann-Whitney-U-Test the 2006 Meeting concluded that the application of boscalid to barley and wheat straw results in a comparable residue population and may be combined for a recommendation of an STMR value and a maximum residue level. In summary, residues of boscalid in barley and wheat straw in rank order were: 0.51, 2.5, 3.0, 3.1, 5.3, 5.8, <u>7.9</u>, 7.9, 11, 13, 14, 15 and 27 mg/kg (fresh weight).

In field studies on succeeding crops mean, median and highest residues in fresh wheat straw were 1.1 mg/kg, 0.81 mg/kg and 2.8 mg/kg, respectively. The Meeting concluded that residues in barley and wheat straw due to an additional uptake of boscalid via the roots contribute less than 25% to the total residue in comparison to residue levels following direct treatment and are therefore considered as non-relevant for the estimation of STMR values and maximum residue levels.

Under the assumption of a default dry-matter content of 88% the Meeting calculated boscalid residues in barley and wheat straw in rank order were: 0.58, 2.8, 3.4, 3.5, 6.0, 6.6, 9.0, 9.0, 12.5, 14.8, 15.9, 17.1 and 30.7 mg/kg (dry-matter). The Meeting concluded that residues on straw and fodder from barley and wheat may be extrapolated to straw and fodder from oats and rye.

The Meeting estimated a maximum residue level and an STMR value for boscalid in straw and fodder from barley, oats, rye and wheat of 50 mg/kg and 9 mg/kg respectively (dry-matter). A highest residue level of 30.7 mg/kg (dry-matter) was estimated for calculating the dietary burden of farm animals.

Straw and fodder of cereal grain, except barley, oats, rye and wheat

Although boscalid is not used for treatment of further cereal straw and fodder plants (except barley, oats, rye and wheat), these crops may still be subject to crop rotation and therefore contain boscalid residues after uptake via the roots. The Meeting decided to use the mean, median and maximum residues found in wheat straw in field studies on succeeding crops of 1.1 mg/kg, 0.81 mg/kg and

2.8 mg/kg (fresh-weight) respectively for an estimation of STMR and maximum residue values in straw and fodder of cereal grain, except barley, oats, rye and wheat.

Under the assumption of a default dry-matter content of 88% the Meeting calculated mean, median and highest boscalid residues of 1.25 mg/kg, 0.92 mg/kg and 3.2 mg/kg (dry-weight) in straw and fodder of cereal grain, except barley, oats, rye and wheat.

The Meeting estimated a maximum residue level, an STMR value and a highest residue value for boscalid in straw and fodder of cereal grain, except barley, oats, rye and wheat of 5 mg/kg, 1.25 mg/kg and 3.2 mg/kg respectively (dry-matter).

## Legume animal feeds

In 2006 the following residues were identified by the Meeting for peanut and soybean fodder although a recommendation on STMR values and maximum residue levels could not be given due to the outstanding evaluation of the uptake of boscalid through the soil.

The residues in peanut hay in ranked order were: 3.2, 5.8, 6.7, 6.7, 7.8, <u>9.0</u>, 13, 20, 24, 28 and 29 mg/kg (fresh weight).

The residues in soybean hay in ranked order were: 1.3, 1.4, 1.8, 2.0, 2.1, 2.3, 2.8, 3.6, 4.6, 4.8, 5.3, 6.7, 7.1, 7.3, 7.8, 11 and 21 mg/kg (fresh weight).

The Meeting concluded that the application of boscalid to peanuts results in the highest residues in legume animal feeds and can be used for a recommendation of a STMR value and a maximum residue level for the whole group.

In field studies on succeeding crops mean, median and highest residues in legume animal feeds were 0.17 mg/kg, 0.079 mg/kg and 1.46 mg/kg, respectively. The Meeting concluded that residues in peanut fodder due to an additional uptake of boscalid via the roots are insignificant in comparison to residue levels following direct treatment.

The Meeting estimated an STMR and a highest residue value for boscalid in legume animal feeds of 9 mg/kg and 29 mg/kg respectively (fresh weight).

# Fate of residues during processing

Processing data on various commodities are reported in the initial evaluation from 2006 for boscalid. All data relevant for a recommendation of maximum residue levels in processed commodities or for dietary intake calculations are summarized in the following table.

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	Median or best estimate
Apples	Fresh juice	0.05, 0.06, 0.08(2), < 0.09, < 0.10	0.08
	Wet pomace	2.08, 3.90, 5.73, 6.38, 6.77, 8.26	6.06
Plums	Prunes	0.52, 2.42, 2.80, 3.15, 3.66	2.8
Grapes	Raisins	2.42	2.42
	Wet pomace	1.95, 2.40, 2.60, 3.41	2.5
	Wine	0.09, 0.34, 0.36, 0.47	0.35
	Juice	0.42	0.42
Tomato	Canned juice	0.09, 0.13, 0.16, 0.27	0.15
	Puree	0.19, 0.24(2), 0.73	0.24
	Paste	0.53, 0.63, 0.82, 2.24	0.73
Soya bean	Hulls	1.74	1.74
	Meal	< 0.16	0.16
	Refined oil	0.42	0.42

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors	Median or best estimate
Barley	Pot barley	0.22, 0.29, 0.37(2)	0.33
	Beer	0.01, 0.02, 0.02, 0.02	0.02
Wheat	Wholemeal flour	1.10, 1.14, 1.29, 1.82	1.22
	Flour type 550	0.22, 0.23, 0.45, 0.47	0.34
	Wheat bran	3.29, 3.87, 4.64, 5.44	4.26
	Wheat germs	0.97, 1.29, 1.36, 1.58	1.33

The processing factors for wet apple pomace (6.06) and apple juice (0.08) were applied to the estimated STMR for apple (0.365 mg/kg) to produce STMR-P values for wet apple pomace (2.2 mg/kg) and apple juice (0.03 mg/kg).

The processing factor for plum to dried plums (prunes) (2.80) was applied to the estimated STMR for plums (1.21 mg/kg) to produce an STMR-P value for prunes (3.39 mg/kg).

The Meeting estimated a maximum residue level for boscalid in prunes of 10 mg/kg.

The processing factors for dried grapes (raisins) (2.42), wet pomace (2.50), wine (0.35) and juice (0.42) were applied to the estimated STMR for grapes (1.09 mg/kg) to produce STMR-P values for raisins (2.6 mg/kg), wet pomace (2.7 mg/kg), wine (0.38 mg/kg) and grape juice (0.46 mg/kg).

The Meeting confirmed its recommendation on a maximum residue level for boscalid in dried grapes (currants, raisins and sultanas) of 10 mg/kg.

The processing factors for tomato to juice (0.15), pure (0.24) and paste (0.73) were applied to the estimated STMR for tomatoes (0.565 mg/kg) to produce STMR-P values for tomato juice (0.085 mg/kg), tomato pure (0.136 mg/kg) and tomato paste (0.413 mg/kg).

The processing factors for soya bean hulls (1.74), soybean meal (0.16) and refined soya bean oil (0.42) were applied to the estimated STMR for soya beans (0.145 mg/kg) to produce a STMR-P value of 0.25 for soya bean hulls, 0.023 for soya bean meal and 0.061 mg/kg for refined soya bean oil.

The processing factors for pot barley (0.33) and beer (0.02) were applied to the estimated STMR for barley grain (0.075 mg/kg) to produce STMR-P values for pot barley (0.025 mg/kg) and beer (0.002 mg/kg).

The processing factors for wheat wholemeal flour (1.22), wheat flour type 550 (0.34), wheat bran (4.26) and wheat germs (1.33) were applied to the STMR value for wheat grain (0.075 mg/kg) to produce STMR-P values for wheat wholemeal flour (0.092 mg/kg), wheat flour type 550 (0.026 mg/kg), wheat bran (0.32 mg/kg) and wheat germ (0.1 mg/kg).

The Meeting concluded that the STMR-P values for wholemeal flour of 0.092 mg/kg and flour type 550 of 0.026 mg/kg also apply to rye wholemeal flour and barley, and rye and triticale flour, respectively.

## Residues in animal commodities

## Livestock dietary burden

The Meeting received two feeding studies of boscalid on lactating dairy cows which provided information on likely residues resulting in animal tissues and milk from residues in the animal diet.

The <u>first study</u> on dairy cattle was submitted to the 2006 JMPR. The results presented in 2006 are amended by adding individual data for boscalid parent and the metabolite M510F01.

Lactating Holstein cows were dosed with boscalid at the equivalent of 1.5 (1×), 4.5 (3×) and 18 (12×) ppm in the dry-weight diet for 28 consecutive days. Milk was collected twice daily for

analysis. Animals were sacrificed within 23 hours after the final dosing, except for one cow of the 12× group which was sacrificed seven days after the final dose to determine residue levels post dosing.

No residues were detected in milk samples taken from the control and the  $1\times$  dose groups. In a few samples from the  $3\times$  dose group, residues just above the LOQ of 0.01 mg/kg for boscalid parent were detected, but no residues of M510F01 or M510F02 were observed. In the group average, residues were below the LOQ. In the  $12\times$  dose group, residues of boscalid parent occurred regularly from day one onward with residues reaching a plateau on day 14 with average residues between 0.04 mg/kg and 0.05 mg/kg. M510F53 was below LOQ (< 0.01 mg/kg) in milk from all three treatment groups.

Separation of milk and cream indicated that residues are only detectable in cream  $(0.03 \text{ mg/kg}, 0.11 \text{ mg/kg} \text{ and } 0.32 \text{ mg/kg} \text{ for } 1\times$ ,  $3\times$  and  $10\times$  samples, respectively) while most of the results in skim milk were below the LOQ of 0.01 mg/kg. In all cream samples only boscalid parent was found.

In the tissues, the mean residues of the sum of boscalid and M510F01, expressed for boscalid at the three dosing levels were: muscle (<0.05, <0.05 and <0.05 mg/kg); fat (0.06, 0.11 and 0.27 mg/kg); liver (<0.05, 0.06 and 0.18 mg/kg); kidney (<0.05, 0.07 and 0.24 mg/kg). Individual results indicate that boscalid parent is the only analyte detectable in fat, whilst being at or below the LOQ in liver and kidney. M510F53 was below LOQ (<0.01 mg/kg) in liver from the 1× and 3× dose groups, and up to 0.09 mg/kg from the 12× dose group.

Residues depleted quickly from the milk of a high-dose animal after dosing was stopped, falling below LOQ (0.01 mg/kg) after 2 days. Residues fell to below the LOQ (< 0.05 mg/kg) in all tissues. It was shown by samples from the withdrawal animal that no residues in milk was observed two days after dosing had stopped, and boscalid was rapidly excreted.

In an <u>additional study</u> submitted to JMPR in 2009 lactating Holstein cows were dosed with boscalid at the equivalent of 35.8 and 116.3 ppm in the dry-weight diet for 28 consecutive days. Milk was collected twice daily for analysis. Animals were sacrificed within 23 hours after the final dosing. All samples were analysed for residues of boscalid and its metabolite M510F01.

In milk obtained from the 35.8 ppm group boscalid mean residues above the LOQ of 0.01 mg/kg were detected, but their levels were relatively low, ranging up to 0.019 mg/kg. In the high dose group (116.3 ppm) boscalid was measured in all samples at levels of up to 0.078 mg/kg. The data indicates that a residue plateau in milk is reached after 7 days. No residues of M510F01 above the LOQ of 0.01 mg/kg were found in both dose groups.

Milk collected on day 22 and 28 of the dosage period was separated into skim milk and cream. The data indicated that most of the boscalid is present in the cream. For the 35.8 ppm group mean residues in whole milk, skim milk and cream were: day 22 (0.016, < 0.01 and 0.066 mg/kg); and day 28 (0.011, < 0.01 and 0.056 mg/kg). For the 116.3 ppm dose group the following residues were found: day 22 (0.05, < 0.01 and 0.23 mg/kg); and day 28 (0.044, 0.01 and 0.23 mg/kg).

In tissues, the mean residues of boscalid at the two dosing levels were: muscle (< 0.025 and < 0.025 mg/kg); fat (0.16 and 0.22 mg/kg); liver (0.051 and 0.085 mg/kg); and kidney (< 0.025 and 0.026 mg/kg).

The maximum residues within each dose group were: muscle (< 0.025 and < 0.025 mg/kg); fat (0.22 and 0.25 mg/kg); liver (0.061 and 0.091 mg/kg); and kidney (< 0.025 and 0.029 mg/kg).

For M510F01 detectable residues above the LOQ of 0.025 mg/kg were found in liver and kidney only. Mean residues were: liver (0.048 and 0.12 mg/kg); and kidney (0.084 and 0.16 mg/kg). Highest residues, within each dose group, were: liver (0.054 and 0.14 mg/kg); and kidney (0.09 and 0.22 mg/kg).

# Estimated maximum and mean dietary burdens of livestock

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are presented in Annex 6. The calculations were made according to the livestock diets from US-Canada, EU and Australia in the OECD Table (Annex 6 of the 2006 JMPR Report).

	Livestock dietary burden, boscalid, ppm of dry matter diet						
	US-Canada		EU		Australia		
	max.	mean	max.	mean	max.	mean	
Beef cattle	28.4	9.3	25.8	9.3	34.0 <sup>a</sup>	12.1 <sup>b</sup>	
Dairy cattle	27.0	8.8	27.1	9.5	33.4	12.0	
Poultry - broiler	0.13	0.14	0.82	0.41	0.13	0.13	
Poultry - layer	0.11	0.12	8.4°	2.82 <sup>d</sup>	0.13	0.13	

<sup>&</sup>lt;sup>a</sup> Highest maximum beef or dairy cattle burden suitable for MRL estimates for mammalian meat and milk

## Animal commodities, MRL estimation

In the table below, dietary burdens are shown in round brackets (), feeding levels and residue concentrations from the feeding studies are shown in square brackets [] and estimated concentrations related to the dietary burden are shown without brackets.

Dietary burden (ppm) Feeding level [ppm]	Milk	Cream	Muscle	Liver	Kidney	Fat
MRL	mean	mean	highest	highest	highest	highest
MRL beef or dairy cattle (34.0) [18]	0.055 [0.029]	0.62 [0.33]	0.062 [0.033]	0.15 [0.08]	0.083 [0.044]	0.51 [0.27]
STMR	mean	mean	mean	mean	mean	mean
STMR beef or dairy cattle <sup>b</sup> (12.1) [4.5, 18]		0.32 [0.12, 0.34]	0.035 [< 0.05, 0.053]	0.12 [0.057, 0.177]	0.16 [0.074, 0.236]	0.18 [0.105, 0.268]

a based on boscalid

For the estimation of maximum residue levels the Meeting recognised that residues found in tissues and milk found in the feeding study submitted in 2006 using a maximum dose level of 18 ppm were at higher levels than residues found in the 35.8 ppm group of the study submitted in 2009. The Meeting decided that the results obtained from the 18 ppm dose group should be extrapolated beyond the dose range of the study to the maximum dietary burdens estimated for beef and dairy cattle of 34.0 and 33.4 ppm to reflect the critical case of boscalid residues in animal tissues and milk. For the estimation of STMR values the results for the sum of boscalid and M510F01 obtained from the 4.5 and 18 ppm dose groups are interpolated to the mean dietary burdens for beef and dairy cattle of 12.1 and 12.0 ppm.

Under consideration of an average fat content in cream of 40-60% resulting in a factor of 2 the Meeting estimated a maximum residue level for boscalid (parent only) in whole milk and milk fat of 0.1 mg/kg and 2 mg/kg respectively. On the fat basis, the Meeting estimated maximum residue

<sup>&</sup>lt;sup>b</sup> Highest mean beef or dairy cattle burden suitable for STMR estimates for mammalian meat and milk

<sup>&</sup>lt;sup>c</sup> Highest maximum broiler or laying hens burden suitable for MRL estimates for poultry meat and eggs

<sup>&</sup>lt;sup>d</sup> Highest mean broiler or laying hens burden suitable for STMR estimates for poultry meat and eggs

<sup>&</sup>lt;sup>b</sup> based on sum of boscalid and M510F01

levels for meat (fat) from mammals (other than marine mammals) of 0.7 mg/kg. For edible offal (mammalian) the maximum residue level was estimated at 0.2 mg/kg based on liver.

Under consideration of an average fat content in cream of 40–60% resulting in a factor of 2 the Meeting estimated STMR values based on the sum of boscalid and M510F01 for whole milk and milk fat of  $2 \times 0.033$  mg/kg = 0.066 mg/kg and  $2 \times 0.32 = 0.64$  mg/kg respectively. For meat (fat) an STMR value of 0.18 mg/kg was estimated. STMR values for meat (muscle) and edible offal (based on kidney) were estimated at a level of 0.035 mg/kg and 0.16 mg/kg respectively.

For poultry no livestock feeding studies using boscalid were submitted to the Meeting. In the metabolism study on laying hens described in the Evaluation 2006 the animals were dosed with a rate of approx. 12.5 ppm over 10 consecutive days. In muscle boscalid and M510F01 were found at a very low level of 0.0025 mg/kg. Fat tissue contained boscalid at a concentration of 0.023 mg/kg and M510F01 at < 0.0025 mg/kg. In liver no residues above the LOD of 0.0025 mg/kg were found, after solvent extraction, but minor residues of M510F01 could be released after microwave treatment. Eggs gave residues of 0.02 mg/kg for boscalid and 0.015 mg/kg for M510F01.

Under consideration of the maximum dietary burden for laying hens of 8.4 ppm and the LOQ of the analytical method for animal commodities the Meeting estimated maximum residue levels and STMR values of 0.02 mg/kg for poultry meat, fat and edible offal as well as for eggs.

#### RECOMMENDATIONS

The Meeting estimated the STMR, highest residue and MRL values shown below:

Definition of the residue (for compliance with the MRL for plant and animal commodities and for estimation of dietary intake for plant commodities): *boscalid*.

Definition of the residue (for estimation of dietary intake for animal commodities): *sum of boscalid*, 2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl)nicotinamide including its conjugate, expressed as boscalid.

The residue is fat-soluble.

		MRL	, mg/kg	STMR or	HR, mg/kg
CCN	Commodity	New	Previous	STMR-P, mg/kg	
AB 0660	Almond hulls	15	15	4.1	13 (highest residue)
JF 0226	Apple juice			0.03	
AB 1230	Apple wet pomace			2.2	
FP 0226	Apples	2	2	0.365	
FI 0327	Banana	0.6	0.2	0.05	
-	Barley beer			0.002	
GC 0640	Barley	0.5		0.075	
FB 0018	Berries and other small fruits (except strawberries and grapes)	10	10	2.53	
VB 0040	Brassica vegetables	5		1.52	2.7 (highest residue)
VA 0035	Bulb vegetables	5		2.2	
GC 0080	Cereal grains (except barley, oats, rye and wheat)	0.1		0.05	
VO 0444	Chili peppers, dry	10		1.4	
SB 0716	Coffee beans	0.05(*)	0.05(*)	0.05	
DF 0269	Dried grapes	10	10	2.6	

		MF	RL, mg/kg	STMR or	HR, mg/kg	
CCN	Commodity	New	Previous	STMR-P, mg/kg		
MO 0105	Edible offal (mammalian)	0.2		0.16		
PE 0112	Eggs	0.02		0.02		
VC 0045	Fruiting vegetables, cucurbits	3		0.565		
VO 0050	Fruiting vegetables, non-cucurbits (except fungi, mushroom and sweet corn)	3		0.565		
JF 0269	Grape juice			0.46		
-	Grape pomace, wet			2.7		
FB 0269	Grapes	5	5	1.09		
FI 0341	Kiwi fruits	5	5	0.073		
VL 0053	Leafy vegetables	30		2.95		
AL 0157	Legume animal feeds			9	29 (highest residue)	
VP 0060	Legume vegetables	3		0.5		
MM 0095	Meat (from mammals other than marine mammals)	0.7 (fat)		0.18 (fat) 0.035 (muscle)		
FM 0183	Milk fats	2		0.64		
ML 0106	Milks	0.1		0.066		
GC 0647	Oats grain	0.5		0.075		
SO 0088	Oilseed	1		0.145		
DF 0014	Prunes	10		3.39		
TN 0675	Pistachio nuts	1	1	0.27		
-	Pot barley			0.025		
PO 0111	Poultry, edible offal of	0.02		0.02		
PF 0111	Poultry fats	0.02		0,02		
PM 0110	Poultry meat	0.02		0.02		
VD 0070	Pulses	3		0.12		
VR 0075	Root and tuber vegetables	2		0.305	0.71 (highest residue)	
GC 0650	Rye grain	0.5		0.075		
AB 0541	Soya bean hulls			0.25		
AB 1265	Soya bean meal			0.023		
OR 0541	Soya bean oil, refined			0.061		
FS 0012	Stone fruit	3	3.0	1.21		
AS 0081	Straw and fodder (dry) of cereal grains (except straw and fodder of barley, oats, rye and wheat)	5 (dw)		1.25 (dw)	3.2 (highest residue, dw)	
AS 0640	Barley straw and fodder, dry	50 (dw)		9 (dw)	30.7 (highest residue, dw)	
AS 0647	Oats straw and fodder, dry	50 (dw)		9 (dw)	30.7 (highest residue, dw)	
AS 0650	Rye straw and fodder, dry	50 (dw)		9 (dw)	30.7 (highest residue, dw)	
AS 0654	Wheat straw and fodder, dry	50 (dw)		9 (dw)	30.7 (highest residue, dw)	
FB 0275	Strawberry	3		0.555		
	Barley flour			0.026		

		MRL, 1	ng/kg	STMR or	HR, mg/kg
CCN	CN Commodity		Previous	STMR-P, mg/kg	
CF 1250	Rye flour			0.026	
CF 1251	Rye wholemeal			0.092	
JF 0048	Tomato juice			0.085	
VW 0448	Tomato paste			0.413	
-	Tomato puree			0.136	
TN 0085	Tree nuts (except pistachio)	0.05(*)	0.05(*)	0.05	
	Triticale flour			0.026	
CF 0654	Wheat bran			0.32	
CF 1210	Wheat germs			0.1	

# DIETARY RISK ASSESSMENT

## Long-term intake

The evaluation of boscalid resulted in recommendations for MRLs and STMR values for raw and processed commodities. Where data on consumption were available for the listed food commodities, dietary intakes were calculated for the 13 GEMS/Food Consumption Cluster Diets. The results are shown in Annex 3 of the 2009 JMPR Report.

The IEDIs in the thirteen GEMS/Food Consumption Cluster Diets, based on the estimated STMRs were 10–30% of the maximum ADI (0.04 mg/kg bw). The Meeting concluded that the long-term intake of residues of boscalid from uses that have been considered by the JMPR is unlikely to present a public health concern.

#### Short-term intake

The 2006 JMPR decided that an ARfD is unnecessary. The Meeting therefore concluded that the short-term intake of boscalid residues is unlikely to present a public health concern.

#### REFERENCES

CODE	Author	Year	First submitted to JMPR	Title, Report-No.
BOSC09_001	Stephan, A	1999	Feb. 2006	Metabolism of BAS 510 F ( <sup>14</sup> C-diphenyl and <sup>14</sup> C-pyridin) in soil under aerobic conditions. BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. BASF unpublished report 42381, issued 21.12.1999. 1999/11807
BOSC09_002	Ebert, D and Harder, U	2000	Feb. 2006	The degradation behaviour of <sup>14</sup> C-BAS 510 F in different soils (DT <sub>50</sub> /DT <sub>90</sub> ). BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. BASF unpublished report 41860, issued 20.06.2000. 2000/1013279
BOSC09_003	Staudenmaier, H	2000	Feb. 2006	Anaerobic metabolism of BAS 510 F in soil ( <sup>14</sup> C-pyridine-label). BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. BASF unpublished report 41858, issued 18.12.2000. 2000/1014990
BOSC09_004	Staudenmaier, H and,	2000	Feb. 2006	Anaerobic metabolism of BAS 510 F in soil (diphenyl- <sup>14</sup> C-label)  BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany

CODE	Author	Year	First submitted to JMPR	Title, Report-No.
	Schaefer, C			Fed. Rep. 2000/1014986
BOSC09_005	Kellner, O and Keller, W	2000	Feb. 2006	Field soil dissipation of BAS 510 F (300 355) in formulation BAS 510 KB F (1997-1998). BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. BASF unpublished report DE/FA/047/97, issued 25.01.2000. 2000/1000123
BOSC09_006	Bayer, H and Grote, C	2001	Feb. 2006	Field soil dissipation of BAS 510 F (300 355) in formulation BAS 510 KA F (1998–1999). BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. BASF unpublished report EU/FA/051/98, issued 16.02.2001. 2000/1013295
BOSC09_007	Hamm, RT and Veit P	2001	Feb. 2006	Confined rotational crop study with <sup>14</sup> C-BAS 510 F. BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. BASF unpublished report 42560, issued 27.02.2001. 2000/1014862
BOSC09_008	Kellner, O, Grote, C and Platz, K	2004	Oct. 2006	Accumulation behaviour of BAS 510 F under field conditions over a 5-year-period (1998–2003) after application onto grapes in a vineyard
				BASF AG, Agricultural Center Limburgerhof, Crop Protection Division, Ecology and Environmental Analytics, Germany Fed. Rep. 2004/1003851
BOSC09_009	Grote, C and Platz, K	2005	Oct. 2006	Accumulation behaviour of BAS 510 F under field conditions over a 7-year-period (1998–2004) after application onto vegetables
				BASF AG, Agricultural Center Limburgerhof, Crop Protection Division, Ecology and Environmental Analytics, Germany Fed. Rep. 2005/1013964
BOSC09_010	Jordan, JM	2002	Oct. 2006	Cereal Grains and Soya bean Field Rotational Crop Study for BAS 510 F, BASF Agro Research, 26 Davis Drive, Research Triangle Park, NC 27709 2002/5001341
BOSC09_011	Jordan, JM	2002	Oct. 2006	Field Rotational Study for BAS 510 F on Grasses, Alfalfa, and Clover As Livestock Feed Crops, BASF Agro Research, 26 Davis Drive, Research Triangle Park, NC 27709, 2002/5002063
BOSC09_012	Haughey, DW and Abdel- Baky, S	2001	Oct. 2006	Limited Rotational Crop Study for the Use of BAS 10 F in Strawberries, BASF Agro Research, 26 Davis Drive, Research Triangle Park, NC 27709, 2001/5000966
BOSC09_013	Versoi, PL and Abdel- Baky, S	2001	Oct. 2006	Magnitude of the Residue of BAS 510 F in Peas and Beans Planted As Rotational Crops and of BAS 500 F in Peas and Beans When Applied as a Foliar Spray BASF Agro Research, 26 Davis Drive, Research Triangle Park, NC 27709, 2001/5003311
BOSC09_014	Leonard, RC	2002	Oct. 2006	Sugar Beet, Garden Beet and Turnip Field Rotational Crop Study for BAS 510 02 F Residues, BASF Agro Research, 26 Davis Drive, Research Triangle Park, NC 27709, 2002/5004273
BOSC09_015	Beck, J, Lehmann, A, Grote, C and Mackenroth, C	2003	Oct. 2006	Study on the residue behaviour of Boscalid (BAS 510 F) on succeeding crops after application of BAS 510 01 F on bare soil and cultivation of potatoes under field conditions in Denmark, France, Germany and Great Britain, 2002, BASF AG, Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep, 2003/1001358
BOSC09_016	Jordan, MJ	2002	Oct. 2006	Cotton Field Rotational Study for BAS 510 F, BASF Agro Research, 26 Davis Drive, Research Triangle Park, NC 27709, 2002/5002425
BOSC09_017	Beck, I	2008	May 2009	Boscalid (BAS 510 F): Study on Soil Degradation and Long-Term Sorption in Soil, BASF SE, Agricultural Center Limburgerhof, Limburgerhof, Germany Fed.Rep, 2008/1013108
BOSC09_018	Schroth, E	2008	May 2009	Study on the residue behaviour of BAS 510 F on the rotational

CODE	Author	Year	First submitted to JMPR	Title, Report-No.
				crop: carrots after the application to the soil of BAS 510 01 F under field conditions in France (South), Germany, Netherlands and Spain, 2007, BASF SE, Crop Protection Division, Ludwigshafen, 2008/1036949
BOSC09_019	Schweda, Z	2009	May 2009	Study on the residue behaviour of BAS 510 F in the rotational crops: wheat, spinach and radish after growing on soil with different aged Boscalid, BASF SE, Agricultural Center Limburgerhof, Limburgerhof, Germany Fed.Rep., 2009/1069175
BOSC09_020	Malinsky, D and Pryadun, R	2009	May 2009	A Meat and Milk Magnitude of the Residue Study with BAS 510 F in Lactating Dairy Cows, BASF Agro Research, 26 Davis Drive, Research Triangle Park, NC 27709, 2008/7015330
BOSC09_021	Kobayashi, S	2001	June 2009	The Residue Analysis of BAS 510 F in Succeeding Crops, BASF Agro Ltd., Roppongi, Minato-ku, Tokyo, NCAS00-161NG/00-169NG, 2001/1019663
BOSC09_022	Penning, H, Richter, T and Schriever, C	2009	July 2009	Accumulation of BAS 510 F in soil under field conditions over several years after application onto vegetables, BASF SE, Agricultural Center Limburgerhof, Limburgerhof, Germany Fed.Rep., 2009/1070939
BOSC09_23	Tilting	2000	Feb. 2006	Boscalid: Residues in milk and edible tissues following oral administration of BAS 510 F to lactating dairy cattle. BASF AG, Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed. Rep. BASF unpublished report 42401, issued
				Boscalid 298 09.03.2001. 2000/1017228